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The Regulation of Chemicals in the European Union

by

Veerle Heyvaert

Thesis Submitted for Assessment with a View to Obtaining the Degree of Doctor of Laws of the European University Institute, Florence

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COPING WITH UNCERTAINTY
The Regulation of Chemicals in the European Union
Veerle Heyvaert

Abstract
The project of this thesis is to investigate how law operates in politically precarious, scientifically complex and uncertain areas. It examines whether the legal framework for the regulation of health and environmental threats adequately takes into account problems of risk and uncertainty. Furthermore, it proposes structural legal reforms to optimise the conditions under which decisions for risk control are taken.

Chapter I of the thesis lays down a theoretical framework for analysis of the tensions between law, risk and uncertainty. It explains why traditional modes of legal reasoning are ill-suited to deal with contemporary health and environmental threats, and proposes the adoption of a risk-oriented approach to law and regulation as a more productive alternative.

The remainder of the thesis examines the practical utility of a risk-oriented approach for health and environmental protection. The substantive area selected for analysis, is the European Community regulatory framework for the control of chemicals.

The structure of the thesis mimics the "regulatory life cycle" of chemical substances. Chapter II focuses on the first major prerequisite for chemical control: the availability of sufficient information on chemical hazards and risks. It provides an overview and critique of existing arrangements to stimulate the production of chemical data.

Chapter III addresses the question how this data is processed into a format that is relevant for the purposes of risk regulation. The prevalent technique is risk assessment. Chapter III analyses risk assessment practices prescribed in EC law, and discusses the controversies that surround the use of risk assessment in regulatory decision-making.

Chapter IV discusses the stage of risk decision-making. It reviews a range of regulatory techniques that aim to secure health and environmental protection, and examines chemical risk reduction mechanisms in EC law. It furthermore investigates whether and how information on chemical risks is put to use to inform decision-making processes. Each Chapter concludes with an evaluation of the incumbent legal framework, focusing in particular on its compatibility with the risk-oriented approach developed in Chapter I.

Finally, Chapter V draws the strands of the preceding analyses together, and offers an overview of the main leitmotifs, strengths and weaknesses of European chemical legislation. Chapter V concludes with a number of reform proposals that, hopefully, will contribute to the ongoing discussion and elaboration of a legal framework that does not shy away from uncertainty.

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The story is based on true events that occurred in the town of Woburn, Massachusetts. Woburn’s economic base is grounded in a long tradition of chemical manufacture and industrial leather tanning. In 1979, two wells supplying drinking water to the local community were found to be polluted with industrial solvents, which discernibly affected the smell and taste of drinking water. Later that same year, toxic waste sites were discovered, and the suspicion grew that the water pollution was caused by the chemical industries in Woburn. When in 1981, a local resident lost her son to leukaemia -- not the first child to die of such cause in Woburn -- she began to surmise that the illness was caused by polluted drinking water, and could be traced back to the toxic waste site. This signalled the beginning of a painful and protracted battle, fought out between bereaved parents, community action groups, public authorities, scientific experts, private litigators and industrial enterprises, to reveal the connection between the disposal of toxic waste and the increased incidence of leukaemia, to bring the case to justice and obtain damages for families who had lost their children to leukaemia, and, ultimately, to have the companies clean up the waste dump and change their disposal practices.

The story behind “A Civil Action” poignantly illustrates many of the problems that beleaguer contemporary society in the pursuit of health and a clean environment. Never before have public entitlements to health and environmental quality found as strong an expression in individual rights. Correspondingly, never before have public mandates to safeguard these values been discussed, implemented and scrutinised as vigorously. Yet the surge in formal health and environmental rights and duties have made the many practical obstacles on the road to their fulfilment all the more visible. The process is hindered, first, by the often mountainous discrepancies in resources and expertise of those who are directly or indirectly responsible for health and environmental threats on the one hand, and those who most stand to suffer from them on the other. In simple terms, industry is a powerful opponent. However, the latter statement needs qualification, since the dynamics between industry and the public cannot adequately be expressed in terms of a
straightforward "us against them" formula. For instance, one element addressed quite powerfully in "A Civil Action" is the concern that, by challenging industrial, wealth-creating enterprises, we might bite the hand that feeds us. On a more general level, this translates into the concern that a drop in the overall level of economic welfare, caused by reduced industrial output, also has significant, negative health and environmental impacts; impacts that might offset the gains resulting from the imposition of stringent performance or compensation duties on industry.

A further aspect qualifying the interchange between the public and industry emerges with particular urgency when we consider the necessary conditions for regulatory intervention. To control health and environmental risks effectively, public authorities are increasingly dependent on cooperation from the enterprises they seek to regulate. Industry is, after all, an important repository of knowledge and expertise relating to those technologies, processes and substances that pose health and environmental concerns. As scientific and technological developments are being introduced into society at an exponentially high pace, it has become practically impossible for "outsiders" to relate health and environmental threats to specific industrial processes or products -- and, hence, to make informed decisions about risk control options -- without access to the information and expertise produced within corporate walls. Additionally, regulators and courts alike are increasingly dependent on scientific experts to inform and guide their decisions. The level of complexity and specialisation of the information submitted to regulatory and judicial decision-makers, invites us to question whether they are still up to the challenge.

A last, but by no means least important aspect complicating the pursuit of health and environmental goals relates, again, to the availability of scientific and technological information pertaining to health and environmental risks. In the Woburn case, access to conclusive data documenting the cause-effect relationship between the toxic waste dump and childhood leukaemia was predominantly obstructed by a web of corruption and deceit. However, in many other cases, the truth is more mundane, and therefore perhaps even more chilling: we simply do not know. It is by rare exception that even the most sophisticated tests and research, conducted by paragons of the scientific community, are capable of producing incontestable answers pertaining to the causes of health and environmental damage. As a rule, the best we can hope for is information that is approximate, plausible. As a rule, we have to contend with
a substantial degree of uncertainty, and make decisions on the basis of partial, constantly evolving knowledge.

The latter predicament is particularly distressing when introduced into a legal setting. Law is strongly beholden to the dynamics of cause-and-effect reasoning. Liability rules, for example, generally require proof substantiating a causal link between an activity (or omission) and ensuing damage for this damage to be legally recognised as the basis for a claim of compensation. Similar evidentiary requirements have traditionally framed regulatory interventions.

In light of this list of complications, which is by no means exhaustive, it is hardly surprising that the "strong arms of the law," both executive and judicial branches, are strained with the burden of upholding and enforcing the level of health and environmental protection to which the public is formally entitled. All too frequently, the outcomes of regulatory and judicial attempts to control health and environmental risks are perceived as unsatisfactory.

The project of this thesis is to investigate how law operates in these politically precarious, scientifically complex and uncertain areas. More specifically, it examines whether the legal framework for the regulation of health and environmental threats adequately takes into account the above-described problems of risk, uncertainty, dependency on information and on multi-party cooperation. Furthermore, it proposes structural legal reforms that aim to optimise the conditions under which decisions for risk control are taken.

Before turning to the heart of the matter, I would like to add a few comments about the genesis and methodology of this work. It goes without saying that I am not the first or last researcher to address the challenges of devising a legal framework that responds to problems of uncertainty. My research has been greatly facilitated by a growing body of literature on the development of a flexible, risk-oriented approach to law and regulation. This literature offered me a solid basis on which to construct the theoretical framework laid down in Chapter I of the thesis.

My study of existing scholarship on the tensions between law, risk, and uncertainty, left me with feelings of both fascination and frustration. The fascination is easy to understand: the adoption of a risk-oriented approach invites us to re-examine some of the basic tenets of existing law and legislation, and opens opportunities for law to penetrate areas that were formerly thought beyond its grasp. The frustration, in turn, arose from an apparent scarcity of
studies that fully exploit the practical utility of the risk-oriented framework as a tool to analyse substantive areas of law and regulation, and as a generator of ideas for their reform.

The remainder of my thesis could therefore be seen as an attempt to fill in this gap. The substantive area selected for analysis, is the regulatory framework for the control of chemicals in the European Community.

The choice of chemicals as a subject matter requires little explanation; it is widely acknowledged that exposure to chemicals can cause serious damage to people, animals and ecosystems. Yet, in spite of this general knowledge, it remains extremely difficult to attribute identified health or environmental effects to specific exposures. Scientific experts would hesitate to proclaim that they know all there is to know about even the most intensely studied substances, or that they are able to pin down with exactitude the concentration level at which a toxin ceases to produce harmful effects. Risk assessment techniques, which are used to estimate the probability that a chemical will cause harm, produce plausible rather than accurate results. Moreover, bearing in mind the burgeoning production of new chemical compounds and the continuous introduction of new uses for existing chemicals, it is highly unlikely that the uncertainty surrounding chemicals risks is a temporary concern.

My study focuses on European Community legal instruments for the control of chemicals. I use the term “European Community” instead of the more encompassing “European Union” because the European competencies on the basis of which legislation pertaining to chemicals is adopted, are part of the first pillar, the European Community pillar, of the European Union. The selection of EC legislation as a focus for the analysis was, first of all, a pragmatic one: over the past decades, the European Community has been a prolific source of legal instruments that affect the control of chemicals in Europe. Furthermore, the risk-oriented approach holds particular attractions for the European Community, since it aims to frame, direct and optimise the conditions for health and environmental decision-making rather than to impose substantive outcomes. Bearing in mind that the implementation and enforcement of EC legislation is mainly in the hands of the fifteen Member States, and recalling the allegiance due to the principle of subsidiarity, this emphasis on procedures and coordination appears well-adapted to the European context. Finally, a few words about the timing of the study. Shortly, the Treaty of Amsterdam will come into force. While the amendments that this Treaty makes to its predecessor, the
Maastricht Treaty, have limited implications for the content of my study, the adoption of the Treaty of Amsterdam does imply that the Articles of the EC Treaty will be renumbered. Throughout the text, I refer to the Articles as they are numbered under the Maastricht Treaty. The corresponding numbers pursuant to the Treaty of Amsterdam ("ToA") are supplied in footnotes.

The structure of the thesis mimics the "regulatory life cycle" of chemical substances. Following the general theoretical framework in Chapter I, Chapter II focuses on the first major prerequisite for chemicals control: the availability of sufficient information on chemical hazards and risks, or risk identification. It provides an overview and critical analysis of existing legal arrangements to stimulate the production of chemical data, concentrating on the EC notification system for new chemicals, and the reporting scheme for older or "existing" substances. Chapter III addresses the question how this raw data is translated; processed into a format that is relevant for the purposes of risk regulation. The prevalent technique, which has also found expression in European law, is risk assessment. Chapter III offers an analysis of the risk assessment practices prescribed in EC law, and a discussion of the controversies that surround the use of risk assessment as a tool for health and environmental decision-making.

Chapter IV discusses the last stage of the cycle: the stage of risk decision-making. It reviews a range of regulatory techniques that aim to secure health and environmental protection, and examines chemical risk reduction mechanisms in EC law. It furthermore investigates whether and how the information produced in the first stage (risk identification) and in the second (risk assessment) are put to use to inform decision-making processes. Each Chapter concludes with an evaluation of the incumbent legal framework, focusing in particular on its compatibility with the risk-oriented approach developed in Chapter I. Finally, Chapter V draws the strands of the preceding analyses together, and offers an overview of the main leitmotifs, strengths and weaknesses of European chemical legislation. On the basis of this assessment, Chapter V concludes with a number of reform proposals that, hopefully, will contribute to the ongoing discussion and elaboration of a legal framework that does not shy away from uncertainty.
CHAPTER I

INTRODUCING RISK AND UNCERTAINTY

Casting a Wider Net for Health and Environmental Regulation

INTRODUCTION

Contemporary social scientists have it that we live in a post-industrial, post-modern society. This claim can hardly be referring to dwindling levels of industrial productivity: global supply of products and services hits new record peaks with every passing year. For example, the European production of chemicals, which substances are the focus of this dissertation, reached an all-time high of 358 billion EURO in 1997.1 Rather, post-industrialism alludes to the emergence of new social paradigms that complement or even replace the "logic of wealth distribution," the latter being the driving force and organising principle of the industrial society.2

One of the main contenders for the title of "post-industrial social paradigm" or "new distribution logic" is the paradigm of the risk society, a term coined by the German sociologist Ulrich Beck.3 It refers to a society where concerns over the production and distribution of wealth are matched (or even overtaken) by concerns over the systematic and inevitable by-production of hazards and insecurities. Indeed, past experience has shown beyond the shadow of a doubt that increased productivity, and particularly the ceaseless introduction of new products and services into society, is inexorably twinned with the production of new and greater hazards and risks. Hence, a society which is successful in maintaining or raising its level of productivity will simultaneously experience a need for rules, behavioural codes or additional products and services aimed to manage or compensate these newly created hazards. To illustrate the link between productivity and rule-making, we need only consider the enormous spree of legislation, rules and behavioural codes sparked off by the development and ever wider spreading use of cars (as well as

1 CEFIC (1998), Profile of the chemical industry, facts & figures ’97, CEFIC document available on Internet, pp. 6 & 12.
3 Ibid.
other motorised transportation means) in our lives. Most obviously, the proliferation of cars on public roads necessitated the elaboration of codes of traffic -- destined both to decrease the hazards of car-driving through the introduction of generalised expectations (e.g., establishing a right of way) and to enable conflict-settlement by reference to a set of pre-established behavioural requirements -- and the introduction of various road signs. Moreover, objectives of hazard management can equally be discerned in, for instance, the introduction of driving license schemes, the adoption of safety standards for the manufacture of cars, the compulsory use of safety belts, and the obligatory subscription to an insurance scheme.

Sometimes, the potential for harm caused by new products or services is so great that it outweighs the benefits entirely. Asbestos, for example, is generally believed to have created more hazard than happiness. The deserted Berlaymont building in Brussels, former residence of the European Commission, serves as a constant reminder of the difficulties attached to controlling and managing hazards that have already materialised.

Systematic wealth-production, in other words, engenders systematic risk-production, which in turn kindles a need, experienced in even the most liberally oriented societies, for instruments that enable the exercise of some kind of control over these risks. More frequently than not, these instruments have assumed the form of laws and regulations. In this Chapter, I will focus on the management of those side-effects of industrial activity that materialise in the form of hazards to human safety, health and/or the environment. I will argue that, due to changes in production environments as well as in our expectations relating to the level of protection we are entitled to, the traditional legal mechanisms put into place to manage those particularly negative side-effects of economic activity have come under severe stress. They no longer adequately respond to what is, essentially, a changed social paradigm. The development of this claim obviously presupposes a general understanding of the way law traditionally coped with industrial hazards, which is offered in the following section.

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4 See, e.g., DAVID HUGHES (1996), Environmental Law, Butterworths, p. 273; UK Health & Safety Executive, Note MS 13 - Asbestos, pp. 2-3.
1. **Traditional Legal Frameworks for Hazard Management**

It is possible to distinguish two main currents of "classical" legal interference into industrial activity with the purpose of hazard management and control. First, legal interference may happen through the establishment of rules and regulations, developed within the realm of the legislative and executive branches. Prescriptions of this kind generally introduce some limitation on the freedom of enterprise (for example, by conditioning industrial exploitation upon prior acquisition of a licence, which is in turn conditioned on compliance with specified safety standards and/or qualitative norms) for the common good, and aim to prevent the materialisation of harm *ex-ante.* The second venue for legal interference resides in the domain of the judiciary, and traditionally operates through the allocation of responsibility to those whose activities are deemed to have harmed other parties, or other parties' property. I am referring, of course, to the well-known dynamics of civil liability suits. Here again, freedom of enterprise may be curtailed, however not to defend the common good but in order to protect the specific interests and entitlements of the plaintiffs who initiated litigation. In other words, whereas rules and regulations seek to further public interests, the basic, traditional mission of the judiciary lies in the protection of individual rights. Furthermore, while rules and regulations aim to prevent harm *ex-ante,* the judicial apparatus can only be activated *ex-post,* namely after harm (or at least a case-specific, identifiable and well-circumscribed threat of harm; see below) has occurred. Civil liability's most obvious purpose, therefore, lies in the compensation of injured parties.

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8 Undeniably, there are instances of both rules that are extremely case-specific and aim to protect the interests of a narrowly defined or definable group, and, on the other hand, of claims reflecting public interests being defended in the courtroom (e.g., in class action cases, or litigation where one of the parties is a public interest groups). However, these form the exception to the general principle of division of competencies and tasks between the second and third branch.
However, as repeatedly emphasised by the discipline of economic analysis of law, the threat of liability suits equally has a deterring effect on those undertaking potentially harmful activities. From this perspective, liability schemes may encourage a proactive rather than compensatory attitude to hazard management and control.9

It goes without saying that not every summoning of the public interest warrants regulatory intervention. Nor is every damage claim awarded. In order to determine whether regulatory intervention is appropriate, the legislative and executive branches rely on sets of criteria that enable them to distinguish, to draw boundaries between those activities that are acceptable, and should therefore not be subjected to regulatory control measures, and those that are not. Similarly, the judiciary resorts to a number of decision-making rules in order to determine whether or not a claimant should be compensated for alleged wrongs. The criteria that have shaped public and judicial decision-making, are analysed below.

1.1. Policing dangers

When is an activity or situation considered serious enough a threat to health, safety or the environment to warrant regulatory intervention? To make this determination, regulatory authorities traditionally draw on a pre-established set of norms, and relate these to the facts of the case.10 Facts, in turn, are derived from various sources of knowledge, including technical information relating to the activity at issue, experience with regard to similar undertakings and their effects, information concerning the link between the activity and its desired as well as undesired effects, and information concerning the legal status and entitlements of those people and objects potentially affected by the activity. In essence, the exercise of evaluating threats posed by industrial activities — and of weighing the corresponding need to impose regulatory controls and/or constraints on these activities — trickles down to a two-tiered examination,

comprising, on the one hand, the investigation into the existence of a causal link between the activity under scrutiny and identifiable present or future harmful effects and, on the other hand, the assessment and normative evaluation of the present or future harm.¹¹

This two-pronged analysis is clearly reflected in, for example, the concept (or norm) of "danger" as it has been developed in German jurisprudence.¹² A century ago, the Prussian High Administrative Court identified danger where "[k]nown present situations produce other known damage-creating situations in accordance with the laws of causality".¹³ Following the Court ruling, the establishment of danger by regulatory authorities in the first place revolves around the identification of a causal relation between the industrial activity at issue, and an ensuing damage-producing situation ("in accordance with the laws of causality"). As the damage which regulation seeks to prevent ideally has not yet materialised, the construction of causal chains usually necessitates the recourse to a body of experience or, more precisely, "[a] concept of experience that presupposes an “average,” context-bound form of knowledge from practice."¹⁴ In other words, relying on existing technical knowledge relating to industrial activities, on examples of past, comparable activities which had resulted in health and safety (or, with less frequency, environmental)¹⁵

¹² FRANZ KOHOUT (1995), Vorsorge als Prinzip der Umweltpolitik, Verlag Thomas Tilsner, München, pp. 61, 107. In common law countries, the justifiability of private or public intervention is determined on the basis of concepts such as "nuisance" and "reasonableness." While allowing more flexible interpretations than the quite rigidly defined danger standard (see below), these concepts equally fail to capture all the intricacy and complexity of modern environmental problems. See DANIEL C. ESTY (1996), "Revitalizing Environmental Federalism," Vol. 95, Michigan Law Review, № 3, pp. 576-577.
¹⁵ Clearly, the environmental consequences of industrial activity early this century were substantial. However, as will be explored in greater detail below, since the environment had not yet emancipated into a value entitled to regulatory and legal protection, damage to the environment itself, disconnected from its ramifications for human health and property, did not yet constitute a legally significant criterion for regulatory intervention. Cf. "Implementing Community Environmental Law." Commission Communication to the Council of the European Union and the European Parliament, 22 October 1996, COM (96)500, and Council Resolution of 7 October 1997 on the drafting, implementation and
damage, on common sense-based estimates as well as the opinions of technical experts active in the industrial area under scrutiny, regulatory authorities sought to forge cause-and-effect chains with generally recognised high probabilities of materialising.

The construction of a causal link is a necessary, however in itself insufficient condition to meet the regulatory threshold of danger. As indicated in the definition supplied by the German Administrative Court, the concept of danger was equally connected to the likelihood of damage occurring. First of all, it is important to note that damage, as a legally and regulatory relevant concept, is closely bound up with the protection of legally recognised values, such as property and personal integrity, against undue interference. In other words, damaging characteristics, whether present or potential, are attributed to those activities that encroach on other people's rights and entitlements, or diminish the value of legally protected goods and commodities. From this perspective, damage, hence danger, is situated in the conflict-zone where freedom of enterprise touches and overlaps with other values entitled to legal protection. As will be explored in greater detail below, the emergence of new, complex values or "goods" that are deemed worthy of legal protection constitutes one of the factors complicating contemporary policing of dangers in accordance with the traditional framework.

Furthermore, similar to the construction of causal chains, the occurrence or likelihood of future damage -- and therefore of danger -- is at least partially perceived through reference to a body of experience which incarnates the status quo; the "normal," hence acceptable, state of affairs in industrial undertakings. Reference to a normal state of affairs is reflected in, *inter alia*, the adoption of technical standards such as the "generally accepted technical rules" (Allgemein

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16 Cf. KARL-HEINZ LADEUR (1998), "Deregulating Environmental Law in a Perspective of Stimulating Knowledge Generation," in UTE COLLIER (ed.), Deregulation in the European Union. Environmental Perspectives, Routledge, London, p. 43: "[T]he core component of this knowledge base was experience, conceived of as a set of practical rules formulated on the basis of single events, particularly accidents (...) that are empirically observable".

17 WOLFGANG HOFFMANN-RIEM (1990), "Reform," o.c., pp. 441-442.


20 ARNO SCHERTZBERG (1993), "Risiko als Rechtsproblem - Ein neues Paradigma für
anerkannten Regeln der Technik), which are a body of technical expertise incorporating current practices and standard safety measures in an industrial discipline. Regulatory activity targets those industrial activities the impact of which evidently transgresses the flexible boundaries of this generally recognised and acknowledged normality. Correspondingly, the goal of regulatory intervention is to re-establish safety; to reel these activities back within the boundaries of normality, for example through the development of authorisation procedures that condition exploitation licences upon adherence to the generally accepted technical rules.

Summarising, in order to breach the threshold of danger, which triggers opportunities for regulatory intervention, the following factors have to be united:

- a causal chain between industrial activities and present or future damage;
- well-established bodies of technical and practical knowledge and experience, both to reaffirm the plausibility of the causal chain and to allow assessment of an allegedly dangerous activity against the backdrop of generally acceptable industrial practices; and
- an encroachment on legally protected values, which permits a legal qualification of “damage.”

Undeniably, assessments of danger necessarily involve a certain degree of conjecture, even in cases where established technologies are well-tried and tested, and technological change is implemented in a gradual, incremental way. Nevertheless, the availability of information and experience, combined with the relative straightforwardness of a mechanistic approach linking individualised inputs to unilateral effects, traditionally allowed regulatory authorities to distinguish dangerous from safe situations in a credible -- and therefore acceptable and legitimate -- manner. Within this framework of relative certainty, uncertainties are cast as aberrations, irritable yet too small to

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das technische Sicherheitsrecht,* Vol. 84, Verwaltungsarchiv, p. 490.
threaten the fundamental mechanism of causation- and experience-based
decision-making. It is, however, highly questionable whether this view is still
tenable in a post-industrial society. As uncertainties multiply, the irritation of
established decision-making mechanisms exacerbates to the point of disruption.
Further in this text, I will explore the circumstances that precipitated this change.

1.2. Allocating liability: an exercise in causal thinking

Anyone who has ever ventured into legal studies is familiar with the basic
concept of civil liability: those who, through their fault, have caused damage to
others, are to be held liable for this damage. Although formulations may differ
from one country to the next, civil liability in continental as well as common law
systems is founded on the pillars of fault, damage, and causation.\textsuperscript{24} The
concepts of damage and causation are essentially similar to the ones deployed in
policing practices: they are closely bound up with encroachments on vested
interests (\textit{e.g.}, property, personal integrity) and the attribution of damage to a
singled-out, identifiable cause. With regard to fault, it is interesting to note that
the operating principles to determine fault resemble the ones relied on for
danger determinations, in that "fault," like danger, is perceived as a deviation
from the norm; from the "normal state of affairs." Fault, in other words, is
staked out by reference to a general framework of expectations and standards of
what constitutes faultless behaviour. Such frameworks are reflected in legal
reference criteria such as the "bonus pater familias" and the generalised duty of
care. Thus, an alleged perpetrator will be considered to have committed a fault
if his behaviour was significantly different from that of an imaginary "good
housefather" or person observing his duty of care. The presumed behaviour of
this symbolic good housefather or careful person is, in turn, construed on the
basis of a generally recognised "normality;" a body of knowledge that has been
gradually formed through past experience, and that is continually being
modified, in a gradual, incremental way, as new experiences accrue. From this

\textsuperscript{24} FRANZ KOHOUT, o.c., p. 165. In common law systems, the concept of nuisance as a
basis for private litigation is traditionally interpreted to include the elements of
intentional or negligent conduct that interferes substantially with the use or enjoyment
of the land of another. See ROBERT A. BOHRER (1984), "Fear and Trembling in the
Twentieth Century: Technological Risk, Uncertainty and Emotional Distress," Vol. 83,
perspective, the use of legal precedents in liability suits, which may be invoked by either plaintiff or defendant, can be interpreted as an attempt to select and reconstrue a body of experience against which to measure and evaluate the facts in the case at issue.

The "ingredients" of a traditional civil liability case are clearly illustrated by a 1955 decision of the District-Court of Groningen, The Netherlands. The case was brought by a group of home-owners living in the vicinity of a chemical plant called "Aagrunol," against the latter. The plaintiffs contended that Aagrunol's practice of spraying chemicals in the environment damaged their property and health, and demanded, inter alia, the cessation of this practice. They were furthermore hindered by the stench and the noise produced by the factory, and consequently demanded that all chemical production should stop. The fact of spraying being uncontested, the Court had few problems establishing a causal link with the alleged damage, consisting of perpetual dust floating about, condensing on windows and laundry hung out to dry, and making it impossible for the inhabitants to open their windows. Moreover, several inhabitants complained of headaches, throat aches and nausea caused by the chemical dust. Interestingly, whereas the defendant did not counter the claims relating to the plaintiffs' property, the chemical plant did challenge their statement that its spraying activities caused physical indisposition, arguing that these symptoms were caused by an allergic hyper-sensitivity for which it could not be held responsible. Even though the defendant's argument failed in the case at issue, it is exemplary of the difficulties inherent in linking physical ailments to identified causes, difficulties which will only increase when technologies become more complex and sources of pollution more diffuse.

With regard to the complaints of stench and noise, the District-Court dismissed these claims, arguing that they did not exceed the thresholds of the socially acceptable. In particular, it invoked the testimony of witnesses who confirmed that a certain degree of "malodorousness" was unavoidable, and therefore normal, in industrial areas, and that the smell from other sources was often more intense than the one coming from the chemical plant. As to the noise, the Court was satisfied that it did not exceed the noise level caused by busy traffic, and was therefore "not beyond the limits of the socially acceptable." Thus, the Court referred to a generally accepted state of affairs, measured the

severity of the alleged intrusion against it (which intrusion would constitute a breach of the defendant's general duty of care), and found the argument wanting.

Admittedly, over time liability rules have become more flexible. The scope of damage has been expanded to include future harm, provided that a persuasive claim can be made that, ceteris paribus, the damage will materialise. Interest groups and associations have been given (limited) access to justice to defend values other than property rights and personal integrity. In certain instances, the criterion of fault has made way for that of negligence or -- particularly in cases where the damage-causing parties are economically more powerful than the injured parties and moreover stand to gain from their harmful activities -- has been dropped altogether (no-fault liability). These alterations are indicative of social changes that provoke both liability and policing systems to stretch their boundaries and digress from the well-trodden paths of danger, causation and fault.

2. **The Characteristics of Change**

As I mentioned before, assessments of danger and establishments of causation have always and unavoidably contained a modicum of uncertainty.26 However, whereas before uncertainties were considered relatively small and manageable, and the consequences of "occasionally getting it wrong" remained socially bearable, uncertainties have gradually assumed different proportions, both quantitatively and qualitatively. The changes in scale and perception of uncertainties seriously call into question whether the predominantly causation-, danger- and experience-based style of legal decision-making -- in which paradigm uncertainties are treated as marginal disturbances that might irritate but certainly do not disrupt decision-making -- still provides the legal answers that our society wants and needs.

2.1. **Accelerated scientific and technological developments**

The multiplication of uncertainty is paradoxically and logically intertwined with the acceleration of scientific and technological innovation. Paradoxically, because the growth of science and technology brings with it the production of new information, new knowledge which sheds light on previously unresolved phenomena, and would therefore appear to reduce uncertainty. However, the connection between development (or progress) and uncertainty is also logical when we consider the increased complexity to which scientific and technological developments give rise. Developments in medical science during the second half of this century clearly illustrate the ambivalent relationship between scientific discovery and uncertainty: on the one hand, the discovery of DNA helped to reveal and explain many aspects of the make-up and functioning of organic life forms. On the other hand, it unleashed a plethora of new questions, medical-scientific challenges and, not in the least, ethical dilemmas that will continue to preoccupy experts and laymen alike for generations to come.

In other words, the creation of new certainties irreversibly leads to the emergence of new uncertainties. It is therefore not surprising that uncertainty is particularly prevalent in those areas that are characterised by rapid scientific and corresponding technological growth, such as chemistry and its application in the chemical industry, biotechnology, genetic engineering, and nuclear energy. The example of biotechnology is furthermore indicative of a society where the potential for salvation as well as self-destruction has been driven to extremes: the capacity to produce more food in a world where certain parts are still chronically undersupplied is enormously promising, however this potential

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27 FRITZ NICKLISH, o.c., p. 161.
28 FRANZ KOHOUT, o.c., pp. 74-76.
30 Cf. HENRI OBERDORFF (1991), "L'administration publique face au progrès médical. L'exemple de la recherche biomédicale," *Droit Administratif*, p. 411. Barry Furrow (1983) points out that, even at the level of scientific research, the study DNA creates a number of risks. BARRY S. FURROW, o.c., p. 1405: "The putative risks involve pathogens, altered organisms, and changed immunological defenses. Harmful organisms can reproduce and mutate if an adaptive niche is available. The level of production required for self-sustaining growth may require only a single laboratory experiment, in contrast with toxic chemical by-products linked to commercial levels of production."
blessing cannot be evaluated without taking into account the equally
tremendous threat of uncontrollable mutations causing large-scale and
irreversible harm to global ecosystems. Nuclear energy is another case in point:
it might attenuate our dependence on fossil fuels, which is one of the greatest
environmental problems confronting society today. On the other hand, we need
only think back to Chernobyl to recall the potential for disaster. Thus, scientific
“progress” precipitates changes of a qualitative as well as quantitative nature: it
enables us to raise the stakes to unprecedented levels.32

Technology has equally been subjected to rapid changes. First,
technological processes, procedures and equipment have become highly
complex; they can no longer be understood without availability and mastery of
very specialised information.33 This implies, inter alia, that third parties called
upon to assess and sanction new technologies (such as public authorities in
charge of granting authorisations for industrial exploitation) are increasingly
dependent on a small group of experts to perform their tasks. Moreover,
increased complexity, together with the proliferation of technology, makes the
identification of causal chains between production methods, emissions or
products (potential causes) and damage to property, health or the environment
much more difficult.34 Going back to the case of the disgruntled home-owners
living in the neighbourhood of Aagrunol, we can readily perceive a number of
factors that helped the plaintiffs in reconstituting the causal chain. First,
Aagrunol deployed a relatively simple and highly visible spraying technique to
dispose of its chemical waste. Arguably, had the company used a more
sophisticated disposal method (for example, emitting the chemicals into
surrounding waterways), the connection between Aargunol’s activities and
ensuing health and environmental deterioration might have been far more
insidious and less easy to pin down. Perhaps the main effects would have been
felt by people living outside the industrial zone, who were unaware of Aagrunol’s
existence and activities. Second, Aagrunol was not able to diffuse the issue of its
liability by identifying other potential sources of pollution; it merely contended
that the headaches and throat aches from which its neighbours suffered were
due to “hypersensitivity.” However, we can easily imagine contemporary

32 FRITZ NICKLISCH, o.c., p. 163; GOTTHARD BECHMANN (1991), “Risiko als
Schlusselkategorie der Gesellschaftstheorie,” Vol. 74, Kritische Vierteljahresschrift für
Gesetzgebung und Rechtswissenschaft, p. 223; PAUL KIRCHHOF, o.c., p. 98.
33 Ibid.
34 FRANZ KOHOUT, o.c., p. 103; DIETRICH MURSWIECK (1991), “Technische Risiken als
scenarios with multiple potential causators, all disclaiming responsibility and pointing an accusing finger at their neighbours. Such complications would have seriously burdened the plaintiffs' case.\textsuperscript{35}

The faster pace of discovery and innovation has not only affected the respective disciplines of science and technology, but also the relation between them. The domain of science and research used to be the testing ground for new ideas and discoveries, and operated relatively independently from the realm of technology. Technology, in turn, represented the stage of application, where those scientific discoveries that were deemed relevant for technological processes were gradually and incrementally incorporated and tested in a pre-established technological framework. This gradual absorption stimulated the generation of practical knowledge and experience, which in turn facilitated the contouring and management of danger.\textsuperscript{36} However, this rather simplified sketch of the relationship between science and technology no longer seems appropriate when we consider the development of science-based technologies (such as chemical production and biotechnology) today. The borders between the two disciplines have become blurred: scientific discoveries find a much more direct, socially relevant application, often without going through the long and gradual process of translation-into-technology.\textsuperscript{37} Instead of incorporation into a pre-established technological framework, scientific progress may now necessitate the development of entirely new and relatively untested technologies. In such scenarios, remaining scientific uncertainties are no longer cancelled out or

\textsuperscript{35} Evidently, the alternative scenarios sketched above could still be further complicated. For example, one pollutant might be harmless in itself, but develop toxic properties in synergy with a second substance emitted by the same or a different industrial plant. \textit{Cf.} FRANZ KOHOUT, o.c., p. 96. Or, the effects of pollution might only materialise after a long latency period, when all tangible evidence of pollution has ceased (for instance, when a polluting company has in the mean time switched to cleaner technologies). \textit{Cf.} JOHN S. APPLEGATE (1991), "The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control," \textit{Columbia Law Review}, p. 272.


rendered marginal through technological experience.\textsuperscript{38} Rather, science-based technologies become themselves characterised by a lack of experience and a corresponding higher level of uncertainty.

2.2. The environment: an unruly object of legal protection

The proliferation of uncertainty and the corresponding loss of experience as a reliable reference point for legal decision-making have put traditional methods of policing and liability-allocation under severe pressure. This pressure is further augmented when we turn to examine the third pillar upon which danger-based policing practices as well as liability determination methods are founded: the encroachment on legally protected values, or "goods," which permits a legal qualification of damage. Traditionally, damage was seen in the context of a violation of either personal safety (integrity) or property. However, in the wake of new technologies and new uncertainties, different kinds of threats emerge which are no longer narrowly related to a potential loss of personal integrity or property, but nonetheless jeopardise values which are now generally thought worthy of protection.\textsuperscript{39}

The first of these values to spring to mind is, of course, the preservation of the environment.\textsuperscript{40} Whereas, if environmental deterioration was at all noticed during the heydays of industrialism, it was considered an unavoidable by-product of progress, concern for the environment has matured into one of the most distinguishing attributes of our contemporary, post-industrial society.\textsuperscript{41}

Naturally, the increased concern is explained to a considerable extent by the realisation of our dependence on a healthy environment for our own


\textsuperscript{40} KARL-HEINZ LADEUR (1994a), "Von der Gefahrenabwehr zum Risikomanagement im Stoffbezogenen Umweltrecht," in GERD WINTER (ed.), Risikoanalyse und Risikoabwehr im Chemikalienrecht. Interdisziplinäre Untersuchungen, Umweltrechtliche Studien, p. 244. In the context of nuclear technology, Reinhard Damm (1993) additionally identifies the following values: a fundamental right to safety, a right for future generations and a claim to "freedom from fear." REINHARD DAMM, o.c., pp. 168-169.

preservation, coupled with the accelerated depletion of environmental resources and the increased potential for environmental disasters. Yet, however anthropocentric the origins of our ecological sensibilities, it stands beyond reason that the environment has joined the ranks of personal integrity and property as an object worthy of legal protection through both policing and judicial measures. This development is reflected, inter alia, in the enactment of environmental rights in national legislation, which in some countries have attained constitutional status.

As a legally protected "good," however, the environment is quite different from property, or even personal integrity. There is, strictly speaking, no such thing as the environment; it is a composite, multifaceted concept the constituting elements of which are anything but fully revealed and understood. Time and again environmental studies have shown that life-cycles in ecosystems do not follow the mechanistic, linear principles that underscore causation-based rationales; instead they are characterised by a high degree of complexity, instability, idiosyncrasy, even randomness. Because of the high level of complexity (which mirrors the increased complexity and, hence, uncertainty, in scientific and technological development) and instability, predictions of damage become extremely precarious. In many cases, they will be too unstable to meet the danger-based threshold of "high probability of ensuing harm." Furthermore, even where effects of human activity on the environment are established, these effects cannot unequivocally be classified as damage. Ecosystems generally have a capacity for biodegradation and regeneration, and are therefore able to "digest" some level of human interference. However, as

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42 Whereas production-, transport- and disposal-techniques may over time become safer and "greener," the expanding scale of industrial production raises the potential for the occurrence of "low-probability-high-impact" disasters.
47 HOWARD A. LATIN, o.c., at p. 203: "[E]cosystems generally possess an assimilative capacity that enables them to recover with little damage from low levels of environmental pollution. Thus, when the environment is relatively unstressed, the damage per unit of pollution will be minimal (...) Thereafter, as assimilative capacity is exhausted and as
with many aspects pertaining to ecosystems, the dynamics of resistance and recovery are anything but fully understood.

Determinations of damage are further confounded by the fact that the relationship of society to the environment is, again, multifaceted and ambiguous. Since we are dependent on the exploitation of environmental resources for our own preservation, it is clear that not every intrusion on the environment should be qualified as "damage" triggering legal intervention. Environmental rights are by no means absolute; the pursuit of environmental objectives must be balanced against the protection of other social goals and values, such as the pursuit of economic growth, freedom of enterprise and the protection of property rights. The balancing exercise is, for example, reflected in the concept of sustainable development, which is the leitmotiv of the European Community's Fifth Environmental Action Programme. Similar to the notion of environmental damage, the concept of sustainability is extremely flexible and underdetermined, and depends upon further political (and, eventually, judicial) decision-making to imbue it with meaning. Finally, the multi-finality with which public authorities have to contend to determine the appropriate scope and intensity of protection is repeated within the confines of environmental protection itself. Environmental protection can refer to the higher pollutant concentrations increase the frequency of synergic effects, the damage per unit of additional pollution rises rapidly (...) Eventually, the environment is so degraded that little more damage is possible and the marginal harm per unit of added pollution is again low (...)"

49 Cf. Nigel Haigh on the principles of European Community environmental policy: "[2]. Exploitation of natural resources which causes significant damage to the ecological balance must be avoided. The natural environment can only absorb pollution to a limited extent. It is an asset which may be used, but not abused". NIGEL HAIGH (loose-leaf edition), Manual of Environmental Policy: the EC and Britain, Longman Publishers, s. 2.4.

50 WOLFGANG VAN DEN DAELE (1991), "Freiheiten gegenüber Technikoptionen. Zur Abwehr und Begründung neuer Techniken durch subjektive Rechte," Vol 74, Kritische Vierteljahresschrift für Gesetzgebung und Rechtswissenschaft, p. 258; DIETER MURSWIECK, o.c., p. 158; PAUL KIRCHHOF, o.c., p. 98. Admittedly, one could rightfully claim that no rights, not even the sacrosanct property rights, are absolute. Constitutional courts, for instance, are often called upon to perform precisely such balancing exercises between conflicting rights and/or interests. Nonetheless, this exercise becomes substantially more difficult when the object of the right itself is partially shrouded in uncertainty and defies clear boundary-drawing, as is the case with environmental rights.


52 RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 64.

safeguarding of a range of different values, including climate, preservation of wildlife, maintenance of ecosystems, biodiversity, clean air, sustainable management of natural resources, etc. The diversification of objectives within environmental protection, which brings with it a potential for conflicts and inconsistencies, raises legal decision-making to yet a higher level of complexity.

Because of the reasons listed above, the environment is an unruly, even elusive object of legal protection. Moreover, the very complexity of environmental decision-making, which requires an impressive amount of information and is furthermore shaped by the necessity to make tradeoffs, to plan and to coordinate, calls into question the appropriateness of a system where the pursuit of environmental goals happens through the vindication of environmental rights pertaining to the individual.\(^{54}\) Rainer Wolf (1996), for one, groups environmental protection together with economic growth, employment and price stability under the heading of collective goods that do not strictly correspond to subjective or individualisable legal entitlements.\(^{55}\) A full analysis of the usefulness of environmental rights to secure environmental objectives would go beyond the scope of this discussion. Suffice it to point out that their usefulness has been challenged, and that this scepticism casts at least a doubt on the adequacy of both danger-based regulatory approaches and causation-based adjudication, dependent as they are on the presence of clearly identifiable goods corresponding to legal entitlements.

2.3. Great expectations

The “symptoms” described above -- the growing level of uncertainty and complexity, the dissolution of causal chains, the emergence of new, underdetermined threats and the maturing of complex social goals -- are indicative of a society in the throes of metamorphosis: the mechanistic, linear and causation-based logic that has dominated our thinking and perceptions...
since the Enlightenment is slowly and painfully being eroded by a new paradigm premised on complexity, multi-causality and non-linearity. Danger- and causation-based approaches to decision-making, which are still beholden to a relatively static and mechanistic world view, fit ill within the changed paradigm; the criteria they deploy no longer resonate in the social reality they seek to structure. In fact, when uncertainty, complexity and multiple protection goals are factored into traditional legal decision-making techniques, the outcome must almost necessarily consist of a decision not to intervene or a dismissal of liability claims.

While such outcome may still be legally correct, it is no longer socially desirable. Not only our scientific and technological prowess, but also public expectations to be protected against the threats and risks it creates, have grown steadily. Increasingly, we look at public authorities to safeguard our health, our environment and even our mental well-being through the adoption of laws, regulations and decisions. Udo Di Fabio (1994) observes that “[p]articularly in the last decades, the old liberal idea to keep society fundamentally free from public control and only exceptionally to intervene in dangerous situations, has lost many of its partisans” (translation from German). Thus, public authorities find themselves in a bedevilling position, since some of the very causes of stronger demands for public intervention -- greater uncertainty, new, not fully understood threats and raised stakes -- simultaneously obstruct decision-making following tried and tested techniques. Given the unlikelihood that social reality will change back to fit legal reasoning, we are confronted with the choice of either abandoning law as a steering mechanism under conditions of complexity and uncertainty, or of developing new approaches within the legal system to cope with changed scientific, technological and social conditions. Below, I will explore the latter option.

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58 Cf. PAUL KIRCHHOFF, o.c., p. 97.
59 Cf. REINHARD DAMM, o.c., p. 160.
3. **Recasting the Net**

In this section, I will examine the legal response to the set of changed circumstances which are discussed above. Certain facets of the new approach -- which I will provisionally label the "risk-oriented approach" -- to legal decision-making, such as information production as a legal objective, are by now fairly well-established, whereas others, such as the introduction of learning capacity and proceduralised approaches in health and environmental legislation, are still maturing. Therefore, some words of warning are in order: it is important not to take the theoretical framework and suggestions that will follow as a *fait accompli*; much like the subject matter it seeks to govern, the opportunities and limits of the risk-oriented approach are anything but fully explored. Furthermore, the substitution of a linear, mechanistic worldview for one that is much more complex, synergetic and dynamic finds its counterpart in the development of legal theories and practices that are less parsimonious, that do not lend themselves easily to categorisation and "if A then B" reasoning, but instead encompass a variety of methodologies, considerations and objectives, which may influence, reinforce, or at times even contradict each other. It would therefore be more fruitful to approach the following description of the legal response to complexity and uncertainty as an open-ended, dynamic attempt at problem-solving rather than a hermetic, chiselled and "ready-to-apply" solution.

3.1. *Lowering the threshold for intervention: from danger to risk/precaution*

A first and crucial step towards a new approach to complexity and uncertainty consists of lowering the threshold for intervention.60 To this effect, the concept of danger, which is conditioned upon the demonstrable presence of a high likelihood of harm, is complemented by the twin concepts of risk and precaution.61 Of the latter, risk is the more delineating concept which introduces the probability of harm (as opposed to the high likelihood of harm) as an alternative triggering point for intervention.62 Distinguishing risk from danger, Udo Di Fabio (1991) points out that we qualify situations as risky instead of dangerous when the possibility of harm occurring is plausible, but

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60 KARL-HEINZ LADEUR (1994a), "Von der Gefahrenabwehr," o.c., p. 244.
61 RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 75.
neither the causation process ("Schadensverlauf") nor the likelihood of occurrence of harm can be evaluated with sufficient certainty. Precaution, in turn, alludes to the kinds of actions undertaken in situations that cannot be classified as dangerous in accordance with the traditional, restrictive criteria (high likelihood of harm, causation, and clearly definable damage encroaching on identifiable entitlements). Examples of such approaches will be discussed further in the text.

Both concepts are intimately related in that they broaden the scope for legal intervention to areas located below the danger threshold. Differently put, the integration of risk and precaution into decision-making gives law a wider reach: it creates an opportunity for legal intervention into activities that, given our growing expectations to be protected against health and environmental harm, should be subject to some form of control, but that are beyond the grasp of traditional, danger and causation-based approaches.

While carving out a territory for risk and precaution, the latter statements simultaneously hint at the first of many problems and paradoxes we will encounter in the development and assessment of a new, risk-oriented approach to decision-making: risk and precaution suggest themselves as alternatives to danger and danger-based approaches (aimed at the restoration of safety), but remain nonetheless beholden to these concepts since they are negatively defined against the backdrop of danger. One of the challenges of risk-based legal theory, and its application in practice, will therefore be progressively to imbue the concepts of risk and precaution with a more positive meaning.

3.2. Drawing in the future: risk, choice and expertise

Danger is the high likelihood of harm, validated by experience. Risk, in turn, is the probability of harm, indicated by suspicion and prediction. It would, however, be too easy to define risks as "weak dangers" and leave it at that. Because of its higher level of uncertainty, risk is a much more socially

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63 UDO DI FABIO (1991), "Entscheidungsprobleme," o.c., p. 345: "[l]m Gegensatz zum traditionellen Gefahrenbegriff wird von Risiken aber gerade dann gesprochen, wenn zwar schadensmöglichkeiten angenommen werden, Schadensverlauf und Eintrittswahrscheinlichkeit aber nicht hinreichend sicher beurteilt werden können".
64 Cf. SERGE GUTWIRTH & ERIC NAJM-GESBERT, o.c., p. 94.
ambivalent concept than danger. The existence of a risk does not only draw our attention to the possibility of ensuing harm, it equally stirs our awareness of the opportunities and benefits that may be derived from risk-taking.\textsuperscript{68} In other words, the identification of risk invites decision-making and choice, under less-than-certain conditions.\textsuperscript{69} From this viewpoint, the multiplication of risk could be labelled a social accomplishment, since it signals an expansion of our decision-making ability.\textsuperscript{70} The regulatory or (to a lesser extent) judicial reaction to risk correspondingly covers a range of possible actions, which -- unlike danger-based approaches -- do not necessarily target the restoration of safety, or the status quo (see below). Furthermore, the concepts of danger and risk reflect the two faces of Janus: danger refers back to the past, relies on experience and spontaneously accumulated knowledge to determine present courses of action. Risk, by comparison, is oriented towards the future; its predominant source of information are predictions about future consequences of new techniques, products or processes -- usually developed within the confines of scientific research institutes and testing laboratories -- rather than previously acquired experiences in the course of practice.\textsuperscript{71}

The shift to alternative, predictive and future-oriented sources of information for legal decision-making, hence the shift towards a risk-oriented legal framework, resonates in the proliferation of relevant standards for the authorisation of industrial enterprises and new technologies. I have mentioned that, in German law, the archetypal requirement for authorisation of industrial enterprises is adherence to the “Generally Accepted Technical Rules” (“allgemein anerkannte Regeln der Technik” or “aaRdT”). The “aaRdT” stand for a body of technical conceptions that have been incorporated and refined in practice, and that are generally well documented and understood.\textsuperscript{72} The “aaRdT” thus mirror the concept of danger, applied as a positive criterion. Now, in areas of increased scientific and technological complexity, the “aaRdT” standard has been supplanted by “Stand der Technik” -- which could be translated as “state of the

\textsuperscript{68} FRANZ KOHOUT, o.c., p. 63.
\textsuperscript{70} Cf. Adalbert Evers (1993), who describes risk as a social construct; a social technology for handling dangers. ADALBERT EVERS, o.c., p. 348. Also FRANZ KOHOUT, o.c., p. 64.
\textsuperscript{71} FRANZ KOHOUT, o.c., p. 64.
"state of the art in science and technology" criteria. Unlike the "Stand der Technik" and "Stand von Wissenschaft und Technik" are not so much informed by technological practice as by specialised, differentiated knowledge including "the latest" in science and technology; knowledge that has not yet found widespread application in practice and therefore still resides within the province of scientific and technological experts from a variety of disciplines such as physics, biochemistry, engineering, ecology, statistics, etc.

As the latter example indicates, while the shift towards a risk-oriented legal framework in areas of complexity and uncertainty may herald a loosening of the ties with practical knowledge and experience, it by no means implies a decreased demand for information. Quite to the contrary, the introduction of risk-based criteria goes hand-in-hand with an exponentially growing want of new knowledge and information, which are filtered into highly complex (and precarious) predictions, technical estimations and probability calculations that attempt to contour the potential for harm, as well as the likely benefits that may ensue from risky activities. Moreover, in contrast to knowledge from experience and practice, which constitutes the cornerstone of danger-based determinations, the kinds of knowledge and data that inform risk do not reveal themselves spontaneously, in the course of practice, but instead call for deliberate efforts in scientific and science-related research.

Thus, the medium of risk forges new and intricate bonds between law and science. This has a number of important implications. First, since the creation of scientific information does not occur spontaneously, but requires deliberation, organisation, infrastructure and investment, the production of this data will gain importance for legal decision-making to the point where it becomes a legal medium.  

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76 KARL-HEINZ LADEUR (1994a), "Von der Gefahrenabwehr," o.c., p. 245.
objective in its own right. This development will be discussed in greater detail below. Second, the processes through which scientific data are generated and validated differ substantially from the accumulation of experience. The production of science is a much more systematic and centralised enterprise than the gathering of experience. Karl-Heinz Ladeur (1994) puts it as follows: "Scientific knowledge is not only more complex than knowledge from experience, it is rather characterised by the fact that it is not embedded in deployment practices in a local, practical context ("situativ-praktisch an einen Anwendungszusammenhang gebunden"), but instead develops self-defined and self-institutionalised rules and control-mechanisms." Hence, with the integration of scientific data into legal decision-making, legal norms and scientific norms become enmeshed. As will become clear in future analysis (see, in particular, Chapter III, Section II on risk assessment), the relation between the two is by no means free of tension.

On an institutional level, the integration of science in law furthermore implies the involvement of the scientific community (expertise) into decision-making. Scientific and high-technological risks are usually considered too complex for government to assess. This is most obviously the case for the legislative and judicial branches, two institutions with general competencies that are confronted with the near-insurmountable task of coming to grips with vast amounts of extremely technical and specialised information, as well as scientific rules of reasoning. Regulatory authorities and administration are somewhat better positioned to accomplish this feat, since their organisation allows a greater degree of functional differentiation, hence specialisation, than that of Parliament or the judiciary. Nonetheless, even bureaucracy increasingly has to

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77 FRANZ KOHOUT, o.c., p. 97.
78 KARL-HEINZ LADEUR (1994a), "Von der Gefahrenabwehr," o.c., p. 245.
82 Ibid.
rely on outside sources of expertise.\textsuperscript{83} Bearing in mind that scientific knowledge is produced in compliance with self-defined, self-institutionalised rules and control-mechanisms, the involvement of the scientific community may not only respond to a practical necessity to supplement knowledge produced within the bureaucratic environment with more specialised forms of expertise, it may furthermore be indispensable to secure the scientific validity, and credibility, of the information produced.

Scientific institutions, expert communities and methodologies need to be folded into legal decision-making. This happens through the development of legal procedures that standardise the use of scientific tests and rules of reasoning for regulatory purposes,\textsuperscript{84} and formalise the cooperation between legal and scientific authorities.\textsuperscript{85} The result is a circular interaction between the disciplines of law, science and technology, whereby law still undeniably maintains a grip on technological developments, however is increasingly determined in its choice of instruments and criteria by scientific and technological developments.\textsuperscript{86}

3.3. \textit{Treading with precaution: the objective of risk reduction}

Danger-based interventions into social -- predominantly industrial -- practices are generally aimed at the re-establishment of safety. Risk-oriented criteria might equally be used to pursue this objective. Applying "traditional" legal reasoning to risk, the outcome would be the following: those activities that might produce harm should be curtailed; they should be reined in to restore the status quo and, hence, safety. Applied to regulation, this approach would result in the prohibition of a significantly larger number of industrial activities, particularly those taking place at the frontiers of scientific and technological developments.

\textsuperscript{83} PAUL KIRCHHOF, o.c., p. 101.
development. In litigation, it would lead to the across-the-board allocation of liability to parties who engage in risky undertakings. Here, risk is used as a functional equivalent to danger in its most narrow sense: the modernisation of the legal framework essentially trickles down to a broadening of the scope for intervention. However, the objective remains the restoration of safety, which also characterises danger-based approaches.

Although certain scholars, as well as legislative initiatives, do indeed advocate this rather minimal form of legal modernisation,\textsuperscript{86} this approach appears neither very productive, nor does it do justice to the qualitative differences that distinguish risk from danger.\textsuperscript{88} It is important to recall that, owing to its higher level of uncertainty, risk is both a more ambivalent and a more dynamic concept than danger. The decision simply to exclude all risky activities creates a different kind of risk, namely the countervailing risk of foregoing opportunities and foreclosing avenues of scientific and technological innovation that, in the long run, might prove safer, or greener, than tried and tested production methods. Furthermore, the elimination of one risk might result in the emergence of others, which may prove more insidious or difficult to control than the target risk. In "Risk vs. Risk," John Graham and Jonathan Wiener (1995) illustrate how the elimination of one risk often leads to the creation of another.\textsuperscript{89}

In light of the foregoing, the exclusion of all risk as a legal objective appears both logically impossible and practically undesirable. The example of biotechnology helps us understand the dilemma public authorities face when choosing the appropriate level of control: an all too stringent, forbidding approach to the risks inherent in the development and commercialisation of biotechnology would prove a powerful disincentive to further scientific research and innovation, and could effectively block all progress in this area. Considering that malnutrition and famines continue to threaten the lives of many people on this planet, the countervailing risks are anything but negligible. Moreover, it is

\textsuperscript{86} Cf. FRANZ KOHOUT, o.c., p. 99.
\textsuperscript{87} See, e.g., PAUL KIRCHHOF, o.c., p. 99: "[T]echnische Überwachung braucht einen Rechtsmaßstab, der das Überwachungsziel konkret benennt und mit gegenläufigen Zielen abstimmt, die zu vermeidenen Risiken und Gefahren zu rechtssstaatlich handhabbaren Tatbeständen macht und dem Überwachten die freiheitliche Sicherheit in Tatbestandlichen beläßt". See also DIETER MURSWIECK, o.c., p. 152, on the shortcomings in modernisation of technology law.
not as though naturally grown foodstuffs are by definition risk free. In a series of widely publicised studies, the eminent US toxicologist Bruce Ames (1987) argued that so-called natural pesticides, which can be found in, for example, peanut butter, broccoli and mushrooms, may pose higher cancer risks than many man-made chemicals. In addition to science-based consideration, it should furthermore be taken into account that a blanket prohibition on entrepreneurship in areas of high scientific uncertainty and complexity would cut deeply against the grain of the liberal ideology of the "Rechtsstaat" which, although it has been relaxed over time to accommodate, inter alia, welfare and environmental considerations, still represents an important parameter to assess the legality of state intervention. On the other hand, to allow the unbridled proliferation and marketing of uncertain, incompletely tested and unstable new technologies, particularly if there are serious indications that, if the risks materialise, the consequences could be disastrous and irreversible, would be equally inappropriate. Somewhere in-between these two extremes, the desirable level of intervention is situated. The corresponding target is not risk elimination, but rather risk reduction. The approach followed aims towards precaution rather than restoration of the pre-existing status quo, often expressed as "safety."

The goal of risk reduction affords greater flexibility than elimination: it is compatible with a range of different risk management options, and allows the balancing of a variety of considerations to be taken into account in legal decision-making. Considerations might include, for example, the likelihood of ensuing harm (are there only vague indications, or has the probability of harm been predicted in accordance with standardised, plausible risk analysis techniques), the kind of damage anticipated (damage to health/safety/the environment; reversible/irreversible damage; large scale/small scale impact), the cost of intervention, the availability and risks of alternative approaches, etc. Depending on the weight and merit of such factors in each specific case, a range of risk control alternatives might be considered under the umbrella of risk

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90 See, for example, BRUCE AMES, RENAE MAGAW & LOIS SWIRSKY GOLD (1987), "Ranking Possible Carcinogenic Hazards," Science, pp. 272-275.
91 RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 79.
92 FRITZ NICKLISCH, o.c., p. 163.
93 RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 75: "[R]isiko läßt sich minimieren, aber nicht ausschließen".
94 Ibid., p. 70; FRANZ KOHOUT, o.c., pp. 108-109; DIETER MURSWIECK, o.c., p. 157.
In cases where the risks of, say, a certain pesticide are fairly well understood, the costs of risk abatement are reasonable and moderately priced, more promising alternatives are available (in other words, where risks lean towards the danger threshold), a prohibition on the manufacture, marketing and use of this substance might indeed be the most advisable course of action. On the other hand, if alternatives are not readily available, risks might more sensibly be contained through the prescription of safety precautions and mandatory training of those involved in risky activities. In areas of high scientific and technological uncertainty, the most appropriate option might be to insist that undertakings that use new, unstable technologies develop emergency plans that map out courses of action in the event of accidents, and/or to require that risky activities, technologies and products are constantly monitored and reported, in order to inform future decision-making.

The latter measures (monitoring, reporting) re-affirm the close ties between precaution, targeted at risk reduction, on the one hand, and information production on the other (see above). The importance of information can hardly be overstated; it constitutes the pivotal axis of a risk-oriented approach to legal decision-making, and its production, processing, interpretation and distribution are crucial elements in any risk reduction strategy.

For reasons that will be discussed in greater detail in the next Chapter, the task of producing and supplying risk information to a large extent has been allocated to parties who engage in risky undertakings ("risk creators") and usually stand to gain from risk-taking, typically industrial enterprises. Information-related obligations imposed on risk creators cover a wide range of different activities. Risk creators may have to comply with one, or several, of the following requirements:

- to keep abreast of scientific and technological developments;
- to engage in research in order to contribute to the pool of information, hence knowledge, pertaining to risks;
- to subject new products and technologies to tests and assessments before bringing them on the market;

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• to inform public authorities, employees, users and consumers about risks;
• to monitor, or contribute to the monitoring of, the impact of risky substances and activities on health and the environment; and
• to make monitoring reports publicly available.

In risk reduction strategies, information performs a dual role: it is both the objective of risk control measures (for instance, where risk creators are required to engage in ongoing scientific research) and the basis, or background, for other risk decisions (for example, where consumers adapt their behaviour in accordance with safety instructions on the packaging of a risky product).99 This has a number of implications, which I will examine more closely in the following section. Preliminarily, we might observe that, while science forges links between the legal and the scientific community, the medium of information furthermore draws public authorities, industry, experts, interest groups and consumers — all of which receive and produce information — into an intricately branched network of information supply, reception and exchange.100 In other words, risk reduction strategies to a considerable extent hinge on communication.101 Consequently, within a risk-oriented framework, a new mission for law takes shape, namely that of facilitating and steering communication between social actors and institutions.102

3.4. Implementing risk reduction strategies, or, how to engineer a risk-oriented legal framework

Let us suppose that we accept the underlying premise of this manuscript, namely that the adoption of a risk- and precaution-based approach could help society in dealing with problems of uncertainty and complexity (problems that cannot adequately be managed with traditional danger- and causation-based approaches), and that the legal apparatus is retained as the instrument of choice

102 FRANZ KOHOUT, o.c., p. 86: "[M]it Hilfe des Rechts als "legislativen Programm" versucht der Staat nun gesellschaftliche Prozesse bewusst zu steuern". Cf SERGE GUTWIRTH & ERIC NAJM-GESBERT, o.c., p. 62, on the "relational" concept of law, which stresses law’s mediating functions.
to implement risk-oriented strategies. This leads into an inquiry of how the legal system can be sensibilised, or opened up, to accommodate the scope, characteristics and goals of risk-orientation and precaution. In other words, what should risk-oriented laws, rules and decisions look like, and which institutions should be in charge of implementing and enforcing risk-oriented legislation?

3.4(a) Institutions for risk decision-making

Tackling the last question first, we recall that, in the traditional framework, both regulatory and judicial authorities perform vital functions in the implementation and enforcement of legislation aimed towards safety. Typically, regulatory authorities issue authorisations, conditioning exploitation on the adherence to safety standards that have been developed in industrial practice (such as the "aaRdT") and prohibit those processes, practices, products and technologies for which experience has shown that, in all likelihood, they will result in harm. Victims of dangerous products and procedures can seek relief in the courtroom, where perpetrators are held to a general duty of care, again informed by practice and experience. The allocation of liability does not only allow for compensation of the damaged party, it furthermore sends a warning signal to others involved in similar dangerous activities.

While the adoption of risk-oriented approaches undoubtedly precipitates fundamental changes in regulatory and administrative practice, it is widely accepted that regulatory bodies, and bureaucracy generally, continue to play an important role within a risk-oriented legal framework. In fact, for a number of reasons set out below, it is often claimed that the integration of risk and precaution into law engenders a regulatory explosion. The position of the judiciary within a risk-oriented legal paradigm, on the other hand, is far more contested. Authors such as Stephen Breyer (1993), Dieter Murswieck (1991) and Clayton Gilette (1990) assert that the swing towards risk institutes a bias in favour of regulatory, and against judicial action.¹⁰³ Courts, so they claim, are less capable of handling the higher level of uncertainty that comes with risk, than are regulatory bodies. Judges generally have a wider area of competence

than regulators,\textsuperscript{104} which also means that they have to spread their expertise more thinly. Bearing in mind that the factual complexity alone of risk decision-making already strains the regulatory apparatus to its limits, it is easy to see how it could overtax the judiciary. Logistic constraints, however, are only the tip of the iceberg. Hypothetically, it would be possible to boost the judiciary's scientific and technological credentials, for example, through the establishments of science courts (see fnt. 104) or the employment of more scientifically and technologically versed manpower. Yet, underneath this quite manageable problem lurks the far more daunting issue of judicial authority. I have previously indicated that the uncertainty that characterises risk implies that decision-making presents itself as a choice, leaving scope for discretion, rather than the inevitable conclusion of an exercise in causal thinking.\textsuperscript{105} Scientific uncertainty is moreover matched by increasing political uncertainty, since accelerating developments and innovations in the scientific and technological arena -- which at times beckon radical take-offs from tried and trusted research principles, production methods and technologies -- constantly urge society to rethink and reconceptualise its views on progress, welfare, and the goals it seeks to attain.\textsuperscript{106} Thus, uncertainty and complexity lay bare the political content of decision-making, which implies that risk decision-making assumes the form of policy-making rather than an application of the rules of law to the (scientific) facts of each case.\textsuperscript{107} Whereas the judiciary's credentials as interpreters of the law are firmly established, its authority as an overt policy-making institution is far more debatable.\textsuperscript{108}

\textsuperscript{104} Possible exceptions are specialised courts, such as the Belgian labour courts, which have mixed membership of professional judges and lay judges who are experts in the subject matter adjudicated by the court. Proposals have been made to establish "science courts," where scientists would assist professional judges in decision-making. Cf. CARL CRANOR (1993b), "Science Courts, Evidentiary Procedures and Mixed Science-Policy Decisions," Vol. 4, RISK - Issues in Health & Safety, pp. 113-132, in which the author argues against science courts as science-policy decision-makers. Criticism aside, it is unlikely that the proposal to establish science courts will gain sufficiently strong footing to be implemented in the foreseeable future.

\textsuperscript{105} Cf. SERGE GUTWIRTH & ERIC NAIM-GESBERT, o.c., p. 53.

\textsuperscript{106} ADALBERT EVER, o.c., p. 342.

\textsuperscript{107} Cf. RONALD BRICKMAN (1987), Commentary on "Uncertainty, Ignorance and Policy" by Jerome R. Ravetz, in HARVEY BROOKS & CHESTER COOPER, o.c., pp. 90-91.

\textsuperscript{108} Cf. Dieter Murswieck (1991) on the German Federal Constitutional Court's "Kalkar" decision, in which the Court itself denied the ability of lower courts to second-guess policy decisions in areas of uncertainty. DIETER MURSWIECK, o.c., p. 149: "[S]o hat das Bundesverfassungsgericht im Kalkar-Beschluß dem OVG ("Oberverwaltungsgericht") Münster wegen seine Befürchtungen hinsichtlich der Folgewirkungen der Brüter-Technologie für den Freiheitsstandard in unserem Staat entgegengehalten, hinsichtlich des möglichen Eintretens "künftiger politischer Entwicklungen allgemeiner Art" gebe es
A last and compelling argument against the judiciary's candidacy for risk decision-making is that, even if courts had sufficient authority to act as policy-makers, they would be ill-equipped to implement rational risk policies. Risks are ubiquitous, and in a society that disposes of limited resources, they cannot all receive attention and be dealt with at the same time. The omnipresence of risk makes risk decision-making extremely vulnerable to inefficiency, since focusing on the assessment and control of one risk may easily imply that another, potentially far more serious, risk slips through the mazes of regulatory and/or judicial attention. Risk decision-making could therefore greatly benefit from a certain amount of strategy and planning, to which I will come back in the next section. As risk decision-makers, courts are constrained to rule only over those issues that are brought to their attention; they cannot themselves provoke litigation in areas which, in their opinion, most urgently need legal intervention. Additionally, we recall that, with the emergence of new threats, social goods and values are jeopardised which do not clearly correspond to the interests and entitlements that litigants traditionally seek to vindicate through judicial action. Given restrictive rules of standing -- or, even if those are loosened, collective action problems -- it is highly possible that, in private litigation, common interest considerations (such as concerns for the environment, climate, and even cost/benefit calculations weighing the social costs of a decision against its private benefits) would not even enter into judicial decision-making. Admittedly, collective action problems might equally bias regulatory action in favour of specific interests. However, unlike judges, regulatory bodies are at least bound systematically to take into account the common interest. Judicial action, on the other hand, is framed by the facts and interests represented in the case, and judges do not have the power to broaden the scope of deliberation beyond the requests submitted by the parties.

Taken together, the aforementioned factors seriously hamper the court's ability to act as the driving force behind the implementation of a risk-oriented legal framework. More likely, its role will largely be restricted to reviewing risk decisions and policies developed in other fora. And even in this function, scientific and political uncertainty, as well as an awareness that individual decisions might thwart regulatory planning and thus in the long run cause more
harm than good, may sway judges to grant regulatory authorities a high degree of deference.110

3.4(b) Planning

Going back to the first question (which characteristics should a risk-oriented legal framework embody), I have already mentioned that risk-based approaches should make room for a certain amount of planning and strategic decision-making. Essentially, planning aims to respond to the problem of decision-making under conditions of uncertainty, given scarce resources. Planning is first of all important in the formulation of information supply duties. Information that is produced at the frontiers of scientific and technological development is extremely expensive, but indispensable for risk decision-making. Hence, information production and supply laws should carefully aim to avoid data gaps as well as unnecessary duplication.111 While information-sharing and -exchange should be stimulated for the sake of efficiency, sharing arrangements should be finely calibrated to afford sufficient protection to those who have made the initial investment in data production.

A second aspect of planning is that of coordinating different pieces of risk-oriented legislation. Again, the example of information duties offers a helpful illustration: since information is costly and hard to come by, and considering that the introduction of production and supply duties requires a significant amount of forethought and organisation on the part of the legislature, it is paramount that the results of data production efforts are indeed relevant and effectively used in risk decision-making. To further this goal, it is necessary to target risk data production and processing duties with reference to risk management (or risk reduction) goals set in health and environmental legislation and regulation. In other words, risk reduction objectives might be used to inform and fine-tune information duties. Conversely, the information generated in accordance with production and supply duties should be fed into decision-making processes. This means that legislation and regulation calling for risk management measures should refer to information duties, and contain requirements for the decision-maker (typically a regulatory authority) effectively

110 Ibid.
to use this information. Thus, information production and risk management should co-exist in a delicately balanced symbiosis. This is not easy to achieve, since the mutual interdependence between information and risk management could easily foster the development of a catch-22 situation: in order to target information duties, we need to link them to risk management goals, and in order to set these goals, we need information. The legal framework therefore needs both flexibility and focus to ensure that information production and risk management stimulate rather than obstruct each other. Needless to add, this will require a considerable amount of strategic thinking and planning during the law-making process.

Finally, planning is often discussed in the context of priority-setting, or "worst things first," meaning that the most serious risks should rank highest on the regulatory agenda. Risk-oriented legislation should move beyond -- or rather, above -- the level of case-by-case decision-making on individual risks, and provide an overarching framework that allows some form of comparative risk ranking. This calls for the adoption of standards, criteria and procedures that assist regulatory bodies -- or whichever other institution is in charge of implementing risk policies -- in comparing and prioritising risks. Obvious as this solution may sound in theory, in practice it is one of the most complicated aspects of risk decision-making. Determinations of which risks should receive priority, are easily confounded by both the insufficiency and complexity of information, by differences in assessment techniques which impede comparisons between different risks, by the multiplicity of protection goals (should risks to health by definition rank higher than risks to the environment, should risks the effects of which may be felt by future generations take a backseat vis-à-vis risks threatening the present population, is wildlife more important than climate change, etc.), and many other factors. In light of changing value patterns and new information becoming available on a daily basis, priority lists should moreover be open to review and modification, which complicates the process.

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3.4(c) Corrigeability, experimentation and open-endedness

While discussing the advantages and shortcomings of regulatory, respectively judicial risk decision-making, I mentioned that because of uncertainty, risk decisions will inevitably be taken with a certain degree of discretion. Answers to problems of risk do not come with a foul-proof guarantee; the complexity of the subject matter frequently defies the formulation of clear-cut, uniformly applicable solutions. Given the range of factors to be taken into account in risk analysis, many of which are incompletely understood or documented at the time of decision-making, occasional "miss-hits" may well be unavoidable in risk regulation.\footnote{JOHN S. APPLEGATE (1992), "Worst Things First," o.c., p. 283: "[R]isk regulation acknowledges the inability to predict who will be harmed and when".} Grim as this predicament may sound, it is nevertheless possible to map out regulatory approaches that to some extent mitigate against the underdeterminacy of risk, or even positively exploit this underdeterminacy to develop more responsive, risk-sensitive forms of intervention.

First, errors are obviously less dramatic if they are readily detected and rectified.\footnote{PAUL KIRCHHOF, o.c., p. 99.} A legal framework for risk regulation must therefore be able to observe the impact of its decisions (self-observation), accommodate the integration of both observation and new information after initial risk control measures have been decided on, and leave room for \textit{ex-post} correction and improvement. This requirement has been captured in German legal scholarship by the terms "Nachbesserung" -- which might loosely be translated as "subsequent or \textit{ex-post} improvement" -- or "Verbesserung durch Selbstrevision," which emphasises the role of self-observation in the development of \textit{ex-post} improvements.\footnote{KARL-HEINZ LADEUR (1994c), "Zur Prozeduralisierung," o.c., p. 329.} To facilitate "Nachbesserung," risk legislation and regulation will not infrequently adopt a layered or staged approach to decision-making,
resulting in decisions that are not absolute or final, but are instead periodically subjected to review and re-evaluation.120

One of the side-effects of this approach is the higher frequency and intensity of communication between regulatory authorities and the addressees of layered regulatory intervention. The altered dynamics between regulating and regulated parties furthermore imply that, slowly, concepts of legal certainty and legitimate expectation acquire a changed meaning.121 For the addressees of risk regulation, which incorporates a layered approach to decision-making, certainty and expectations have less bearing on the content or presumed finality of decisions that affect them, but are rather reflected in the guarantee that, if decisions are to be modified, they will be alerted at an early stage and involved in the review process. Thus, under conditions of uncertainty, general principles of law (such as legal certainty and legitimate expectation) may find a more participatory, procedural expression. I will come back to this in the following section.

Approaching the underdeterminacy of risk decisions from a positive angle, regulators might view this problem as an opportunity to experiment with a range of risk control measures, and learn from the experience through self-observation.122 This, again, presupposes a high level of cooperation and communication between regulators and regulated parties.123 Proposals for "experimental regulation" and even "optional regulation" have a great potential for controversy, since they radically depart from established legislative and regulatory theory, traditionally rooted in ideas of uniformity, enforceability of

120 The EC Directive for pesticides authorisation, for example, stipulates that the competent authorities of EC Member States may grant authorisations for a maximum period of 10 years, after which they are subject to review and renewal. Moreover, authorisations may be reviewed at any time when there are indications that the authorisation standards (including effectiveness of the pesticide, absence of unacceptable effects on plants, etc.) are no longer met. Articles 4(4) and (5) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230/1 (1991).


122 Cf. GÜNTER TEUBNER (1993), Law as an Autopoietic System (Eng. translation), Blackwell Publishers, p. 93: "[l]aw can increase its regulatory interference by developing an "option policy" based on the knowledge of the regulatory subsystem in its capacity as an outside observer."

123 MARIUS AALDERS (1993), "Regulation and In-Company Environmental Management in the Netherlands," Vol. 15, Law & Policy, N° 2, pp. 93: "Variation in enforcement styles is a requisite for adequately provoking polluters to comply with the rules; this can be considered as responsive regulation".
rules and deterrence.\textsuperscript{124} Experimentation and optional regulation being relatively novel concepts, their advantages and disadvantages, as well as their applicability in regulatory practice, are still in need of further exploration and analysis.

Similar to proposals for optional regulation are suggestions for the adoption of open-ended risk legislation. Experience has shown that the adoption of rigid, ambitious standards and rules in health and environmental legislation may prove counterproductive, and practically result in non-implementation and/or non-enforcement.\textsuperscript{125} In areas of high uncertainty, it may be preferable to leave solutions open, thus creating space for the settlement of conflicts, as they come up, in a more informal way. In fact, laws might even deliberately be designed to provoke some level of "irritation;"\textsuperscript{126} to stimulate the emergence of problems or conflicts within a confinable area in order to learn from attempts to resolve them.\textsuperscript{127} Comparable to technology-forcing through law, where the benchmark is deliberately set beyond the current "state of the art" in order to compel industrial enterprises to innovate, open-ended legislation could be described as an attempt at knowledge-forcing.\textsuperscript{128} It causes both regulatory authorities and private parties affected by legal or regulatory underdeterminacy to look for workable solutions on a case-by-case basis, thus enabling further learning and knowledge-gathering.\textsuperscript{129}

3.4(d) Proceduralisation

Glancing over the characteristics that risk control measures ideally should embody (planning, revision, experimentation and open-endedness), it becomes apparent that the supporting legal framework needs to be strong on both organisation and flexibility. Increasingly, developments in legal theory and practice indicate that, to accomplish this dual objective, it would be desirable to

\textsuperscript{124} Cf. EDWARD L. RUBIN, o.c., pp. 424-426.
\textsuperscript{125} MARIUS AALDERS, o.c., p. 86.
shift from a substance-oriented framework to one that focuses on procedures.\textsuperscript{130} The somewhat ungainly term of “proceduralisation” has been coined to describe a style of legislation that in the first place aims to structure communication and decision-making processes, but is reserved as to the substantive content of decisions.\textsuperscript{131} Simply put, proceduralised approaches stress “how to do it” as opposed to “what to do.” Rather than ensuring specific outcomes, procedural rights seek to guarantee the legitimacy and effectiveness of decision-making processes.\textsuperscript{132}

The latter aspect makes proceduralised approaches particularly appropriate instruments for legal decision-making in areas of high uncertainty. Clearly, when both the factual foundations and the outcome of decisions are controversial, it becomes immensely difficult to assess their legality with reference to substantive criteria, hence to ascertain whether the decisions taken are commensurate to the legal objectives which they allegedly serve. Procedural guarantees provide an alternative basis for checking the legality of regulatory decisions, thus offering a counterbalance to the administrative discretion that is inextricably part of risk decision-making.\textsuperscript{133}

Because proceduralised laws and regulations are far less content-specific, they are more open to the integration of new information and knowledge. The relative openness of proceduralised approaches may to a considerable extent abate the problem of “law running behind the facts,” and therefore reduce the number of times that laws and regulations need to be amended and brought in line with the most recent developments in science and technology, as well as

\textsuperscript{130} Cf. the economist HERBERT SIMON (1978), “Rationality as Process and as Product of Thought,” Vol. 68, \textit{American Economic Review}, N° 2, p. 9: “[I]n a world (of uncertainty and cognitive complexity), we must give an account, not only of substantive rationality -- the extent to which appropriate actions are chosen -- but also of procedural rationality -- the effectiveness, in light of human cognitive powers and limitations, of the procedures used to choose action.”


\textsuperscript{133} Interestingly, proceduralised approaches might also re-invigorate opportunities for judicial intervention and judicial review of rules and regulations. I mentioned previously that courts are ill-suited to second-guess the substantive content of regulatory decisions taken under conditions of uncertainty. Controlling whether prescribed procedures have been followed, on the other hand, is very much within the competency of courts. Thus, proceduralisation grants courts a clear, if limited, role in risk decision-making. Cf. RAINER WOLF (1996), “Der ökologische Rechtsstaat,” o.c., pp. 57-58.

On the other hand, see Martin Shapiro (1996), who claims that, over time, procedural control has a tendency to develop into substantive control. MARTIN SHAPIRO (1996), “Codification of Administrative Law: The US and the Union,” Vol. 2, \textit{European Law}
developments in political and social arenas. In this regard, proceduralised laws and regulations might prove more durable, and thus less costly, than substantive rules.

There is a popular American saying that if you give a man a fish, you feed him for one day, but if you teach a man to fish, you feed him for a lifetime. In the same vein, it could be argued that proceduralised approaches provide stronger stimuli for regulatory and administrative learning and knowledge-gathering through self-observation, and thus strengthen their long-term ability to make decisions under conditions of uncertainty. Substantive rules, to their credit, allow for uncomplicated compliance control. For example, a provision in air pollution law might stipulate that regulatory authorities may only authorise cars that produce a maximum level X of carbon monoxide emissions. Here, compliance control is relatively straightforward: it suffices to measure the carbon monoxide emission level of different car models to know whether car manufacturers abide by the conditions for authorisation. By inference, it is easy for the administrative body issuing the authorisations to monitor its own compliance with legal prescriptions. Proceduralised rules, in contrast, do not impose outcomes, but offer guidance on how regulatory and administrative bodies themselves can arrive at acceptable outcomes. This clearly requires more intelligence and creativity on the part of bureaucracy. On the other hand, it does enable regulatory and administrative bodies to accumulate experience in problem-solving, experience that can be put to use in future decision-making.

A final argument in favour of proceduralisation is that it facilitates communication and cooperation between public authorities and other social actors. As established earlier on, risk decisions draw on differentiated sources of information, held by a plurality of institutions (public authorities, the scientific community, industry, consumers, environmental interest groups, etc.). The effectiveness of risk regulation will therefore to a considerable extent depend on its success in securing the involvement of these groups and institutions in the regulatory enterprise, by means of participatory procedures. From this angle, proceduralised risk regulation strikes us as less
hierarchically structured than substantive top-to-bottom regulation. Public authority is not so much imposed on society, but rather manifests itself in dialogue with regulated parties, as well as with other social actors who are directly or indirectly involved in risk decision-making, and who are connected through a network of mutual interdependence.138

3.4(e) Conclusion

In the foregoing sections, I have attempted to outline the main desiderata for a risk-oriented approach. Throughout this analysis, it has become apparent that the integration of risk-oriented objectives — for instance, planning, flexibility, open-endedness and proceduralisation — sensibly affects both the outlook and impact of law and regulation. Catch-words such as communication, cooperation and interdependence speak of changing dynamics between regulators and regulated parties, dynamics that have less to do with hierarchy and coercion, and more with participation and consensus-building.

According to critics, these characteristics beg the question of whether the resulting legal and regulatory framework will have enough “bite” to guarantee the achievement of socially desirable objectives. Will co-operation and interdependence not simply play into the hands of the most powerful interest groups — incidentally also the ones who stand to gain most directly from risk-taking activities — who will deploy new channels of communication and participation to secure outcomes that are economically but perhaps not environmentally sustainable? Recalling that the predominant motive behind the adoption of risk regulation is, after all, the improvement of health and environmental protection, this concern merits careful consideration.

Since the theory and practice of proceduralised decision-making are still maturing, it is still too early completely to refute or corroborate the misgivings about the effectiveness of this approach. Nonetheless, preliminary evidence

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138 Cf. MONIKA BÖHM, o.c., p. 193: “[l] der pluralistische Demokratie verfaßen Industriegesellschaft (kann) die inhaltliche Lösung gesellschaftlicher Probleme durch die Verfassung nicht mehr hinreichend vorgegeben werden, sondern (ist) im Dialog von
suggests that cooperative, communicative forms of regulation may indeed be more productive, particularly in the area of information-gathering. Furthermore, it is important to remember that the model of procedural, risk-oriented legislation was designed to enable decision-making in those areas that are beyond the reach of traditional, substantive legislation. In areas of high uncertainty, the alternative to flexible, proceduralised legislation is not stringent, substantive legislation, but the very absence of legislation. It would be particularly imprudent to dismiss proceduralisation on the basis of concerns which the traditional framework cannot resolve. It would therefore be more productive, in my opinion, to continue exploring the concept of risk-oriented, proceduralised decision-making, to examine how it is and further can be put into practice, and to grapple with its shortcomings, looking for perhaps not the perfect, but the best possible solution under conditions of uncertainty and complexity. The remainder of this manuscript aims to contribute towards this mission.
CHAPTER II

RISK IDENTIFICATION

The Quest For Information

INTRODUCTION

It would be difficult to overestimate the role of information in society today. More than at any time in the past, we are immersed daily in a sea of information; following never-ending paper trails, phoning and faxing, plunging into databases, surfing on the electronic waves of the Internet... The pervasiveness, diversity and importance attached to information, together with the seemingly unstoppable growth and diversification of media for the production, storage, transport and communication of information, have become perhaps the most distinctive features of contemporary society, affecting people's lives to such an extent that the epitaphs "information society" or "knowledge society," which were introduced to describe this phenomenon, appear remarkably astute.139/140

A good indication of the pivotal role of information in modern society is the growing body of legislation that deals with information-related issues; a development that has assumed truly explosive proportions over the past few decades. Intellectual property rights legislation is becoming increasingly sophisticated, redefining concepts of property and looking for new ways to protect the economic value of information without unduly hampering accessibility.141 Telecommunications legislation, dealing predominantly with the infrastructure for information flows and communication, has gradually assumed

140 Interestingly, the explosive growth in supply of information and its increased accessibility do not seem to have caused a devaluation of information's worth as a commodity. Quite to the contrary, society today is characterised by an acute awareness of the economic, political and social value of information, and the overriding importance of preserving and protecting this value.
the proportions of a legal discipline in its own right. Information security or "Infosec," dealing with the protection of (electronically stored) data against unauthorised access, modification, theft and loss, is becoming a familiar term in legal parlance.

In addition to the above-mentioned developments that directly address the new challenges, opportunities and demands posed by the proliferation of information and media, the information age affects and modulates legal systems in perhaps less obvious, but by no means less influential ways. More and more frequently, the legal validity of activities, social interactions and agreements is preconditioned upon the supply of information. To take an example from corporate law, the Belgian law of 2 March 1989 relating to the transparency of important participations in companies with publicly traded shares, conditions the lawful acquisition of five percent or more of voting rights in a company listed on the Stock Exchange upon notification of this acquisition to the Belgian Bank Commission and the targeted company. The objective of this law is not to enable either the Bank Commission, the company's board of directors or other shareholders to prevent the buyer from purchasing a five percent interest in the company -- she does not need to obtain an authorisation pursuant to notification -- but simply to ensure that the buyer acts transparently.

Inextricably linked to transparency requirements and information supply duties is the concept of information rights. Information rights or the "right to know" are based on the principle that people are legally entitled to be informed about activities, decisions or agreements to which they are not privy, but which may nevertheless affect their person, property or environment. Going back to the corporate law example, one might argue that the purchaser's duty to notify the company and public (through the intermediacy of the Bank Commission) of sizeable acquisitions of voting rights responds to the company's and shareholders' right to be informed of market developments that, immediately or in the long run, may affect the organisation, management and, hence, market value of the shares.

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142GERD WINTER (1994a), "Regelungsmaßstäbe," o.c., p. 916.
Of all legal disciplines, environmental law is probably the one that is most dependent on supply of and access to information. It is in the field of environmental law that the doctrines of information duties, transparency and rights of access to information have found their most fertile soil, as evidenced by the spree of "environmental information legislation" that has been adopted over the last fifteen years; legislation which aims to ensure that information relating to activities with potentially harmful effects on health and the environment is produced, updated and made publicly available. To quote but a few examples from EC environmental law, it is first of all noteworthy that Article 130R(3) of the EC Treaty, first indent, states that: "In preparing its policy on the environment, the Community shall take account of available scientific and technical data," thereby implicitly confirming the importance of information -- and more specifically scientific and technical information -- for the development of environmental law and policy. In secondary legislation, 1985 was marked by the adoption of the Environmental Impact Assessment Directive, which seeks to ensure that information on potentially harmful effects of industrial and related activities on the environment is produced and made publicly available before the damage actually occurs. Five years later, Directive 90/313/EEC introduced a generalised public right of access to environmental information held by public administrations. At the institutional level, the crucial role of information for the development of environmental strategies was a key factor spurring the establishment of the European Environment Agency, the main function of which consists precisely of collecting and coordinating environmental data.

These are but a handful of examples of environmental policy's information

\[\text{146 In this context, environmental law should be understood to include issues pertaining to human health protection, as is provided for in Article 130R of the EC Treaty (Article 174 ToA).}\]
\[\text{147 Cf. JOSEF FALKE (1994), "Informationspolitische Maßnahmen im Chemikalienrecht," in GERD WINTER [ed.], Risikoanalyse, o.c., p. 68.}\]
\[\text{149 Article 174 ToA.}\]
needs, and the legislative responses to these needs. In the following Sections, I will examine the close links between information and the law in the field of chemicals legislation. More specifically, the following Sections will investigate whether and how EC law encourages the production of data on chemical hazards and risks, and how the supply of chemical information is orchestrated and implemented.
SECTION I - SOURCES OF INFORMATION ON CHEMICAL SUBSTANCES AND RISKS

As discussed in Chapter I, a risk-oriented, preventative and precautionary approach to controlling chemicals is enormously information-intensive. Moreover, it has been clarified that, in order to develop the knowledge basis required for the implementation of a risk-oriented approach, experience is no longer sufficient for the purposes of legislation and decision-making; other sources of information — such as scientific data, expert assessments and biological models — are drawn into the legislative process.

It is useful briefly to summarise the main differences between experience- and science-based knowledge production. In contrast to experience, the accumulation of science-based information does not happen spontaneously, but requires careful planning and the establishment of an organisational framework and infrastructure where deliberate efforts at data-production take place. Whereas experience grows "in the public eye," scientific information is almost exclusively created and fostered within the confines of research institutes and testing laboratories, where access is often literally restricted to qualified personnel such as medical researchers, professors, laboratory assistants; in short: to members of the expert community. Finally, knowledge production on the basis of experience as a rule happens incrementally. Science-based knowledge, on the other hand, is constructed in a systematic way.

The tasks of generating and collecting appropriate information for risk-based decision-making are particularly challenging in the area of chemical substances control. First, the production of scientific data on chemical

154See Chapter I under Heading 3.2.
156JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c., p. 262. Further in this article, Applegate identifies five aspects of regulatory decision-making on chemicals control which explain the enormous need for information on the part of regulatory authorities: (1) the practices of standard setting and quantitative risk assessment; the need to (2) identify regulatory concerns and (3) set priorities for regulatory action; (4) the need for information to monitor enforcement; and (5) the impact of Right-to-Know legislation. Even if not explicitly confirmed by Applegate, it is evident that the above-listed five qualities of current regulatory practice are signposts of the development of a preventative, risk-oriented rather than harm-based approach to chemicals control.
properties, for instance toxicity, carcinogenicity and ecotoxicity, is a complicated, time-consuming and costly endeavour.\textsuperscript{157} It furthermore follows a path riddled with uncertainties. Because of the singularities of many chemically induced diseases (which, for the purposes of this discussion, include environmental deterioration), it may be near impossible to forge solid causal links between exposure to chemicals and health or environmental effects. For example, a substantial number of chemically induced ailments are "non-signature" diseases, meaning that they may be caused by more than one kind of exposure. In fact, relatively few marker or signature symptoms have been identified to connect a particular disease with a particular substance.\textsuperscript{158} Moreover, whether certain chemicals (including most known carcinogens) become activated and cause detrimental effects may depend on the presence -- or absence -- of a variety of surrounding factors, which further complicates cause-effect determinations.\textsuperscript{159} Additionally, quite some chemical effects have long latency periods. In other words, a long period may lapse between exposure and the manifestation of a disease.\textsuperscript{160} Finally, as will be explored in the next Chapter, uncertainties grow even larger when public authorities or expert risk assessors attempt to estimate the risks related to exposure to chemicals with certain hazardous properties.

Thus, the information needed to develop risk legislation is not only copious; in the case of chemical legislation it is laborious and expensive to produce, highly sophisticated, specific and yet precarious, and, by consequence, very difficult to obtain.\textsuperscript{161} Hence, the first question to be addressed becomes: is a sufficient quantity of this complex, hard-to-obtain information produced to serve legal and regulatory purposes? To answer this query, I will take a look at three different institutions that are traditionally believed capable of encouraging the production of information -- markets, courts and public authorities -- and

\textsuperscript{157}See Section II.1 of Chapter III.
\textsuperscript{159}ADAM M. FINKEL (1994), "A Second Opinion on an Environmental Misdiagnosis: the Risky Prescriptions of Breaking the Vicious Circle," Vol. 3, N.Y.U. Environmental Law Journal, p. 309: "[I]t is now recognised (...) that cancer is not caused by a single event, but that a variety of factors, including genetic changes, epigenetic factors, inter-individual differences in genetic constitution and health status, and post-initiation phenomena such as immune response all influence cancer development. The multiplicity of factors implies a multiplicity of causes for any given tumor, with at least four and perhaps several more separate stimuli required to complete the pathway".
\textsuperscript{160}JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c., p. 272.
\textsuperscript{161}Ibid., p. 261: "[F]or regulation whose principal purpose is direct control of certain activities, (...) information is a transaction cost of the regulatory scheme itself."
assess whether, for the production of chemical hazard and risk information, the stimuli they provide are adequate and sufficient.

1. **Markets**

Information on chemicals, and particularly their health and environmental effects, is a very valuable good, the production of which is in the interest of many different social actors. I have already pointed at its usefulness for legislative bodies and regulatory authorities in the development and implementation of a risk-oriented legal framework. Additionally, information on adverse health effects and potential harm to the environment may assist consumers in making informed decisions about which products to buy and which industries to support. Obviously, the fortunes of victims from chemical accidents and people suffering from illnesses that may be the result of exposure to chemicals will often be determined by the availability of information on these issues. Employers who use chemical substances in industrial processes are dependent on chemical information in order to meet their legal obligations of health and safety protection vis-à-vis their employees. Furthermore, a high production and availability of information may prove a positive input for the chemical production industry itself, allowing manufacturers to improve production and gain competitive advantages by offering “better” information services and by marketing products that are demonstrably safer or greener than those of their competitors.

One may therefore safely conclude that there certainly exists a demand or “market” for (environmental) health and safety data. Yet, left to its own devices, the market fails to produce such data in sufficient quantities. Various factors contribute to market failure. In the case of chemicals production and marketing, these factors all come together and mutually reinforce each other. The result is an almost insurmountable wall of obstacles preventing the free production and flow of chemical information.

A first obstacle is linked to the fact that information, generally, has some of the characteristics of a public good. The production costs may be quite high -- they even skyrocket in complex, hi-tech areas such as chemicals production -- and are borne by one party, whereas the benefits are shared

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amongst many.\textsuperscript{163} This creates free-rider opportunities which discourage information production.\textsuperscript{164} Moreover, the value of information becomes apparent only after it has been created.\textsuperscript{165} The risk of investing into information which, in the end, does not pay off, further stifles enthusiasm for such investments.

Information is one public good; the environment another.\textsuperscript{166} Being unable to defend its own interests on the market, the environment is dependent on others (individuals, environmental organisations, etc.) to champion its causes and protect it against harm. Even though during the last decades people have shown themselves increasingly willing to defend environmental interests, collective action problems and legal constraints (for instance, limitations on standing for green groups in court) still prevent a full internalisation of environmental costs into production processes.\textsuperscript{167} Equally, it keeps the production of information pertaining to the environment below par.\textsuperscript{168}

The low visibility of chemical effects -- effects on the environment but also on human health and safety -- and uncertainties about the actual scope of chemical risks constitute a third barrier to information production. Of all the factors contributing to market failure, this one is most specific to chemicals, and probably also the most difficult to overcome. Chemicals are relatively invisible. At most, people are aware that they are "out there," and that exposure to toxins may cause harm. However, it is extremely difficult -- if not impossible -- for laymen to determine precisely when, and to which cocktail of chemicals, they are exposed. Even if exposures were generally recognised, problems created by chemical characteristics, such as the long latency of effects, the manifestation of non-signature diseases, or synergic effects occurring only in the case of exposure to a particular combination of substances, continue to complicate the task of

\textsuperscript{163}MARY L. LYNDON (1989b), "Information Economics," o.c., p. 1810.
\textsuperscript{166}Cf. WOLFGANG KÖCK (1996b), "Umweltökonomie, Umweltpolitik und Umweltrecht," in ALEXANDER ROßNAGEL & UWE NEUSER, o.c., pp. 144-147.
connecting identified exposures to specific health and environmental effects.\textsuperscript{169} Consequently, not only is it impossible for outsiders (people who are not involved in the production, marketing and/or release of chemicals) to make their own hazard and risk assessments and act upon them; they are usually not even in a position to insist on the production and release of such information by insiders because they are not sufficiently informed about which chemicals they, or their environment, are exposed to and which enterprise is responsible for this exposure.\textsuperscript{170}

Moreover, low visibility and uncertainty are powerful disincentives against information production from the point of view of the chemical industry. Prevailing uncertainties jeopardise the reliability of health and safety data, which renders the already costly investment in information production doubly unattractive.\textsuperscript{171} Furthermore, chemical health and safety data are likely to reflect badly on the chemical industry, since they may unveil a number of health and environmental threats of which the public was previously unaware.\textsuperscript{172} From a business opportunistic perspective, it is therefore a tempting option to let sleeping dogs lie. In doing so, industry might successfully insulate itself from consumer action and liability suits. As long as there are no basic requirements for information production -- their existence may turn the supply of environmental and health information from a liability into a competitive opportunity (see above) -- ignorance is industry’s bliss.

Summarising, due to various kinds of market failure, the market (left to its own devices) is an unreliable mechanism for the production of chemical health and safety data. In the following section, I will investigate whether courts are capable of filling in the information gap.

2. **Courts**

A less obvious, but nonetheless important institution capable of affecting the production and supply of information relating to chemicals, is the judiciary. In the recent past, courts have shown themselves increasingly willing to qualify


\textsuperscript{170}MARY L. LYNDON (1989b), “Information Economics,” o.c, p. 1796; HOWARD LATIN, o.c, p. 212.


\textsuperscript{172}Ibid., p. 1813; HOWARD LATIN, o.c, p. 218.
information production and supply as constitutive elements of manufacturers' legal obligations vis-à-vis the buyers of their products. Thus, a chemical manufacturer may be held liable if he fails to communicate information relating to the hazardous nature or risks connected to his product, or even if he fails to discover the existence of such hazardous properties or risks due to insufficient product research and testing.

Not surprisingly, the connection of testing and information requirements for chemicals to product liability rules has in the first place been developed and discussed in the country with the highest number of chemical product liability (or toxic tort) cases, namely in the United States; a singularly litigious society by any standard. However, even in the less lawsuit-oriented European countries, there are indications that the inclusion of research and information requirements in product safety and liability standards is gradually gaining ground. For example, in a 1986 decision the German Bundesgerichtshof concluded that chemicals manufacturers and suppliers have a general duty to inform laymen of the risks relating to the use of their chemical products, and to provide detailed warnings and instructions for safe use. Furthermore, a manufacturer or supplier could not assume to have automatically fulfilled his information duties ("Instruktionspflichten") simply because he had complied with all the regulatory labelling and warning requirements: "[D]urch die behördliche Genehmigung geht deshalb in derartigen Fällen die Verantwortung grundsätzlich nicht vom Hersteller auf die Behörde über."

A similar, more recent pair of decisions in the area of food law took manufacturers’ research and information duties even further. The facts to the first case, decided by the German Bundesgerichtshof in 1991, were the following. The defendant, the company Milupa, produced sugared teases for infants, as well as baby bottles that were smaller and lighter than previously existing models, and could therefore be held by babies without assistance. An unanticipated side-effect of the marketing of these teas and bottles was that babies used the bottles as pacifiers rather than drinking cups, holding the

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174 Translation: Therefore, in such cases approval by public authorities does not cause a shift of responsibility from the manufacturer to the public authority. BGH, Urteil v. 7/10/1986 - VI ZR 187/85, Neue Juristische Wochenschrift (1987), No. 4, p. 327. 
bottles in or close to their mouths for prolonged periods of time. The fact that babies could handle the bottles independently moreover meant that their drinking and suckling habits were now less closely monitored by their parents. Consequently, the babies' mouths were overexposed to the sugar-containing beverages in the bottles, which in turn resulted in all sorts of dental problems and decay. This phenomenon, labelled the "Nursing Bottle Syndrome," became the subject of a medical report published in 1981. In November of that same year, Milupa added the following warning under the heading "Preparation," which figured on the packaging of the tea products: "[H]old the bottle yourself and do not hand to you child as suckling bottle; frequent or continuous rinsing of babies' teeth with teas, for example before bed time, may cause caries." In December 1982, this information was placed under the heading "Important Instructions," and was furthermore printed in Milupa brochures.

At first sight, one might plausibly conclude that Milupa had acted diligently: after the medical report was published, it set out to change the labelling on its products, and later repeated the warning under different headings and in different formats. However, for the parents of the plaintiff -- as for many others -- the warning came too late. The plaintiff was born mid-October 1979, and started teething approximately eight months later. By the beginning of 1981, and thus before the warning was issued, caries was spotted.

In its deliberation of whether Milupa should be held liable for the plaintiff's dental problems, the Bundesgerichtshof developed a number of arguments which made it unequivocally clear that warning and labelling duties should be interpreted very broadly indeed. A first issue revolved around the question whether Milupa should have known about and acted upon the Nursing Bottle Syndrome before 1981. The plaintiff pointed out that, as early as 1971, an article on the subject had been published in a Swiss journal. The defendant contended that, by itself, this early article did not breach the threshold of scientific evidence, and that, therefore, 1981 was the relevant date. However, the Bundesgerichtshof decided that, in any event, the argument was moot because, in its opinion, the Nursing Bottle Syndrome develops within the context of baby bottle and tea production. Hence, Milupa could not have ignored that continuous suckling exposed infants' teeth to the beverages for extended periods of time, and should itself have investigated whether this exposure could have negative side-effects. In other words, warning and labelling duties do not simply require manufacturers to instruct consumers about known and documented
risks, but furthermore imply the obligation to conduct research and tests to discover additional potential negative side-effects of the products in question.

The gravity attached by the Bundesgerichtshof to warning and labelling duties also transpires from a second line of reasoning. In the same 1991 decision, the German court stated that, even after Milupa had added the warning concerning the Nursing Bottle Syndrome under the heading of “Preparation” on the tea packaging in November 1981, and after it had repeated this warning under the heading “Important Instructions” and included information on the Nursing Bottle Syndrome in Milupa brochures as of December 1982, the company still did not fully meet its warning and labelling duties. The Bundesgerichtshof considered the efforts made by Milupa to warn its users insufficient. The labels and brochures were not visible enough. Moreover, no special efforts had been undertaken to warn repeat users of the teas, who generally do not read the instructions anymore because they have been using the product for a long time. Thus, the Bundesgerichtshof clearly interpreted warning duties to mean that users should be effectively, and not just formally, alerted to the risks pertaining to the products.

The second baby bottle decision, issued by the Bundesgerichtshof in 1994, reconfirmed the broad scope given to warning and labelling duties in 1991. In fact, the circumstances in the second baby bottle case strayed even further from the traditional setting for the allocation of product liability than in the 1991 example. In the 1994 case, the company being sued for damage to infants’ teeth was not Milupa, but a rival children’s tea producer. In contrast to Milupa, the defendant in the second case did not produce the light baby bottles that were partly responsible for the occurrence of the Nursing Bottle Syndrome. Moreover, the 1994 defendant did not, as Milupa had done, market its product as a “good night drink;” it even warned against its use after the infants’ teeth had been cleaned in the evening. In spite of these mitigating circumstances, the Bundesgerichtshof still held the defendant company liable. It argued that a cursory warning was not enough; the defendant had to alert users of the specific risks of the Nursing Bottle Syndrome in all its aspects. The argument that the tea, in itself, was a harmless product, and only presented a risk when consumed in a specific type of container (a container which the defendant did not market), did not make a discernible impression on the Court. It simply replied that

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warning duties should not only be complied with by light baby bottle producers, but by all children's tea manufacturers, because their product will mainly be used for consumption in such containers.

Summarising, both the 1991 and the 1994 decision clearly bring home the message that, in product liability suits, pleas of ignorance have hardly any impact. The Bundesgerichtshof expected the defendants to make themselves aware of the risks their products pose -- either by themselves or in combination with other products if that is a foreseeable use -- and to provide clear, unambiguous, highly visible and detailed information on these risks. In fact, one might even claim that the Bundesgerichtshof expected the defendants to be aware of certain peculiarities of modern parenting, such as leaving bottles within children's reach. The defendants' failure to undertake a more extensive form of research, and act upon it, was sufficient for the court to rule against the companies.

The above examples indicate that courts have an important role to play as incentive-givers for information production. However, whether liability-induced incentives would be sufficient to fill in the chemical data gap is highly questionable. For one thing, there are simply not enough court decisions to warrant such large-scale effects. The scarcity of court decisions goes back, once again, to the low visibility of chemical damage. The cited decisions, although innovating in their broad interpretation of product liability rules, are quite traditional in another sense: in both cases there was a clear, easily identifiable causal chain of events which resulted in damage (in the 1986 decision, the plaintiff suing the chemical manufacturer had heated the inside of a kettle which had been sprayed with an inflammable substance. The combination of the heat with gases evaporating from the sprayed-on chemicals coating caused an explosion which injured the plaintiff). However, as has been repeated throughout this text, causal links are the Achilles' heel of chemical hazard and risk assessment. It is therefore unlikely that court decisions would ever reach a sufficient "critical mass" to prod industry into producing chemical information that is extensive and detailed enough to meet the regulatory demand.

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177 According to John Applegate, this holds true even for the United States (JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c., p. 300).
3. Public Authorities

Neither markets nor courts provide sufficient incentives for the production of chemical hazard and risk data. Hence, the success and effectiveness of a legal framework for risk regulation will in the first place hinge on public authorities' ability to generate (or stimulate the production of) chemical hazard and risk information, and subsequently to organise the collection of this information and its use as an input for risk-oriented regulatory decision-making.\(^{179}\)

Public authorities can go about their task of improving the information supply in a variety of ways.\(^ {180}\) The most familiar one is direct knowledge-mandating, where governments or regulatory bodies, using public funds, commission public or private institutions (for instance universities, expert committees, private research laboratories, consultants) to do research and prepare assessments, reports and other documents for the purposes of public chemical risk control.\(^ {181}\) The European Commission very frequently resorts to this tactic: when it wants a study performed, and has gathered sufficient funds to finance it, it will publish a call for tender in the Official Journal, and commission the study to the "best," most promising bidder. This might be a university department, an NGO, an ad-hoc team of experts, a private consulting firm, or any combination of the above. Such direct government investment in chemical data production can be very effective: research mandates are tailored specifically to respond to regulatory needs; the immediate relation between the public commissioner and the commissioned institutions allows for the imposition of quality standards and a high degree of control, and (in principle at least) the information produced by publicly commissioned bodies should be free of the biases that might affect privately produced data (see below).\(^ {182}\) However, publicly funded research and testing cannot possibly keep up with privately


\(^{180}\)HOWARD LATIN, o.c., p. 223.


organised production and release of chemical substances and preparations; due to, *inter alia*, budgetary and personnel constraints, the number of substances that can be investigated remains extremely limited, even in countries with high expenditures in research and development.183

Where information is not sufficiently created through market and liability mechanisms, and public authorities lack the necessary funds and manpower to fill in the data gap themselves, there remains but one alternative: to compel those parties who are in a position to produce and supply the required information to do so, and to bear the costs of this information production and supply. In somewhat euphemistic terminology, this option is referred to as indirect knowledge-mandating.184 In the case of chemical hazard and risk data, indirect knowledge-mandating implies the creation of legally binding obligations, imposed on the chemical industry, to generate and disclose data pertaining to chemicals.185

Leaving information production up to the chemical industry has some clear advantages. First, it allocates information duties to those parties who stand closest to, and therefore are most knowledgeable of, chemical production and release. The degree of specialisation and expertise existing within the chemical industrial community secures a potential for high-quality research and testing that could hardly be duplicated in other fora. Furthermore, considering the financial and economic importance of the chemical industry, it is an industry with deep pockets and therefore better able to bear the high costs of chemical research and testing.186 Finally, it seems equitable that the costs of investigating into chemical hazards and risks should be borne by those entities who stand to gain most from their release.187 One could view this allocation of costs as being in line with the polluter pays principle,188 by claiming that the chemical industry, which is the main beneficiary of the release of potentially harmful chemicals on the market, should bear the costs that are directly or indirectly aimed at minimising this risk of harm to health and the

183 Ibid.
186 CEFIC, o.c., p. 9.
188 Cf. Article 130R of the EC Treaty; Article 174 ToA.
environment.\textsuperscript{189}

On the down-side, indirect knowledge-mandating to some extent requires industry to write its own bad press and potentially expose itself to more stringent regulations.\textsuperscript{190} One may wonder whether this might not compromise the reliability of the data it is called to produce. Although there are few examples of outright distortion, certain indications do lend credibility to the view that industry may not be as scrupulous in exposing and emphasising the hazardous properties of their own products as outside research and testing bodies might be.\textsuperscript{191} Also, knowledge-mandating may foster an uncomfortably close relationship between industry and the public authorities that depend on industry-supplied information. Critics have questioned whether this does not compromise public authorities' assessment of the data they receive.\textsuperscript{192}

In Europe, the development and organisation of information production and supply duties stand out as landmark achievements of EC chemical control policy.\textsuperscript{193} In fact, the notification procedure, which is the most comprehensive of the information supply schemes, is frequently referred to as one of the Community's most successful efforts at market harmonisation.\textsuperscript{194} Hence, the following Section examines the EC-developed legal machinery which was put in place to ensure information availability, concentrating in the first place on the notification procedure.

\textsuperscript{189} Cf. J. McLoughlin & E.G. Bellinger (1993), Environmental Pollution Control. An Introduction to Principles and Practice of Administration, Graham & Trotman / Martinus Nijhoff, p. 154.

\textsuperscript{190} Michael Reinhardt, o.c., p. 653.

\textsuperscript{191} In "Informationspolitische Maßnahmen," Josef Falke points out that, whereas 15% of existing substances have been classified as carcinogenic, mutagenic and/or teratogenic, only 1% of new notified substances has been classified (by the notifiers) as such. Similarly, the percentage of very toxic and toxic substances went down from 38% to 10%. Josef Falke, o.c., p. 78. This discrepancy might be explained by an improvement of the health and environmental quality of newly produced chemicals, or by the fact that characteristics such as carcinogenicity are precisely those which are the most difficult to establish based on pre-market testing alone. We should, however, not ignore a more cynical hypothesis, namely that, in the absence of definitive proof, industry is more prone to adopt a best-case scenario, which may result in a more benign classification than pursuant to a more conservative approach (cf. Section II.2 of Chapter III).


\textsuperscript{193} Franz Kohout, o.c., p. 145.

SECTION II - AN EC LEGAL FRAMEWORK FOR INFORMATION ON CHEMICALS

So far, the European Community's greatest contributions to the development of a flexible, risk-oriented approach to chemicals control have been made predominantly in the area of information production and supply arrangements. Throughout the last twenty years, the Community has managed to set up quite a sophisticated and expansive legal framework of secondary legislation, which was designed primarily to ensure a steady production and flow of chemical hazard and risk data.

Without doubt, the most famous piece of legislation is the so-called "Sixth Amendment" to Council Directive 67/548/EEC, which in 1979 established an EC-wide notification procedure for newly marketed substances.\textsuperscript{195} Later on, the EC turned its attention to the many chemicals that already circulated on the market before notification was introduced, and complemented the notification scheme with an information regime for old or "existing" substances.\textsuperscript{196} Furthermore, there are information and reporting arrangements specific to certain categories of chemicals, such as pesticides, biocides and food additives. Finally, information duties which, \textit{inter alia}, cover chemical substances, their uses and effects, are more and more frequently integrated into general EC legislation aimed at the protection of human health and the environment (for instance, reporting duties developed in EC workers' health legislation, or in the environmental management and audit scheme). Taken together, the different strands of information-oriented rules and provisions weave a far-reaching and intricate network for the production and transmission of chemical data.

1. \textbf{A European Framework for the Notification of New Substances}

The sixth amendment to Directive 67/548/EEC, which harmonised classification, packaging and labelling requirements for chemical substances,


was adopted on 18 September 1979.\textsuperscript{197} In contrast to previous amendments, the sixth amendment did not merely update existing classification, packaging and labelling rules, but introduced an entirely novel EC-wide procedure for the notification of new chemical substances prior to their release on the common market.\textsuperscript{198} The term “Sixth Amendment” became the commonly used reference for the document in which this notification procedure was established. An obvious choice of words at the time perhaps, however the subsequent adoption of a seventh and eight amendment in which, \textit{inter alia}, the notification and information supply duties were updated and expanded, have rendered the name “Sixth Amendment” somewhat confusing and outdated.\textsuperscript{199} For this reason, I hereinafter shall use the term “Notification Directive” to indicate the body of legislation comprising the Sixth Amendment and follow-up amendments.

In the late ‘70s, the European Community was not the only arena where the need for chemical hazard and risk information -- and, consequently, the need to develop notification and information supply requirements -- was being debated. Several countries in and outside Europe, such as Japan (1973), Canada (1975), France (1977) and Denmark (1979), had already enacted (or were in the process of adopting) some kind of data reporting scheme before the EC Notification Directive came into force.\textsuperscript{200} Internationally, impetus for the development of notification and screening systems was supplied by OECD activities.\textsuperscript{201} In 1977, the OECD adopted a \textit{Recommendation concerning procedures and requirements for anticipating the effects of chemicals on man and the environment}. The \textit{Recommendation} contains guidelines for action by OECD member countries, the first of these guidelines being the progressive implementation of administrative requirements, imposed on chemical manufacturers and importers, to:

\begin{itemize}
  \item maintain the results of their assessment of the effects of a chemical for
\end{itemize}

\textsuperscript{197}See ftn. 195.
\textsuperscript{200}CHRISTOPHER ARUP, o.c., pp. 52-53; SAM GUSMAN \textit{et. al.}, o.c., pp. 15-16.
\textsuperscript{201}In this context, screening is the act of reviewing information on chemical substances
examination by the authorities on request;

- notify the authorities of all new chemical substances, with a declaration containing specified information about the substance at issue, such as a declaration of nomenclature for the chemical, projected quantities to be manufactured and intended usage; and

- submit to the notified authorities a dossier on the substance, containing the information required to conduct an initial hazard assessment.\textsuperscript{202}

To be complete, it should be mentioned that in 1981, the OECD Council adopted a \textit{Decision Concerning the Mutual Acceptance of Data in the Assessment of Chemicals}. Through acceptance of this \textit{Decision}, OECD member countries have undertaken to accept test data produced in other member countries, provided that these data were generated in compliance with the OECD guidelines and Good Laboratory Practice (GLP).\textsuperscript{203} Together with the 1977 \textit{Recommendation}, the \textit{Decision} forms the cornerstone of the OECD’s chemical information policy.

Previously mentioned national initiatives and OECD activities certainly helped to spark the European Community’s interest in developing a notification scheme applicable throughout the Community. In all likelihood however, the strongest and most decisive push to stir the EC into action came from the United States. In 1976, the States adopted a “Toxic Substances Control Act” (TSCA).\textsuperscript{204} Much to other (and mainly European) countries’ dismay, the United States had decided not to go through the lengthy process of international negotiation and coordination before putting into place a notification scheme for chemical substances, but instead unilaterally to impose notification requirements for all substances, whether domestically produced or imported, that were traded on the US market. Fearing that this newly erected procedural barrier would put European industry at a competitive disadvantage, the European Community responded by levelling the score: if European importers would have to fulfil notification requirements in the United States, then so would

\textsuperscript{202}Other guidelines cover: a) the development of an initial hazard assessment procedure; b) the type of information that should be supplied when a chemical substance is being transferred along the commercial chain; and c) the surveillance and monitoring of effects in order to control the adequacy of the assessments. See CHRISTOPHER ARUP, \textit{o.c.}, pp. 49-50.

\textsuperscript{203}\textit{Ibid.} On GLP, see Section II.2.4 of this Chapter.

Americans (and Europeans) supplying chemicals to the EC market.\textsuperscript{205}

In spite of one having sparked off the other, there are some marked differences between US and EC notification requirements.\textsuperscript{206} In some instances, the differences help to elucidate the idiosyncrasies, the unique opportunities and also the problems posed by the EC-developed procedure. For this reason, the following analysis occasionally draws comparisons between the Notification Directive and the TSCA.

2. \textbf{The Notification Directive}

The Notification Directive is based on Article 100A of the EC Treaty.\textsuperscript{207} As many instruments in the area of chemical control, the Directive's preamble professes a dual goal, aiming both to further the functioning of the single market and to guarantee the same level of protection of public health and the environment throughout the European Community.\textsuperscript{208} Since this duality of objectives is one of the pre-eminent characteristics of EC chemicals legislation, and moreover of EC environmental law generally, the following Chapters will pay considerable attention to the synergy, as well as the complications, to which the dual rationale gives rise.

Article 1(1) of the Notification Directive reiterates its purpose in more specific terms: the Directive seeks to approximate national laws, regulations and administrative provisions relating to (a) the notification of chemical substances;\textsuperscript{209} (b) information exchange on notified substances; (c) the assessment of the potential risk to man and the environment of notified substances;\textsuperscript{210} and (d) the classification, packaging and labelling of those substances that are dangerous to man or the environment.

In essence, notification entails the presentation of documents, containing

\textsuperscript{206}SAM GUSMAN et. al. o.c., p. 10.
\textsuperscript{207}Article 95 ToA.
\textsuperscript{209}The Directive defines "substances" as "[c]hemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." (Article 2(1)(a)).
\textsuperscript{210}See Chapter III.
the information required by law, to the competent authority of a Member State
(for example, the Ministry of Health and Environmental Hygiene in Belgium; the
Health and Safety Executive in Britain). Any EC-based manufacturer or importer
who intends to put a new chemical substance on the market, must comply with
the notification requirements. Article 10 of the Directive confirms notification
as a pre-condition to market release: "[I]n the absence of any indication to the
contrary from the competent authority, the substance may be placed on the
market no sooner than 60 days after receipt of a conform (notification) dossier."
The minimum delay of 60 days starts running once the competent authority has
established that the submitted dossier is in conformity with the requirements of
the Directive. The assessment of conformity, in turn, has to be made within
60 days after submission.

Certain categories of chemical substances are exempt from notification.
Most importantly, the notification scheme only applies to new substances and
compounds; not to existing substances, i.e., chemicals that were already on the
market prior to the adoption of the scheme. 18 September 1981 was generally
accepted as a reference date to mark the adoption of the notification
requirements by the Member States. In order to alleviate the burden for
individual manufacturers or importers of having to examine whether the
substances they intend to market were in circulation before 18 September 1981,
it was decided that a joint EC-organised effort would be undertaken to draw up
an inventory of all "existing substances." This inventory was completed and
published in 1990, and is commonly referred to as the EINECS (the European
Inventory of Existing Commercial Chemical Substances) inventory. Consequently, Article 13(1) of the Notification Directive provides that substances
listed in the EINECS are exempt from notification. Equally exempt are certain
substances covered by other EC legislation (such as animal feedingstuffs and
medicinal products) or subject to equivalent notification or approval procedures.

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211 Article 2(1)(d) of the Notification Directive.
212 Article 16(2) of the Notification Directive.
213 For substances manufactured under a certain tonnage threshold, both the conformity
assessment period and the minimum delay for market release are shortened to 30 days.
See point 2.5(a) below on tonnage thresholds.
214 LUC LAVRYSEN (1994), "Strategies for the Control of Chemical Substances in the EC,"
in BETTY GEBERS & JERZY JENDROSKA (eds.), Environmental Control of Products and
215 SAM GUSMAN et. al., o.c., p. 62.
216 See point 2(7) below.
(for instance, the EC pesticides authorisation procedure\(^{217}\)). Finally, there are those substances that are not technically exempt, but are "considered to have been notified." They include substances placed on the market in extremely limited quantities (less than 10 kg per year and per manufacturer), substances sold in limited quantities (less than 100 kg per year and per manufacturer) and intended solely for the purposes of scientific research and development carried out under controlled conditions, and, for the period of one year, substances placed on the market for process-oriented research and development with a limited number of registered customers in quantities limited to the purpose of process-oriented research and development.\(^{218}\)

For the purpose of market integration, the most crucial Article of the Notification Directive is undoubtedly Article 30. It stipulates that Member States may not prohibit, restrict or impede the placing on the market of substances that comply with the requirements of the Directive on grounds relating to notification, classification, packaging or labelling within the meaning of the Notification Directive. In other words, a substance that has been duly notified in one Member State should not be subjected to additional notification requirements when it enters another; one notification is valid throughout the Community. It is important to bear in mind, however, that this mutual recognition of notifications is, indeed, nothing more than that; Article 30 in no way encroaches on Member States' competencies to restrict domestic trade in chemical substances on the basis of, e.g., health or environmental considerations.\(^{219}\) The harmonised notification scheme therefore should not be confused with an EC-wide authorisation of new chemicals; the strengths of the Notification Directive lie predominantly in its ability to generate and distribute chemical hazard and risk information and in the administrative simplification made possible by the harmonisation of information production and supply requirements.\(^{220}\)

Before going into a detailed examination of the EC notification scheme,
two remarks need to be made. First, it is essential not to forget that the Notification Directive covers more than notification alone; it equally contains provisions for the harmonisation of classification, packaging and labelling of dangerous substances, dating back to 1967.\textsuperscript{221} Since the latter activities have a more direct risk management impact, they are mainly discussed in Chapter IV on chemical risk management. However, undeniably classification and labels are also important sources of information, and therefore the following sections do make reference to these provisions where appropriate.\textsuperscript{222} Second, even though the information duties that are encapsulated in the notification scheme have been identified earlier as one of the basic building blocks for the development of a risk-oriented approach to chemicals control, one hardly finds any reference in the Notification Directive to risk thresholds as a trigger for basic information duties.\textsuperscript{223} The discovery of chemical risks is presented as one of the objectives rather than one of the prerequisites for the imposition of information duties. Instead, basic information and testing duties are linked to more "mundane" and tangible concepts such as access to the internal market and the chemical production volume. Paradoxical as it may sound, this Chapter will argue that it is precisely because information supply and testing duties are not conditioned upon a prior, substantiated, finding of risk -- a characteristic that moreover sets the EC notification scheme apart from US data-gathering arrangements -- that notification, as developed in the European Community, is a sufficiently productive instrument to implement a risk-oriented approach. However, before going deeper into this argument, I will explore the notification

\textsuperscript{221}Articles 22 to 25 of the Notification Directive.

\textsuperscript{222} Schiffer and Delbrück mention the gathering of information concerning products as one of the main functions of labelling, alongside the warning function and the effect of labels on the competitive position of a labelled product. HANS-WILLEM SCHIFFER \& KILIAN DELBRÜCK (1991), "Kennzeichnung als Instrument des produktbezogenen Umweltschutzes," \textit{DB}, No. 19, p. 1002.

\textsuperscript{223} The Notification Directive mentions risks in the following contexts:
1) Article 7(1) states that the technical dossier should include all information relevant for assessing foreseeable risks. The notifier may include a risk assessment in the dossier, and the competent authorities have to perform a risk assessment of the notified substance. However, these provisions do not link information production and supply duties to an earlier finding of risk;
2) when discussing the conditional notification exemption for substances used in process-oriented research, Article 13(2) authorises national competent authorities to impose additional restrictions on the handling of such substances "[i]f the competent authority considers that there may exist an unacceptable risk for man and the environment."
3) According to Article 16, competent authorities may ask for more information than stipulated in the Notification Directive where it can be shown to be necessary for the evaluation of risks.
requirements (in their present form) in greater detail.

2.1. Division of competencies

Competencies and responsibilities for the adoption, implementation and supervision of the notification scheme reside primarily with the Member States. Article 5 of the Notification Directive confirms that it is up to the Member States to ensure that substances cannot be placed on the market unless they have been notified in one of the States and have been appropriately packaged and labelled. Additionally, Member States are to ensure that the provisions concerning safety data sheets are observed.\(^{224}\) The Directive furthermore supplies a mechanism allowing national compliance control: in accordance with Article 32 of the Directive, Member States are required to submit three-yearly implementation reports to the Commission. Thus, Article 32 aims to assist the Commission in fulfilling its task, allocated to it in Article 155 of the EC Treaty,\(^{225}\) of watchdog over the national application of Community law provisions.

Notification takes place at the national level: each of the Member States have designated an authority competent for the receipt of notification dossiers and follow-up information (the "competent authority"). The competent authority furthermore examines and decides on the conformity of the dossier with the requirements of the Directive (determining whether sufficient information is supplied or additional information needed), and carries out a risk assessment on the basis of the information received. Essentially, it is the national competent authority who decides whether, as far as EC notification, classification, packaging and labelling requirements are concerned, a substance may circulate freely on the Community market.

Considering the important international ramifications of decisions taken at the national level -- and bearing in mind the undiminished competency of individual Member States to control the circulation and use of chemical substances for reasons relating to health, safety and environmental protection -- all Member States obviously have an interest in obtaining information about notifications (and follow-up information) received in other Member States of the European Community. For this reason, the EC has developed a relatively detailed information exchange system between the notified Member State and

\(^{224}\)See point 2.3.b below.  
\(^{225}\)Article 211 ToA.
other EC countries, with the Commission acting as an intermediary. Article 17 of the Notification Directive obliges the Member States to send a copy of the notified dossier, further information or a summary thereof to the Commission "as soon as possible." Also, in the case where a competent authority has decided that the basic information supply and testing requirements as set out in the Directive are insufficient for an evaluation of the risks attached to the release of a notified substance, and has consequently ordered additional examination and testing of the substance, the competent authority is to notify the Commission of the tests chosen, the reason for their choice, the results and (where appropriate) an assessment of the results. The duty to supply information equally applies to information which the national competent authorities have received relating to substances that are considered to have been notified (see above), and which would be "of common interest" for the Commission and other competent authorities.

The Commission then passes the received copies (along with any other information it deems relevant) on to the other Member States.

The Member States' rights, however, are broader than the right simply to receive information concerning notifications made in other Member States. Article 18 of the Directive allows the competent authority of any Member State directly to consult the competent authority that received the notification, or the Commission, on the details of the notification or risk assessment. Moreover, any competent authority may suggest to the notified body that further information or tests are required. The notified competent authority is under an obligation, confirmed in Article 18, to reason a decision not to take on board such suggestions. If no agreement is reached, any competent authority that considers, on the basis of detailed reasons, that additional information or testing is nevertheless really necessary may refer the issue to the Commission and ask it to take a decision. The Commission will decide following the committee procedure laid down in Article 29(4)(b) of the Directive.

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226See Article 16(2) of the Notification Directive and point 2.2.c below.
227For example, Article 13(2) of the Notification Directive requires that manufacturers or importers making use of the exemption for substances used in scientific research keep written records of the identity of the substance, labelling data, quantities and a list of customers. Upon request by the competent authority, this information has to be made available.
228Article 18 of the Notification Directive.
229Article 29(b)(4) lays down the famous contre-filet procedure (see Decision 87/373/EEC of the Council of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission (comitology), OJ L 197/33 (1987)).
Summarising, the Notification Directive indicates that the main responsibility for receiving notifications, checking their conformity and, if necessary, requesting additional information and testing remains with the authorities designated by the Member States. Information is shared between the different Member States and the Commission, however the notified competent authorities do appear to retain quite some flexibility with respect to information sharing: they have the choice between forwarding copies of the dossier in its entirety or sending a summary, and do not have to comply with strict deadlines; the Directive restricts itself to requiring that the information be sent to the Commission as soon as possible.\(^{230}\)

Whereas some degree of flexibility is undoubtedly necessary to cope with the varying levels of complexity of individual notifications, it would nevertheless be advisable to develop certain target deadlines for submission of a copy of the dossier (or a summary) to the Commission. For example, the notified competent authority might be requested to exchange information on a notification within one month after the decision that the notification is conform with the requirements of the Directive. If it is not feasible to respect this deadline in specific cases, the competent authority would have to inform the Commission thereof, attach a statement explaining the delay and give an approximate indication of when information will be made available. Such an arrangement would not only encourage notified authorities to develop some general planning with respect to the processing of notifications, but could equally function as an early warning system for other Member States. Most importantly, a flexible deadline for information exchange would benefit the notifying manufacturer or
importer of a substance. Particularly when one considers the Member States' right to ask for explanations and, if necessary, suggest that additional information or test results be submitted (a suggestion that may ultimately lead to a Commission decision on the issue), it becomes clear that the time period between the notification of a substance and placing it on the market may be very substantial. Article 10 only gives a minimum (60 days), but no maximum delay for market release. Therefore, it is in the interest of the notifier to have as many indications as possible on the progress of his dossier.

While the submission of technical information to other Member States may benefit from some additional structure and direction, procedures dealing with requests for additional information might suffer from the opposite weakness in that they could be perceived as excessively formalised. As discussed, when Member States reach no agreement on the need to obtain additional information, the question is referred to the Commission, which processes it through the rather "heavy machinery" of a comitology procedure. It is not inconceivable that the prospect of calling in the Commission, and of the delays, costs and occasional vexation that comitology procedures give rise to, would deter a competent authority from asking additional information in the first place, or from pressing the issue if its request does not meet with immediate approval from the Member State that received the notification. Here, a more open-ended approach, deliberately not providing a pre-set procedure for every eventuality, might have proved a greater incentive for competent authorities to engage in flexible problem-solving on a case-by-case basis, which, ultimately, might have resulted in more flexible and productive procedures than the one foreseen in Article 29(b)(4).

2.2. What is to be notified

Article 6(1) of the Notification Directive sums up the various documents and indications that have to be included in a notification. They are listed below. Arguably the most interesting of the notification requirements are those to include information and results of tests performed on chemical substances. Since the requirement to include such results -- which inevitably implies a requirement to perform chemical testing prior to putting a new substance on the market -- constitutes the most demanding and far-going of the notifier's information supply duties, it will be explored in greater detail after the general
overview of the components of a notification. Finally, the notifier's duty to supply information does not necessarily end with the submission of a first dossier. As indicated above, notified competent authorities as well as authorities located in other Member States may request additional information. Furthermore, manufacturers and importers of notified substances are under a general obligation to keep the competent authorities up to date on new information and developments relating to those substances. The supply of both additional and follow-up information is examined in the last of the following three subsections.

2.2(a) Components of a notification

A full notification consists of the following elements:

- A technical dossier.\(^{231}\)
  The technical dossier has to supply "[t]he information necessary for evaluating the foreseeable risks, whether immediate or delayed, which the substance may entail for man and the environment," and contain "[a]ll available relevant data for this purpose" (Article 7(1) of the Notification Directive).
  Although seemingly straightforward, this description of the technical dossier is far from unproblematic. As will be discussed in greater detail in Chapter III, there are many different opinions about which factors should be included in the assessment of chemical risks. Some contend that risk assessment should be based strictly on scientific data, whereas others claim that non-scientific elements -- such as whether the risks are equally distributed over the entire population or mainly threaten particular segments of the population -- should also be taken into account.\(^{232}\) To facilitate matters, and to guarantee the harmonisation of notification requirements throughout the Community, the Directive specifies that, as a minimum, the technical

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\(^{232}\)See Section II of Chapter III.
dossier should contain "[t]he information and results of the studies referred to in Annex VII.A, together with a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to them." Thus, a full notification must at the very least include: (0) the identity of the manufacturer and of the notifier, the location of the production site; (1) the identity of the substance (molecular structure, composition, methods of detection, etc.); (2) information on the substance (production, proposed uses, recommended methods and precautions to be observed, emergency measures, etc.); (3) physico-chemical properties of the substance (melting point, density, etc.); (4) toxicological studies; (5) ecotoxicological studies; and (6) information on possibilities of rendering the substance harmless.

The lists of information laid down in Annex VII.A lend themselves to the following observations. First, considering that the Annex essentially is a specification of "all information necessary to evaluate foreseeable risks," it transpires that the Notification adheres to a quite technical definition of foreseeable chemical risks: the emphasis is clearly on scientific data and test results, whereas broader, more contextual issues pertaining to risks (such as the relative familiarity or novelty of the risk, the distribution of the risk, the potential benefits of introducing a new risk into the environment) are not included in the minimum reporting requirements. Second, although the Annex standardises information supply requirements for notifiers, it does allow some degree of flexibility, providing that: "[I]f it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority." Flexibility, coupled with a concern to protect trade secrets, is equally reflected in the instructions relating to information supply on the production of the notified substance, which specify that information should be sufficient to allow "[a]n approximate but realistic estimation of (...) exposure," but that precise details on the production process are not required. Third, the Annex reveals some traces of a concern for continuity in information production and supply: section 1.4 on the description of
methods of detection and determination provides that: "[A]part from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of direct exposure of humans." (emphasis added). Information of this kind, supplied during the pre-marketing stage, can be of crucial importance for the establishment of post-marketing and -release monitoring systems, and thus forms an important contribution to the stimulation of an uninterrupted information flow covering the entire life-cycle of a chemical substance. In light of its usefulness, it might be advisable to strengthen the requirements of section 1.4: the provision as it stands simply requires that information "known to the notifier" is included in the dossier, but does not require any special effort to produce such information. It is however conceivable that, during the design and production stage of new substances, manufacturers would be expected deliberately to take into account the need for ensuing detection and monitoring, and to incorporate this goal into their product engineering standards so as to facilitate information production and gathering at a later stage.

- A declaration concerning the unfavourable effects of the substance in terms of various foreseeable uses.

- Proposed classification and labelling of the substance in accordance with the Directive.

- A safety data sheet proposal in the case of dangerous substances.

- In the case of importation, a statement from the manufacturer that, for the purposes of notification, the notifier is designated as the manufacturer's sole representative.

- If applicable, a reasoned request asking to be exempted from the "animal testing" provisions.\textsuperscript{234}

\textsuperscript{233}See point 2.6 below.
\textsuperscript{234}See point 2.5 below.
The above-listed documents and references constitute the minimum components of a complete initial notification. Additionally, the notifier may include his own risk evaluation of the substance, which competent authorities can refer to or rely on when performing the risk assessment of newly notified substances. Moreover, as mentioned before, the notifier's information duties do not end with the submission of the original notification: he may be requested to furnish additional information and is under a general obligation to keep the competent authority informed when new tonnage thresholds are reached and/or new information on the substance becomes available. However, before going into more detail on these additional information and updating requirements, I will take a closer look at the chemical tests on which the notifier has to report in accordance with Annexes VII and, for substances produced in high quantities, VIII of the Notification Directive.

2.2(b) Testing of chemicals

One of the most important and innovating aspects introduced by the Notification Directive is its requirement to perform tests on new substances and include the test results in the notification dossier. The inclusion of testing requirements as part of the notification sets the EC-developed scheme apart from American notification procedures under the TSCA. In the United States, across-the-board notification duties are limited to the submission to the Environmental Protection Agency (EPA) of a pre-manufacture notice (PMN), which contains basic information on the substance to be manufactured, but usually either extremely limited or no information relating to the toxicity or ecotoxicity of the chemical. In addition to these limited reporting requirements, the EPA may decide to develop a test rule for those previously notified substances which, according to the EPA, deserve closer scrutiny.

It would appear that this arrangement introduces both flexibility (because the EPA can pick and choose those substances that should be subjected to testing in accordance with its priorities for ensuing risk reduction measures) and

235 See Section III.2 in fine of Chapter III; LUC LAVRYSEN, o.c., p. 39.
236 See point 2.2(c) below.
efficiency (since substances that are at first sight harmless do not have to go through extensive and expensive testing) into the information gathering process. However, the advantages of the American approach are largely undone by the rigid procedural requirements which the EPA has to meet prior to the adoption of a test rule. When the EPA decides that testing is required, it needs to justify this decision by demonstrating that: (1) the chemical may present an unreasonable risk of injury or health to the environment or is manufactured in substantial quantities to which significant human exposure is likely; (2) there is insufficient data and experience relating to the substance; and (3) testing is necessary to develop such data. In other words, contrary to the EC Notification Directive, the TSCA does not provide an a priori testing requirement, but conditions testing upon the preliminary finding of a risk which may either be linked to the properties of the substance ("unreasonable risk") or the anticipated exposure ("significant human exposure").

It takes little imagination to anticipate that, frequently, the linking of test requirements to risk thresholds will result in a catch-22 situation: for the EPA to be able to demonstrate that an unreasonable risk indeed exists, it may need information on the toxicity and/or ecotoxicity of a substance. However, in order to obtain this type of information, tests need to be performed, and the EPA may only order testing if ... it can demonstrate that an unreasonable risk exists. This situation -- which in a way requires the EPA to plead its case before having access to the evidence -- and the lack of testing and availability of test results resulting from it, have often been lamented in US literature on the subject. It may therefore rightfully be considered as one of the great strengths of the EC notification scheme that it has avoided this kind of dilemma by disconnecting testing requirements from risk thresholds, and including test results as one of the standard components of the notification dossier.

In the EC framework, the basic set of tests is laid down in Annex VII.A, points 4 (Toxicological studies) and 5 (Ecotoxicological studies) of the Notification Directive. The prescribed toxicological tests include acute toxicity testing, repeated dose toxicity testing (where the dose is administered for a period of 28 days), and some preliminary testing to assess mutagenicity, toxicity relating to

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239Ibid., pp. 315-316.
240Ibid., passim.
241A similar problem may resurface, however, with regard to EC requirements for additional testing. See point 2.2(c) below.
reproduction and toxicokinetic behaviour. With respect to ecotoxicity, acute toxicity for fish and daphnia is examined, together with biodegradability and absorption/desorption capacity of the substance.

The testing requirements in the Notification Directive form an important step towards the development of a legal framework capable of filling in the chemical data gap. As discussed, for the purposes of information production and supply, the situation in the EC is certainly preferable to the one in the US, where ill-balanced administrative burdens of proof more frequently than not bring the information flow to a grinding halt. However, these observations should not lead one to conclude that, in the European Community, shortage of chemical hazard and risk data is a thing of the past. It would indeed be overly optimistic (and naive) to assume that, on the basis of the limited number of prescribed tests, one would be able to obtain "full knowledge" of the various ways in which chemical substances -- released at different stages along the production, processing, marketing, use and disposal chain, transported via different channels, and accumulated or biodegraded in a host of different recipient bodies, which in turn may be absorbed or consumed by other organisms -- affect human health and the environment. To take but the simplest of examples: the toxicity tests listed in Annex VII.A clearly focus on acute and short-term toxicity. However, it has been emphasised repeatedly that many chemically-induced effects have long latency periods. It is anything but guaranteed that acute high dosage testing, and even repeated dose testing for a period of 28 days, would reveal the potential multitude of chronic, latent effects of the substance under examination.

The limitations of the standard tests become even more obvious in the area of ecotoxicity, where no repeated dose testing is required. Moreover, tests are performed on only two reagens: fish and daphnia. Even though both these species are highly sensitive to toxins -- they were indeed selected (and, in the case of daphnia, developed) for precisely this reason -- it still requires quite a leap of faith positively to believe that tests performed on two species are capable of producing results which are universally applicable on "the environment" in all its facets.242 Thus, the basic testing requirements in the Notification Directive

242 In "Eigenschaften ökologischer Systeme und Prognostizierbarkeit von Belastungsfolgen," Susanne Smolka and Gerd Weidemann discuss more representative models for ecotoxicological chemical testing, including multi-species systems. They conclude that, if regulatory decision-making authorities intend to broaden their scope to take into account ecological processes and interactions within ecosystems, this would
offer an important contribution, but not a definitive solution to the problem of chemical information production and supply.

That the EC legislator was well-aware of the limited reach of the basic testing requirements is evidenced by two additional provisions in the Notification Directive. First, Article 16 allows the competent authorities of the Member States to “[a]sk for further information, verification and/or confirmatory tests” if it can be “shown to be necessary” for the risk evaluation.\(^{243}\) Second, for those substances that are placed on the market in quantities of 10 tonnes per year per manufacturer, or when the total quantity of a substance on the market reaches 50 tonnes per manufacturer, the competent authority may require all or some of the additional tests described in Annex VIII, Level 1, of the Directive.\(^{244}\) Additional toxicity tests in Annex VIII, Level 1, include, \textit{inter alia}, fertility studies, reproductive toxicity studies and sub-chronic and chronic toxicity studies. In the area of ecotoxicity, the range of testing organisms is expanded to include earthworms and higher plants, and prolonged toxicity studies as well as supplementary degradation and absorption/desorption studies are added to the list. If tonnage thresholds of 100 tonnes per manufacturer per year, or alternatively 500 tonnes per manufacturer, are reached, requesting additional tests is no longer an option, but becomes an obligation for the national competent authorities.\(^{245}\) Finally, when the quantity placed on the market reaches 1000 tonnes per year per manufacturer (5000 tonnes per manufacturer), the Directive requires the competent authorities to draw up a testing and studies programme, in accordance with the guidelines established in Annex VIII, Level 2.\(^{246}\) Level 2 demands, \textit{inter alia}, more advanced chronic toxicity studies, carcinogenicity tests, and toxicity studies with birds and higher organisms.

It thus appears that, the greater the quantity of a certain chemical put on the market, the more specific and advanced (and correspondingly time-consuming and expensive) the required tests become. However, once again it is

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\(^{243}\)See point 2.2(c) below.

\(^{244}\)Article 7(2) of the Notification Directive.

\(^{245}\)Unless the notifier can give good reason why a given test/study is not appropriate or an alternative scientific test/study would be preferable (Article 7(2), second indent in \textit{fine}).

\(^{246}\)Article 7(2), last indent.
important not to be deceived by the apparent stringency of the testing requirements. In a 1994 study, Eckard Rehbinder pointed out that very few substances reach the threshold of 100/500 (the threshold at which additional testing becomes compulsory) or 1000/5000 tonnes. In fact, out of the 588 substances notified in Germany as of October 1993, not more than 9 reached the 100/500, and only 3 the 1000/5000 threshold.\textsuperscript{247} One may therefore safely assume that the vast majority of notified substances only have to be subjected to the basic, relatively limited tests of Annex VII.A.\textsuperscript{248}

\textit{2.2(c) Updating requirements and additional information}

In addition to the information supply duties linked to the initial notification, Article 7(2) of the Notification Directive requires of the notifier that he alerts the competent authority which received the notification when the quantity of the substance on the market reaches one of the above-listed thresholds (10/50; 100/500; and 1000/5000). The purpose of this provision is clear: it enables the competent authorities to monitor where the relevant tonnage thresholds, which trigger the option or obligation imposed on the competent authorities to request further testing, are reached.

The notifier's duty to give information to the competent authority relating to changes in quantities of the substance placed on the market, is reconfirmed in Article 14 of the Directive. This Article furthermore requires the notifier to supply the authority with written information concerning (a) new knowledge of the effects of the substance on man and/or the environment of which he may reasonably be expected to have become aware; (b) new uses for which the substance is placed on the market of which he may reasonably be expected to have become aware; (c) any change in the composition of the substance; and (d) any change in his status as manufacturer or importer.

The first of these requirements, the duty to supply information on new knowledge, is potentially very important. I have already indicated the rudimentary and incomplete character of information supplied pursuant to the initial notification: at best, the technical dossier and accompanying descriptions

\textsuperscript{247}ECKARD REHBINDER (1994b), "Control of Products and Substances: Overview of Recent Developments in the European Community," in BETTY GEBERS & JERZY JENDROSKA, o.c., p. 27.
\textsuperscript{248}Moreover, as will be discussed under point 2.4(a) below, testing requirements are reduced for substances marketed in small quantities.
give a rough first impression of the risks connected to the exploitation of a new substance. There are hardly any cases where pre-market testing results are considered sufficiently reliable and conclusive to remove all the uncertainties surrounding chemicals and their effects on man and the environment; at present, scientific knowledge has not advanced far enough to be able to determine, with certainty, the harm resulting from chemicals solely on the basis of predictive, analytical methods (such as bio-analysis, animal bioassays under controlled conditions).

After the notification stage (including the fulfilment of the corresponding testing requirements), new knowledge on the notified substance may become available from a variety of sources. For example, new scientific developments may result in a better understanding of how chemicals "work" (for instance, there may be an improved understanding of how carcinogens are transported through different media or accumulated in recipient organisms, extrapolation models may be fine-tuned, new theories may be developed which enable clearer insights into the conditions for and effects of synergies between categories of substances, etc.). Moreover, some of the most valuable and reliable data on chemical substances only become available after the substances have been put into circulation and released in the environment. I am referring to, for instance, the practical experience that is accumulated when substances are used in industrial settings, or epidemiological studies conducted on humans, animals or biological organisms that have been exposed to certain substances for longer periods of time. This type of "knowledge through application" -- which is created through observation, experience from practice and monitoring rather than by means of testing under controlled (hence artificial) conditions and scientific modelling -- is of the utmost importance for a better understanding of the health and environmental effects of identified chemicals, and is furthermore indispensable to verify the adequacy and reliability of the scientific and predictive tools used during the pre-marketing stage.

Considering the value of the updating requirement as an instrument to fill

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249 See, for example, Michael Gough on dioxins, one of the most intensively tested of toxic chemicals: "[A]nimal studies convincingly show that it is toxic, and there is no doubt that humans have been, and are, exposed to it. Yet, despite scores of investigations of possible associations between exposures to dioxin and various diseases, there is no convincing evidence that it has caused any human disease except chloracne, a serious skin disease (...)" in MICHAEL GOUGH (1993), "Dioxin: Perceptions, Estimates and Measures," in KENNETH R. FORSTER, DAVID E. BERNSTEIN & PETER W. HUBER (eds.), Phantom Risk. Scientific Inference and the Law, The MIT Press, Cambridge MA, p.
in the data gap, it is regrettable that the Notification Directive does not supply a more solid framework for compliance with this requirement; it confines itself to stating that the notifier shall supply information on new knowledge of which he may reasonably be expected to have become aware. The requirement as formulated has the potential to become a hearth of controversy. First of all, what constitutes "new knowledge": the results of an epidemiological study conducted on a group of 500 people, an article in a scientific journal on new bioassay techniques, a general report on the state of the environment, a dissenting opinion on extrapolation models, a newspaper article on the increased incidence of respiratory ailments among the inhabitants of a town located in the vicinity of a chemical plant? Second, how closely can we reasonably expect manufacturers and importers to monitor knowledge developments in this area? In addition to problems of interpretation, one may wonder how national administrations manage effectively to control whether notifiers are living up to this generally formulated updating duty.

Unfortunately, inquiries into how the updating requirement of Article 14 has been transposed in national legislation offer little clarification. The Belgian provisions, for instance, merely offer a literal translation of the relevant text in the Directive. In the English version, the requirement of reasonable expectation has been dropped, which potentially limits the reach of the Directive. Apart from this omission, no changes or additions to the text of the Directive have been made. German law is only slightly clearer on the issue: Paragraph 16(3) of the 1994 Chemicals Law (Chemikaliengesetz) provides that notifiers are

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250 Cf. SAM GUSMAN et al., o.c., p. 69.
251 It would appear that national administrations could only effectively monitor compliance with the updating requirement if they kept abreast of new developments themselves, and were thus in a position to determine which notifiers fulfilled the updating duty and which were negligent. However, the necessity for administrations to keep abreast of new developments and new knowledge in the field of chemicals and their effects completely defeats the purpose of the updating provision, which aims to shift the burden of monitoring and reporting on new developments away from public authorities and to industry.
252 Belgium: Arrêté Royal du 24 mai 1982 réglementant la mise sur le marché de substances pouvant être dangereuses pour l'homme ou son environnement, Moniteur Belge, 2.7.1982, p. 7893. Article 7: "[T]out notifiant d'une substance déjà notifiée est tenu de communiquer au Ministre: (...) les nouvelles connaissances relatives aux effets de la substance sur l'homme et/ou l'environnement dont il peut raisonnablement avoir pris connaissance; (...)"
253 England: Notification of New Substances Regulations 1993, Statutory Instruments 1993/3050, p. 392. 'Part II, regulation 10(1): "[T]he notifier of a substance already notified in accordance with regulation 4 or 6 shall inform the competent authority of (...) new knowledge of which he may be aware of the effects of the substance on human
to inform the competent authority in writing of new knowledge concerning the effects of chemical substances on man or the environment or concerning methods of analysis to assess human exposure or presence of substances in the environment. Similar to the British provisions, the Chemikaliengesetz does not include the standard of reasonable expectation.

The burden of identifying which information constitutes or contains new knowledge on the effects of chemicals, of devising a system for controlling notifiers' compliance with updating duties, and (in the Belgian case) of determining whether a notifier could reasonably be expected to be aware of new knowledge, thus predominantly rests on the shoulders of national administrations. One can readily identify potential problems connected to this particular division of competencies. First, in spite of the existence of an EC-wide updating requirement, reflecting a generally acknowledged need to harmonise information supply duties so as to improve efficiency, equal competition among the Member States and the same (high) level of health and environmental protection, information duties to be complied with after the initial notification may differ substantially from one country to the next. Second, in the absence of a framework for interpretation, implementation and compliance control, there is an undeniable risk that provisions, formulated in so broad and general a manner as the updating requirements, will remain a dead letter. It would therefore have been preferable had the EC Directive (or an implementing Directive or recommendation) offered some more specification and guidelines — if only in the guise of examples — on which types of information should be qualified as new knowledge, and some direction pertaining to the scope of reasonable expectations. Possibly, the Directive might have called for the establishment of a default procedure facilitating administrative review and compliance control. As experience with information gathering accumulates,

health or the environment or both.”


255 Cf. the preamble of the Notification Directive: “[W]hereas disparity between the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and to the notification of new substances in the Member States may lead to barriers to trade in Member States and create unequal conditions of competition, whereas the disparity between these measures in the Member States has a direct impact on the functioning of the internal market and does not guarantee the same level of protection of public health and the environment”.

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such recommendations might be reviewed, revised or formalised, and the role and duties of both notifiers and competent authorities further clarified. At present -- and bearing in mind the overall low level of judicial action in this area, which limits the opportunities for courts to flesh out the regulatory framework through interpretation and clarification -- there is probably too little basis for self-learning and improvement processes to take root.256

The last category of information supply duties to be discussed under this heading do not concern new, but rather additional data requested pursuant to the initial submission of the technical dossier. As I mentioned previously, additional information may be requested by the notified competent authority, acting either on its own initiative or at the suggestion of another Member State. Article 16(1), second indent, of the Notification Directive reads as follows: "[M]oreover, if it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authorities may ask for further information, verification and/or confirmatory tests concerning the substances or their transformation products, of which they have been notified or have received information under this Directive; this may also include any of the information referred to in Annex VIII (additional test results) earlier than provided for in Article 7(2) (the tonnage thresholds)". Additionally, Article 16(1) continues, competent authorities may carry out sampling, request notifiers to supply them with quantities of the substance necessary for verification purposes, and take interim measures for the safe use of a substance pending the introduction of Community measures.

Article 16(1) thus substantially broadens the national competent authorities' discretion to tailor information supply duties depending on the circumstances and complexity of specific cases. It is however unclear whether, and to what extent, the competent authorities have to substantiate, or motivate, a request for additional information. The English version of the Directive leads one to presume that Article 16(1) preconditions the request for additional information on the competent authority's ability to demonstrate the necessity of this information for the evaluation of the risk ("if it can be shown to be necessary"). In other words, in order to justify its request, the competent authority should be able to demonstrate the existence of a risk, or at least the likelihood of a risk (of thus far undetermined proportions). After all, if there is no risk, there is no need to evaluate it, and therefore no need for additional

256 See Heading 3.4(c) of Chapter I.
information. Thus, based on a reading of the English version of the Notification Directive, the information supply system seems intended to work as follows: the initial burden of production of information is allocated to the manufacturer or importer of a chemical substance. In order to gain access to the Community market, he is bound to produce the information requested in Article 7 of the Notification Directive. Moreover, the notified competent authority may ask for additional information. However, in this scenario the burden of proof shifts to the competent authority: it has to legitimate its request by demonstrating ("showing") that the additional information is necessary for risk evaluation.

The British implementation of Article 16(1) appears in line with this interpretation; since Regulation 9(2) states: "[T]he competent authority may only require further information (...) if it is satisfied that the further information is reasonably required to evaluate the risks created by the substance to human health or the environment" (emphasis added). The use of the term "only," and the specification that the information be reasonably required, both indicate that the English competent authority (the Health and Safety Executive) is not to wield its power indiscriminately, but needs to examine each case and motivate a request for more information in a manner that could withstand judicial scrutiny. However, this interpretation seems at odds with the formulations in different language versions of the Directive as well as implementations in, e.g., Belgium and Germany. In the French, German and Italian text of the Notification Directive, Article 16(1) says: "[W]here it appears necessary for the evaluation of the risks, the competent authority may request (...) additional information." The replacement of the words "is shown to be necessary" by "appears necessary"

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257 Thus construed, the requirement resembles the "unreasonable risk standard" in the American TSCA, albeit in a less stringent form (by requiring that the risk be "unreasonably" high, the TSCA excludes low level risks -- *de minimis* risks, discernible risks -- whereas the above interpretation of the EC necessity clause does not incorporate this additional constraint). Still, like the unreasonable risk standard, it might make the EC-established framework vulnerable to the same type of circular reasoning that stifles the information gathering potential of the TSCA: in order to determine whether a substance poses a risk, the competent authority needs additional information, but in order to obtain such information, the authority needs to demonstrate the existence of a risk.

258 French: "[E]n outre, si cela se révèle nécessaire pour évaluer le danger que peut causer une substance, les autorités compétentes peuvent demander des renseignements complémentaires (...)" German: "[E]rwies es sich zur Beurteilung der mit einem Stoff verbundenen Gefahren als notwendig, so können die zuständige Behörden ferner zusätzliche Auskünfte (...) fordern." Italian: "[Q]ualora appaia necessario per valutare i rischi di una determinata sostanza, le autorità competenti possono chiedere informazioni complementari."
casts a doubt on whether, according to these versions, the competent authority must offer some evidence of the existence of a hazard, or whether a statement confirming that additional information “appears necessary” suffices.

The absence of a clearly formulated duty imposed on the competent authority to reason its requests for additional information equally characterises national provisions implementing Article 16(1) in a number of countries. Article 5 § 4 of the Belgian Royal Decree of 1982, for example, states: “[W]here it appears necessary for the evaluation of the hazard which a substance may represent, the Commission (Commission for dangerous substances, established within the Ministry for Public Health) may [ask additional information].” The German Chemikaliengesetz strays even further from the English version of the Directive (and its implementing Regulation in British law). It explicitly distinguishes two alternatives: the competent authority may request additional information if either (1) there are indications, particularly those based on best available science (“Stand der wissenschaftlichen Erkenntnisse”), that a substance may be dangerous, or (2) it is required for the evaluation of the risk posed by a substance, in accordance with the relevant provisions of the EC Directive. Consequently, whereas in the first alternative the competent authority does bear a burden of proof, this does not appear to be the case in the second alternative, which is the transposition of Article 16(1) of the Notification Directive.

Summarising, depending on the language version of the Directive (and depending on which national implementation is consulted), the ease with which national competent authorities may obtain additional information on notified substances varies widely.

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259 Like the 1979 version of the Notification Directive, the Royal Decree refers to hazards instead of risks.
260 § 11(1) of the 1994 Chemikaliengesetz.
261 This interpretation was confirmed in a 1992 decision of the German Bundesverwaltungsgericht (BVerwG, Dec. Of 12.6.1992 - Case 31/90 (Munster); Neue Zeitschrift für Verwaltungsrecht, 1992, No. 10, pp. 984-986). In the case at issue, the German administrative court annulled an administrative order addressed to the notifier of a chemical substance (Basic Yellow FG 98338) to supply additional information. The court reasoned that the competent authority -- the Bundesanstalt für Arbeitsschutz -- had failed to substantiate its request because it did not offer “real indications that it was highly probable (“erhebliche Wrscheinlichkeit”, which was the standard prior to the more flexible 1994 version rendered above as the first alternative in §11(1)) that the substance was dangerous to life, health or the environment”. In its concluding sentence, the court acknowledged that, according to Article 7 of EC Directive 79/831/EEC (the Sixth Amendment; now Article 16(1) of the Notification Directive) the competent authority may ask for additional testing without there being indications of risk (“ohne Verdachtsmomente”). However, the court continued, at the time of the administrative request for additional information on “Basic Yellow,” this EC provision had net yet been
substances appears to differ substantially. As was the case for the updating requirement (see above), the absence of a genuinely harmonised approach, or a harmonised understanding about how Article 16(1) should be implemented and how rights and duties should be allocated between industry and public authorities, might thwart the Directive's objectives of eliminating trade barriers, creating a level playing field and guaranteeing the same high level of health and environmental protection throughout the Community. Here again, the notification system might benefit from some additional consideration targeted at harmonising implementation at the national administrative level. Such harmonisation, if it were to be effected, should aim to avoid overly demanding burdens of proof imposed on the national competent authorities. If not, the EC notification system -- at least where it concerns information that goes beyond the basic data listed in the technical dossier -- might fall into the "American trap" of regulatory bodies having to substantiate information and testing requests on the basis of evidence which they cannot yet possess. Giving competent authorities a carte blanche, on the other hand, might leave notifiers in too much uncertainty about whether, when and at what cost (in terms of investment in additional information production and delays) a new substance can be released on the market.262 It is questionable whether unrestrained powers to request additional information would constitute legitimate and proportional measures when balanced against the notifiers' constitutional rights of freedom of enterprise and profession.263 Furthermore, an administrative carte blanche for notified substances prior to marketing would bias regulation against new substances and in favour of those that are already on the market, a situation which may be undesirable for both economic and environmental

transposed into national law and was therefore not applicable.

262 It is furthermore possible to object to unlimited powers to request additional information on the basis of very pragmatic considerations. It is conceivable that, after having imposed additional burdens and costs on the notifier (and possibly having solicited his cooperation to acquire a better understanding of the implications of the information submitted), national authorities might become reluctant to take a negative decision with respect to the admissibility of the substance on the market on the basis of health and environmental grounds. In other words, after having forced industry to make heavy investments in a substance prior to market release, national authorities may be "captured" in the sense that they feel they can no longer reasonably decide to prohibit the substance.

A harmonised approach towards additional information supply duties would therefore need to straddle an appropriate middle ground between these two extremes.

2.3. User-oriented information

As mentioned before, the Notification Directive not only contains a harmonised notification scheme, but equally incorporates requirements concerning classification, packaging and labelling of chemical substances. Additionally, the 1992 amendment to the Notification Directive introduced a provision requiring manufacturers, importers or distributors of dangerous substances to supply industrial users with a safety data sheet. The provisions relating to classification, packaging, labelling and safety data sheets apply to existing as well as newly notified substances.

In contrast to the scientific data and testing results in the technical dossier, the classification terminology, the corresponding labels and the information in safety data sheets are more readily accessible to non-scientists, particularly to industrial users and/or consumers of chemical substances, products and preparations. They therefore constitute an additional, qualitatively different form of information gathered about chemical hazards and risks.

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265 Cf. HOWARD LATIN, o.c., p. 353, on the need to develop an allocational doctrine that neither paralyses regulatory authorities nor bars industry from defending its economic interests.
266 For packaging, see Section II.1.3(a) of Chapter IV.
267 A dangerous substance is one that has been classified according to one or several of the categories listed in Article 2(2) of the Notification Directive. The safety data sheet requirement can be found in Article 27 of the Directive.
268 Classification, packaging and labelling rules for dangerous chemical preparations, i.e., mixtures or solutions of two or more substances, are dealt with in a separate Directive; Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 187/14 (1988). The rules for preparations run along the same lines as those for substances. Considering that most of the chemicals non-industrial users are exposed to in their daily lives are in preparations (for instance, dyes, aerosols, solvents), the Preparations Directive is the one which is most important for consumer protection (see also Chapter IV on risk management).
2.3(a) Classification and labelling

Before the notification system came into existence, classification and corresponding labelling requirements aimed to ensure that some (minimal) information relating to dangerous substances was produced and passed on to the consumer. Initially, Article 2(2) of Directive 67/548/EEC distinguished eight different categories or classes of dangerous substances; by the time of the adoption of the seventh amendment to the Notification Directive (1992), the list had grown to fifteen. The current classification system distinguishes:

- explosive substances and preparations;
- oxidising substances and preparations;
- extremely flammable substances and preparations;
- highly flammable substances and preparations;
- flammable substances and preparations;
- very toxic substances and preparations;
- toxic substances and preparations;
- harmful substances and preparations;
- corrosive substances and preparations;
- irritant substances and preparations;
- sensitising substances and preparations;
- carcinogenic substances and preparations;
- mutagenic substances and preparations;
- substances and preparations that are toxic for reproduction and
- substances and preparations that are dangerous for the environment.

The 1967 Directive furthermore laid the groundwork for a harmonised classification system: its Annex I (now Annex I of the Notification Directive) provides a list of dangerous substances, i.e., substances that fall into one or more of the above-mentioned categories and for which uniform classification (and labelling) in the Community has been decided. By 1994, approximately 1500 substances had received a harmonised classification. However impressive this effort at uniform classification may be, according to data supplied by Josef Falke (1994) these 1500 substances only represented 1.3% of

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269 In the original 1967 version, explosive, oxidising, easily flammable, flammable, toxic, harmful, corrosive and irritant substances were listed.
270 Formerly called teratogenic substances and preparations.
271 JOSEF FALKE, o.c, p. 72.
existing substances, and approximately 1/5 of new notified substances. These data are yet another reminder of the vastness of the existing data gap, and the enormous efforts that will be required to complete this initiative.

Since the entry into effect of the notification scheme, new substances that have not yet been included in Annex I are provisionally classified and labelled by the notifier: the proposed classification and labelling of the substance is one of the elements required to complete the technical dossier. Article 6 of the Notification Directive broadens the provisional classification and labelling requirement to cover those substances that were on the market prior to 18 September 1981: "[M]anufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I shall be obliged to make themselves aware of the relevant and accessible data which exist concerning the properties of the substance." Article 6 continues that, on the basis of this information, they are to package and provisionally label those substances. A comparison with the original clause, as it was formulated in the 1979 Sixth Amendment, offers a fine example of the gradual tightening up of industry’s information supply duties. In the 1979 version, existing substances had to be packaged and provisionally labelled "[i]n so far as the manufacturer whether or not established in the Community may reasonably be expected to be aware of their dangerous properties." By 1992, the reasonable expectation had been replaced by an obligation to make themselves aware of relevant and accessible data.

Annex VI.A of the Notification Directive contains instructions on how to carry out classification. These instructions, which furthermore reconfirm the notifier’s duty to have the substances tested (in order to determine, for instance, the median lethal dose of a chemical), mainly aim to standardise categories and degrees of “danger” in order to prevent that the same or similar levels of, for instance, toxicity would lead to a different classification by different notifiers. For example, Part I.A (a) states:

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272 Ibid., p. 77.
273 See GERD WINTER (1994b), "Maßstäbe," o.c., fnt. 3 at p. 4.
274 The “reasonable expectation” clause, however, still exists for new substances subject to reduced notification requirements (See point 2.5(a) below). Article 8(5) of the Notification Directive states: "[T]he substances notified in conformity with paragraphs 1 and 2 (i.e., following reduced notification requirements) must, in so far as the notifier may reasonably be expected to be aware of their dangerous properties, be packaged and provisionally labelled [...]" Here, the reasonable expectation clause makes sense because, if the Notification Directive would require of the person applying for a reduced notification to make herself aware of relevant and accessible data, this would potentially...
"[W]here the acute toxicity in animals of the commercial substance or preparation has been determined by a method which permits estimation of the LD50 or the LC50,\textsuperscript{275} classification as very toxic, toxic or harmful shall be effected using the following parameters as reference values:

<table>
<thead>
<tr>
<th>Category</th>
<th>LD50</th>
<th>LD50</th>
<th>LC50</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Oral in rat</td>
<td>Dermal in rat or rabbit</td>
<td>(inhalation) in rat</td>
</tr>
<tr>
<td></td>
<td>mg/kg bodyweight</td>
<td>mg/kg bodyweight</td>
<td>mg/kg bodyweight</td>
</tr>
<tr>
<td>Very toxic</td>
<td>&lt; or = 25</td>
<td>&lt; or = 50</td>
<td>&lt; or = 0.25</td>
</tr>
<tr>
<td>Toxic</td>
<td>25 to 100</td>
<td>50 to 400</td>
<td>0.25 to 1</td>
</tr>
<tr>
<td>Harmful</td>
<td>200 to 2000</td>
<td>400 to 2000</td>
<td>1 to 5</td>
</tr>
</tbody>
</table>

Depending on the classification, the substances have to be labelled with the appropriate danger symbols, risk phrases ("R-phrases") and safety phrases ("S-phrases").\textsuperscript{276} Danger symbols include, inter alia, the universally recognised symbol of a skull with two crossed bones to indicate toxicity, a flame to alert the user that the substance is flammable, and, as a latest addition, a rather grim drawing of a dead tree and an agonising fish to indicate that the substance is dangerous for the environment. Risk phrases are short sentences that provide information on those risks arising from the use of dangerous substances which cannot be deduced from the danger symbols (e.g., "may cause cancer" or "may affect reproduction abilities"), while safety phrases give standardised prescriptions for safe use (e.g., "do not mix with.." "never add water to this product"). Finally, for substances that fall under the reduced notification scheme (i.e., substances that are marketed below certain threshold quantities; see point 2.5(a) below) and that are consequently subjected to a more limited set of information supply and testing requirements, it may not be possible to determine all the appropriate labels. Article 8(5) of the Notification Directive stipulates that, should this indeed be the case, "[t]he label should bear, in

\textsuperscript{275} Lethal Dosis 50 or Lethal Concentration 50, i.e., the dosis or concentration of a substance (or preparation) that kills 50% of the animals in the test group.

\textsuperscript{276} Article 23 of the Notification Directive. In addition to danger symbols, risk phrases and safety phrases, labels must include: (a) the name of the substance; (b) the name and full address of the person established in the Community who is responsible for placing the substance on the market; and (c) for substances that are listed on the EINECS, the EC number that has been allocated to them.
addition to the label deriving from the tests already carried out, the warning "Caution - substance not yet fully tested".

Essentially, labels translate the data gathered in the technical dossier, in particular the information concerning the chemical properties and testing results, in a more accessible, user-oriented language. Their main function is to warn the users, alert them of the risks relating to the substance and enable them to make risk management decisions. This aspect of labelling will be further explored in Chapter IV.

2.3(b) Safety data sheets

The 1992 amendment to the Notification Directive introduced an obligation for manufacturers, importers or distributors of dangerous substances to draw up a safety data sheet for each substance, which should be communicated to industrial users before the first delivery of the respective substance. Furthermore, where a notification needs to be made and the substance to be notified is dangerous (in other words, is provisionally classified according to one of the fifteen categories listed), the notifier has to submit a proposal for a safety data sheet along with the technical dossier, the classification and labelling proposal and other required information.

Safety data sheets contain "information necessary for the protection of man and the environment." They are intended to detail and supplement the information supplied on the labels and communicated in the R- and S-phrases, and are aimed specifically at industrial users in the workplace.

Article 27(2) of the Notification Directive calls on the Commission, assisted by the Committee on the Adaptation to Technical Progress of the Directive for the Elimination of Technical Barriers to Trade in Dangerous Substances and Preparations (the "Dangerous Substances Committee"), to lay down general rules for the elaboration, distribution, contents and format of safety data sheets. These can be found in Commission Directive 93/112/EC,

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277 Article 27 of the Notification Directive. The requirement to draw up safety data sheets was not entirely novel: in 1988, it was inserted in Directive 88/379/EEC covering packaging and labelling of dangerous preparations. The seventh amendment to the Notification Directive broadened the scope of the safety data sheet requirement to cover dangerous substances as well as preparations.

which applies to preparations as well as substances. The information supplied in safety data sheets should enable industrial users to develop and/or improve risk prevention, abatement and remedial policies in the work place with respect to the dangerous substances or preparations used. In addition to information relating to the chemical's physico-chemical properties, its toxicological and ecotoxicological make-up, the sheets supply practical information about, inter alia, first aid measures in the case of accidental release, the type of equipment required for personal protection, transport, handling and storage guidelines, and even information with a predominantly educational purpose, such as information on existing regulatory restrictions applicable to the substance or preparation at issue.

Before moving on to the next section, a word needs to be said concerning the connection between safety data sheets and labour law, particularly workers' health and safety protection. I mentioned that safety data sheets are drawn up solely for the benefit of industrial users; not for consumers or other end-users. Michael Au (1994) regrets this restriction, and claims that non-industrial users (for example, people who work at home and use chemical substances or preparations professionally, but in a non-industrial setting) might also benefit from access to safety data sheets.

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280 The complete list of information to be supplied includes:
1. identification of the substance/preparation and of the company/undertaking;
2. composition/information on ingredients;
3. hazard identification;
4. first-aid measures;
5. fire-fighting measures;
6. accidental release measures;
7. handling and storage;
8. exposure controls/personal protection;
9. physical and chemical properties;
10. stability and reactivity;
11. toxicological information;
12. ecological information;
13. disposal considerations;
14. transport information;
15. regulatory information; and
16. other information (such as training advice, recommended uses).

See the Annex to Directive 93/112/EC.

281 Cf. SCHIFFER & DELBRÜCK, o.c., p. 1005.
One might counter that focusing on a particular, defined group of users allows a more targeted, and hence more effective form of information supply. Having to concentrate on too many different user groups might render safety data sheets either too general or unmanageable. It would, nonetheless, be possible to improve the system by making safety data sheets available to other groups of users -- such as the professional users working in non-industrial settings who form the object of Michael Au's concern -- on request, with the added caution that they have been drawn up for a different user group.

The link between information supply and workers' protection is equally clear in the 1998 Council Directive on the protection of the health and safety of workers from the risks related to chemical agents at work. The Directive provides, inter alia, that employers may not introduce chemical agents in the workplace before having received the respective safety data sheets. Doing so would be in breach of employers' protective duties vis-à-vis their employees, and might result in damages and penal sanctions imposed on the employer at the national level. Hence, it is in the interest of industrial users that chemical manufacturers (or processors) meet their informational duties. Once implemented, this system, whereby one party's compliance depends another party's fulfilment of information duties, may result in a productive and self-organising system of private compliance monitoring between contracting parties, which could sensibly alleviate the tasks of public inspection and control bodies.

2.4. Quality control of supplied information

The Notification Directive handed Member States' regulatory authorities a means to obtain information about the characteristics and potential risks connected to the marketing of chemicals in a systematic and organised manner. Rather than having to generate and collect information themselves, notification shifts the burden of information supply from regulatory bodies to those entities who want to introduce the substances or products on the EC market. The advantages of this shift, from the regulatory point of view, have already been

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282 MICHAEL AU, o.c., p. 239.
discussed: the information is created and submitted by those parties who, 
assumedly, have the easiest access to it and the greatest expertise in the area. 
For reasons of equity as well as feasibility and efficiency, it makes more sense 
that the party who stands to gain from the marketing of chemicals should bear 
the costs of hazard and risk information supply.

However, in the introduction to this Chapter I hinted at one of the main 
problems connected to this particular form of distribution of information duties. 
At the end of the day, it is a problem of trust: since national regulatory bodies 
use the information submitted to make determinations with respect to the 
acceptability and marketability of the substances, the information has to be 
reliable. How can competent authorities know that tests have been conducted 
with reliable measuring instruments, that samples have not been contaminated, 
that test results have been recorded appropriately and accurately? The question 
becomes particularly pressing in instances where an accurate recording of test 
data runs counter to a company's business interests, for example, in cases 
where testing results are indeterminate (which may lead the competent authority 
to impose further, more sophisticated and costly testing) or indicate that the 
substance might indeed jeopardise human health or the environment.

Furthermore, what is to be made of chemical data and assessments made 
in other Member States? Since, pursuant to the Notification Directive, 
competent authorities in other Member States may not demand an additional 
notification after a substance has been duly notified in one Member State, the 
data submitted and accepted during the original notification obtain international 
validity. This implies that competent authorities in the Member States not only 
have to trust the quality of the data submitted locally, but equally need to be 
able to rely on data submitted elsewhere and on the judgements made by other 
competent authorities pertaining to the accuracy and validity of this information.

One of the first fora to address the issue of reliability of information and 
test data on an international scale was the Organisation for Economic 
Cooperation and Development. During OECD negotiations going back as far as 
the late 70's, interdisciplinary working groups composed of scientists and 
technical administrators from various OECD countries elaborated standards for 
chemical test methods and for Good Laboratory Practice (GLP). In 1981, their

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284 Cf. VEERLE HEYVAERT (1998), "Access," o.c., p. 61-62; MATTHIAS SCHMIDT-
PREUSS, o.c., p. 172.
285 RONALD BRICKMAN, SHEILA JASANOFF & THOMAS ILGEN, o.c., p. 283.
efforts culminated in the OECD Council Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals, in which the OECD member countries pledged to accept test data produced in each other's countries, provided that the data had been generated in compliance with the newly made test guidelines and GLP principles. Additionally, the Decision recommended that member countries should take measures to ensure that the OECD principles are applied when testing is performed within their own countries.286

At the European level, EC institutions have gratefully made use of the existing OECD principles and incorporated them into EC legislation. Article 3(1), last indent, of the Notification Directive stipulates that "Laboratory tests shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC," which Directive in turn refers to the OECD Decision of 1981 and a further OECD Recommendation of 1983 concerning the mutual recognition of compliance with GLP.287 The Directive imposes the use of GLP principles (Article 1), and exhorts the Member States to set up a system for verification of compliance with these principles by testing laboratories (Article 3).

Quality control of submitted data may be further detailed at the national level. For example, administrative practice of the German competent authorities (the Umweltbundesamt or "UBA") involves quality testing of information on the basis of two criteria: plausibility and validity. To be plausible, the information in the notified documents should be free of gaps and internal contradictions, and should be in accordance with knowledge obtained from different sources. The information is valid when tests have been conducted in accordance with the prescriptions of Annex V of the Notification Directive, GLP principles and "best available scientific practice."288 Also, where testing prescriptions allow the choice between different tests, those methods should be chosen that are appropriate to reveal the characteristics of the substance.289

The rules for quality control offer a fine example of proceduralised legislation, developed to cope with the uncertainties inherent in testing and control procedures. Since it is impossible to foresee what valid test results for

286 CHRISTOPHER ARUP, o.c., p. 50.
288 In German: allgemein anerkannten Standard wissenschaftlichen Arbeiten.
thus far undiscovered substances and preparations should look like substantively, the provisions developed in German administrative practice as well as those established under the auspices of the OECD pay greater attention to how and by whom the tests are conducted, how the results are reported and how the information is structured. If the German requirements for internal consistency and external confirmation of the submitted information still contain a modicum of substantive control (although here, too, the control is structural rather than test-specific), OECD guidelines for good laboratory practice are entirely procedural: the focus is completely shifted away from the content of the actual submissions. Instead, all quality criteria relate to how the information has been produced, collected and reported. In essence, quality control through GLP trickles down to a verification of the institutions that produce chemical data.

The benefits of proceduralisation — in terms of enabling the law to operate under conditions of uncertainty — were outlined in Chapter I.290 The example of GLP uncovers some additional advantages: proceduralised rules allow decentralisation of information production and decision-making without forfeiting the possibility of (centralised) public control. One might even claim that procedural rule-making enhances the opportunities for control, since it is far easier for public authorities to control whether prescribed procedures are in place in testing laboratories, than to verify the content of individual submissions, which would almost inevitably trickle down to a duplication of all the performed tests and measurements, a situation which, for reasons to be addressed immediately below, would be far from ideal.291

2.5 Limitations on information production and supply

Given the central role of chemical hazard and risk data in the development of a preventative chemical control policy, one might arrive at the conclusion that you can never have too much of a good thing: the more information, the better. However, before advocating that information requirements and corresponding supply duties should be extended as far as possible, touching and even stretching beyond the frontiers of scientific

290 See Chapter I under Heading 3.4(d).
291 Interview with Marleen Pauwels, member of the Belgian High Council for Public Health, June 1996.
knowledge, a number of considerations should be taken into account.

First of all, it is important to remember that even stable and relatively wealthy economic sectors like the chemical industry dispose of limited resources. Chemical hazard and risk data, as we have seen, are high-priced commodities, which are obtained at the expense of a great deal of money, time and, frequently, animal lives (see below). At some point, the additional time and expenses invested into information may actually outweigh its added utility. Furthermore, an information overload might not only overburden the industries responsible for supplying it, but might equally immobilise the public authorities who are in charge of controlling, inter alia, the completeness of the dossiers, a task for which the Notification Directive grants them 60 days at most. Finally, as transpired from our discussion of the technical dossier, even the most expensive and elaborate testing procedures have their limitations, which renders the objective of acquiring full knowledge concerning the consequences of producing and releasing new chemicals, laudable as it may be, elusive.

In light of these practical and conceptual constrains, one might argue that, rather than focusing on the sheer quantity of information, investments in chemical data production should be concentrated where they are most effective, and that information duties should be limited in cases where one cannot reasonably expect additional information to result in either better knowledge or, ultimately, improved health and environmental protection. In other words, the scarcity of information as a resource underscores a need for both selectiveness and flexibility.

Several provisions in the Notification Directive indeed appear to respond to this need. With regard to flexibility, it is useful to recall that the Annexes listing the notifier's information duties start with the proviso: "[I]f it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority." As to selectiveness, Article 8 of the Directive introduces reduced notification requirements for substances placed on the market under certain tonnage thresholds; less than 1 tonne per year and per manufacturer and less than 100 kg per year and per manufacturer

293 JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c., p. 266.
respectively.297/298 The reasoning behind the maintenance of tonnage thresholds is clear: when substances are placed on the market in small quantities, the level of exposure in all likelihood will be low, which in turn minimises the environmental and health risks posed by the substance. Thus, substances marketed below certain quantities are presumed to represent only a de minimis, or negligible, risk.

While fully agreeing with the necessity of limiting information demands, Gerd Winter (1994) questions the soundness of tonnage thresholds. He argues that, in certain instances, low-level exposure might be more than offset by high toxicity or ecotoxicity. However, since technical dossiers for reduced notification contain only very limited information to that effect, these hazards may well go undetected. On the other hand, (eco)toxicity information may be superfluous for certain substances that do reach the 1000 kg threshold. As an alternative arrangement, Winter proposes that competent authorities request information on those aspects of the substances which, according to the manufacturer’s assessment, are most relevant.299

With regard to Winter’s suggestion that, for substances for which full notification is required, certain information might be unnecessary, it should however be noted that the Notification Directive, as it stands, already offers a flexible solution in the form of the above-mentioned clause providing that, if it does not appear scientifically necessary to provide certain information, this should be stated and the statement subjected to clearance by the competent authority. This provision also has the potential to limit the risks of ineffective information expenditures, while allowing a greater degree of control by the competent authority, which has to approve the reasons stated by the notifier. In Winter’s proposal, in contrast, the balance of decision-making power seems slanted towards the notifier, and it is unclear how a competent authority could effectively question a notifier’s judgement as to which information is relevant.

As to information requirements below the tonnage thresholds, it is undeniable that low exposure does not necessarily guarantee a negligible risk

297 Moreover, substances placed on the market in extremely limited quantities (less than 10 kg per year and per manufacturer), and substances sold in limited quantities (less than 100 kg per year and per manufacturer) and intended for scientific research are “considered to have been notified” (see Section II.2 above).
298 As for tonnage thresholds above the standard level, once the tonnage threshold is exceeded, the notifier has to comply with the information duties corresponding to the new level.
level. Therefore, in exceptional cases, the real risk related to the release of a small quantity of a substance on the market might indeed exceed the *de minimis* threshold. Yet, one might question whether such exceptional cases warrant the abandonment of the concept of tonnage thresholds, which does, after all, enable swift and efficient decision-making, and moreover provides much clearer guidelines to prospective notifiers than the rather murky criterion of relevance proposed by Winter. Perhaps, a better solution would be to expand the competent authorities' right to request further information "if it can be shown to be necessary" (Article 16(1), second indent of the Notification Directive), which for the moment only covers substances subjected to full notification, to include substances marketed below the tonnage thresholds.\(^{300}\) In this case, notifiers would in principle retain the benefits characteristic of reduced notification (relatively clear guidelines, lower information costs and a speedy notification), but competent authorities would be able to step in if there are indications that, in spite of low exposure, the substance poses a greater than *de minimis* risk.

A second consideration involves the relation between tightening regulatory standards (in *casu* information supply standards) and innovation. Placing unrestrained information burdens on industry might deter investment into the development of new substances and chemical products (innovation).\(^{301}\) It is easy to see how this investment barrier might stifle economic growth and competitiveness. Although less obvious, overly strenuous information burdens might moreover prove counterproductive for health and environmental protection reasons.\(^{302}\) More extensive information requirements, imposed on the chemicals regulated under the Notification Directive, would increase the production cost of new substances, and consequently augment the costs of innovation. Higher costs for new substances might favour those companies that produce existing substances (i.e., substances that were marketed prior to September 1981), irrespective of whether these existing substances are more or less harmful to health and the environment. In fact, considering that public risk awareness and concern relating to health and environmental effects of chemicals was substantially lower in the past,\(^{303}\) and taking into account scientific

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\(^{300}\) Cf. Section II.2.2(c) of this Chapter. Obviously, as in the case of substances subjected to full notification, the requirement of "shown to be necessary" would also need to be fleshed out further for substances marketed in small quantities.


\(^{303}\) See PETER M. WIEDEMANN, BERND ROHRMANN & HELMUT JUNGERMANN (1990, eds.), Risiko-Konzepte, Risiko-Konflikte, Risiko-Kommunikation, *Forschungszentrum*
progress towards a better understanding of how chemicals "work" (for example, how they are transported, how they accumulate, how they interact and affect human, animal and vegetal organisms), one might reasonably expect older substances to be either more harmful, or less studied and therefore more uncertain, than modern day alternatives.

The Existing Substances Regulation, which aims, *inter alia*, to collect hazard and risk information on existing substances from manufacturers and importers, remedies this discrepancy to some extent. However, as will be discussed below, information duties imposed pursuant to the Existing Substances Regulation are still less stringent than the ones in the Notification Directive. Hence, it remains necessary to avoid that excessive information duties would paralyse attempts at innovation. In this light, the Notification Directive's provisions with regard to chemicals developed for experimental and scientific purposes, which soften information supply requirements for substances that are still under development (see Section II.2 of this Chapter), appear particularly helpful.

Finally, ethical considerations need to be taken into account. To this day, toxicity and ecotoxicity involve animal testing. For humanitarian reasons, the body count should be kept as low as possible, which practically implies that testing cannot go on until every shred of uncertainty concerning the effects of a substance is dispelled. The Notification Directive aims to contribute to the goal of minimising animal suffering in several ways. On a general level, it requires that testing is conducted in accordance with the principles laid down in Council Directive 86/609/1986 relating to animal testing, which sets out standards for animal testing under humane conditions and includes a requirement that "[A]n experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practically available." Additionally, the Notification Directive's provisions to avoid duplication of tests, which are discussed in the following section, are tightened up when the tests involve the use of animals.


304 For example, Article 3, last indent, of the Existing Substances Regulation states that: "[M]anufacturers and importers must make all reasonable efforts to obtain existing data regarding points (e) to (j) (physico-chemical properties, toxicity and ecotoxicity, pathways, etc.). However, in the absence of information, manufacturers and importers are not bound to carry out further tests on animals in order to submit such data."

2.6. **Information sharing**

If selectiveness is important, it goes without saying that duplication of information, particularly of expensive and time-consuming test results, should be avoided wherever possible. To this effect, the Notification Directive encourages information sharing among successive notifiers of the same substance.

In essence, the Directive contains the following basic framework. If a substance has already been notified at least ten years earlier, prospective notifiers no longer need to supply data on the physico-chemical properties, toxicity and ecotoxicity of the relevant chemical (the 10-year rule).\(^{306}\) If, on the other hand, the substance has been previously notified within the last ten years, subsequent notifiers may refer to the results of studies and tests performed by the first notifier, provided that (a) the first notifier gives his agreement in writing, and (b) the competent authority agrees with the arrangement.\(^{307}\) With regard to the necessary approval issued by the competent authority, it is important to evaluate its discretion in light of the European Court of Justice decision of 17 December 1981 on plant protection products.\(^{308}\) In its ruling, the Court stated that, even if Member States were free to subject plant protection products, which had already received approval in another Member State, to a fresh procedure of examination and approval,\(^{309}\) the authorities were nevertheless required to “assist in bringing about a relaxation of the controls existing in intra-Community trade. It follows that they are not entitled unnecessarily to require technical or chemical analyses or laboratory tests where those analyses and tests have already been carried out in another Member State and their results are available to those authorities, or may at their request be placed at their disposal.”\(^{310}\) Following this reasoning, and bearing in mind Member States’ obligations pursuant to Council Directive 86/609/EEC to constrain animal

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\(^{306}\) Article 9 of the Notification Directive.

\(^{307}\) Article 16(1).


\(^{310}\) Ibid., p. 3291. *See also* College van Beroep voor het Bedrijfsleven, 13/11/92, *Milieu*
testing as much as possible, one might reasonably infer that, under normal circumstances, the competent authority is bound to grant its approval to an information sharing agreement reached between notifiers in different Member States.\footnote{111}

In cases where the information to be shared concerns animal testing data (see above), Article 15(2) of the Notification Directive furthermore obliges prospective notifiers to: "[e]nquire of the competent authorities of the Member State in which they intend subsequently to notify; as to: (a) whether or not the substance they intend to notify has already been notified; and (b) the name and the address of the first notifier." The request to the competent authority has to be accompanied by evidence substantiating the prospective notifier's intention effectively to place the substance on the market. The competent authority will give the prospective notifier the name and address of the first notifier, and inform the latter of the name and address of the prospective notifier, if the following three conditions are met:

1. the competent authority is satisfied that the prospective notifier's intentions are genuine;
2. the substance has previously been notified; and
3. the first notifier has not asked and been granted a temporary exemption from this arrangement. In accordance with Article 7(1) of the Notification Directive, such exemption, in any event, may not exceed one year following the date of the notification.

Article 15(2) continues stating that both parties "[s]hall take all reasonable steps to reach an agreement on the sharing of information". Furthermore, when the first and the prospective notifier do indeed reach an agreement to share information (whether or not this information involves animal testing results), they also have to take "all necessary steps" to share the animal test results that have to be submitted when one of the higher tonnage thresholds, listed in Article 7(2), is reached.\footnote{12} Finally, Article 15(4) provides that, in cases where both the first and the prospective notifier are located within their territory, and failing an agreement to share information, Member States may introduce national measures that oblige both parties to share data generated by means of animal testing.

\& Recht (1994), N° 4, pp. 138-140.
\footnote{111} And also, in the case of animals testing data, within one Member State.
\footnote{12} See Section II.2.2(b) of this Chapter.
The above-described arrangements aim to achieve a finely calibrated balance between the proprietary interests of original notifiers and countervailing considerations, namely the increased efficiency produced by information sharing (which coincides with the interests of prospective notifiers), and reaching the lowest possible level of animal suffering. The provisions indicate that, over time, proprietary interests gradually decrease in importance. During the first year after the first notification, the notifier may obtain a temporary exemption from the provisions that require her to cooperate in attempts to share animal testing data. Here, the first notifier's interest in protecting her investment in information, and thus her competitive advantage vis-à-vis prospective notifiers, clearly prevails over alternative considerations.

From the second to the tenth year after notification, the balance gradually slides in favour of prospective notifiers: they are able to avail themselves of the name and address of the first notifier, who is furthermore bound to "make all reasonable efforts" to reach an agreement on information sharing pertaining to animal testing. This obligation, or its transposition into national law, offers the prospective notifier a legal basis for recourse in cases when, for example, the first notifier flatly refuses to negotiate with a prospective notifier, or effectively makes it impossible to reach an agreement (e.g., by requiring an exorbitant compensation for the supply of animal test results). Alternatively, the competent authority can resort to its power, conferred to it in Article 15(4), to issue a ruling obliging the first notifier to share information (provided that both notifier and prospective notifier are located in the same territory). Nevertheless, the first notifier retains considerable control over the information: she still has full control over data other than animal testing data, and retains a strong bargaining position in negotiations over the sharing of animal tests since delays, caused either by protracted bargaining over the terms of information sharing or by the necessity to resort to the competent authority for a ruling or, in extremes, judicial action, work in her favour and to the disadvantage of the prospective notifier.

Finally, after a period of ten years the balance tilts fully in favour of prospective notifiers: they no longer have to submit information on physicochemical properties, toxicity and ecotoxicity. In other words, after ten years the information supplied by the first notifier acquires the status of public property.
for the purposes of notification.313

On the whole, the provisions in Article 15 lay a sound foundation for information sharing among notifiers. However, the system may be susceptible to further improvements. First, the Notification Directive might contemplate the possibility of joint notifications, made by companies that both intend to market the same substance and wish to share the investment costs of information.314 Possibly, companies under a joint notification scheme could be exempted from the rule that notification has to take place in the country of manufacture (or importation), so that the administrative costs might be halved. Second, it is conceivable that the information sharing provisions, in their present state, will predominantly encourage data exchanges between first and prospective notifiers located in one and the same Member State, if only because of the threat of public interference, in the form of an administrative ruling, in instances where negotiating notifiers fail to reach an agreement. However, it may very well be that, in an international setting, a simple exhortation to endeavour to reach an agreement is not sufficient. The transaction costs are higher, and different national rules concerning, for example, confidential treatment of commercially sensitive information,315 might deter parties from entering into agreement with each other.

To promote international information sharing more effectively, the European Community might consider to draw up framework contracts with default provisions relating to the exchange of testing data, compensation, confidentiality and legal remedies in case of breach of contract, possibly developed in concert with representatives of the chemical industry in Europe and national administrations. The existence of such framework contracts might well lower negotiation thresholds between individual notifiers, while maintaining

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313 This arrangement is comparable to the “exclusive use period” and “compensation period” afforded in the US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The exclusive use period grants the original registrant of a pesticide a time span of ten years during which he can freely decide whether or not to sell his data to future registrants. These ten years are followed by a compensation period of another ten years, during which the original data submitter has the right to be compensated by future applicants. Comparing the different time spans (the “exclusive use period” in the EC Notification Directive only lasts maximum one year for animal testing data, and the European “compensation period” does not go beyond ten years after notification), it appears that US legislation attaches a relatively greater value to the protection of business proprietary interests vis-à-vis countervailing considerations than EC legislation. See MARGARET ROSSO GROSSMAN (1994), “Pesticide Registration under FIFRA in the United States,” Milieu & Recht, No. 7/8, p. 209.

314 The US FIFRA, for example, does provide in the possibility of joint registration for new pesticides. Ibid.
sufficient flexibility to be tailored in accordance with the specifics of each case.

2.7. Confidentiality

One of the last issues to be discussed in the framework of the Notification Directive concerns the confidentiality of commercially sensitive information submitted to the competent authorities in compliance with notification requirements. Confidentiality represents yet another aspect of the broader debate on how to balance individual, proprietary business interests in the exclusivity of information against public interests in its disclosure. To enter into the details of this debate would go beyond the scope of the present analysis. Nonetheless, the following observations should be made.

In balancing the interests of private industry against the public interest in access to health, safety and environmental data, the EC legislator has apparently opted for an approach that predominantly favours the public. Notifiers may request that the information they submit be treated as confidential (Article 19 of the Notification Directive), however their request will only be granted under certain conditions. First of all, notifiers have to give “full justification” of their request for confidential treatment. Compared to confidentiality provisions applicable in, for example, merger proceedings and injury submissions in anti-dumping cases, where it is practically sufficient that the information supplier indicates which sections of the submitted documents are commercially sensitive, the standard of proof that must be met before confidential treatment is granted in notification procedures, is decidedly higher. The approach followed in the Notification Directive moreover avoids that notifiers would simply rubberstamp all the data they submit as “confidential,” and leave the initial evaluation up to the competent authorities.

315 See point 2.7 below.
317 Cf. JOZEF FALKE, o.c., p. 112.
Furthermore, the Directive lists a number of items that are a priori excluded from industrial and commercial secrecy treatment, including the trade name of the substance, physico-chemical data, summary results of toxicological and ecotoxicological tests, and analytical methods that make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure to humans.\textsuperscript{320} In essence, confidentiality clauses seem intended mainly to protect information concerning production processes of chemicals.

A second observation is that it are the public authorities of the different Member States who in the end decide whether requests for confidential treatment will be granted. For example, in Belgium such requests are first submitted to the Dangerous Goods Commission, which issues an opinion on the subject. Its report is then transferred to the Minister of Health and Environmental Hygiene, who takes a decision in light of the findings in the report.\textsuperscript{321} Unfortunately, concepts of what constitutes an industrial and/or commercial secret still differ from one country to the next,\textsuperscript{322} as do the notifiers' opportunities for appeal against an unfavourable decision. As mentioned previously, different standards and uncertainty surrounding the treatment of industrial and commercial secrets might deter notifiers from sharing their data internationally. The adoption of harmonised rules for the evaluation of trade secrets, if only in the form of non-binding guidelines addressed to the administrations in the various Member States, might lower proprietors' apprehension of submitting sensitive data to foreign public authorities, which might in turn stimulate information sharing across national boundaries.

\textbf{2.8. Data collection (inventories)}

Before moving on to post-market gathering of chemicals hazard and risk data, I would like briefly to point at one last feature of the Notification Directive: the inventories. The Directive calls for the compilation of three different inventories. One, the EINECS (European Inventory of Existing Commercial Chemical Substances), was published on 15 June 1990 and contains all those substances that do not have to be notified because they were already on the

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{320}] Article 19 (1) of the Notification Directive.
\item[\textsuperscript{321}] J.-M. DEVOS, o.c., p. 304.
\end{itemize}
\end{footnotesize}
market on 18 September 1981. It is based on yet another inventory, the European Core Inventory (ECOIN), which was drawn up by the Commission from the data at its disposal, and a list of substances declared by chemical manufacturers and communicated to the Commission by the Member States.

Second, there is the ELINCS (European List of Notified (New) Chemicals), which, predictably, lists all new substances notified under the Directive. Finally, Annex I of the Notification Directive contains a list of those substances that are classified as dangerous. As discussed, dangerous substances are subjected to some additional information requirements, for instance, the drawing up of a safety data sheet. Both the ELINCS and Annex I are updated regularly.

3. Post-Marketing Production of Information: The Existing Substances Regulation

Whereas the Notification Directive proved a highly valuable instrument to generate information on the chemical hazards and risks related to the production, marketing and use of new substances, it obviously did little to close the enormous data gap for the thousands of chemical substances and preparations that were already on the market before notification schemes were enforced. In order to remedy this situation, the EC Council adopted, in 1993, Council Regulation (EEC) N° 793/93 on the evaluation and control of the risks of existing substances (hereinafter the Existing Substances Regulation).

The Existing Substances Regulation has many aspects in common with the Notification Directive. Like the latter document, the Regulation draws on the cooperation of manufacturers and importers of chemicals to supply hazard and risk data. The types of data requested roughly correspond to the items listed in the Notification Directive’s technical dossier, and substances marketed below

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324 NIGEL HAIGH, ss. 7.3-4 and 7.3-5; LUC LAVRYSEN, o.c., p. 37.
325 Ibid. The EINECS inventory of existing substances contains no less than 100106 substances.
326 OJ L84/1 (1993).
327 Article 3 of the Regulation lists:
   (a) the name and EINECS number of the substance;
   (b) the quantity of the substance produced or imported;
   (c) the classification of the substance according to Annex I of the Notification Directive, or the provisional classification;
certain tonnage thresholds (in quantities exceeding 10 tonnes per year but no greater than 1000 tonnes) benefit from reduced reporting requirements and longer delays for submission. The Regulation equally includes an updating requirement, demanding of manufacturers and importers that they spontaneously submit new information concerning (a) new uses of the substance which alter the type, form, magnitude or duration of exposure of man or the environment; (b) new and probably relevant data on physico-chemical properties, toxicological or ecotoxicological effects; and (c) any change in the provisional classification under the Notification Directive (Article 7(1) of the Regulation). Article 7(2) specifies that any manufacturer or importer "[w]ho acquires knowledge which supports the conclusion that the substance in question may present a serious risk to man or the environment shall immediately report such information to the Commission and to the Member State in which he is located."

The Regulation furthermore allows information sharing, in the sense that one manufacturer or importer may submit the requested data acting on behalf of other manufacturers or importers who market the same substance (with their agreement), and stipulates that laboratory tests, if they prove necessary (see below), need to be performed in compliance with GLP principles and with the provisions of Directive 86/609/EEC on animal testing. Finally, Article 16 of the Regulation on the confidentiality of data mirrors Article 19 of the Notification Directive: the need for confidential treatment of commercially sensitive information must be fully justified by the manufacturer or importer, and certain

(d) information on the reasonably foreseeable uses of the substance;
(e) data on the physico-chemical properties of the substance;
(f) data on the pathways and environmental fate;
(g) data on the ecotoxicity of a substance;
(h) data on the acute and subacute toxicity of the substance;
(i) data on carcinogenicity, mutagenicity and/or toxicity for reproduction of the substance; and
(j) any other indication relevant to the risk evaluation of the substance.

328 Article 4 of the Regulation. Where it appears necessary, the Commission may request the manufacturers and importers for additional information relating to substances below the 1000 tonnes threshold (they are however not bound to carry out further animal tests for that purpose). See Article 4(2) of the Regulation.

329 It is possible that such data become available after the initial reporting because, in contrast to the Notification Directive, the Existing Substances Regulation generally does not force manufacturers and importers to carry out further tests (particularly animal tests) to produce new data. It is sufficient that they "[m]ake all reasonable efforts to obtain existing data" (Article 3, in fine).

330 We recall that, like the provisions on packaging and labelling, the classification scheme in the Notification Directive applies to existing as well as new substances. See Section II.2.3(a) of this Chapter.

331 Article 6 of the Regulation.

332 Article 10, in fine.
data (such as the EINECS name of the substance, summary results of toxicological and ecotoxicological studied, and information which, if withheld, might result in animal experiments being carried out or repeated needlessly) cannot qualify for confidential treatment.

More revealing than the similarities are, of course, the differences between the two instruments. The information gathering system set up under the Existing Substances Regulation differs from the one in the Notification Directive in three important ways: (1) it represents a more centralised approach to data collection; (2) it introduces a priority setting mechanism going beyond initial selection on the basis of volume of the substance produced or sold; and (3) it includes provisions on risk management.

3.1. A centralised approach to data collection

Reporting on existing substances involves a more direct relationship between manufacturers and/or importers and EC instances — in particular the European Commission and the European Chemicals Bureau (see below)\(^{333}\) than notification of new substances.\(^{334}\) This is first of all evidenced by the different legal instruments selected for the respective arrangements: while the notification scheme is developed in a directive, reporting duties for existing substances are contained in a regulation. The choice of a regulation was made specifically because, in contrast to EC directives which in principle only bind the Member States and need to be transformed in national rules, leaving a margin of flexibility as to the means of national implementation selected, regulations are immediately applicable, i.e., without requiring further implementing measures, and directly bind their addressees (who, in the case at issue, comprise manufacturers and importers as well as the Member States and the Commission).\(^{335}\) The preamble to the Existing Substances Regulation confirms as much: "[W]hereas a Regulation is the appropriate legal instrument as it imposes directly on the manufacturers and importers precise requirements to be implemented at the same time in the same manner throughout the Community".

Manufacturers and importers of existing substances do not report to

\(^{333}\) The European Chemicals Bureau, Commission communication (93/C 1/02) to the Council and the European Parliament, OJ C 1/3 (1993).


\(^{335}\) See KAPTEYN & VERLOREN VAN THEMAAT (1987), Inleiding tot het recht van de
Member States' competent authorities, but directly to the Commission (Articles 3 and 4 of the Existing Substances Regulation). The same goes for updates on previously submitted information (Article 7(2)). The various submissions are collected by the European Chemicals Bureau, a recently established institution under the auspices of the Joint Research Centre (JRC) Environment Institute, located in Ispra (Italy). There, the information is processed into a comprehensive EU-wide data-base called "Euclid," which, as will be explained in the following section, constitutes one of the main sources of information for the selection of priority substances. Thus, one can safely claim that, on the whole, the Existing Substances Regulation displays a far more centralised approach to data gathering than does the Notification Directive.

Although the centralised approach offers the obvious advantages of expediency -- compared to the almost unavoidable delays incurred by the time-consuming implementation process for directives -- and uniformity of requirements throughout the Community, the choice of a regulation as the legal instrument to enforce data supply duties also has some drawbacks. As Carol Harlow (1996) remarked, "[i]t is one thing to introduce rules and quite another to see them implemented". In the European context, this comment alludes to the following problem: while the Council's authority to issue regulations that are directly applicable in each of the Member States is undisputed, it usually remains dependent on the Member States for the actual enforcement of its rules. Thus, the gains in expediency and uniformity flowing from the adoption

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336 Member States may, however, provide that manufacturers and importers located in their territory shall be obliged simultaneously to submit the same information to their competent authorities (Article 6(3)).

337 See fn. 333. Additional tasks of the Chemicals Bureau include the maintenance of the EINECS; the performance of scientific and technical support activities associated with the adaptation of the Annexes to the Notification Directive as well as the implementation of the notification scheme; and the development of guidance notes on risk assessment (See Chapter III).


340 Article 189 of the EC Treaty (Article 249 ToA).

341 To this effect, Article 17 of the Existing Substances Regulation requires that "[N]o later than one year following adoptions of this Regulation, Member States shall establish appropriate legal or administrative measures in order to deal with non-compliance with the provisions of this Regulation."
of a regulation may be partially undone by ineffective or delayed compliance control exercised at the Member State level.342

A second potential problem relates to the method of reporting established by the Existing Substances Regulation. Initial data reporting performed by manufacturers and importers is done on the basis of a standardised "prefabricated" software package, the Harmonised Electronic Data Set (HEDSET), which was developed for this purpose by the Commission.343 Clearly, the advantages of deploying standardised reporting tools reside both in the opportunities for ensuing comparisons of the characteristics of different chemical substances (see below), and in the maintenance of a competitive level playing field through the imposition of uniform reporting requirements on all manufacturers and importers.344 On the other hand, standardised reporting may result in inefficiencies and loss of flexibility, where valuable but non-standardised information slips through the mazes of the reporting system, whereas time and expenses are wasted on the production or collection of information that is generally required but, in specific cases, unnecessary.

The situation is thus reminiscent of the problems related to standardised notification dossiers. We recall that, for new substances, opportunities for overcoming the potential rigidity of notification duties were re-introduced by introductory clauses in the Annexes, stating that: "[I]f it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority." Within the framework of the Notification Directive, these clauses lay the foundations for a dialogue between data suppliers and local administration, possibly resulting in the supply of more sharply targeted and better understood information. However, in the framework of a regulation, where communication, if any, should be directly conducted between manufacturers and EC authorities, there may well be less room for negotiation and case-specific customising of information supply duties. Thus, the absence of an intermediary, in the shape

342 Certainly, the European Commission has the power to initiate proceedings against Member States' non-compliance, including non-compliance with requirements to set up national systems to ensure the enforcement of Community rules (Article 169 of the EC Treaty; Article 226 ToA). However, these proceedings, which may ultimately result in a European Court ruling against the non-complying Member State, are not generally known for their swiftness.

343 PATRICK McCUTCHEON, o.c., p. 368.

of national or regional competent authorities, may indeed curtail the possibilities for more selectively assembled information and mutual learning processes.345

3.2. **Priority setting for data-gathering: a two-step system**

Compared to the Notification Directive, the Existing Substances Regulation takes the need to impose information duties selectively literally one step further. Data gathering happens in two stages. During the first stage, which has been commented upon above, manufacturers and importers supply information on chemicals to the Commission and, if so requested, national competent authorities. The reporting requirements applicable at this first stage are similar to, but less stringent than those for new substances: Article 3, in *fine*, states that: *[M]anufacturers and importers must make all reasonable efforts to obtain existing data (...) However, in the absence of information, manufacturers and importers are not bound to carry out further tests on animals in order to submit such data*. This clearly contrasts with notification requirements for new substances, where animal tests form a standard part of the technical dossier, and thus have to be performed in order to complete notification. As to those existing substances falling under the volume thresholds (production in quantities exceeding 10 tonnes per year but no greater than 1000 tonnes per year), which are subject to reduced reporting requirements, the Commission (in consultation with the Member States) does have the authority to request additional information, but again data suppliers cannot be forced to

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345 In a similar vein, Gerd Winter (1994) comments on a potential problem with respect to requests for additional information which, in the case of the Notification Directive, are made by the competent authorities and, in the case of existing substances appearing on a priority list (see Section II.3.2 of this Chapter), by the Commission following a committee procedure. In both instances, requests for additional information and testing are conditioned upon the necessity of such information for the purposes of risk evaluation. The Notification Directive stipulates: *[i]f it can be shown to be necessary for the evaluation of the risk which may be caused by a substance, the competent authorities may ask for further information, (...)* The Existing Substances Regulation, in turn, provides: *[w]here there are valid reasons for believing that a substance appearing in EINECS may present a serious risk to man and the environment, a decision to ask the manufacturers and importers of the said substance to supply the information which they possess and/or to subject the existing substance to testing shall be taken (...)* Winter points out that the portent of both these clauses is vague. For new substances, he continues, this does not necessarily pose a problem, since the necessity requirement can be further specified at the Member State level. However, this is not the case for existing substances, where underdetermined yet directly applicable clauses may indeed prove more problematic. See WINTER (1994b), "Mafigabe," *o.c.*, p. 45.
conduct further animal testing for that purpose.\textsuperscript{[346]}

Both provisions suggest that, in devising initial reporting duties, the Council was not predominantly motivated by the objective of obtaining "full and complete information." Rather, the main aim of the initial data supply requirements is to amass sufficient information to allow a determination of whether existing substances should be subjected to a more thorough evaluation, for which more in-depth information will be required. This process is often referred to as "screening."\textsuperscript{[347]} Screening processes allow regulatory authorities to establish priority lists of those substances that merit further examination.

Priority lists are drawn up as follows. The information gathered during the "first round" is subjected to a preliminary assessment, taking into account a number of factors listed in Article 8 of the Regulation.\textsuperscript{[348]} Interestingly, one of these factors is "the lack of data on the effects of the substance on man and the environment." In addition to avoiding that lesser known substances continue to lurk in the shadows of the Regulation, this provision gives manufacturers and importers an extra incentive to cooperate in the first reporting stage. If they do not, a substance might land on the priority list due to "lack of data," which in turn might entail the imposition of more extensive, and more forcibly formulated, information supply duties on these same manufacturers and importers.

The first list with priority substances was published in May 1994, and contained 42 selected substances; a second and third followed in September 1995 and January 1997 respectively.\textsuperscript{[349]} Each of the prioritised substances is assigned to a Member State, which is responsible for its evaluation. To this end, the Member States appoint a national rapporteur to perform the evaluation.\textsuperscript{[350]}

Even though the evaluation of prioritised substances does involve national rapporteurs and the Members States, the system advocated in the

\textsuperscript{[346]} Article 4(2) of the Existing Substances Regulation.


\textsuperscript{[348]} These factors include, \textit{inter alia}, the (known) effects of the substance on man and the environment; information about exposure; the appearance of substances on national priority lists; and work already carried out in other international fora, such as the OECD and IFCS (Intergovernmental Forum for Chemical Safety). See Section II.3 of Chapter III.

Existing Substances Regulation is one of delegation rather than decentralisation. Rapporteurs are to communicate their findings directly to the Commission. Where their decisions need to be confirmed or reviewed, this happens pursuant to the committee procedure, laid down in Article 15 of the Regulation, which involves the Commission as well as Member States representatives. Perhaps the clearest indication that a delegation of tasks rather than a decentralisation of competencies is envisaged, can be found in the assignment of Member States to each of the prioritised substances. In the 1994 Regulation, for instance, Germany, the United Kingdom and the Netherlands were allotted the lion's share, being responsible for 34 of the 42 substances featuring on the first priority list, whereas the workload of countries such as France (4), Spain (2), Ireland (1), Italy (1) and Denmark (1) was much smaller. Belgium, Luxembourg, Greece and Portugal did not figure on the first list at all. Undoubtedly, had this division of tasks been coupled with an allocation of decision-making competencies for the Member States appointing the rapporteurs, a more proportionate representation would have been insisted on by the Member States representatives.

After the establishment of a priority list and the appointment of rapporteurs, a second stage of data-gathering is launched. In accordance with Article 9(1), manufacturers and importers who had submitted information during the first stage are obliged to “within six months of publication of the list, submit to the rapporteur (...) all relevant available information and corresponding study reports for risk assessment of the substance concerned”. As a minimum, this information should cover the data requested pursuant to Annex VII.A of the Notification Directive. If any of this information is not readily available, the manufacturers and importers “shall be obliged to carry out the testing necessary to obtain the missing data and to provide the test

350 Article 10 of the Existing Substances Regulation.
352 The reader will note that the sum of substances assigned to Member States is 43, whereas only 42 substances had been prioritised. This is because France and the United Kingdom were jointly appointed for two substances, and one substance (aniline) was not assigned.
353 The first priority list was drawn up prior to the accession to the European Union by Austria, Finland and Sweden.
354 The second and third priority lists continue to allocate a greater workload to Germany, the United Kingdom and The Netherlands than, for example, France, Spain and Italy.
355 Cf. Section II.2.2 of this Chapter.
results and test reports to the rapporteur within 12 months" (Article 9(2)).

After having received the data submitted and having consulted the respective manufacturers and importers, rapporteurs may furthermore decide that additional information and/or tests are necessary for the purpose of risk evaluation (cf. fn. 345). In this case, they are to inform the Commission, which will take the decision to impose on the importers or manufacturers a request for further information and/or testing following the Committee procedure of Article 15. In contrast to information requests made during the first stage, requests for test results may include tests performed on vertebrate animals. The latter provisions leads us, once again, to question whether the arrangements for additional information gathering have not been overburdened by procedural hurdles. The Regulation might, for instance, have left some scope for negotiation between the rapporteur and the data supplier, stipulating that a Commission decision would only be taken in cases of disagreement between the rapporteur and the manufacturer or importer concerning the necessity of additional information. This might have alleviated and speeded up the process of data gathering to some degree.

Technical implementation issues aside, the system of priority setting for data gathering has much to recommend it. It demonstrates both an awareness of the scarcity of information as a resource for regulatory decision-making and the corresponding need to adopt a strategy to manage this finite resource, and a determination not to let the absence of "full and complete knowledge" concerning chemical hazards and risks paralyse the decision-making process. As I will argue in Chapter V, a similar system of priority setting -- possibly drawing on the experience acquired with the two-tiered system of information gathering developed above -- might equally be contemplated in the stage of risk management.

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356 Article 9(3) offers a possibility for derogation from the requirements of Article 9(2), provided that the manufacturer or importer can demonstrate that either the 12 months-deadline needs to be extended, or the information is unnecessary for risk assessment or impossible to obtain. Decisions to grant exemptions from the application of Article 9(2) are made by the rapporteur, but may be reviewed following the committee procedure if one of the other Member States objects to it.

357 Cf. Article 10(5) of the Existing Substances Regulation.

358 Cf. Section II.2.2(c) above.

359 The slow pace of implementation of the Regulation, as it stood in late 1998, suggests that the above concern is anything but academic.
3.3. Inclusion of risk assessment and management provisions

A final aspect in which the Existing Substances Regulation differs from the Notification Directive, is in its inclusion of summary guidelines for risk assessment and risk management. The Notification Directive confines itself to the requirement that a risk assessment of new substances, possibly based on a preliminary assessment submitted by the notifier, should be performed by the national competent authorities, and that this assessment should follow the steps outlined in an implementing directive.\textsuperscript{360}

The Existing Substances Regulation recapitulates the latter provision, stating that “[T]he rapporteur for a given priority substance shall evaluate the risk of that substance to man and the environment,” and that “[T]he real or potential risk to man and the environment shall be assessed on the basis of principles adopted (in an ensuing Commission Regulation)”.\textsuperscript{361} However, the Regulation moves beyond the framework of the Notification Directive by adding that, where appropriate, the rapporteur is to suggest a strategy for limiting the risks related to the evaluated substances, including control measures and/or surveillance programs. Such proposals could ultimately lead to the inclusion of chemicals in the lists of substances subject to market restrictions in Council Directive 76/769/EEC.\textsuperscript{362} Thus, the Existing Substances Regulation seeks to link information gathering initiatives, chemicals risk assessment and regulatory control measures together. One could therefore claim that the Regulation places a stronger emphasis on the goals of health and environmental protection than the Notification Directive, which derives its legitimacy in the first place from the objective of market harmonisation. It should however be noted that, according to some Commission officials, the national rapporteurs and the Commission display a certain reluctance to tap into the regulatory potential offered by the Existing Substances Regulation; apparently, most of the efforts accomplished so


\textsuperscript{361}Articles 10(3) and 10(4) of the Existing Substances Regulation. The ensuing Commission Regulation is Regulation (EC) N° 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) N° 793/93, OJ L 161/3 (1994). See Chapter III.

far within the framework of the Regulation are limited to exercises of data gathering and assessment, and have not yet resulted in substantial risk reduction proposals.363

4. Additional Data Gathering Arrangements

The Notification Directive and the Existing Substances Regulation lay the basic foundations for a generalised risk regulation programme, the first objective of which consists of gathering hazard and risk information relating to chemical substances that are either already circulating on the EC market, or for which manufacturers and importers seek access to the market. Because of their universal character -- in the sense that they establish a legal framework that lays down information supply requirements as well as exemptions from such requirements for all chemical substances that are not covered under other, more narrowly targeted pieces of legislation -- and because of their uniquely strong and explicit emphasis on information gathering as a regulatory goal, the Notification Directive and the Existing Substances Regulation were selected as the primary focus of the foregoing analysis.

Of course, there are other legal instruments, both at the EC and the national levels, that directly or indirectly contribute to our knowledge of chemical hazards and risks. They include measures targeted at particular groups of chemicals, such as pesticides, biocides and pharmaceuticals, as well as rules regulating the behaviour of enterprises that manufacture, use, process or emit chemicals in their industrial processes. In the former category we find, for instance, the 1991 Council Directive on pesticides,364 which establishes an EC-wide authorisation scheme for plant protection chemicals used in agriculture and conditions authorisation, inter alia, on the supply of toxicity data and testing results, and a similar Directive covering biocidal products.365 With regard to rules regulating company behaviour, we might in the first place think of the extensive EC and national workers' health and safety regulations, which compel employers to generate and/or disclose information on the risks related to the use of chemicals -- in particular toxins, carcinogens and substances harmful

363 Interview with Ludwig Krämer, February 1997.
to reproduction — in the workplace. In Germany, for example, employers are under a legal obligation to investigate whether dangerous substances can be replaced by less dangerous ones, an investigation which, unavoidably, results in the creation of new, applied chemical hazard and risk data. Furthermore, the production of information on environmental, health and safety effects of chemicals may be required on the basis of legislation aimed at the prevention of environmental harm and industrial disasters, such as the second Environmental Impact Assessment Directive and the Seveso II Directive.

Although certainly interesting, a discussion of the contributions made by the above-mentioned legal rules and arrangements — and similar ones — to the growing volume of data, information and knowledge related to chemical substances, their interactions, synergies and effects on man and the environment, would go beyond the scope of the present analysis. Nonetheless, for future reference it is useful to remember that, in decision-making processes concerning the (un)desirability of certain substances on the market and the selection of appropriate control mechanisms, EC and national regulatory authorities might draw on several kinds of information: the technical, scientific data and test results that have been submitted in compliance with notification requirements or, for existing substances, the Council Regulation, but also information that has come to them (or of which they might avail themselves) via a different trajectory: for instance, as a result of the implementation of a major accidents prevention policy, or via health inspections performed on employees working with dangerous substances, in accordance with employers' inspection and monitoring duties. This information qualitatively differs from the scientific

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367 JOZEF FALKE, o.c., p. 97; MICHAEL AU, o.c., p. 239. Similar substitution principles were developed within the framework of the new Council Directive on chemical agents at work and the Biocides Directive (see above).

data generated in testing laboratories; it has been borne out in scientific and/or technological practice, straddling the line between scientific research and application. It thus gives an extra dimension to health and environmental hazard and risk information, a dimension which unfortunately, as will be discussed in the next Chapter, is somewhat lost -- or at least understated -- during the ensuing phases of risk assessment and management.
SECTION III - FACILITATING DECISION-MAKING AS LEGAL TELEOLOGY

Recalling the environmental rationale that underpins the legislation analysed in Section II, both the Notification Directive and, to a somewhat lesser extent, the Existing Substances Regulation may appear rather odd pieces of legislation. Both documents purportedly aim for the same high level of health and environmental protection throughout the European Community, and yet they are notably free of those kind of provisions, commands and prohibitions that are typically seen as the legal expression of health and environmental protection objectives. What I mean by this is the following: neither the Notification Directive, nor the Existing Substances Regulation impose direct rules limiting the industrial freedom (and business options) of potential polluters, in the form of market restrictions for certain chemicals, emission standards, requirements to use best available technology in production processes, etc. Instead (and as underscored by the analysis of both documents in the previous Section), the main purpose, the ratio legis of the Notification Directive as well as the Existing Substances Regulation lays in the systematic production of chemical hazard and risk data. The information or knowledge thus produced is then used to inform decision-making processes that take place outside the reach of the legislation itself: in an administrative setting, for instance, but also in a business environment, in the work place, or even in the form of individual decisions on whether or not to endorse certain products, made by consumers.

Here, public law is not so much the embodiment of the rules promulgated pursuant to political and normative deliberation on the substance of health and environmental protection, but rather functions as a facilitator of subsequent decision-making, which will be taken with an eye to the protection of human health and the environment. Christopher Arup (1987) puts it as follows: "[A] country's regulatory traditions may favour administrative discretion over statutory obligations to act, information processes rather than formalised

372 JOZEF FALKE, o.c, p. 68.
373 Facilitating objectives are traditionally attributed to private law (e.g., the law of contract, which creates a general framework aiming to facilitate negotiations between contracting parties. See ANTHONY OGUS (1994), Regulation, o.c, p. 26), but are recent phenomena in public law. See, e.g., JULIA BLACK (1998), "Regulation as Facilitation:"
procedures, and guidelines to industry rather than directives. In general, the approach may reflect reservations about the capacity of the law to regulate in such areas of complexity and controversy. A country may regard it as more legitimate for the law to assume a constitutive or auxiliary role rather than responsibility for the substance of regulation or even the procedures whereby the context of regulation is determined. The role of this responsive or reflexive law may be to provide support for industrial or administrative sub-systems so that they may regulate according to their internal needs and the demands of their environment.\textsuperscript{374}

The particular teleology of this kind of "informative legislation," which aims to facilitate decision-making rather than impose or preclude specific decisions, needs to be taken into account when the effectiveness of informative laws and regulations is under examination. Clearly, an evaluation of their effectiveness should not limit itself to weighing the quantity of data produced and/or made available in compliance with information duties. Rather, the operative question should be whether the existing legal instruments are successful in bringing about the kind of information that is adequate, accurate, sufficient and relevant to the decision-makers they seek to accommodate. Furthermore, the effectiveness of informative legislation depends on the timeliness of the information received.\textsuperscript{375}

In the context of chemical control, the relevant decision-makers are in the first place EC and national regulatory authorities responsible for the safeguarding of health and the environment. However, decision-makers located in the private sphere should not be discounted: chemical hazard and risk data, as well as the time and expense that goes into their development, may equally offer guidance to business managers with respect to -- to name but a few of many factors -- the required investments, the marketability, the expected profitability, and the foreseeable administrative hurdles that accompany the production and release of new chemical products. Finally, there are the

\footnotesize{Negotiating the Genetic Revolution," Vol. 61, Modern Law Review, pp. 621, 650-653.}
\footnotetext[374]{CHRISTOPHER ARUP, o.c., p. 65.}
\footnotetext[375]{In "The Perils of Unreasonable Risk," John Applegate identifies six criteria that determine the effectiveness of regulatory techniques to generate information. They are: (a) the newness of the data produced; (b) the cost at which the information comes; (c) the quality and reliability (absence of bias) of the data; (d) the data's relevance to the decision-makers concerns; (e) the timing of the supply; and (f) the coverage of the information.}
industrial users and private consumers of chemical substances and preparations. The inclusion of labelling rules in both the Notification Directive and the Dangerous Preparations Directive, as well as the requirement to furnish professional users with safety data sheets, indicates that they too are targeted as potential decision-makers concerning health, safety and environmental issues.

In the remainder of this Chapter, I will canvass some of the issues that influence the effectiveness of the Notification Directive and the Existing Substances Regulation as facilitators of risk-based decision-making, particularly with an eye to the informational needs and constraints of regulatory authorities.

A first, basic issue to be resolved is whether the provisions in the Notification Directive and the Existing Substances Regulation are indeed capable of fuelling the production of chemical hazard and risk data. In other words, does the deployed regulatory technique, aimed at creation of information for the purposes of future decision-making, work? Even though I have claimed above that the sheer quantity of data produced should not be the sole, or even the predominant criterion by which to measure the success of the EC notification and data reporting system, there can be no doubt that a reasonably high output of data is a necessary (albeit insufficient) condition for its effectiveness. This predominantly quantitative appraisal is followed by a more qualitative examination, namely, whether the European Community's data gathering system works for different kinds of information. In particular, I will examine and contrast the notification and reporting systems' ability to generate human health related information, to their aptitude for the production and collection of environmental data. A third and connected question flowing from the foregoing discussion, is whether differences in efficacy within the existing data gathering and collection arrangements can be linked to a structural bias in the Notification Directive and Existing Substances Regulation. Finally, the discussion offers a hypothesis of why such a structural bias might have been introduced, and why it is not addressed or, potentially, corrected.


376 The provisions on labelling in the Notification Directive apply to existing as well as new substances (see Section II.2.3 (a) of this Chapter).

377 Decision-making on the basis of health, safety and environmental information by industrial users and consumers of chemical products is addressed in Chapter IV on risk.
1. **The Data Output**

At first glance, the Notification Directive and the Existing Substances Regulation appear successful in stimulating the production and supply of new data concerning chemical hazards and risks. However, both instruments have certain limitations. These are particularly obvious in the Existing Substances Regulation: the threat of restrictions, imposed as a result of risk assessments performed by national rapporteurs on the basis of information submitted by chemicals manufacturers and importers, has an adverse effect on industry's willingness to cooperate, giving rise to delays in the implementation of the reporting scheme.378 We can readily imagine the chemical industry's concerns that the more it cooperates, the more the balance of power tilts in favour of public authorities, and that, at the end of the day, its willingness to cooperate will translate into less leverage in public risk decision-making processes than it had before data gathering activities started. The lack of positive incentives for industry to contribute information may have caused national rapporteurs and Commission officials responsible for the Regulation's implementation to focus predominantly on the reporting aspect of the Regulation and somewhat abandon the regulatory side, in an attempt to maintain good working relations with the chemical industry.379 Such developments do not necessarily paralyse the regulatory system completely, however they do in all probability preemptively curtail regulatory authorities' freedom to impose health and environmental measures that are perceived by industry as being overly stringent or radical. The potential bias in favour of industrial entrepreneurship that is created by this relation of dependency, is a major concern for consumer and environmental interest groups.380

As to the Notification Directive, several factors shift the balance more in favour of regulatory bodies. First, in contrast to existing substances that were already circulating on the market before EC information supply requirements were enacted, chemical manufacturers and importers are able to estimate the

management.

378 Comment of Patrick McCutcheon (Commission official responsible for the implementation of the Existing Substances Regulation until end 1997) during the December 1995 Workshop on Regulatory Policies to Control Chemical Substance, held in Amsterdam.

379 Interview with Ludwig Krämer, February 1997.

costs of testing and information supply for new substances prior to marketing. Hence, the cost of complying with regulatory requirements can be factored into preliminary assessments to determine whether investments in the production and marketing of new chemical substances are economically worthwhile. By the same token, pre-market information gathering and testing function as a screening process for industrial entrepreneurs, and may lead them to abandon production plans for substances that, on the basis of initial test results, have a high probability of falling foul of regulatory health and environmental standards. For these reasons, the information supply requirements pursuant to notification are less likely to lead to unanticipated economic losses than those imposed by way of the Existing Substances Regulation. This may strengthen industry's willingness to cooperate.

Second, and most importantly, the EC system conditions access to the EC market on a successful notification, the determination of which is in the hands of national regulatory authorities. Needless to add, this puts regulatory bodies in a relatively stronger position vis-à-vis manufacturers and importers. Furthermore, even though EC-wide notification requirements imposed new data supply burdens on the chemical industry, particularly in those Member States that did not have well-developed national data gathering systems prior to the implementation of the Directive, they on the other hand simplified market access through the harmonisation of access-to-market rules. Instead of having to submit slightly different dossiers for each different country where the notifier seeks to market her new product, she only has to draw up one which, once approved, will be valid throughout the Community. In other words, the benefits of harmonisation counterbalance the additional reporting duties imposed on the chemical industry, making extensive but harmonised information supply duties the more attractive option. Finally, the notification system is not immediately linked to restrictive environmental and health protection measures, which, from industry's perspective, projects a more favourable light on the Directive.

By and large, the chemical hazard and risk data gathering systems developed at the EC level merit a positive evaluation, particularly when compared to similar structures in other countries, such as the US toxic substances reporting system. As mentioned before, the American Toxic Substances Control Act (TSCA) of 1976, which fuelled regulatory action in the European Community, requires chemicals manufacturers to submit a pre-
manufacture notice (PMN) to the Environmental Protection Agency (EPA) before embarking on the production of a new substance. The PMN contains basic information on the properties of the envisaged substance, which should, in theory, enable a preliminary screening of risky substances. However, the discrepancy between the small quantity and uneven quality of the information submitted in the PMN, and the high burden of proof (the "unreasonable risk standard") which the agency has to meet in order to impose further testing on a substance, has greatly reduced the effectiveness of the screening system.

Thus, Stephen Breyer pointed out in 1993 that, as of 1990, the responsible EPA Committee had recommended only 386 substances for testing. According to the US General Accounting Office, the testing programme had made very little progress, and EPA had received complete test data for only six chemicals. When we compare this result to the EC notification scheme, which had reached a total number of 592 full first notifications by June 1991, in spite of having entered into effect five years after the TSCA, the European scheme is incontestably more productive.

2. Improving Information Supply: The Challenge of Environmental Risks

The analysis of notification requirements in Section II.2 revealed the importance of pre-market measurements and laboratory testing as instruments for the production of risk relevant information pertaining to new substances. Together with data on physico-chemical properties, test results form the core of the information supplied pursuant to the notification scheme. The Existing Substances Regulation, relating to substances already on the market concerning which a wider range of information and experience may already be available, places a slightly stronger emphasis on the inclusion of data other than measurements and test results. Nevertheless, for the purposes of risk assessment...

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382 ANDREW HANAN, o.c., pp. 405 etc.
383 A showing of unreasonable risk does not have to be made if the chemical in question is manufactured in substantial quantities to which significant or substantial human exposure is likely. This condition, however, is only met in a minority of cases. Cf. JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c, p. 319: "[T]he most frequently used part of the initial finding under section 4 (the test rule) of TSCA requires EPA to impose a test rule if it finds that the chemical "may present and unreasonable risk of injury to health or the environment".

385 Stephen Breyer, o.c., p. 19.
assessment of existing substances, physico-chemical properties and test results do remain the primary source of information.

It is undeniable that laboratory testing has made an unparalleled contribution to our knowledge about chemical risks. The price we pay for experience can all too often be expressed in loss of human or animal lives, or in the destruction of ecosystems, through short or long term exposure, accidents, spillage, etc. Laboratory testing gives us the opportunity to acquire knowledge in a relatively safe and controlled environment, and to make deliberate decisions concerning the amount of resources, time, and (animal) lives we are willing sacrifice in pursuit of knowledge. Yet, as I discussed in Section II.2.2 and will take up again in the next Chapter, testing has its limitations; the knowledge created through tests is partial and, at best, approximate.

The limitations inherent in laboratory testing are particularly troublesome for information gathering efforts that focus on environmental risks. As mentioned before, whereas scientific predictions about the health effects of chemical substances -- fraught with difficulties and uncertainties as they are -- only have to concentrate on the reactions of one particular and quite well-studied organism, namely the human body, ecotoxicological assessments have to come to terms which the dazzling complexity of ecosystems, which renders the production of reliable predictions a near impossible task. The problems start as soon as one attempts to pin down the object of study; the elusive "ecosystem." Due to, *inter alia*, the large number of components, the existence of many species in any system which occur only rarely and therefore defy qualification, and the multiplicity and complexity of interactions between system components, it is extremely difficult to describe with any measure of accuracy what constitutes an ecosystem.387

It is furthermore impossible to speak of "the" ecosystem; biocultures, for example, display a wide variety of geographic differentiation. Moreover, many questions concerning whether and to which extent ecosystems have a natural capacity for re-generation, as well as which circumstances are conducive to regeneration, remain unresolved.388 Ecosystems clearly illustrate the dictum that the whole is more -- and infinitely more complex -- than the sum of the parts.389

386 NIGEL HAIGH, o.c., s. 7.2.
389 WOLFGANG WILD (1991), "Dürfen wir heute noch neugierig sein?" in HANS LENK &
Consequently, studies conducted on sectioned off, isolated parts of ecosystems, as performed in ecotoxicity testing, are as a rule not capable of rendering an even approximately complete picture of the whole of environmental effects of chemicals.

The complexity of ecosystems, and the gaps in our knowledge about them, seriously hamper -- if they do not altogether destroy -- our ability to forge credible chains between man-made influences and environmental effects; when submerged into an ecosystem, causal links dissolve into a myriad of alternative possibilities, the realisation of which depends on factors that (at present) are beyond our control or even comprehension.

In light of the above considerations, the limits of ecotoxicity testing, performed in the artificial environment of a testing laboratory where ecosystems are represented by a number of isolated species (fish, daphnia) and tested under controlled conditions, become painfully clear. In this area, hard earned certainties form the rare exception to the rule. Moreover, it is highly questionable whether the introduction of an additional battery of tests -- more sophisticated, more detailed, of longer duration -- would make more than a dent in this vast, grey area of uncertainty. Bearing in mind the prohibitive cost of extensive ecotoxicity testing, the option of improving available information on environmental hazards and risks through additional testing becomes very unattractive. Unfortunately, the efforts that thus far have been undertaken to improve the information supply pursuant to notification, have only focused on precisely this aspect, namely the expansion of testing requirements.

Given the limitations of pre-market testing for environmental risks, there is a clear need to supplement test results with alternative sources of information. Ecotoxicologists agree that serious environmental risk assessment cannot do without at least some experience-based, epidemiological information relating to the actual effects of substances released in the environment through

MATTHIAS MARING (eds.), o.c., p. 41.
391 FRANZ KOHOUT, o.c., p. 86.
a variety of pathways.\textsuperscript{394} This kind of information cannot be replicated in testing laboratories, but is gradually accumulated through continuous monitoring of chemical releases and of the environmental conditions in exposed ecosystems.

In a regulatory context, the goal of monitoring is twofold: first, to control compliance with existing environmental requirements, in particular emission standards, and, second, to generate new information about the state of the monitored environment. The combination of information on chemical releases -- accidental or deliberate; occurring in the course of production, transport, use or disposal -- and data on changing environmental conditions provides crucial insights into the complex interactions between chemicals and ecosystems. During the last ten years, the European Community has become increasingly aware of the importance of monitoring strategies as instruments in environmental policy development, both for compliance control and, most recently, for data production purposes. Recent EC legal instruments and proposed instruments, such as the 1996 Directive on Integrated Pollution Prevention and Control and the Commission proposal for a Community-wide water policy framework, establish a limited set of monitoring duties as part of the Member States' obligations in the area of environmental protection.\textsuperscript{395} However, up to now no proposals have been launched to include monitoring duties within the framework of active data production and collection duties imposed on manufacturers and importers of chemical substances. In light of the limitations of testing, particularly for knowledge-production on environmental risks, such an inclusion might prove more productive than the imposition of ever more extensive, and expensive, testing requirements.

Finally, it goes without saying that the introduction of environmental monitoring duties for chemical manufacturers and importers would require serious groundwork to secure organisation, coordination and implementation. To name but one complicating factor, because of their relevance for compliance control, as well as the scale and cost of monitoring programmes, EC monitoring obligations are usually imposed on Member States rather than private parties. It is therefore more likely that monitoring duties within the notification and data


reporting schemes would assume the shape of contributions to existing, publicly organised monitoring programmes, instead of individual initiatives undertaken by manufacturers and importers. Sections II.2.c. to II.2.5. of Chapter V further explore how private environmental monitoring obligations might be put into practice.

3. **Improving Information Supply: Balancing Short Term and Long Term Obligations**

The introduction of industrial responsibilities for environmental monitoring would lead to the requalification of monitoring from a public duty to one in which public and private actors participate. Furthermore, it would decisively confirm that the information supply for which chemical manufacturers and importers are responsible -- and, in the case of new substances, upon which access to the market is conditioned -- should not end with the submission of an initial dossier, however comprehensive. Rather, when monitoring duties are included, information supply clearly becomes a continuous, long term commitment.

The latter observation might cast some light on the question why, in spite of the many known limitations of pre-market testing for environmental data production, monitoring duties have not yet been considered, and improvements in environmental data supply are still, as a matter of course, linked to more sophisticated ecotoxicity testing. The preference for short term data supply arrangements is not unique to environmental risks; it pervades the entire framework for chemical data reporting. The Notification Directive, for instance, accommodates a fragmentary, short term approach to data gathering: the lion’s share of chemical information is produced for the express purpose of notification and market access, and is derived from laboratory tests spanning a maximum period of 28 days. Data are submitted as a “lump sum,” in one copious technical dossier.

There are, admittedly, certain follow-up obligations, yet we perceive a stark contrast in the level of care taken in the formulation of initial reporting duties, and the almost casual style that characterises updating duties. The few additional data requirements that are well-defined, are connected to pre-set tonnage thresholds and, again, concentrate on laboratory testing. General follow-up requirements appear almost as an afterthought; they are vaguely
circumscribed and disassociated from any compliance control structure. The analysis of the Notification Directive in Section II revealed a number of instances where follow-up information supply duties might benefit from a more structured approach.\footnote{See Section II.2.2(c) of this Chapter.} Requests for additional information in the framework of the Existing Substances Regulation, in turn, might be overburdened by heavy procedure, which curtails their practical utility.\footnote{See Section II.3.2 of this Chapter.} And yet, a few basic, simple steps could easily be undertaken to give updating duties a firmer footing without turning them into procedural nightmares. One might, for example, envisage an arrangement where the Commission, or the competent national authorities, periodically circulate updating questionnaires to manufacturers and importers of notified substances. The issues addressed in such questionnaires would help notifiers structure their updating tasks, and the replies submitted by notifiers would, in turn, constitute a useful basis for revision and updating of the questionnaire. Moreover, if questionnaires are used as a blueprint -- or a "default document" -- rather than a uniform reporting format, they would probably leave greater scope of substance-specific variety and differentiation than standardised testing formulae afford.\footnote{Updating questionnaires are further discussed in Section II.2.1. of Chapter V.}

In sum, taking a close look at information gathering arrangements in European Community legislation on chemicals, it becomes possible to discern a bias favouring the short term over the long term, the "one-stop-shop" over the gradual implementation approach, and the standardised over the specific. I would suggest that this bias is not accidental, but rather can be connected to the dual (and superficially compatible) objective that chemicals legislation seeks to serve: market harmonisation on the one hand, and health and environmental protection on the other. While formally on equal footing, the methodological options that underscore EC legislation on chemicals are better suited to one goal than the other. Standardisation, one-stop-shopping and clearly defined cut-off points for the fulfilment of obligations, are virtues for the purposes of market integration and market functioning. Short-term requirements and the visibility of cut-off points facilitate the formation of legitimate expectations relating to market access. In other words, they create "certainties" for market actors. Standardisation guarantees uniform treatment, to which industry attaches great importance.\footnote{\textit{Cf.} SUSAN ROSE-ACKERMAN (1995), Umweltrecht und -politik in den Vereinigten} However, as discussed in Chapter I, health and environmental
protection objectives, particularly when pursued in areas that are characterised by a high degree of scientific uncertainty, might be better served by an approach that allows a greater extent of flexibility, variety and reversibility. The latter concepts, virtues for progressive health and environmental protection, will sound odious in the ears of many business managers.

In conclusion, I argue that, below a surface of apparent compatibility, an undercurrent of tension exists between the objectives of market harmonisation and health and environmental protection that are brought together in European chemical legislation. Judging from the type of commitments and the style of data reporting that prevails in both the Notification Directive and the Existing Substances Regulation, it seems that, as far are chemical data gathering is concerned, the objective of market harmonisation has the upper hand. Admittedly, a variety of people, including many European decision-makers, may find this balance in favour of market considerations entirely appropriate. Nevertheless, it is important to bring this tension to light because statements confirming the dual rationale of market and environment, and the compatibility between these objectives, are frequently made but hardly ever questioned in European Community law. Unconditionally accepting the symbiosis between the two goals might blind us to regulatory options that, from an environmental point of view, are more productive. Thus, decision-makers might miss opportunities to develop environmentally superior regulatory strategies, even in areas where environmental protection should take precedence over, or at least be brought on real equal footing with, market concerns. Risk regulation for chemicals may well be such an area.
CHAPTER III

RISK ASSESSMENT

Nothing But Measurement or a Measurement of Nothing?

INTRODUCTION

The 1980s were characterised by a growing awareness of the crucial role of information in the development of chemical control policies. At the international, European and national level, efforts were being undertaken to gather scientific information and test results relating to chemical properties, in particular their toxicity and, more recently, ecotoxicity. The Notification Directive, which established pre-market testing, hazard assessment and notification as legal requirements to introduce new chemical substances on the European internal market, can be viewed as a logical consequence of the growing importance of scientific knowledge as a basis for legal and regulatory decision-making (see Chapter II). The process of developing an EC-wide information base for chemicals, which now also includes testing and assessment of existing substances marketed prior to the entry into force of the Notification Directive (as foreseen in the Existing Substances Regulation), continues to this day, and remains one of the top priorities of EC chemical policies.

Indispensable as it may be, establishing a legal framework that encourages the production of scientific data and pre-market testing constitutes but a first step towards the implementation of a risk-oriented approach. Imagine the problem as follows: in our left hand, we hold a thick file containing scientific and technical descriptions, usually expressed in numerical values and molecular and structural formulae. Headings bear names such as "physico-chemical data: density," "inflammability," and "toxicity: sensitisation". In our right hand, we have a list of questions that are relevant for regulatory decision-making: is this substance safe; should it only be used in restricted quantities or under specified conditions; how great are the risks attached to marketing the substance; how much will a ban cost the chemical industry; what are the risks attached to the use of alternative substances or technologies; do we have enough information to decide on any of the above-mentioned issues? It quickly becomes
clear that these questions cannot be answered by a simple, straightforward reference to the numbers, values and formulae contained in the technical file. This would be like a physician replying "You have a temperature of 38.4°C" to her patient's query whether he is fit enough to go for a walk. The patient, however, is probably very well capable of reading the results registered on the thermometer; the question was rather one of how this result should be interpreted and used as an element in deciding whether or not it is safe for him to go out. Analogously, scientific data need to be interpreted, read in combination, translated and put into a context that is meaningful for the purposes of decision-making. This processing of scientific research and test results in order to create information, which can be used as an input for regulatory decision-making, is called risk assessment.

In light of the foregoing observation, it is hardly surprising that, after having established a relatively solid legal framework for the production and supply of scientific information on chemical substances, the European Community turned its attention to risk assessment. The development of a harmonised approach to risk assessment was singled out as one of the chief goals for the EC in the Fifth Environmental Action Programme and the Dobris Report. The following Sections cover the EC's first attempts at harmonisation, analysing what has been accomplished so far, questioning the adequacy of the approach taken and discussing the pros and cons of alternatives. As before, the US experience, where risk assessment is at the heart of an ongoing, controversial debate on the legitimacy and legality of chemical control policies, provides an interesting point of comparison.

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400 SUSANNE SMOLKA & GERD WEIDEMANN, o.c., p. 205.
403 See Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council of 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development (Fifth Environmental Action Programme), OJ C 138/1 (1993); and Chapter 38 of the Dobris Report.
1. **What Is Risk Assessment?**

In its broadest possible meaning, risk assessment is a methodology for making predictions about the risks attached to the introduction, maintenance or abandonment of certain activities (for example, the marketing of a new chemical substance) based on available information relating to the activity under examination.\(^{404}\) In other words, risk assessment is a way of ordering, structuring and interpreting existing information with the aim of creating a qualitatively new type of information, namely estimations on the likelihood (or probability) of the occurrence of adverse effects.\(^ {405}\)

Applied to the study of chemical safety, risk assessment combines data on adverse environmental or health effects (such as toxicity and ecotoxicity) with information on foreseeable exposure. The procedure most frequently used to make this assessment, which is also the one prevailing in European Community legislation, consists of a four-step analysis.\(^ {406}\) The first level of analysis is called *hazard identification*, and aims to determine the intrinsically hazardous physico-chemical and (eco)toxicological properties of a substance. In practical terms, during the hazard identification stage chemical substances are subjected to a series of tests to establish their intrinsic characteristics, including their boiling point, density and corrosivity, but also qualities that are far more difficult to examine, such as carcinogenicity and effects on reproduction. When this "chemical identity card" is mapped out, risk assessors move on to the second stage: *dose-response assessment*. As the name indicates, a dose-response assessment seeks to clarify the relation between the required quantity or concentration of a dangerous substance, and the occurrence of adverse effects. To this end, risk assessors determine significant levels of concentration, such as

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the "lowest observable adverse effect level" (LOAEL) and the "no observable adverse effect level" (NOAEL) for health risk assessment, and the "predicted no-effect concentration" (PNEC) for environmental assessments. The third step, exposure assessment, has as its objective to make a quantitative or qualitative estimate of the dose or concentration of the substance to which a population is or may be exposed, and of the size of the population exposed. In the case of environmental risks, exposure assessment aims to predict the concentration of the substance that will eventually be found in the environment. This concentration is tagged by the term "predicted environmental concentration" (PEC). Finally, the fourth stage is dedicated to the process of risk characterisation. Here, risk assessors combine the test results, data and estimates generated during the identification, dose-response measurement and exposure assessment stages, and on this basis try to determine, or even calculate, the likelihood that the examined substance will adversely effect human health or the environment, and the severity of the anticipated negative effects. It is this final determination that can be used as a basis for legal and regulatory decision-making.

2. The Different Faces of Risk Assessment: A First Encounter

Having supplied some basic information on the processes that together constitute chemical risk assessment, it is now possible to take a closer look at the risk assessment procedures as they have been laid down in European Community legislation. However, even a nutshell description as the one provided above offers more than a starting point for the study of risk assessment from a purely technical point of view; it equally opens the door to the ongoing and often heated debate concerning the different, even divergent qualities ascribed to risk assessment or, as I will refer to them, the different "faces" of risk assessment. Since this debate is at the core of many of the controversies surrounding the use of risk assessment methods as a legal basis for the development of chemical control policies, it is useful to obtain a preliminary insight into the debate before going into a more detailed analysis and discussion of the existing legal framework in the European Community.

Rereading the short overview of the four stages of risk assessment, it is

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striking how the language used to describe them draws on terminology appertaining to (at least) two different societal spheres. On the one hand, expressions and words such as hazard identification, establishment of intrinsic characteristics, determining levels of concentration, quantitative, and calculate clearly belong to the jargon of scientists, and help to create an image of risk assessment as a predominantly scientific and quantitative enterprise, firmly based on facts and falsifiable test results. On the other hand, activities such as seeking to clarify relations, estimating, predicting and trying to determine the likelihood of adverse effects are rather associated with decision-making, and therefore more fitting within the realm of policy-making and adjudication than in an environment of white coats and laboratories.

This mixture of distinct vocabularies, which can be associated with different practices conducted within different institutions, is a first indication that the phenomenon of risk assessment is difficult to grasp, a "complex series of factual characterisations and judgements." The perceived absence of a pre-existing disciplinary and institutional "niche" for risk assessment is discussed in the work of sociologists Ulrich Beck and Helga Nowotny. In Politische Wissenstheorie der Risikogesellschaft, Beck (1993) situates risks on the crossroads between theory and praxis, crossing disciplinary and professional boundaries, blurring the distinction between fact and value and affecting the different, institutionally separated spheres of politics, public policy, science and economy. Nowotny (1977), in turn, claims that in complex, technical spheres of decision-making, of which risk assessment is the prime example, traditional divisions of labour between science and society are breaking down. Adam Finkel, a US legal scholar active in environmental law, would probably agree with Nowotny. In his analysis of the various tasks performed by risk assessors, Finkel (1994) identifies no less than twelve different disciplines relevant for risk assessment: toxicology, epidemiology, biostatistics, chemistry, demography, psychology, sociology, engineering, regulatory analysis, economy, business

administration, and decision science.\footnote{ADAM M. FINKEL, o.c., pp. 360-361. It should be mentioned that, in Finkel's work, risk assessment is defined in a broad sense, including activities such as estimating efficiencies of available pollution control and prevention actions, estimating the cost of potential interventions and articulating a calculus for balancing the benefits of risk reduction against the cost of intervention, and for balancing the choice for immediate action against gathering more information and acting later. Certain authors (e.g., Russell and Gruber, see below) would consider these activities outside the scope of risk assessment and forming part of risk management (see below). However, as will be discussed further in this Chapter, the tasks of risk assessors as defined in EC legislation include evaluating risks and, where appropriate, making recommendations for risk reduction. For this reason, Finkel's description appears relevant in a European framework.}

The characterisation of risk assessment as a multi-faceted, interdisciplinary activity construed both by fact and value, is by no means uncontroversial. A number of authors, mainly scientists, adhere to the view that risk assessment is, in essence, a scientific undertaking that can and should be purged of non-scientific (social, political, ethical) considerations.\footnote{Cf. ROBERT NILSSON, MARTHA TASHEVA & BRUCE JAEGGER (1993), "Why Different Regulatory Decisions When the Scientific Information Base Is Similar - Human Risk Assessment," Regulatory Toxicology and Pharmacology, No. 7, p. 293; RUSSELL & GRUBER (1987), "Risk Assessment in Environmental Policymaking," Science, pp. 286-290; K.S. SCHRADER-FRECHETTE (1991), Risk and Rationality, University of California Press, p. 39; and "Reductionist Approaches to Risk" in DEBORAH G. MAYO & RACHELLE D. HOLLANDER, o.c., pp. 230-238. Schrader-Frechette identifies advocates of this view as "naïve positivists."} In their opinion, values and subjective judgements are not inherent in risk assessment, but are reduced to the level of impurities. To free risk assessment from these impurities, a wall is constructed around the alleged scientific, value-neutral and objective core of risk assessment, and extraneous elements, i.e., value-laden, subjective and ethical considerations, are expelled and relegated to the field of risk management, which is the appropriate arena for objective data, resulting from scientific risk assessments, to be processed into social policy.\footnote{ELLEN K. SILBERGELD, o.c., p. 99.} Here is how Russell and Gruber (1987) separate assessment from management:
<table>
<thead>
<tr>
<th>Methodology</th>
<th>Typology</th>
<th>Ownership</th>
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<tbody>
<tr>
<td><strong>Risk assessment</strong></td>
<td>&quot;hard&quot; science, incorporating biomedical science, statistics, engineering</td>
<td>Preserve of scientists and technicians</td>
</tr>
<tr>
<td>Hazard identification, dose-response assessment and analysis of exposure,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>including possible quantitative risk assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Risk management</strong></td>
<td>social science, with emphasis on political science and economy, and</td>
<td>Policy makers and the public</td>
</tr>
<tr>
<td>All processes of judgement, including considerations of</td>
<td>increasing incorporation of decision theory</td>
<td></td>
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<tr>
<td>acceptability, feasibility, equity and economics</td>
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The notion of a tenable, clear-cut separation between risk assessment and risk management echoes the more general idea that science finds the facts, politics evaluates the options, and law delivers the rules to stabilise political choices and make them operational.  

Disagreements concerning the "true face" of risk assessment deeply affect opinions on how risk assessments should be conducted and, ultimately, on the legitimacy and legality of the process. Those in the "scientific corner" will contend that risk assessment should be the exclusive territory of scientists, and will favour assessments strictly guided by standardised scientific rules that are also commonly used in non-regulatory scientific research, relying on quantification and resulting in numerical estimates of the maximum individual risk (typically expressed as number of excess deaths per population) or degree of environmental deterioration. This type of assessment is called quantitative risk assessment or QRA. Erroneous predictions and uncertainty will be considered a

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side-effect of insufficient information and gaps in knowledge, and therefore amendable once more information becomes available.

The other corner, preliminarily labelled the "fact and value corner," harbours dissenting opinions, based on the premise that it is impossible to conduct value-free, objective risk assessments because they inevitably comprise evaluations and judgements as well as scientific facts.\footnote{In this corner, we find authors such as Sheila Jasanoff, Ellen Silbergeld, Carl Cranor, Adam Finkel and Mark Eliot Shere.} Accordingly, advocates of the latter view will be reluctant the accept scientists as the authorities solely and exclusively competent to conduct risk assessments, and will question both the feasibility and appropriateness of a strict separation between risk assessment and risk management.\footnote{See JOHN S. APPLEGATE (1991), "Unreasonable Risk," o.c., p. 279: "[A]s a rigid dichotomy (between risk assessment and risk management), of course, this is an unrealistic view of government action and of science, since political and judgmental factors pervade the entire risk assessment function."} In the fact and value corner, attempts to boost risk assessment's scientific credentials through application of rigorous scientific evidentiary rules and increased use of quantification are viewed with scepticism and denounced as efforts to shield the subjective, value-laden elements inherent in risk assessment from public scrutiny. Alternative methods, which aim better to adapt risk assessment to its regulatory purposes and/or explicitly acknowledge and incorporate the social, political and ethical values embedded in risk assessment, are put forward.\footnote{See, for example, CARL F. CRANOR (1993a), Regulating Toxic Substances. A Philosophy of Science and the Law. Oxford University Press, New York, Oxford, pp. 252.} At its most extreme, opponents of the scientific corner may claim that scientific risk assessment is inherently flawed and biased, and consequently should be outlawed as a basis for environmental, health and safety policy decision-making.\footnote{See, for example. MARK ELIOT SHERE (1995), "The Myth of Meaningful Environmental Risk Assessment," Vol. 19, Harvard Environmental Law Review, pp. 409-}

The sketchy portrayal of the risk assessment debate in terms of a conflict between those who believe risk assessment is, or should be, a purely scientific enterprise, and those who consider that values and judgements are, or should be, inextricably linked to the assessment process, does not do full justice to the gamut of different views and opinions voiced in the debate. It would be mistaken to think that all members grouped together in the same corner, whether the scientific or the fact and value corner, think alike and arrive at identical conclusions based on their shared conviction that risk assessment is or is not strictly within the realm of science. In Section II of this Chapter, I offer a more
detailed and nuanced overview of the debate and its ramifications for law- and policy-making relating to chemical substances. Nevertheless, as an initial dividing line the “science v fact and value” distinction is extremely useful, since most -- if not all -- specific evaluations and criticism of risk assessment as a legal basis for decision-making can be related to and understood in the general framework of the distinction. Thus, this first encounter with the different faces of risk assessment may serve as an organisational tool to guide and structure further analysis, thereby facilitating closer encounters.
SECTION I - A LEGAL FRAMEWORK FOR RISK ASSESSMENT IN THE EUROPEAN COMMUNITY

In the early 90s, the European Community turned its attention to the development of harmonised guidelines for chemical risk assessment. The Dobris Report mentioned that, in order to cope with specific environmental problems caused by identified chemicals, remedial, preventative or legislative measures had been taken in many industrialised countries. At the EC level, the predominant instrument dealing with identified dangerous chemicals was Directive 76/769/EEC, which restricts access to the internal market for certain harmful chemicals (including PCBs, DDT, etc.) and establishes maximum quantities for the use of these substances in compounds and preparations. However, the Report continued: "[I]n the last years it has generally been recognised that such an approach is not sufficient. There must be an integrated concept which addresses the impact of all chemicals that may cause detrimental effects in the environment" (emphasis added).

A second noteworthy comment relating to the development of a harmonised risk assessment approach can be found in DG XI's 1994 publication on chemical risk control. Page 5 contains the following statements: "[I]n the past, EC chemicals legislation took the form of directives requiring implementation by the Member States. However, it sometimes takes years to fully implement directives and Member States may differ about the interpretation of these directives into national law;" "[T]he European Commission also uses less formal means - publication of recommendations, technical standards, guidelines or handbooks, or the convening of seminars or training sessions - to promote the harmonised implementation of the chemicals control system throughout its territory;" and "[T]he EC chemicals control system provides a foundation and a framework which industrial managers can rely on to assess the environmental risks throughout the entire life-cycle of a chemical product. In this way, they can take steps to control these risks without the need for government intervention. Over the coming decade, industry and European governments will be collaborating closely on gathering information and assessing.

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419 Dobris Report, Chapter 38.
the risks from existing chemicals*.422

These general statements reveal a number of interesting aspects of the former and current philosophy underscoring EC chemical control policy, and the role of legislation in the development thereof. The alleged insufficiency of remedial, preventative or legislative measures to cope with specific environmental problems caused by identified chemicals, and the emphasis on the time-consuming and complicated process of implementing EC legislation, point at a disenchantment with single-target, substantive rules that set limits and fix outcomes. The restrictions in Directive 76/769/EEC are the prevalent example of this approach. Instead, the emphasis shifts to the development of integrated concepts, guidelines and handbooks, and reliable frameworks.423 What is significant about these new categories of measures is that, in the case of harmonised guidelines for risk assessment, they do not supply the parties who make use of them (Member States' public authorities and private actors, such as industry, which party is explicitly mentioned in the last quotation) with general, substantive information on chemical risks, but confine themselves to outlining the different steps these parties should undertake in order to determine and weigh chemical risks. In this regard, the harmonised risk assessment measures that have been developed in accordance with the EC's above-mentioned search for an integrated concept, represent an attempt at proceduralised legislation, laying down procedures that enable the addressees to develop their own rules, in accordance with an EC-wide framework but without being bound to pre-set outcomes.424

1. The European Community's Principles for Health and Environmental Risk Assessment

In the Introduction to this Chapter, I have characterised the establishment of a common database for chemical substances and the development of risk assessment principles as related and sequential processes. The structure of EC legislation on the issue of health and environmental risk assessment would appear to support this characterisation: similar to the rules

422 Dobris Report, Chapter 38.
423 Cf. CHRISTOPHER ARUP, o.c., p. 48.
relating to information production and supply, there is one set of risk assessment principles affecting newly notified substances, and another covering assessment of existing substances. New chemicals are dealt with in a 1993 Commission Directive (Directive 93/67/EEC), whereas risk assessment principles applicable to existing substances can be found in a Council Regulation of the same year (N° 793/93) and a Commission Regulation (N° 1488/94) adopted one year later. The latter rules are slightly more complex and include a two-step assessment procedure, the first step allowing prioritisation of the *prima-facie* most dangerous chemicals and the second entailing an in-depth assessment. Obviously, this arrangement was set up in response to the huge information gaps relating to existing substances (in 1994, information sufficient to allow classification in Annex I of Directive 67/548/EEC was available for only about 1% of the substances listed in the EINECS). This problem does not arise in the context of notified new substances. In their more "technical" aspects, however, the risk assessment provisions covering new and existing substances are very similar.


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424 See Heading 3.4(d) of Chapter I.
426 ECKARD REHBINDER (1994b), "Control of Products," o.c., p. 28; PATRICK McCUTCHEON, o.c., pp. 367-372. Cf. Section II.3.2 of Chapter II.
427 LUC LAVRYSEN, o.c., p. 42.
428 The term technical is placed between quotation marks because, as has already been indicated and will be discussed in greater detail below, the technicality of risk assessment procedures is debatable.
shall be regularly reviewed and, where appropriate, revised in accordance with the same procedure." Article 29, in turn, lays down a committee procedure "for adaptation to technical progress." It maps out the following steps: in order to enact measures, the Commission needs to be assisted by a committee (hereinafter the "Committee"), consisting of the representatives of the Member States and chaired by a Commission representative (Article 29(1)). The Committee decides on the draft measures submitted to it by the Commission representative, within a time limit fixed by the latter depending on the urgency of the matter (Article 29(2)). Subsequent to Committee approval, the Commission is to confirm the measures (Article 29(3)). If, however, the Committee does not approve the measures initially proposed by the Commission, or fails to deliver an opinion within the deadline specified by the Commission representative, the Commission will forward its proposal to the Council. The Council then has three months to decide on the issue, acting by a qualified majority. If no decision is reached within that period, the Commission shall adopt the proposed measures, unless the Council has decided against them by a simple majority (Article 29(4)(b)).

It is interesting to observe that even the most "mundane" provisions relating to risk assessment, such as the rules governing the decision-making process summarised above, carry within themselves reminders of risk assessment's different faces, highlighting either its more scientific, technical side or its value-embedded, policy-oriented appearance. Thus, the decision to develop risk assessment principles following a procedure which, according to its title, is meant for adaptation to technical progress, and the absence of the European Parliament as a party in the deliberation process, both convey an image of the establishment of risk assessment principles as an executive rather than legislative act; a process of technical implementation that is not intended to affect or alter any of the fundamental principles and goals set out in the

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429 See Chapter II.
430 The Commission Directive is therefore an example of tertiary EC law-making; i.e., rules developed on the basis of a secondary legal act. See GERD WINTER (1996), "Effectiveness," o.c., p. 690.
431 This is yet another example of the comitology contre-filet procedure, as seen previously in Section II.2.1 of Chapter II. See fn. 229.
Notification Directive, and can therefore be decided without the measures having
to be subjected to public scrutiny, represented at the EC-level in the form of the
European Parliament.\textsuperscript{433}

On the other hand, if Article 29 does not refer to the European
Parliament, neither does it formally require the consultation of a scientific
committee, which is remarkable considering that risk assessment relies heavily
on scientific methodology, and is by some even portrayed as a "science" in its
own right.\textsuperscript{434} In fact, the only committee mentioned in Article 29 is composed of
Member States’ representatives. This, and the fact that the Council is able to
reject proposed measures by a simple majority (provided in Article 29(4)(b) as
opposed to Article 29(4)(a) which, in the absence of a qualified majority decision
in the Council, gives the final word to the Commission), indicate that the
Member States do intend to keep their hands quite firmly on the process. This
in turn suggests that, in the opinion of the national governments, risk
assessment is not exclusively governed by value-neutral, objective scientific
standards and that, consequently, the establishment of risk assessment
principles should not be left solely to scientific experts, operating outside the
sphere of political control and accountability.

Before turning to the provisions of the Commission Directive, it should be
noted that, whereas risk assessment principles are established at the EC-level,
the competency to conduct assessments remains with the Member States. The
Commission Directive refers to Article 16 of the Notification Directive, stipulating
that the national competent authorities that have received the notification of a
new chemical substance shall perform the assessment. It should furthermore be
mentioned that the Notification Directive continues saying that the notifier may
furnish the competent authority with a preliminary risk assessment (Article 7,
last indent of the Notification Directive). Opportunities for industry involvement
in the assessment process are further extended by the Commission Directive,
which states in Article 5(3) that, if the assessment indicates that the substance
may pose a health or environmental problem, “[t]he notifier may be informed by

\textsuperscript{433} KOEN LENAERTS (1993), “Regulating the regulatory process: delegation of powers in
the European Community,” Vol. 18, European Law Review, p. 27.

\textsuperscript{434} MARY LYNDON (1989a), “Risk Assessment,” o.c., p. 296: “[S]cientists largely agree
that QRA (quantitative risk assessment) is science, though they disagree about whether
certain judgements are good science;” and DONALD T. HORNSTEIN (1992), “Reclaiming
Environmental Law: A Normative Critique of Comparative Risk Analysis,” Columbia Law
Review, p. 569: “[T]o many people, the discipline of formal risk assessment has
developed a sufficiently rigorous internal structure to qualify as a science.”
the competent authority of its conclusions and be given the opportunity to comment on those conclusions and to provide additional information." These arrangements raise interesting questions about the desirable level of third party involvement in risk assessment, which will be discussed later in this Chapter.435

Having finally arrived at the content of the Commission Directive itself, the following elements can be identified:

2.1. Ratio legis

In its preamble, Directive 93/67/EEC sets out the reasons why, even though risk assessments are carried out at the Member State level, there is a need for EC-wide, harmonised assessment principles: "[i]t is, however, appropriate that general principles be adopted at Community level to avoid disparities between the Member States which do not only affect the functioning of the internal market but also do not guarantee the same level of protection of man and the environment." As was the case with the harmonised principles for the notification of new substances, the Commission Directive offers a justification that combines two distinct rationales: an economic, market-oriented rationale and a social one. In other words, the adoption of risk assessment principles may kill two birds with one stone: facilitating the functioning of the internal market and ensuring health and environmental protection at the same and, so Article 130R(2) of the EC Treaty informs us,436 high level.

As discussed in Chapter II, the linking of different rationales may serve as a powerful instrument to increase the acceptability of rules and to enlist the compliance and cooperation of different interest groups. However, it has also become clear that the goals of market integration and environmental protection, even when put forward as compatible and/or mutually reinforcing, are by no means natural bedfellows. Hence, one of the issues to be explored in the evaluation of the existing EC system relating to risk assessment will centre on the opportunities, as well as the complications and constraints, that are introduced by this combination of a market and an environmental legitimation, including a discussion of the adequacy, effectiveness and proportionality of the harmonised principles, as they have been laid down in the Commission

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435 See Section III of this Chapter.
436 Article 174 ToA.
Directive,\textsuperscript{437} to attain their dual goal.

2.2. \textit{Legal relevance of risk assessment principles}

The preamble to Commission Directive 93/67/EEC affirms that the results of risk assessments should be the principal basis of decisions under appropriate legislation to reduce the risks arising from the placing of substances on the market.

This statement has interesting potential ramifications for the structure of chemical control policy and legislation, since it creates an opportunity for risk assessment to become one of the tangible, recognisable and controllable connections between "input-oriented" legislation (information collection and processing) and "output-oriented" measures (risk reduction). What I mean by this is the following. According to Article 190 of the EC Treaty,\textsuperscript{438} binding acts adopted by the Council (acting alone or jointly with the European Parliament) or the Commission have to be duly motivated. One of the main purposes of Article 190 is to enable the addressees of decisions taken at the Community level (whether the Member States, other Community institutions or private parties) to review the reasonableness, proportionality and, hence, the legality of these decisions.\textsuperscript{439}

Thus, risk reduction measures, such as the restrictions on dangerous substances listed in Directive 76/769/EEC and ensuing amendments, have to indicate the reasons that led to their enactment. An overview of the different amendments to Directive 67/679/EEC, which gradually increased the number of substances and preparations subject to restrictions, reveals that, throughout the years, the motivations justifying new restrictions have varied quite substantially. Restrictions on toxic, harmful or flammable liquids used in lamps, ashtrays and other ornamental objects, for example, were mainly justified on the basis of experience: "[W]hereas these objects are not always sufficiently stable and are easily overturned especially by young children, with the result that the glass container breaks, the liquid escapes and fumes are emitted which are toxic or harmful and to which the children fall first victim; whereas at least

\textsuperscript{437} And in the Regulations on existing substances, which are also justified on the basis of both market and environmental considerations (see below).
\textsuperscript{438} Article 253 ToA.
\textsuperscript{439} HANS VON DER GROEBEN, HANS VON BOECKH, JOCHEN THIESING & CLAUDIETER EHLERMANN (1983, eds.), Kommentar zum EWG-Vertrag, Vol. 2, Nomos
two deaths have occurred in this type of accident." Other restrictions, such as those concerning benzene, PBBs (polybrominated biphenyls) and the 1983 provisions on asbestos refer respectively to advice given by the Scientific Advisory Committee on toxicity and ecotoxicity (benzene), to examinations and scientific assessments on the basis of structural similarities between established carcinogens and substances concerning which scientific evidence is inconclusive (PBBs), and to "scientific sources" of information generally (asbestos). Some motivations solely emphasise the health and environmental hazards and/or risks posed by the marketing and use of certain substances, whereas others introduce more economically oriented reasoning, focusing on the feasibility of restrictions and the availability of alternatives. For example, in 1982 Council Directive 82/828/EEC allowed the temporary authorisation of the use of PCTs (polychlorinated terphenyls) because of the "[i]fundamental importance of the uses for which they are intended." By 1985, however, substitutes had been developed which were considered less dangerous to health and the environment. Consequently, the preamble of Directive 85/467/EEC confirmed that "[t]he continued marketing of PCBs and PCTs is therefore no longer justified."

The variety of arguments furnished to justify the relevant restrictions (e.g., arguments based on experience, scientific data, economic feasibility) as well as the notable differences in quantity of information and detail supplied in

\[\text{Verlagsgesellschaft, Baden-Baden, p. 590.}\]
different cases (e.g., the ben zene decision confines itself to stating that benzene is recognised as being highly toxic, carcinogenic and liable to affect the central nervous and hermatopoietic systems, whereas the decision relating to 3,3 demethoxibenzididine offers more background information on how the substance came to be qualified as a potential risk to health) complicate the addressees' task of gaining a systematic insight into the elements that go into the decision-making process, and consequently of checking the reasonableness, proportionality and legality of the restrictions. Furthermore, even when explanations such as "examinations have shown that PBB is harmful to health" are given, this does not tell us anything about why regulatory authorities decided to act on this information, whereas other identified harmful substances remain unregulated or are subject to entirely different forms of restrictions. In other words, statements concerning intrinsic properties of chemical substances alone hardly form a sufficient basis effectively to control the reasonableness and appropriateness of regulatory decisions. Thus, the deliberation process situated between information relating to a chemical substance or preparation and the resulting restriction (or decision not to restrict) remains largely invisible, hidden behind the impenetrable walls of a black box.

The adoption of risk assessment principles and the reliance on risk assessment results as the main basis for legal decisions can elucidate this -- previously quite inaccessible -- decision-making process because these reforms impart some structure and regularity to the process. Thus, the black box located between "input" of information and "output" of risk reduction measures becomes more transparent.\footnote{However, as will be detailed in Chapter IV, the practical value of risk assessment as a structuring element in EC risk reduction decision-making, thus contributing to a greater transparency of EC decisions, has up to now been fairly limited. See Section II.2 of Chapter IV.} Even though risk assessment methods do not prescribe outcomes, they do supply guidance on the different steps to be taken in order to arrive at what, according to the internal methodology, are valid conclusions. In this manner, risk assessment principles may help the addressees of risk reduction measures to verify the legality of these measures in the sense that these measures ought to be the result of a correct application of the prescribed principles. Moreover, they offer valuable assistance to regulatory authorities on how to process technically complex information and arrive at decisions, thus increasing their opportunities for self-control and, consequently,
self-learning.447

On the other hand, increased formality and transparency of risk decision-making may come at a price in that it leaves less room for flexibility and idiosyncratic considerations. Differently put, the creation of rules, whether substantive or procedural, usually goes hand in hand with the emergence of a category of exceptions for which the rules appear ill-fitted. Yet, the main challenge harmonised risk assessment principles will face as the legal, procedural basis for regulatory decision-making lies not so much in their ability to cope with exceptions as in the overall acceptability of risk assessment itself as a mode of decision-making. As will be discussed in detail in the following Section, this acceptability should not be taken for granted.

2.3. Risk assessment principles

The risk assessment principles in Commission Directive 93/67/EEC mandate the use of the four-step analysis described earlier in this Chapter: hazard identification, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation.448 In addition, Article 3(4) requires risk assessments to indicate one of the following conclusions:

- the substance is of no immediate concern and need not be considered again until further information is made available;
- the substance is of concern and the competent authority shall decide what further information is required for revision of the assessment but shall defer a request for that information until the quantity placed on the market reaches the next tonnage threshold;
- the substance is of concern and further information shall be requested immediately;
- the substance is of concern and the competent authority shall immediately make recommendations for risk reduction.

The inclusion of such proposals, and particularly the recommendations for risk reduction, in a document dealing with assessment indicates that the European Community adheres to a broad conception of risk assessment; one that includes

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448 Article 3 of Commission Directive 93/67/EEC.
activities which, strictly speaking, belong to the area of risk management. This observation implies, first, that EC assessment rules do not uphold a strict separation between the "scientific/objective" and "evaluative/subjective" faces of risk assessment. Yet simultaneously, it conveys a great trust in science and expertise, since it are the risk assessors (generally members of the scientific community) who are deemed capable of making initial risk management decisions (which are traditionally within the competency of administrative bodies), rather than that risk managers are considered capable of making and evaluating their own, or experts', risk assessments.

The risk assessment principles are elaborated in Articles 4 and 5 of the Directive, in combination with Annexes I to III, and are further detailed in the Commission's Technical Guidance Documents. Three different types of risk assessment are specified: toxicity assessments relating to human health, physico-chemical properties assessments (human health), and environmental risk assessments. Without going into too much detail on the specifics of risk assessment methodology, the following observations can be made.

First, the risk assessment rules do not appear overly rigid, but grant the Member States a reasonably broad range of discretion. For example, section 3.1 on exposure assessments for toxicity identifies as its objective "[t]o make a quantitative or qualitative estimate of the dose/response concentration to which a population is or may be exposed," thus leaving the Member States a choice between a quantitative or qualitative approach. Also, section 3.2 on exposure assessments for environmental risks provides that the predicted environmental concentration (PEC) need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions are reasonably foreseeable. This provision enables the Member States to adapt the scale (and, hence, the expense and duration) of the assessment procedure depending on the circumstances of the case and, possibly, on differing local notions of "reasonably foreseeable exposure."

Second, the harmonisation measures are of a predominantly

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449 See also under Heading 2 of the Introduction to this Chapter.
451 JAN VIEBROCK (1995), "Öffentlichkeit im Verfahren der Chemikalienkontrolle am Beispiel "PCP"" Vol. 18, Umweltrechtliche Studien, Werner Verlag, p. 27.
methodological rather than substantive or normative nature.\footnote{GERD WINTER (1994a), "Regelungsmaßstäbe" o.c., p. 914.} Risk assessors consulting the Directive and Technical Guidance Documents will in the first place obtain information on the "ingredients" that go into risk assessments according to EC harmonised principles (such as no-observed-adverse-effect-levels, lowest-observed-adverse-effect-levels, predicted effect concentrations, assessment factors,\footnote{An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment (Commission Directive 67/93/EEC, Annex III, section 2.4). For example, when it is not possible or feasible to measure the level of concentration at which a chemical is expected to have no effect on the environment (the PNEC), risk assessors may measure the LC50, which is this concentration of the substance at which half of the exposed objects (50%) become lethally affected (the median lethal concentration). Subsequently, the median lethal concentration is divided by an assessment factor of, e.g., 1000 to create an estimate of the level of concentration of the substance that is not high enough to affect the environment. In other words, in the absence of directly measured or measurable data on exposure and effects in the real environment, it is assumed that a substance will have no effect if, in the above example, the level of concentration is 1000 times smaller than the median lethal concentration (extrapolation of uncertainty). Cf STUART DOBSON, o.c., p. 338.} monitoring data) and, to some extent, on the prescribed treatment of these ingredients (e.g., measuring, combining, comparing, estimating) in order to arrive at acceptable outcomes. For example, going back to section 3.1 on exposure assessments, it lists relevant information which risk assessors have to include into their assessment, and requires that estimations of exposure "shall take account of spatial and temporal variations in the exposure pattern."\footnote{Information for exposure assessments, see section 3.2 of Annex I. Exposure patterns, see Annex I, section 3.1 \textit{in fine} and the Technical Guidance Documents.} However, risk assessors would be hard-pressed to find much detail in either the Commission Directive or the Technical Guidance Documents on the relative weight to be attributed to certain types of information used in the assessment or, more generally, on how to make the connection between the measured, estimated and/or extrapolated results on the one hand and one of the above-listed conclusions (no immediate concern / further information / risk reduction measures, etc.) on the other. Hence, harmonised risk assessment principles should not be thought of as constituting a manual that specifies the practical, normative conclusions to be derived from the results of measurements and estimates (an example of an applied, normative rule would be the following: "if the assessment shows that the use of the relevant chemical in the work place would result in the death of 1 in a 500,000 workers, then the risk assessor should choose the third conclusion, namely, that the substance is of concern and further information should be requested immediately"), but rather as an
outline of the necessary steps (procedures) to be taken towards valid -- but
locally determined -- conclusions. In fact, only in one instance does the
Commission Directive explicitly prescribe a normative conclusion on the basis of
measurement results: section 4.1 on environmental risk characterisation
contains the following formula: "If the PEC/PNEC ratio (the predicted effect
concentration compared to the predicted no-effect concentration) is equal to or
less than one, the conclusion in Article 3(4)(i) (i.e., the substance is of no
immediate concern and need not be considered again until further information is
made available) shall apply." However, if the ratio is greater than one, it is again
up to the competent authority to decide which of the four conclusions is
applicable.

Finally, even though the harmonised risk assessment principles generally
focus on methodology, leaving national risk assessors a reasonably broad
margin of discretion relating to both the implementation of this method (see the
first observation above) and the explicitly normative assessment of the
measured, calculated and estimated test results (see the second observation),
some of the risk assessment methods do reveal a conservative (and, thus,
normative) slant.455 This becomes particularly clear in the provisions relating to
the dose (concentration) - response (effect) assessment for mutagenicity,
genotoxic carcinogenicity and skin sensitisation caused by chemical
substances:456 "2.3. For mutagenicity and carcinogenicity, it shall be sufficient
to determine whether the substances have an inherent capacity to cause such
effects (...) 2.4. With respect to skin sensitization and respiratory sensitization,
in so far as there is no consensus on the possibility of identifying a
dose/concentration below which adverse effects are unlikely to occur in a
subject already sensitizised to a given substance, it shall be sufficient to
evaluate whether the substance has an inherent capacity to cause such effects." This approach is conservative because it narrows the basis of assessment: the
mere existence of an inherent capacity, e.g., carcinogenicity, of a chemical is

455On the normative consequences of methodological choices, see K.S. SCHRADER-
456Mutagenic substances are substances which, if they are inhaled or ingested or they
penetrate the skin, may induce heritable genetic defects or increase their incidence;
carcinogenic substances are substances which, if they are inhaled or ingested or they
penetrate the skin, may induce cancer or increase its incidence; and sensitising
substances are substances which, when they are inhaled or they penetrate the skin, are
capable of eliciting a reaction of hypersensitisation such that on further exposure
characteristic adverse effects are produced (Article 2, sections (k), (l) and (m) of the
sufficient to warrant a decision that the substance (given a certain estimated exposure) is of concern and eventually should be subjected to risk reduction measures, even when the carcinogenic qualities of this substance would only become active if it were used in extremely high doses or concentrations. Differently put, even a very favourable dose-response relationship (i.e., a very high dose is required in order to elicit some response by the subjected organism) does not mitigate the risk attached to the inherent capacities in the case of carcinogenicity, mutagenicity, reproductive toxicity and skin sensitisation.

3. **The Council and Commission Regulations on Risk Evaluation for Existing Substances**

The risk assessment principles in the Council and Commission Regulations on existing substances are tailored along the same lines as the ones applicable to new substances. Like Commission Directive 67/93/EEC, the preamble of Commission Regulation 1488/94 mentions the dual rationale of market integration and environmental protection to justify harmonisation at Community level, and points out that the results of a risk assessment should be the principal basis on which to decide risk reduction measures under the appropriate legislation. Furthermore, the detailed description of the four risk assessment steps and the prescribed methodology in the Annexes to the Commission Regulation on risk assessment for existing substances mirror the ones contained in Commission Directive 67/93/EEC. Nevertheless, there are certain differences between the arrangements for new and those for existing substances.

On a formal level, the principles for risk assessment of existing substances are laid down in a Council and a Commission Regulation, and are

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457 Technical differences between the provisions in Commission Directive 67/93/EEC and Commission Regulation 1488/94 are the following:
- the information requested for the purposes of hazard identification in all three sections (toxicity, physico-chemical properties and environment), as well as the remaining information on risk assessment relating to physico-chemical properties, is more limited in the Commission Regulation;
- the Commission Regulation adds one element to be taken into consideration for toxicity and environmental exposure assessments (i.e., the breakdown products and/or transformation products of the substance under examination); and
- whereas the Commission Directive states that, for environmental risk assessment, the predicted no-effect concentration (PNEC) shall be calculated by applying an assessment factor to the test results (see fnt. 453), the Commission Regulation stipulates that the PNEC may be calculated in this manner.
hence directly applicable throughout the Community without requiring national implementation, whereas the principles affecting new substances are set out in Directives.\textsuperscript{458} Thus, the more centralised approach towards risk regulation of existing substances, which we already noted at the level of data gathering, is extended to the risk assessment stage. There is furthermore a small and somewhat incongruous difference in the decision-making procedure for the adoption and modification of risk assessment principles. Like the Notification Directive, the Existing Substances Council Regulation establishes a Committee procedure with referral to the Council when no agreement is reached between the Commission and the Committee of Member States representatives. However, in the case of risk assessment principles for existing substances, the Council has only two instead of three months to arrive at a decision, and does not have the option of rejecting the Commission's proposal by simple majority.\textsuperscript{459} These deviations from the Committee procedure in the Notification Directive could simply be the result of an oversight on the part of the drafters of the Council Regulation. Alternatively, they could be interpreted as a further indication that risk evaluation for existing substances, being a more centralised activity organised at Community level, is less controlled by the Member States as represented in the Council of the European Union.

Finally, the rules governing risk assessment for existing substances do not create the same opportunities for industry involvement as the ones applicable to new substances: suppliers of hazard data are not given the option to submit a preliminary risk assessment. Neither does Regulation 1488/94 mention an opportunity for chemicals manufacturers, industrial users and, possibly, interested third parties (\textit{e.g.}, environmental or consumer health groups) to comment on risk evaluations. On the whole, the structure erected in the Existing Substances Regulations comes across as a notch less communicative than the risk assessment framework developed pursuant to the Notification Directive.

\textit{Risk assessment as an organising principle}

In addition to third party involvement, an important difference between risk assessment for new and that for existing substances is that the latter

\textsuperscript{458}See Section II.3(1) of Chapter II.
\textsuperscript{459}See Article 10(4) in combination with Article 15 of the Existing Substances Regulation.
consists of two stages. After an initial collection of the available information on existing substances, submitted in accordance with the requirements for data reporting and updating (see Section II.3 of Chapter II), the Commission, in consultation with the Member States, makes a first assessment of the substances, taking into account the following elements:

- the effects of the substance on man or the environment;
- the exposure of man or the environment to the substance;
- the lack of data on the effects of the substance on men and the environment;
- work already carried out in international fora (for instance, risk assessments carried out under the auspices of OECD and IFCS (Intergovernmental Forum for Chemical Safety)); and
- other Community legislation and/or programmes relating to dangerous substances.

Additionally, the Commission is to pay special attention to substances having chronic effects, and in particular known or potential carcinogens, mutagens and reproductive toxins.

On the basis of these preliminary assessments, priority lists of substances for which further data collection, testing, assessment and eventual risk reduction measures appear most urgent, are drawn up. Prioritised substances are assigned to national rapporteurs, who are charged to obtain further information from manufacturers and importers if necessary, and subsequently to perform a second stage, in-depth assessment. The principles for this full-fledged assessment are laid down in implementing Commission Regulation 1488/94. As mentioned, these risk assessment rules for the second stage of assessment are almost identical to the principles applicable to newly notified substances.

What is interesting about this two-staged approach is that it reveals an additional and important role for risk assessment in the area of chemical substances control. Looking at the rudimentary assessment requirements that precede the priority-setting process, it becomes clear that the object of the first risk assessment exercise is not so much to obtain a complete and fully accurate picture of the risks attached to the substances at issue, and consequently to formulate risk reduction recommendations, as to organise a workload that otherwise might be unmanageable. Herein lies a great advantage of standardised

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460 PATRICK McCUTCHEON, o.c., pp. 367-372. See Section II.3(2) of Chapter 2.
461 Article 8 of the Existing Substances Regulation.
risk assessments: they supply a basis for comparison, thereby creating opportunities for decision-making that is conscious of the need to manage time, expenses, and other scarce resources.\textsuperscript{462} Even if risk assessment techniques are not universally accepted as reliable methods on which to base risk management decisions, it would be difficult to deny their usefulness as an organising principle and as a facilitator of decision-making. The various pros and cons of risk assessment, both as a way of structuring the workload and as a substantive basis on which to make risk control decisions, will be discussed in greater detail in the following Section.

\textsuperscript{462}MARY L. LYNDON (1989a), "Risk Assessment," o.c., p. 289.
SECTION II - CONTROVERSIES SURROUNDING THE USE OF RISK ASSESSMENT AS A BASIS FOR CHEMICAL REGULATION

To all appearances, the European Community has set its hopes on risk assessment as the preferred technique to digest, process and format scientific and research information relating to chemicals, in order both to organise the workload and set the agenda for the development of EC-wide regulatory policies, and to enable EC and national decision-making relating to risk management.

This move towards the use and institutionalisation of risk assessment procedures in regulatory processes is not unique to the European Community. To name but one example, many United States' regulatory bodies, such as the EPA and the Occupational Safety and Health Administration (OSHA), also rely heavily on risk assessment to cope with the complexities and uncertainties posed by the production, use and release on the market of chemicals.\footnote{See, e.g., \textit{American Petroleum Institute v. OSHA}, 448 U.S. 607 (1980). In the \textit{Benzene} decision, the Supreme Court ruled that before regulating a chemical hazard in the workplace, the regulatory body (\textit{in casu OSHA}) had to demonstrate that the risk at the existing standard was significant, and that a new standard would measurably improve worker health. Continuing, the Court held that to establish the above-mentioned significance, OSHA had to carry out a quantitative risk assessment indicating a numerical probability of harm. \textit{Sheila Jasanoff} (1995), \textit{Science at the Bar}, \textit{o.c.}, pp. 82-83.} Moreover, the development of international assessment standards forms one of the programme areas in Chapter 19 of the UN's Agenda 21, and organisations such as the OECD and the Intergovernmental Forum for Chemical Safety (IFCS) develop and support programmes for the establishment of international and uniform rules for risk assessment of chemicals.\footnote{See, e.g., \textit{Stephan Breyer}, \textit{o.c.}, p. 9 \& \textit{passim}; \textit{John S. Applegate} (1991), "Unreasonable Risk," \textit{o.c.}, pp. 280-284; \textit{Mark Eliot Sheere}, \textit{o.c.}, \textit{passim}; \& \textit{Mary L. Lyndon} (1989a), "Risk Assessment," \textit{o.c.}, \textit{passim}.}


First, reliance on the results of chemical risk assessments enables regulatory authorities to form an opinion of the danger or safety of substances...
and, if deemed necessary, to regulate certain substances before harm materialises. In other words, because of risk assessment's predictive potential, regulators no longer need to wait for experience to show them, sometimes with disastrous results, which substances jeopardise human health or the environment and which do not; they now have access to an alternative source of knowledge that is capable of generating policy-relevant information. Leaving considerations on the accuracy and acceptability of this information aside for the moment, it is undeniable that risk assessments make it possible for regulatory bodies to develop proactive policies, in accordance with public expectations as well as general principles such as the prevention and precautionary principles, listed in Article 130R of the EC Treaty as two of the pillars of EC environmental policy.

Second, risk assessments reduce complexity. This claim may seem badly chosen to explain the fast ascendance of risk assessment as a regulatory tool, since the alleged reductionism caused by reliance on risk assessment methodologies is frequently accused of being one of its severest flaws. This critique will be explored below, however, it should be pointed out that reductionism also has its benefits. Because risk assessment processes inevitably entail a selection of certain types of information relating to chemicals to the exclusion of others (for example, risk assessments take into account certain physico-chemical properties of chemicals such as corrosivity, inflammability etc., but usually do not incorporate information such as aesthetic evaluations of the environmental elements that will be exposed to toxic substances, or the familiarity of workers with processes in which the substances are or will be used), they reduce the complexity of decision-making. Instead of being confronted with composite, vague and hard-to-grasp concepts such as "health," "stress on the ecosystem," and "safety," regulators are presented with smaller, more concrete and specific bits of information, that are sometimes even expressed in numerical values. It goes without saying that the latter kind of

466 See heading 3.2 of Chapter I.
467 Article 174 ToA.
470 Cass Sunstein develops a similar argument relating to the use of cost-benefit analysis (assessing the cost of regulation weighted against the number of lives saved or the environmental improvements achieved). See CASS SUNSTEIN (1996), "Health-Health Tradeoffs," Vol. 63, The University of Chicago Law Review, p. 1551: "[T]he vice and virtue of cost-benefit analysis is that it attempts to provide (...) a metric. If all effects are reduced to the metric of dollars, it may be possible to make simple assessments, in the
information is easier to digest and manage than its less structured, more complete and complex counterpart.\(^{471}\)

Furthermore, systematic selection of the same type of information facilitates comparisons between chemical risks, which in turn make it possible for regulatory authorities to prioritise according to the relative degrees of assessed risk.\(^{472}\) We are often told not to compare apples and oranges. Taken as a whole, it would indeed make little sense to claim that apples are "simply" better than oranges. However, when certain aspects of the fruit are singled out, such as calories per weight, acidity, price per weight, average number of seeds per apple/orange, comparisons become less daunting. Similarly, and once again suspending judgements on the substantive, qualitative outcome of such comparisons, chemical risks may be compared with greater ease on the basis of standardised sets of chemical qualities than on the basis of non-standardised, qualitatively and quantitatively different sets of criteria.\(^{473}\)

The preceding argument moreover suggests an additional element contributing to risk assessment's appeal for regulatory purposes: risk assessment methodologies can be standardised. Even if risk assessment cannot be expected to do away with all the uncertainties that complicate the evaluation and control of chemical substances (see below), it does ensure that uncertainties are treated in the same way.\(^{474}\) As mentioned in the preambles to the Risk Assessment Directive (93/67/EEC) and Regulation (N° 1488/94), this equal treatment is important from the point of view of market competition. Additionally, the application of standardised assessment rules may help to shield regulators against accusations of arbitrariness.

sense that comparisons and hence tradeoffs can become easier. But the reduction of mortality and morbidity effects to dollars can erase important qualitative distinctions among risks.\(^*\)


\(^{473}\) Ibid., pp 575-576, 585.

\(^{474}\) JOSEPH V. RODRICKS, o.c., p. 187.
Fifth, and related to the foregoing point, because risk assessment rules are of a predominantly procedural nature (four-step analysis, prescription of methodologies, etc.), they structure the decision-making process. The existence of a pre-established, fixed framework of procedural hurdles that have to be overcome to arrive at acceptable outcomes facilitates not only the task of decision-making itself, but also the exercise of supervision and control, whether performed by regulatory and administrative bodies (supervision or verification of assessments made by expert bodies, or by the manufacturers of the substances who include a preliminary risk assessment in the notification, a possibility which is explicitly foreseen in the Notification Directive) or by judiciary bodies exercising control on regulatory decision-making. Instead of having to second-guess substantive and normative policy considerations, reviewers of chemical control decisions taken pursuant to risk assessment rules have the opportunity to concentrate on the procedural aspects of decision-making and thus to avoid difficult questions relating to administrative discretion and semblances of judicial activism.

A final element makes reference to the authoritative force of science and the "magic of numbers." Even though the issue of whether risk assessment qualifies as a scientific discipline remain as yet unsettled, it is undisputed that risk assessment rules, such as those developed within the framework of the European Community, rely extensively on scientific methodology. Risk assessment draws on several disciplines, including toxicology, chemistry and biostatistics, the scientific credentials of which are firmly established, and is usually performed and verified by members of the scientific community (scientific experts). The close association between risk assessment and science, a powerful social institution traditionally reputed for its rigorous standards, its dedication to "facts" and to finding the "truth" and its independence, may thus lend increased credibility and legitimacy to those institutions that make use of risk assessments and to the ensuing risk management decisions. With regard

475 E.g., in Belgium risk assessments of newly notified dangerous substances are performed (or verified in case a preliminary assessment has been included in the notification) by the expert members of Section III.5 of the High Council for Health, which is commissioned by the Ministry of Public Health. Interview with Marleen Pauwels, member of the Belgian High Council for Health.
476 See Heading 3.4(d), and particularly footnote 133, of Chapter I.
477 Cf. Heading 2 of the Introduction to this Chapter.
to the attractions of quantified (numerical) assessments, it is interesting to note Sheila Jasanoff's observation (1991) relating to the symbolic neutrality attributed to numerical assessments, a perception of neutrality that, according to the author, "[i]s rarely attained by qualitative formulations about the "weight" or "sufficiency" of the evidence." In summary, owing to connotations of scientific validity, neutrality and quantifiability, risk assessments may create or strengthen the impression that regulatory decisions, made on the basis of (quantitative) risk assessments, are grounded on scientifically "proven" fact and are therefore "rational;" two important qualities for administrative decision-making.

Taken together, the above-listed arguments constitute a persuasive case for the introduction and systematic use of risk assessment in regulatory environments. Nevertheless, ever since its introduction in legal and policy-oriented settings, risk assessment, and particularly quantified and comparative styles of risk analysis, have attracted a wide range of criticism. In the US, many authors have taken a stand against regulatory deployment of risk assessment techniques or specific forms thereof. It is to be expected that, as risk assessment matures in the European Community, similar debates will unfold.

The arguments brought forward by opponents of risk assessment range from predominantly pragmatic ones (such as the claim that risk assessments are too expensive and time-consuming) to sociological and philosophical considerations. Many of the arguments are intertwined and overlap, depending, for example, on the discipline within which context they have been developed (sociology, administration, science). This obviously complicates the task of giving a systematic account of them. For this reason, the discussion of critiques levied against risk assessment rendered below should not be considered as drawing clear-cut boundaries between different arguments. Taken as a whole, the discussion does aim, however, to offer an -- if not systematic, than at least
relatively organised — overview of the range of arguments developed during the last ten years to question the use or practical implementation of risk assessment techniques in chemical risk regulation.

1. Practical Objections: It Takes (Too) Much Information, Time and Money to Make Reliable Risk Assessments

The overview in Section I of this Chapter, which mapped out the risk assessment procedures in both the Risk Assessment Directive and Regulations, already uncovered a major practical problem that risk assessors, and the public authorities making use of their services, have to come to grips with: risk assessments require an enormous quantity and great variety of data pertaining to the chemicals under assessment.\textsuperscript{481} As discussed, these data comprise detailed information about the toxicity of a substance, its physico-chemical properties and ecotoxicological characteristics. Additionally, information relating to expected exposure, and to the population groups and/or ecosystems that may be affected by exposure, is needed.

Virtually none of this information is readily available.\textsuperscript{482} In order to obtain insight into the matter, the chemical is subjected to a battery of studies and laboratory tests. Some of these, for instance the determination of the melting point of a substance, which is one of the physico-chemical characteristics that need to be established in accordance with EC risk assessment requirements, are relatively undemanding. Others, however, such as animal testing to assess the chronic toxicity of a chemical, or epidemiological studies which (in the case of human health assessments) focus on a group of people exposed to certain chemicals and compare their relative health status to that of a control group, following both groups for extended periods of time, are both enormously time-consuming and costly.\textsuperscript{483} Moreover, because of their unavoidably limited scope, epidemiological studies may fail to uncover certain adverse health effects, particularly those that have a relatively low occurrence rate,\textsuperscript{484} but nevertheless represent a substantial hazard. Additionally, the

\textsuperscript{482}See Chapter II on information supply duties of manufacturers and importers of chemical substances.
\textsuperscript{483}For a detailed overview of the information requirements and intricacies of human toxicity testing, see JOSEPH V. RODRICKS, o.c., pp. 49-200.
\textsuperscript{484}For example, a health deficiency that statistically affects one person in a group of 1000 may easily go unnoticed if the target group for the epidemiological study consists of
identification and isolation of health deficits that can be traced back to exposure to chemicals rather than any other imaginable cause of illness, disease or death, is a task fraught with difficulties leaving significant room for error. For these reasons, the "statistical power" of epidemiological studies, even though they are generally considered the most reliable and conclusive of studies, is debatable.\(^{485}\)

The reliability of animal testing as a basis for inferences about human health effects is even more controversial. In his typical inflammatory style, Ulrich Beck (1993) contended that it would take a clairvoyant to make sense of animal testing results' consequences for human health.\(^{486}\) Whether or not one shares this radical viewpoint, it is undeniable that even well tried and tested methods for extrapolating animal test results cannot guarantee accuracy so much as plausibility, and that there exists no uniform consensus among members of the scientific community about which is the better extrapolation model.\(^{487}\) Moreover, considering the enormous expenditures animal studies entail, both in terms of financial resources and animal lives spent, one may question whether the results, consisting of plausible outcomes rather than guaranteed certainties, are not disproportionately modest compared to the efforts.\(^{488}\)

The practical constraints and complexities of human risk assessment are further documented in the Commission's Dobris Report: "[l]n the description of the health status of the European population (...), a major limitation is the difficulty of providing a proper measurement for health. Mild deficits of health are very subjective; small physical changes can be measured but their health significance, e.g., as predictors of a disease, is not always clear. More serious deficiencies, even those requiring treatment, are rarely recorded in a way enabling inference about the popular health status. Epidemiological studies are necessary to establish the prevalence of certain diseases, but the availability of such studies in Europe is very limited due to the costs and resources needed for this kind of research. Therefore, most of the information is based upon limited


\(^{487}\)E.g., PAULETTE L. STENZEL, o.c., p. 503; BRUCE N. AMES, o.c., p. 275. Adam Finkel (1994) discusses current versus alternative extrapolation models in ADAM M. FINKEL, o.c., pp. 341-352.

\(^{488}\)MARK ELIOT SHERE, o.c., p. 434.
registration of death - the most severe health deficiency." The resulting equation of health assessments with mortality assessments indeed implies a narrow definition of the concept of health, thereby drastically reducing the scope and potential regulatory impact of risk assessment.489

Summarising, human health risk assessments are both complicated and restricted due to the limited availability of information, the complexity of the subject matter and the limitations and remaining uncertainties inherent in the use of extrapolations and biological models.

Problems further exacerbate in the area of ecotoxicological risk assessment. For all their complexity, human health risk assessments have at least this advantage of being confined to the study of one chemical recipient, namely the human body. Environmental risk assessments, in contrast, ideally should cover entire populations of organisms represented in exposed ecosystems (a daunting concept in its own right),490 taking into account possible effects of the examined chemical on the organisms separately as well as those effects resulting from interactions between organisms and between organisms and the physical environment.491 Stuart Dobson's article (1993) on environmental risk assessment paints a rather bleak picture of the current state of advancement of ecotoxicological assessments: "[I]t is probably not possible with current knowledge to produce an accurate, predictive picture of the overall effect of a chemical compound on the environment. Only where an observed adverse effect in the field is the trigger for regulation is there likely to be comprehensive data on the fate and effects of chemicals."492 Recalling the theoretical framework established in Chapter I, and in particular the need to supplement or even supplant experience with alternative sources of knowledge in order to comply with contemporary expectations for environmental and health protection and the call for a proactive, preventive regulatory framework, Dobson's observation is alarming: in his opinion, environmental risk assessments are far from capable to replace experience as a source of information about future harm to the

491STUART DOBSON, o.c., p. 338.
environment. Rather, experience (observed adverse effects) is listed as a prerequisite for comprehensive risk assessments. One might question the value of a predictive model that, even according to those who advocate and use it, needs the hindsight of knowledge and experience in order to produce reliable results. It would seem to defeat the purpose.

In conclusion, the above-listed criticism suggests that, even where unlimited resources and time are available to perfect the conditions under which assessments are conducted, the best risk assessment can do is to produce plausible results. However, such ideal conditions almost never materialise: in practice, regulatory authorities, industrial enterprises and risk assessors are constrained by budgets, deadlines, limited availability of equipment, imperfect communication, etc. Thus, risk assessors face an unenviable choice: either, they invest vast amounts of time and recourses in the assessment of all too few chemicals, or they cut corners and produce assessment results that are, generously put, of highly questionable quality. In either case, risk assessment fails to generate results that are acceptable for the purposes of health and environmental protection regulation. Such considerations call into question the viability and legitimacy of the decision, confirmed in EC legislation, that risk assessment should become the predominant basis of risk regulation.493

492Ibid., p. 343.
493 In this regard, it is interesting to recall the 1992 decision of the German Bundesverwaltungsgericht to annul a regulatory decision that requested a manufacturer for additional information concerning the preparation "Basic Yellow" (Cf. Section II.2.2(c) of Chapter II, and particularly fn. 261). The decision was based on a preliminary risk assessment of the preparation. According to the Bundesverwaltungsgericht, the risk assessment in itself did not make the need for additional information sufficiently plausible: "Dem steht auch nicht entgegen, daß die Bundesanstalt ihren aus einem "Vergleich der Wirkungskonzentrationen mit der prognostizierten Expositionskonzentrationen" abgeleiteten Gefahrenverdacht als "wissenschaftliche Erkenntnis" bezeichnet. Selbst wenn man (...) der Bundesanstalt insoweit einen "Beurteilungsspielraum" bzw. eine "Einschätzungsprärogative" zugestehen wollte, so bliebe doch unverzichtbar, daß die Bundesanstalt die ihrer Gefahrenbeurteilung zugrunde liegenden Verdachtsmomente in nachvollziehbarer Weise dahreagt und plausibel macht, aus welchen Anhaltspunkten sich die Notwendigkeit einer weiteren Überprüfung des Stoffs in den zu erwartenden Restkonzentrationen ergibt. Daran fehlt es hier." (BVerwG, Dec. Of 12.6.1992 - Case 31/90 (Munster); NVuZ, 1992, No. 10, pp. 984-986). Even though the decision at issue is a request for more information rather than a risk management decision sensu stricto, it does show a certain reluctance on the part of the court to accept the reliability of risk assessment results.
2. **Science in Risk Assessment: Too Little or Too Much?**

A second category of objections raised against risk assessment as a basis for regulatory decision-making revolves around the relations and tensions between science, risk assessment methodology, legal principles and policy objectives. Earlier on, I listed science and the use of scientific methodology as one of the elements that make risk assessment, and in particular the “quantitative variety,” an attractive choice for policy makers. However, as is so frequently the case, there are two sides to the medal: the “scientificity” of risk assessments -- or the alleged lack thereof -- is as much as source of controversy as it is one of legitimacy.

Within this category of critiques, it is possible roughly to distinguish three different premises upon which arguments against chemical risk assessment, in its current form, are constructed. The first group of objections targets the normative, policy-oriented content that can be an implicit or explicit part of risk assessment methodology. Critics pertaining to this first group complain about the lack of scientific rigour in risk assessment, and usually plead for the maintenance of a strict separation between scientific assessments and policy evaluations. A second group of commentators problematises not the underlying policy considerations, but on the contrary the appropriateness of using scientific modes of reasoning and rules of evidence as a means to attain policy objectives. Both positions are discussed in the subsections following immediately below. Finally, a third critique relating to the science-policy tensions in risk assessment takes issue with the unintentional or deliberate use of scientific arguments with the purpose of making policy decisions more “palatable” or publicly acceptable. The qualification of risk assessment as science, certain scholars contend, deprives the public of a voice in risk assessment procedures: only scientific experts have the competency to perform risk assessments, leaving non-experts unable to participate or even evaluate or criticise risk assessment processes. Since these scholars address the way scientific arguments are used in risk assessment rather than challenging the scientific content of risk assessment itself, considerations of this kind are discussed under Heading 4: "Risk assessment and depolitisation."
2.1. *Objections raised against the policy orientations hidden or revealed in chemical risk assessment*

Throughout the analysis of risk assessment techniques, it has become apparent that, at virtually every stage of the assessment process, risk assessors are confronted with incomplete information and knowledge gaps. Economic, technological and ethical constraints, as well as imperatives of expediency, limit the availability of laboratory tests, bioassays, animal studies, information on expected exposure, and other data that constitute the building blocks of risk assessment. In fact, one could contend, as implied by Stuart Dobson (*see above*), that risk assessments are incapable of completely resolving the level at which a chemical will affect human beings or the environment, unless extensive, even exhaustive, experience exists on human or environmental exposure to the chemical at issue. However, in this scenario risk assessment would no longer signify the measurement of a probability of harm, but would have become the measurement of actual harm, which is an assessment of danger rather than risk.

In order to bridge the inevitable information gaps and complete their tasks, risk assessors have no choice but to rely on certain heuristic tools, such as the previously mentioned extrapolation models and "err on the safe side" assumptions. It is important to understand that these heuristic tools are as much part and parcel of risk assessment as the hard data of test results. However, they are far more controversial.

First, even though certain extrapolation models, safety factors, etc. might count on broad support from scientists and are accepted in mainstream science as adequate, valid bases for predictions, they nevertheless require the acceptance of assumptions -- *e.g.*, the assumption that if 50 mice are exposed to a high dose of a chemical substance and do not develop cancer, the substance may be considered as non-carcinogenic for mice in general and even for other species -- without direct, observable proof. Paraphrasing the terminology used

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495 CARL F. CRANOR (1993a), *Regulating*, o.c., pp. 13-14
496 In the US, regulatory agencies have adopted policy guidelines, indicating which assumptions should be selected for risk assessment purposes. There are called "reference guidelines." See CARL F. CRANOR (1993a), *Regulating*, o.c., pp. 22-23.
497 Still, in practice one hardly finds uniform consensus on the accuracy of currently used extrapolation models. See int. 487.
in classical works of philosophy of science, the assumptions cannot be said to mirror Nature, but rather reflect scientists’ beliefs (or judgements) about Nature and the Laws of Nature.\textsuperscript{498} Hence, the heuristic models and assumptions that complete risk assessors’ tool kits are not “hard” facts in the same sense that test and measurement results are. However, since the assumptions and models used in risk assessment do generally result from long periods of systematic observation, theory-testing and falsification, they do not seem to fit the qualification of “pure” value or subjective judgement either. Instead, they are situated somewhere in the misty area between these two extremes. To some, this duality is sufficient to deny heuristic tools, and those scientific issues that are dependent on the application of heuristic tools for their resolution, the status of science. In a seminal article, Alvin Weinberg (1972) introduced the term “trans-science” for those questions that can be asked, but cannot be answered by science alone.\textsuperscript{499} The hybrid nature of so-called trans-scientific assumptions, and their uneasy position between fact and value, complicates the process of identifying, classifying and therefore also acknowledging risk assessment as a discipline, and more specifically a scientific discipline. Recalling the authoritative force of science as a reliable basis for fact-finding, and recalling that facts are, in turn, considered the preferred basis for legal decision-making, it is hardly surprising that doubts relating to risk assessment’s “scientific purity” generate corresponding doubts concerning risk assessment’s adequacy and reliability as a basis for legal and regulatory decisions.\textsuperscript{500}

Second, the assumptions, models and judgements which risk assessors deploy to fill in the gaps created by incomplete information are not, and frequently do not claim to be, value-neutral. In the preceding analysis of the risk assessment principles established in Council Directive 93/67/EEC, I mentioned that certain of the prescribed methods, particularly those used in the assessment of potentially carcinogenic substances, revealed a conservative approach.\textsuperscript{501} This means that the assumptions deliberately aim to “err on the safe side,” i.e., in case of uncertainty, the worst case scenario is selected as a basis for further decision-making.\textsuperscript{502}

\textsuperscript{498}E.g., RUDOLF CARNAP (1995), The Unity of Science, Thoemmes Press, p. 35; WOLFGANG WILD, o.c., p. 33..
\textsuperscript{500}E.g., WENDY E. WAGNER, o.c., passim.
\textsuperscript{501}See Section 1.2.3 of this Chapter.
\textsuperscript{502}A US example of the conservative approach to risk assessment can be found in the
Many authors, lawyers, policy analysts and scientists alike, have taken issue with the conservative policy-orientations that are covertly or openly present in risk assessment.\textsuperscript{503} In essence, critics of the "erring on the safe side" approach, whom Adam Finkel (1994) refers to as revisionists, claim that this approach leads to a systematic overestimation of risks, which results in a distorted representation of the hazards attached to those chemicals under assessment.\textsuperscript{504} An exaggerated portrayal of the risks attached to the production and release of chemicals may in turn unduly overburden chemical producing and using industries, and may give rise to administrative inefficiency, ineffectiveness and over-regulation.\textsuperscript{505} Moreover, when the practical obstacles to the systematic use of risk assessment -- a heavy workload, high costs and stringent time constraints -- are added to the equation, a further potential problem reveals itself: due to the limited availability of information and resources, many chemical risks may slip through the mazes of public authorities' attention, and, so critics of conservatism claim, those few chemicals risks that are assessed, are overestimated. Consequently, too much attention and resources are spent on the regulation and control of too few chemicals, transforming the regulatory landscape into a patchwork of concentrated areas of over-regulation against a backdrop of under-regulation.\textsuperscript{506}

Opinions on how to amend this situation differ. Some propose the following solution: risk assessment should be purged of public policy

application of the so-called "Delaney clause" of the Federal Food, Drug and Cosmetic Act (USC § 348(c)(3)(A)). This provision stipulates that a food additive is not safe "[i]f it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." The clause was interpreted to mean that these additives were not safe in any amount. Thus, a zero tolerance level was maintained. The clause was subjected to a lot criticism by the pesticide industry. After a study (performed by the US Board of Agriculture of the National Research Council, which resorts under the National Academy of Sciences) concluded that the clause was "unnecessarily restrictive," the EPA implemented a policy of providing a de minimis exception to the clause, applicable to carcinogens that pose a lifetime risk of cancer of less than one person in a million.

MARGARET ROSSO GROSSMAN, o.c., pp. 214-215.

\textsuperscript{503} See, for example, STEPHEN BREYER, o.c., p. 47.

\textsuperscript{504} ALISON C. CULLEN (1994), "Measures of Compounding Conservatism in Probabilistic Risk Assessment," Vol., 14 Risk Analysis, No. 4, p. 302; ADAM M. FINKEL, o.c., pp. 298-304; STEPHEN BREYER, o.c., p. 43: "[R]egulators' assumptions sometimes "conservatively" overestimate potentially relevant differences - by, for example, using results in whatever species proves most sensitive to a high dose of a test substance." Breyer, however, also points at the reverse problem, at p. 47: "[A]t the same time, even such assumptions sometimes can overlook special, much greater than average exposures via multiple pathways or exposures that pose special risks to those who also smoke or are also exposed to other chemicals".

\textsuperscript{505} MARK ELIOT SHERE, o.c., p. 473; PAULETTE STENZEL, o.c., p. 508.
considerations; these considerations should only enter into the regulatory process at a later stage, namely the stage of risk management. Instead of assumptions that err on the safe side, better science, demanding more rigid standards of proof as they are used in independent scientific research, should be used. Others contend that risk assessment is simply too flawed and unscientific for redemption and suggest to lift risk assessment methodology out of the legal framework and replace it by a more suitable, reliable basis for regulatory and legal decision-making. These differences of opinion are reminiscent of the different qualifications of risk assessment as essentially scientific or necessarily a combination of facts and values, which I outlined at the beginning of this Chapter. The issue of availability of alternatives to risk assessment as a basis for legal decision-making, will be taken up in Section III of this Chapter. Before going into this issue, I will address the second science-related critique of risk assessment.

2.2. Objections against the scientific orientation of risk assessment

However critical of the scientific validity of risk assessment they may be, none of the views elaborated above are irreconcilable with the vision that there is such a concept as neutral, value-free science. In fact, Sheila Jasanoff (1987) pointed out in “Contested Boundaries in Policy-Relevant Science” that the very notion of the existence of “trans-science,” as introduced by Alvin Weinberg, is a conservative one, since it serves to draw a boundary between value-laden, peripheral trans-scientific issues and the real, hard core of science. Thereby it at once confirms the existence of hard core science and contrasts its qualities to the subjective, value-riddled characteristics of trans-science. Indeed, it is interesting to note that even the harshest critics, who claim that risk assessment is irredeemably flawed, attribute these flaws precisely to risk assessment’s inability to rid itself of policy considerations and conform to the standards of pure science.

506 ALON ROSENTHAL et. al., o.c., p. 346.
507 See the Russell & Gruber model under Heading 2 of the Introduction to this Chapter.
508 Cf. ADAM FINKEL, o.c., p. 301.
509 MARK ELIOT SHERE, o.c., p. 478: “[D]efenses and reforms to risk assessment share a common flaw in failing to account for the profound uncertainty in the process. When the magnitude of this uncertainty is recognised, risk assessment is properly seen as incapable of generating meaningful information. Sympathetic defenses of risk assessment and proposals to reform the process do nothing to correct this fact.
A different, and in my opinion more sophisticated argument is developed by Carl Cranor. In his book "Regulating Toxic Substances" (1993) and a follow-up article of a more recent date (1995), Cranor, rather than singing the praises of pure science and despairing over risk assessment's scientific impurities, investigates into the programme, agenda and objectives of scientific research and development (the scientific paradigm), and then considers the adequacy of the scientific paradigm for resolving regulatory issues. As mentioned, I consider this approach more sophisticated than those described under Heading (a) above because it takes both science and regulation on their own terms; without assuming a pre-existing, natural superiority of one over the other.

In a nutshell, Cranor's argument runs along the following lines. In its most basic form, the purpose of science resides in the pursuit of scientific truth which, within one scientific paradigm, traditionally happens in an incremental way. This means that scientists attempt to construct scientific facts, which have to be (or become) strong or "hard" enough to survive tests of refutation and falsification. Here, the image of Bruno Latour's (1987) "black-boxing" springs to mind. The elimination of dispute (controversy) surrounding newly constructed scientific facts is of the utmost importance for incremental scientific progress, since "hard" facts (or black boxes) can in turn be used as starting-blocks for further scientific development.

Science's concern with falsification, black-boxing and incrementalism deeply affects how scientific processes unroll. First, it renders scientists extremely cautious and wary of hasty decision-making. In light of the pervasive importance of making their conclusions resistance-proof, scientists, when confronted with partial information, will prefer to defer judgement and ask for more and better data. From a scientific perspective, "no decision" is preferable to a decision based on weak facts. Second, the scientific paradigm determines which kinds of mistakes scientists will be more likely to make. Cranor identifies two possible mistaken outcomes: false positives and false negatives. A false positive is the mistake that happens when one wrongly...

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512 Cf. MARCIA R. GELPE & A. DAN TARLOCK, o.c., p. 388.
assumes that a causal relationship exists between an input and an output. Applied to chemical risk assessment, a false positive occurs when a substance is wrongly thought to cause an identified harm when, in fact, it does not. A false negative is precisely the reverse: an existing input-output relationship (in risk assessment: a chemical - harm relationship) is erroneously thought not to exist.\textsuperscript{516} Obviously, the ideal would be not to make either kind of mistake. Nonetheless, from a scientist's point of view, it is far graver to construct and subsequently build upon false positives than (temporarily) to fail to identify certain existing relations, since, if false positives are later exposed and removed from the scientific process, entire scientific constructs -- representing as many life-long careers dedicated to the pursuit of scientific truth -- may crumble.

However, chemical laws and regulations should have a different agenda: the protection of human health and the environment. Because of the different objectives of science on the one hand, and law and regulation on the other, the above-mentioned attributes of caution and preoccupation with false positives may not work as well in a legal and regulatory framework.\textsuperscript{517} In fact, they may encumber, even frustrate the legal and regulatory process. For instance, for the reasons outlined above, scientists will prefer to make no decision rather than deciding on the basis of incomplete information. It is however highly questionable whether legislators and regulators do and should share this preference. In fact, the precautionary principle, listed in Article 130R of the EC Treaty,\textsuperscript{518} indicates that, at least for the adoption of Community acts, decision-makers should assume exactly the opposite stance: the absence of complete information should not prevent decision-making in cases where there are significant (but inconclusive) indications of a threat to the environment and/or human health.\textsuperscript{519} Moreover, in light of the previously discussed limitations on available information for risk assessment, an insistence on "full and complete data" might inordinately slow down, even paralyse regulatory decision-making.

Science's preoccupation with false positives can form a further obstacle to effective, which in this case means sufficiently protective, regulation. In devising risk assessment tests, extrapolation models and assumptions, scientists will "err on the safe side." However, in the scientific paradigm erring on the safe side

\textsuperscript{516}Ibid., p. 8.
\textsuperscript{517}Cf. MARCIA R. GELPE & DAN A. TARLOCK, o.c., p. 374.
\textsuperscript{518}Article 174 ToA.
\textsuperscript{519}Cf. Section II.3.2 of Chapter IV.
means that, in case of doubt, a substance will be presumed to have a harmful effect on health or the environment. Extrapolation models, safety factors and other heuristic tools are carefully designed to minimise the risk of false positives. To achieve this goal -- and once again recalling the inevitable constraints on time, money, the availability of tests, studies, control groups and other resources -- tradeoffs must be made. These tradeoffs are made on the side of the false negatives; the tests and models are designed to be much more reliable when they positively confirm a relation between a chemical and an effect (scientists usually insist on a 95% reliability) than when they indicate that the examined substance does not affect health or the environment. Differently put, if a mistake is made, it is much more likely that this mistake will consist of the failure to attribute harmful effects to a chemical, than of a wrongful attribution of effects to the substance under examination.

Again, it is doubtful whether this approach is suitable within a legal and regulatory framework. Cranor, for one, considers that, in contrast to scientists, regulatory authorities should be far more concerned with avoiding false negatives than false positives. Wrongfully attributing harmful effects to a chemical substance may lead to regulatory restrictions or, at worst, a ban on the substance in question. Wrongfully denying the existence of harmful effects, however, may result in the exposure of entire populations and ecosystems to health and environmental threats. From a regulatory perspective, Cranor argues, the latter mistake is by far the gravest.

In conclusion, Carl Cranor claims that chemical risk assessment should not attempt to purge itself of policy considerations, but should on the contrary incorporate them more explicitly and rely on them to a greater extent than has happened so far. Risk assessment should be made to fit its regulatory purposes of health and environmental protection. This means that it should

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520 See also WALTER GAWLAK & DANIEL M. BYRD (1987), "Divergent Approaches to Uncertainty in Risk Assessment: Mathematical Expression Compared to Circumstantial Evidence," in VINCENT T. COVELLO et. al. (eds.), Uncertainty in Risk Assessment, Risk Management and Decision Making, Plenum Press, New York & London, p. 43: "[E]xcept for those cases where either the level of confidence is very high (> 0.95) or very few elements are involved, the scientist would probably forego drawing dispositive conclusions about the validity of the proposition but would instead describe the proposition in terms of probability and attendant uncertainty".

521 It should be noted that, to assess the influence of policy considerations in risk assessment, or the lack thereof, Carl Cranor refers to US risk assessment practices.

522 Adam Finkel (1994) makes a similar argument when, in response to Stephen Breyer's attack on conservatism in risk assessment, he claims that the fundamental questions to evaluate the merits of risk assessment should be: "(1) are the final outputs or risk
be expedited, even if this implies assessments on the basis of limited information, and that the evidentiary standards used in science to establish causal relations between substances and harmful effects should be relaxed.523

3. Risk Assessment and Reductionism

A third cluster of objections raised against risk assessment (more specifically the form of risk assessment based on measuring and testing, extrapolation and inference-drawing as is currently performed in the United States and equally reflected in EC legislation) is premised on the belief that chemical risk assessment deploys a too narrow concept of risk. As mentioned before, the performance of risk assessment inevitably entails a selection of information and criteria that are taken into account in the assessment process, and correspondingly results in the exclusion of elements, information and circumstances which, because of the selection mechanism at work, lose their significance for regulatory purposes.524 On the issues of selecting “meaningful risk information,” of boundary-drawing between those criteria that are significant and those that are irrelevant for decision-making, and on the manner in which risks associated with the release of different chemicals are subsequently compared, criticism abounds.525 Currently used risk assessment techniques have been called biased, reductionist, inequitable, distorting and undemocratic.

The problems already commence at the stage of risk information gathering. According to Donald Hornstein (1993), the very fact that regulatory

assessments (as opposed to some hand-picked subsets of their component parts) systematically conservative? and (2) even if the results are conservative, would that be an inappropriate science-policy response to uncertainty?” ADAM FINKEL, o.c., p. 334. Also, at p.335: “It is naive as well as factually suspect to modify science with the term “good” or “bad” without considering the context in which the science is being applied. Rather, thoughtful critics of risk assessment should be asking whether the science is good or bad for the question being asked.”

523 In fact, Cranor advocates the adoption of a proof rule that is far more familiar to lawyers and regulators than to scientists: the preponderance of evidence rule (which is the basic evidentiary standard in US civil litigation). Thus, if a preponderance of the evidence (i.e., more than 50%) indicates that a chemical under assessment may have harmful effects, the substance will be considered harmful for regulatory purposes.

524 SUSANNE SMOLKA & GERD WEIDEMANN, o.c., p. 205.

authorities depend on data generated by the chemical industry to perform their assessments, creates room for informational bias and more or less subtle manipulations.\textsuperscript{526} The potential for bias becomes even greater when we consider that industry is not only the prevalent source for information on chemical risks, but also functions as the prime indicator of the costs of their abatement: in order to estimate the costs of control technologies and other risk managing regulatory interventions, regulators must rely predominantly on data furnished by the chemical industry, which has an interest in exaggerating the negative effects of regulatory risk control.\textsuperscript{527}

In the same vein, Paulette Stenzel (1991) argues that risk assessors' professional allegiance influences the selection of assumptions and the interpretation of test results: "[A]n assessor working for industry, for example, has an incentive to choose assumptions which will show lower risk and thus result in less restrictive regulation and lower costs for the business. An assessor working on behalf of environmentalists who value human life and health over increased profits will choose assumptions reflecting those values."\textsuperscript{528} Thus, following Stenzel, the bias can go either way. However, bearing in mind that industry is the main responsible for chemical information supply, the bias in risk assessment procedures will more likely work in favour of industry than against it.\textsuperscript{529}

Finally, Erhard Treutner (1988) discusses informational bias at a level that transcends deliberate but incidental attempts to manipulate data. He claims that social power and influence -- two assets the chemical industry undoubtedly possesses -- often convey a power to determine and define what constitutes correct and relevant information, especially in cases of informational uncertainty and conflicting scientific concepts.\textsuperscript{530} This would imply that, even if industry does not intentionally seek to paint an all too rosy picture of the risks which their production and activities unleash onto man and the environment, its relative position of power vis-à-vis consumers, employees, environmental interest groups and even public authorities places it at an advantage in determining the

\textsuperscript{526} DONALD T. HORNSTEIN (1993), "Lessons," o.c., p. 436.
\textsuperscript{527} CAROLYN J. TUOHY, o.c., p. 347.
\textsuperscript{528} PAULETTE L. STENZEL, o.c, p. 507.
\textsuperscript{529} Furthermore, we recall that for new substances notifiers and importers have the opportunity both to perform an initial risk assessment and attach it to their technical dossiers, and, possibly, to comment on risk evaluations.
\textsuperscript{530} ERHARD TREUTNER (1988), "Informationelle Grundlagen von Verwaltungsentscheidungen und die Verwaltungsumwelt," in JÖRG FINSINGER &
rules of the game (what constitutes a risk; when is an effect harmful; which criteria should be taken into account in the assessment of risk; which kind of information deserves to be called “relevant,” “valid,” or “reliable”), which in turn increases its chances of “winning” the game. In this framework, a “win” for industry would consist of a relaxation of regulatory restrictions (e.g., fewer bans on toxic substances) or prescriptions (e.g., monitoring and inspection requirements, labelling rules).

Bearing in mind the informational bias of which certain commentators accuse risk assessment, it is not difficult to anticipate the next shortcoming with which the technique is charged: risk assessment, it is said, is not sufficiently comprehensive. In their efforts to crystallise a complex, multi-faceted concept as risk into statistical, measurable units, risk assessors are forced to leave many risk characteristics and considerations out of the equation; considerations which, according to the critics of these reductionist tendencies, co-determine the social acceptability of risk.531 Many of the elements that do not find their way into risk assessment reports could be grouped under the heading “the human factor.” They are the attributes of risk, for instance the familiarity of the risk (compare the familiar risks associated with sun-bathing to the unfamiliar risk of living in the vicinity of a nuclear plant), the magnitude of harm versus probability ratio (the risks of driving a car have a relatively low magnitude of harm but a high probability of materialising compared to airplane crashes, which produce a greater magnitude of harm but have a lower occurrence probability), or the degree of voluntariness (smoking versus drinking water contaminated by industrial pollutants). These attributes influence public fear of different risks and, hence, their acceptability.532 The existence of a human factor, which shapes public perceptions of risk and is frequently at odds with the statistical, quantitative renditions of risk, raises important issues of democracy and responsiveness of regulatory decision-making. These issues are explored in greater detail in the following subsection of this Chapter (“Risk assessment and depolitisation”).

In addition to leaving out public risk perceptions, risk assessments are viewed as incapable of adequately incorporating considerations of risk.

JÜRGEN SIMON, o.c., p. 62.
distribution. Who is this “man” whose tolerance for chemicals is estimated in risk assessments? Is he male or female, young or old, rich or poor, does he exercise regularly, does he live in the city or in a village, does he have a particular medical condition (allergies, asthma, kidney dysfunction)? EC legislation on risk assessment has incorporated a limited number of differentiations to disaggregate risks (both Commission Directive 93/67/EC and Commission Regulation 1488/94 distinguish workers, consumers and people exposed indirectly via the environment), however, by no stretch of the imagination could these three categories be considered fully to represent all the factors that influence people’s susceptibility to chemically-induced ailments. Thus, substances that pose only a negligible risk to the population in general, but present a very real risk to certain sub-groups of society (for example children or pregnant women), may slip through the mazes of regulatory attention. Clearly, the same goes for environmental risks, where generalisations are made on an even larger scale.

Furthermore, with regard to health risks, certain authors point out that aggregate, acceptably sounding risk assessment results may fail to uncover inequitable geographical or social distributions. For example, a risk assessment indicating an aggregate risk of one death per million inhabitants (mortality rate of 0.000001), which could only be averted at a very high cost, could reasonably lead regulatory authorities to decide that this is a risk not worth regulating, but must instead be borne by society. However, the reasonableness of this decision becomes shaky when it turn out that, on a population of, say, 10 million people, the “society” that bears the risk actually consists of 50000 people living in the same area, resulting in a local risk/mortality rate of 1 in 5000. Is a risk that threatens 1 in 5000 people, even if it is limited to a small region, still too minor to warrant regulatory

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533 PAULETTE STENZEL, o.c., p. 505; CAROLYN J. TUOHY, o.c., p. 347. Cf. K.S. SCHRADER-FRECHETTE (1991), Risk and Rationality, o.c., p. 71-72. Where hazards are judged to be negligible in aggregate quantities, but harmful in sub-groups because of different conditions of the affected groups, Schrader-Frechette speaks of a “de minimis dilemma.”


535 Adam Finkel (1994) gives the example of a cost of US$ 180 million per life saved. ADAM M. FINKEL, o.c., p. 316.

536 For more information on risk management decision-making, see generally Chapter IV, and in particular Section II.2.
intervention? Like geographical borders, different social positions and income disparities may separate the risk-bearing from the risk-free, due to, *inter alia*, different working and housing conditions, different nutrition and different health care. To all these distinctions, critics contend, risk assessment turns a blind eye.

In sum, authors such as Donald Hornstein, Thomas Berg and Adam Finkel consider that risk assessment, as it is currently performed, sacrifices case-by-case considerations of equity on the altar of macro-economic efficiency.

We recall from the introduction to Section II that one of the attractions of risk assessment -- and in particular quantitative risk assessment -- was that risks expressed in standardised, measurable units through the application of (reductionist) assessment techniques, can be more easily compared with one another which, in turn, facilitates the regulator's task of selecting areas for regulatory intervention. Not surprisingly, those who question the representativeness of risk assessment results (see above) equally denounce the reductionism of comparative risk analysis.\(^5\)\(^3\)\(^7\) Moreover, comparisons may require even further reductions.\(^5\)\(^3\)\(^8\) Not all risks posed by dangerous chemicals are linked to the same type of harm: some induce cancer, some lead to deforestation, others negatively affect fertility, and so on.\(^5\)\(^3\)\(^9\) How is one to determine which of these risks is the most serious?\(^5\)\(^4\)\(^0\) Possibly, the incompatibilities could be resolved by expressing different types of harm, such as excess mortality, increased occurrence of diseases, reduced quality of life and environmental harm, into one common denominator -- money -- and subsequently ranking risks according to which creates the greatest financial loss. Needless to say, however, translating harm into money would mean yet another reduction, and an extremely controversial one to boot. Alternatively, risk assessors and regulators might bypass the somewhat profane stage of economic valuation, and rank risks according to less mercenary-sounding, qualitative standards of seriousness of harm (for instance, the loss of a human life might be considered more serious than the occurrence of curable ailments, and both these might rank higher than the loss of certain animal species).\(^5\)\(^4\)\(^1\) Of

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\(^5\)\(^3\)\(^7\) See mainly DONALD T. HORNSTEIN (1992), "Reclaiming," *o.c.*, *passim*. Also CAROLYN J. TUOHY, *o.c.*, p. 347.

\(^5\)\(^3\)\(^8\) DAVID A. WIRTH & ELLEN K. SILBERGELD, *o.c.*, p. 1865.

\(^5\)\(^3\)\(^9\) Cf. VICKI NORBERG-BOHM, *o.c.*, p. 6.


\(^5\)\(^4\)\(^1\) Cf. the Introduction to Chapter 11 of the Dobris Report.
course, this system is as reductionist as the previous one, even if the reductionism is less explicit. Furthermore, the latter approach might imply that regulatory authorities will pay attention only to the highest ranking, most visible risk (in practical terms: death) and not even consider risks producing different types of harm, even though their relatively lower degree of seriousness in some case might be offset by a wider dispersion of the damage, or the occurrence of insipid, long-term effects.

To all these functional objections, Donald Hornstein (1992) adds the following, more ideologically-inspired consideration: "[B]y tending to compare environmental risks with each other, rather than to alternative possibilities, comparative risk analysis emphasises the wrong risk baseline, one that fails to capture the law's moral direction (...) The result is an ideological scheme, based on an inward-looking set of comparisons, that is decidedly biased toward the status quo."

In other words, by trading off risks, in a structure where new risks are continually being added and measured against the status quo, comparative risk analysis deprives law and regulation of the necessary drive (or dynamics) to move beyond maintenance of this status quo, which represents a distinctly less than ideal situation.

In German legal scholarship, Karl-Heinz Ladeur (1994) identifies this exercise of "balancing" around a pre-set point of stability (the status quo), as comparative risk analysis tends to do, as an attempt to replicate traditional legal reasoning, which took as its starting point (or point of stability) a body of tried and tested, reliable experience (e.g., experience with the dangers and precautions to be respected when operating a printing press) and measured and evaluated the relative danger associated with the introduction of a new element, for example the introduction of a new technological device to speed up printing, using experience as a yardstick. However, he continues, this attempted replication in comparative risk analysis is flawed. In contrast to the evaluation of technical dangers, where connections between technological causes and resulting harm were still relatively easy to identify, the continuous uncertainties and partial knowledge concerning chemical risks preclude the formation of a relatively stable, gradually evolving body of experience against which to evaluate

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new inputs. Complexity and the uncertainties resulting therefrom erode cause- and-effect chains, and with it the entire exercise of reducing risks to probabilistically calculated effects (caused by identified chemical inputs) loses credibility. Hence, risk assessment and comparative analysis, in their present form, could be considered as outdated, mechanistic decision-making techniques that are ill-equipped to come to terms with modern risks in all their complexity and with all the uncertainties that surround them. Instead, Ladeur concludes, we should develop a new model for risk analysis; one that is less beholden to arcane cause-and-effect reasoning and more open to uncertainty and flexibility in decision-making.545

4. **Risk Assessment and Dépolitisation**

In the previous sections, I have alluded to the tensions between scientific (or semi-scientific) forms of risk assessment as they are performed in testing laboratories, and public perceptions of and responses to risk. Public dread of distinct health and environmental risk does not solely depend on quantified probabilities, but is equally coloured by familiarity, the magnitude versus probability ratio, and voluntariness (see above). In addition to the three aforementioned risk characteristics, factors such as (a) the origin of the risk (natural or man-made); (b) the manifestation of the effect(s) (immediate or delayed; affecting present or future generations); (c) equity of distribution; (d) controllability of ensuing harm; (e) the visibility of benefits from risk-taking; (f) the type of exposure (occasional or continuous); and (g) the necessity of risk-taking (referring to whether the risk is taken in order to fulfil a basic need of society) have been singled out as elements influencing public risk perception.546 Cass Sunstein (1996) drew up the following table to indicate the relation

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546 PAULETTE STENZEL, o.c., p. 509; PETER M. WIEDEMANN et. al., o.c., p. 3; HANS-JOACHIM UTH, o.c., p. 152.
between public estimations of risk and risk characteristics:

<table>
<thead>
<tr>
<th>Risk characteristic</th>
<th>Aggravating factor</th>
<th>Mitigating factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nature of risk</td>
<td>Dreaded</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Permanence</td>
<td>Irreversible/Incontrollable</td>
<td>Reversible/controllable</td>
</tr>
<tr>
<td>Duration</td>
<td>Faced by future</td>
<td>Faced by those now</td>
</tr>
<tr>
<td></td>
<td>generations</td>
<td>living</td>
</tr>
<tr>
<td>Equity</td>
<td>Unfairly distributed</td>
<td>Fairly distributed</td>
</tr>
<tr>
<td>Source of risk</td>
<td>Man-made</td>
<td>Found in nature</td>
</tr>
<tr>
<td>Freedoms</td>
<td>Voluntarily incurred</td>
<td>Forced exposure</td>
</tr>
<tr>
<td>Existing understanding</td>
<td>Known to science</td>
<td>Unknown</td>
</tr>
<tr>
<td>Relation to status quo</td>
<td>New</td>
<td>Old</td>
</tr>
</tbody>
</table>

There are, essentially, two conflicting views on the implications of this tension for risk decision-making. These views mirror the opposing positions held with regard to the scientific content of risk assessment ("assessments are not scientific enough" versus "assessments are too much dominated by scientific reasoning") and are, once again, determined by one's location in either the "scientific corner" or the "fact and value corner" of the risk assessment debate, which was mapped out in the Introduction to this Chapter.

4.1. Resolving the tension: educating the public

The tension between the outcomes of science-based risk assessments and public risk perceptions results from a public misunderstanding of risk. Bearing in mind the limited amount of specialised information that is readily accessible, and the complexities inherent in risk assessment leading to results that might, at first sight, appear counter-intuitive, it is all too understandable that laymen frequently err in their evaluation of risks. After all, many people are still more apprehensive about boarding an airplane than driving a car, while statistic upon statistic confirms that the death-toll on the road is much higher than in the air.

These phrases roughly summarise the first position on the "public perception versus expert assessment" dilemma, which is sometimes referred to as cognitive error scholarship. Following Donald Hornstein (1992), cognitive

error scholarship is based on the assumption that “[t]he public is generally and perhaps inherently dysfunctional in its ability to process and reason about the kinds of probabilistic information at issue in disputes over public risk.”

Hence, left to their own devices laymen would make inconsistent risk choices, which have to be corrected by public authorities acting on expert assessments of risk.

Cognitive error scholarship, and its implied trust in scientific expertise to overcome errors to which we, the general non-specialised public, fall prey, has been perhaps the single most important factor shaping regulatory attitudes (and, particularly in the United States, judiciary attitudes) towards risk assessment. When we look at EC laws on risk assessment, their emphasis on measuring, testing and scientifically approved methodology, and the apparent lack of qualitative descriptions covering familiarity, voluntariness and other “subjective” risk characteristics, it does indeed appear that cognitive error scholarship rules the day. Its prevalence is even reflected in the very terminology we use to circumscribe the tension: we juxtapose the expert risk assessment to the public risk perception, thereby conveying the message that one is actual, whereas the other only perceived.

If we accept the separation between real or actual risks and perceived risks, how then should we proceed to relieve the tension between the two? Clearly, since it is the public that errs, actions to reconcile public and expert risk estimations should aim to alter risk perceptions rather than risk assessments. Through information, awareness-raising and education (risk-communication), the public will receive “better” insights concerning the actual risks attached to different activities, and will gradually espouse perceptions closer to the assessments made by experts, which will in turn result in a greater acceptance, and hence legitimacy, of regulatory decisions based on risk assessment.

549 Ibid., p. 606.
551 K.S. SCHRADER-FRECHETTE (1990), Risk and Rationality, o.c., p. 79-80.
552 HANS-JOACHIM UTH, o.c., pp. 152-153. See also ULRICH BECK (1993), “Politische Wissenstheorie,” o.c., p. 305, describing the cognitive error viewpoint in the following terms: “[M]an muss sie (die Bevölkerung) nur mit technischen Details vollstopfen, dann wird sie sich dem Standpunkt und der Einschätzung der Experten über die technische Handhabbarkeit und damit Risikolosigkeit der Risiken anschließen.”
4.2. **Resolving the tension: scraping away the veneer of false precision**

While cognitive error scholars are spreading the optimistic message that tensions between public perceptions and expert assessments will resolve once the public is brought to a higher level of understanding, sceptics and critics of science-based risk assessment are shifting uncomfortably in their seats. In their view, there is no strict separation between risk perception and risk assessment; all risks, whether seen through the eyes of someone living next to a chemical plant or studied through the lenses of a microscope, are perceived. Rather than labelling the public ignorant or irrational in its risk choices, and opposing these choices to the assessments made by informed, rational experts, Adam Finkel (1994), for one, claims that laymen and experts rank "rationally" according to different criteria.553 Cognitive error scholarship, critics contend, commits a double fallacy: first, by portraying science-based risk assessments as accurate and exhaustive whereas in reality they are only roughly approximate and often fraught with uncertainties; and second, by discounting the social dimensions of risk (voluntariness, equitable distribution, controllability, familiarity, etc.) as exogenous to risk, whereas they should be accepted as an integral part of it. In this perspective, the belief that increased risk communication and education will obliterate the differences between laymen and experts is both naive and erroneous.554

Furthermore, critics claim that, for public authorities, the first view (i.e., "risk assessment is scientific and conflicting public perceptions are based on a lack of understanding") is dangerously attractive. First of all, it puts the burden of change elsewhere: not the regulators, but the people need to reassess their risk choices. Second, by claiming that science is the key to understanding actual risks, non-scientists, still the majority of the population, are de facto excluded from decision-making processes relating to risks.555 Risk assessment results are treated as scientific facts. Consequently, decisions based on these

553 ADAM M. FINKEL, o.c., p. 321.
554 Empirical studies on the subject do indeed suggest that the relation between risk communication and risk perception is far more complex than cognitive error scholarship assumes. See, for example, BRANDEN B. JOHNSON, PETER M. SANDMAN & PAUL MILLER (1992), “Testing the Role of Technical Information in Public Risk Perception,” Vol. 3, Risk - Issues in Health and Safety, pp. 341-342: "[I]t is not clear that knowledge or ignorance of technical facts drives risk estimation, or that risk estimation is the central factor in public risk perception. It is even less clear whether providing citizens with technical risk information will alter their perceptions of risk or their views of how well government agencies are protecting the environment."
results are lifted out of the political sphere and transplanted into the realm of science, far from public scrutiny.\textsuperscript{556} The legitimacy of regulatory decisions is slowly pried loose from content-oriented objectives (such as the protection of health and the environment, or, alternatively, the fostering of freedom of enterprise) and increasingly takes on a circular, self-referential pattern: the decisions are legitimate because they are based on scientific risk assessment, performed by experts who are legitimate because they apply scientific reasoning (which is inherently good).\textsuperscript{557}

Following the above pattern, science becomes both the basis and the justification for decisions. With alarming frequency, regulatory authorities use (or abuse) the scientific reputation for precision and accuracy as a shield to insulate controversial decisions from public scrutiny.\textsuperscript{558} Scientific arguments may thus coat policy choices in a “veneer of false precision,” even where the actual assessment is far from conclusive, or when separate assessments produce different results.\textsuperscript{559} Or, to quote John Applegate (1991): “[T]here is a strong suggestion that policy makers find the apparent precision of quantitative risk assessment extremely useful in supporting significant regulatory choices

\textsuperscript{555} ELLEN K. SILBERGELD, o.c., p. 104.
\textsuperscript{558} WENDY A. WAGNER, o.c., passim; NIKLAS LUHMANN, o.c., p. 213; DONALD T. HORNSTEIN (1993), “Lessons,” o.c., p. 437. Interestingly, in a recent article Bradford Mank (1994) relates that, in a 1994 report drawn up by the US National Academy of Sciences’ Committee on Risk Assessment of Hazardous Air Pollutants (entitled “Science and Judgment in Risk Assessment”), the Committee urged the EPA to express more emphasis on uncertainties in the agency’s risk assessments. This recommendation once again indicates that regulatory agencies may have a tendency to underplay the uncertainties inherent in risk assessment, and to present results as “scientific facts,” even when no such claims are made by the scientific community. BRADFORD C. MANK, o.c., p. 273.
that are subjected to intense public and judicial scrutiny. Even if the precision is illusory, quantitative risk assessment provides an ostensibly objective justification for the imposition of large costs on the economy."

Proponents of the "fact and value" corner seek to pierce the scientific veil covering risk assessments and, by consequence, policy decisions made on the basis of such assessments. In doing so, they aim both to warn against the potential for abuse of the scientific reputation by regulatory authorities, and to plead for greater regulatory openness -- or honesty -- in decision-making, in the sense that the uncertainties and assumptions in risk assessment should be laid bare and exposed to the light of public scrutiny. Rather than hiding behind the fortress of science, risk assessment should be reintroduced into the political process, and become better attuned to public perceptions as well as to regulatory goals of improved health and environmental protection.

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SECTION III - OBSERVATIONS AND EVALUATION

What to make of all these divergent, at times even contradictory critiques? One preliminary conclusion seems obvious: very few of those who have analysed currently practised risk assessment techniques, including lawyers, political scientists and sociologists, are satisfied with the way risk assessments are conducted. Whether they call for greater scientific rigour, denounce risk assessment’s reductionist tendencies, or claim that risk assessment methodology is beyond salvation, all want to see it improved or replaced by a faster, better, more sophisticated, reliable and/or representative technique of evaluating risks to health and the environment in a way that is meaningful for regulatory decision-making.

There is, thus, an undeniable call for risk assessment reform. However, the question remains how to go about structuring such reform. Should we, as revisionists and cognitive error scholars advocate, try to purge value judgements and policy considerations from risk assessment, make higher demands on the quality and exactitude of science-based assessment techniques, and thus strive for improved reliability of assessment results, so that their treatment as factual basis for decision-making becomes justified? Or should we on the contrary abandon the ideal of a “purely scientific” risk assessment, and deliberately open the assessment process to policy considerations, or even let go of risk assessment altogether and evaluate risks on a different, explicitly normative basis? This is the first question to be addressed in the final and concluding part of this Chapter. Continuing, I will investigate the consequences of the preferred approach within the particular setting of the European Community, and whether implementation of this approach would necessitate legislative and regulatory reform.

1. Evaluation of Risk Assessment Critiques

In the first part of the following evaluation discusses the merits of the “fact and value” approach over the “purely scientific” approach, and explains why, in my opinion, risk assessment should openly embrace its normative component. The second part evaluates the legitimacy and legality of risk assessment, and explores the possibility of re-legitimising risk assessment on the basis of procedural criteria. The third part explains why, in spite of all the
difficulties, risk assessment should not be dropped from the legal framework for chemical control.

1.1. Fact and value

As suggested throughout the preceding text, I do not believe that the "scientific" option — to purify risk assessment of non-scientific elements — would produce results that, from a risk regulatory point of view, are desirable. To be sure, there is no harm in the improvement of measurement techniques or the fine-tuning of extrapolation models as such, however, the elevation of risk assessment to the status of pure science appears risky, illusory and unnecessary. Even proponents of scientific and quantitative forms of risk assessment acknowledge that, using the current state of the art, assessments of identical substances may produce vastly different risk characterisations, with risk levels differing sometimes as much as six orders of magnitude. In light of these looming uncertainties, the unshakeable conviction of cognitive error scholars that science-based assessment techniques are in any case more reliable than laymen's assessments, and that it is solely the public that is in need of risk education, borders on paternalism and professional arrogance.

In addition to the previously discussed arguments levied against the "scientification" of risk assessment, it is furthermore important to evaluate different options for risk assessment reform, bearing in mind the practical constraints that were discussed at the beginning of Section II. We recall that, in practice, budgetary constraints, pressing deadlines and incomplete information as well as communication cast a shadow on the reliability of risk assessment which, even under ideal circumstances, produces plausible rather than accurate results. This situation seems hardly reconcilable with a call for greater scientific rigour, which would unavoidably require, inter alia, more extensive

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562 ALON ROSENTHAL, GEORGE M. GRAY & JOHN D. GRAHAM, o.c., p. 357: "[T]he public is justifiably confused when it is told that a single risk level as estimated by different program offices in a single executive agency has multiple meanings. If the methods and assumptions used in QRA are so varied, the existence of an essential truth, which QRA purports to measure, appears dubious."
563 It is, in this respect, noteworthy that scientists are generally more cautious in both their perception of risk assessment as a purely scientific enterprise, and their evaluation of the reliability of risk assessment than regulatory bodies who use assessment results in their decision-making. Cf. STUART DOBSON, o.c., passim; STEPHEN BREYER, o.c., p. 48; SHEILA S. JASANOFF (1987), "Contested Boundaries," o.c., p. 211.
testing, bigger control groups, better equipment and longer testing periods, and would, hence, tax the limited availability of resources and time even more. The result would either be a system of risk assessment where the discrepancy between the alleged scientific accuracy and the actual reliability of results is even greater than is presently the case, or one that meticulously obeys the rules of scientific reasoning and inference-drawing but, consequently, needs to restrict its scope, assessing only a very limited number of the chemical risks that are continually being introduced into society. From the standpoint of health and environmental protection, neither scenario is appealing.

The “fact and value” approach offers, I believe, a more promising basis for risk assessment reform. By denying risk assessment results the status of “scientific facts,” this approach does not just de-emphasise science and expertise as legitimation for decision-making (creating the need for an incorporation of additional legitimacy-conferring activities into the risk assessment process; see below), it also liberates risk assessment from the straitjacket of objectivism, and invites us to question, as Carl Cranor does, whether scientific rigour is really necessary, or even useful, to arrive at sound policy decisions. Instead of desperately trying to suppress value judgements, it might be more productive to make them explicit and attempt to synchronise them with the objectives of health and environmental regulation.

Following this approach, the tensions that usually remain hidden below the surface of predominantly science-based risk assessment procedures -- such as the tension between the underdeterminacy of short-term testing on the one hand, and a need for expedient decision-making on the other, the efficiency versus equity dilemma, or the tension between a scientific preoccupation with false positives and regulatory fears of false negatives -- would be exposed and could consequently be taken into account in (normative) policy considerations. Risk assessment might thus find its place somewhere between science, practice and policy, thereby more closely reflecting the different manifestations of risk as a physiological, economic, psychological and social phenomenon.

With regard to the practical constraints to risk assessment -- which, as discussed above, seriously call into question the feasibility and desirability of “scientific purification” projects -- it goes without saying that such considerations equally have to be taken into account when we adopt a “fact and value” approach. One might contend that, because the latter approach to risk
assessment strives to offer a more comprehensive picture of risk, explicitly taking into account policy-orientations, equity considerations etc., it is even more resource-consuming than the former one. However, one of the advantages of a comprehensive or "mixed* form of risk assessment, as advocated above, is precisely that it creates scope to incorporate practical objections and resource constraints. If risk assessment results are not treated as scientific facts, but rather as "indicators,* the weight of which may depend among other factors (but not solely) on the time and resources available to perform tests and falsify test results, budgetary limits and time constraints would no longer necessarily preclude decision-making.

Attractive as the above-mentioned proposal may sound, we should of course realise that, in the area of risk regulatory reform, there are no free lunches. The results of "mixed* risk assessments are certainly not as easy to compare and rank as those of quantified risk assessments. The introduction of mixed risk assessments would therefore precipitate a need to revisit ideas on risk ranking and priority-setting, and increase their level of complexity or sophistication so that they are better equipped to deal with the relative loss of uniformity in risk assessment results. On a more fundamental level, we would have to accept the consequences of releasing the paradigm of scientific and legal certainty. The deconstruction of reality and the ensuing reconstruction of selective, relevant "facts* is a tradition that is deeply ingrained in both scientific and legal reasoning.565 From this position, it is easy to understand the attraction of science-based and quantified forms of risk assessment for lawmakers and regulators, reminiscent as they are of long-standing judicial techniques of fact-finding and rule-application.566 Moreover, the margins of discretion granted to regulatory bodies and judges traditionally cover the second stage of decision-making (for regulators: the interpretation of policy goals; for judges: the application of legal rules and principles), but do not seem to extend to the initial stage of fact-finding.567 The legality and legitimacy of decisions in both settings hinges on an accurate rendition of the facts as much as on a reasonable exercise of discretion. Thus, the release of the artifice of "scientific fact* in risk regulation has serious ramifications for the legality and legitimacy of

564 Cf. BO CARLSSON, o.c., p. 478.
566 Cf. GÖNTHER TEUBNER (1993), Law as an Autopoietic System, o.c., p. 78.
567 KARL-HEINZ LADEUR (1993), "Von der Rezeption der Erfahrung zum Prozeß der Modellierung,* in GOTTHARD BECHMANN, o.c, p. 216.
risk decision-making.

1.2. Legitimacy and legality of risk regulation

One way of resolving the emerging legitimacy deficit is by shifting the focus from the substance of the decision-making process to the procedure, while looking for a criterion of legitimacy that can be weighed following a procedural rather than a substantive evaluation. For instance, whereas (scientific) authority is one way of establishing legitimacy, participation and adherence to democratic principles is another. Applied to the case at issue, this would imply the conveyance of legitimacy through the involvement of all parties really or potentially affected by risk regulation (or the absence of regulatory restrictions) in the chemical risk assessment process; including, inter alia, people who come into contact with potentially hazardous chemicals in their working environment, consumers of chemical products and preparations, the chemical industry, the environment itself, and people involuntarily coming into contact with substances released in the environment. Probably, participation would have to be constructed through a system of representation, some groups being so numerically large that full participation would bring all risk assessment to a grinding halt, and others, in particular the environment, not being capable of voicing their own interests.

In a system of deliberative decision-making, the predominant question to determine the acceptability of the underlying "factual" basis would no longer be whether good science was used to uncover the facts, but whether good procedures were operative to assure multi-partite participation in the construction and selection of relevant facts and assumptions. Thus, a new emphasis on proceduralisation in combination with deliberation could be deployed to overcome the legitimacy deficit that becomes apparent once the

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568 Cf. HANZ-HEINRICH TRUTE, o.c., p. 963.
570 In this context, Karl-Heinz Ladeur calls for a strengthening of the adversarial nature of procedures, for instance by means of subsidising (and thus assuring participation of) the involvement of social scientists, interest groups representatives, etc. KARL-HEINZ LADEUR (1993), "Von der Rezeption," o.c., pp. 224-225.
input from expertise is divested of its status as indisputable, unquestionable fact.\textsuperscript{572}

Undeniably, the introduction of deliberative risk assessment procedures, replacing purely expert-oriented ones, would pose a major challenge to the organisational talents of decision-makers, and would, especially at the outset, involve high transaction costs.\textsuperscript{573} However, in light of the long term benefits of developing a decision-making process the acceptability of which is not dependent on a construct (or fiction) which is crumbling at the edges, namely the construct of scientific accuracy of risk assessment, I would argue it is an option worth exploring.

Remains the difficult problem of legality. The uncertainties that encumber risk assessment -- and that, let there be no mistake, will not be resolved but rather made explicit by the introduction of "mixed" as opposed to expert-oriented risk assessment processes -- are exemplary of the challenge which problems of uncertainty pose for the traditional legal paradigm, which has as its basic tenets that, under the rule of law, one should be free to do what does not harm others (which in continental legal systems approximately corresponds to the concept of the "Rechtsstaat") and that harm, when invoked, should be proven and causation established.\textsuperscript{574}

In the area of chemical risk control, the conflict plays out as follows: on a general, aggregate level, we know that chemicals may cause harm to health and the environment, and therefore the unconstrained production and release of chemicals would constitute an infringement of people's right to health and environmental rights. However, the techniques deployed to establish harm and causation -- in other words, risk assessment -- leave room for uncertainty and error, meaning that unconstrained intervention would hardly be reconcilable with the basic principles of the "Rechtsstaat" and freedom of enterprise as traditionally interpreted. Clearly, something's got to give. During the last decades, legislative attempts have been made gradually to engineer a way out of

\textsuperscript{572} Cf. Udo Di Fabio's discussion on the establishment of threshold levels for regulatory intervention; UDO DI FABIO, "Entscheidungsprobleme," o.c., p. 358: "[U]m hier "Legitimation für die Dezision" herzustellen, wird überlegt, ob es nicht rechtlich resp. verfassungsrechtlich geboten ist, zumindest das Verfahren der Grenzwert festsetzung transparenter zu machen oder das Entscheidungsverfahren zu pluralisieren resp. eine als "kritische Gegenöffentlichkeit" auftretende Gruppe in das Verfahren der Grenzwertfestsetzung zu integrieren".


\textsuperscript{574} Cf. the traditional legal framework for hazard control developed under Heading 1 of Chapter I.
this impasse, namely through the development of new legal principles that no longer depend on traditional causation to trigger action (see Headings 2 and 3 of Chapter I). Liability rules have been relaxed through the introduction of concepts such as no-fault liability and joint causation; in the area of regulation, the precautionary principle aims to enable regulatory intervention in the absence of conclusive, scientific proof of harm.

However, the adoption of new legal principles is but the first step towards the integration of risk and uncertainty into law; principles require elaboration, both at the doctrinal and practical level, and application to make them come alive. For instance, one might ask which criteria, short of conclusive scientific proof, have to be met to warrant intervention on the basis of the precautionary principle; what kind of intervention is most appropriate when the legal principle triggering action is precaution rather than causation; whether there should be any particular forms of recourse granted the addressees of regulatory intervention on the basis of precaution, etc. A number of these issues will be taken up in the next Chapter on risk management. For the time being, I would like to point out that the development of doctrinal and practical rules to operationalise “non-causation-based” legal principles appears indispensable to assure the legality of risk assessment as a foundation for risk decision-making.

1.3. Hazard v. risk

In light of the many shortcomings of and uncertainties in risk assessment, and the major efforts -- both in terms of organisation and doctrinal development -- that attempts at reform would require, would it not be better to abandon science-based risk assessment altogether and found risk regulation on an altogether different basis? Certain US authors, such as Mark Eliot Shere (1995), do indeed contend that risk assessment is beyond salvation. In Europe, environmental groups are equally wary of the technique. Their concern focuses on two aspects of risk assessment: first, its reductionism, and second, the slowness of risk assessment procedures, which implies that recommendations for risk reduction, drawn up on the basis of assessments, are developed at a snail's pace. In lieu of risk assessment, non-governmental

576 MARK ELIOT SHERE, o.c., p. 479.
organisations such as Friends of the Earth (1999) therefore propose to base risk reduction measures solely on chemical hazards, uncovered during the first stage of risk assessment, the stage of hazard identification.\textsuperscript{577}

The disappointing outcome of five years experience with the Existing Substances Regulation lends additional gravity to the concerns voiced by environmental groups. Thus far, the risks of only 19 of the prioritised existing substances have been assessed. Risk reduction measures were recommended for 14 of the assessed substances.\textsuperscript{578} Up to now, not a single one of these 14 recommendations have been taken by the European Commission and Council as a basis for regulatory restrictions. Bearing in mind that the EINECS lists 100106 chemicals, the result is utterly disheartening. However, I would question the extent to which the ineffectiveness of the Existing Substances Regulation is caused by the use of risk assessment. A comparison with the effectiveness of the legal framework for notified substances is particularly insightful: since 1993, 400 new substances have been subjected to risk assessment in accordance with the Risk Assessment Directive.\textsuperscript{579} Hence, even though risk assessment requirements for new substances entered into force only one year before those pertaining to existing substances, over twenty times as many assessments have been conducted. Admittedly, there is still considerable scope for improvement and acceleration within the framework for new, notified substances. Yet, the discrepancy between assessments for new and existing substances suggests that the ineffectiveness of the Existing Substances Regulation is caused by more than risk assessment. Recalling the analysis in Chapter II, I would venture that the main "culprit" for delays and deadlock is the lack of incentives for the chemical industry fully to cooperate in the data gathering and reporting scheme for existing substances. The greater industrial resistance to the reporting scheme may furthermore reduce the political willingness of European and national regulatory authorities to take up risk reduction recommendations. These conditions will not be improved simply by dropping risk assessment out of the regulatory framework.

It is furthermore questionable whether reliance on hazard assessment by

\textsuperscript{577} Based on comments submitted by Friends of the Earth and Greenpeace International during the Commission workshop "Industrial Chemicals: Burden of the Past, Challenge for the Future," held in Brussels on 24 and 25 February 1999.


\textsuperscript{579} Ibid.
itself would boost the level of health and environmental protection in chemical control regulation. In fact, as will be discussed in Chapter IV, the majority of existing EC risk management measures for chemicals are based on hazard assessment; not on risk assessment.\footnote{See Section II.1 of Chapter IV.} Nonetheless, we may safely assume that most health and environmental groups are highly unsatisfied with the level of protection these hazard-based measures afford. The preceding observations lend additional support to my contention that, however great the harm they predict, assessments alone do not guarantee stringent regulatory outcomes; it takes political willingness to act on assessment results, whether hazard- or risk-based.

Finally, I suggest risk assessment does offer certain advantages over hazard assessment, even from the perspective of health and environmental protection. If we accept the, perhaps unattractive, but nevertheless inescapable fact that the level of health and environmental protection is constrained by limited political willingness and limited availability of resources to spend on risk regulation, it becomes quintessential to make sure that, at least, the most serious health and environmental risks are treated first. And, the seriousness of risks does not depend on their hazard classification alone; it is co-determined by exposure, as well as by a number of social factors (see above). Hazard-based action is quite rigid; it does not permit an inclusion of these factors into the deliberation. Moreover, if we interpret risk assessment in a more flexible and procedural manner, as I proposed earlier in the text, risk assessment need not necessarily be a protracted process; considerations of expediency could openly be integrated into the assessment process. Finally, because risk assessment is more open to social, contextual elements than hazard assessment, it is conceivable that, when the political willingness to manage chemical risks effectively does increase, this changed political climate will more easily be integrated and reflected in risk assessment and ensuing decision-making. For these reason, analyses and critiques of risk assessment should, in my opinion, concentrate on areas within the currently practised system of risk assessment that are open to reform -- such as the potential introduction of social risk factors, equity considerations, and the development of deliberative assessment procedures -- rather than aim to dismantle risk assessment in its entirety.\footnote{Cf. DAVID A. WIRTH & ELLEN K. SILBERGELD, o.c., p. 1862.}
2. Implications for EC Risk Assessment Procedures

Which lessons can -- or should -- Europe draw from the critical considerations which, as I confirmed earlier on, were mainly developed by US scholars and based on American risk assessment practices?

Before going into the applicability of the above-standing evaluation in a European context, I would like to state that, in my opinion, now is a propitious time for an evaluation of EC-developed risk assessment practices. Europe comes from a situation of widely varying national risk assessment and evaluation practices, and has only fairly recently endeavoured to harmonise these practices. Hence, the harmonised risk assessment rules and accompanying guidelines are at this stage still relatively undetermined, and therefore adaptable to interpretation. For example, we recall from Section 1.2.3 of this Chapter that the rules relating to exposure assessment afford Member States a choice between quantitative and qualitative approaches, and that, generally, the harmonisation measures assume the form of broad methodological directives rather than normative prescriptions. In light of these circumstances, and bearing in mind that risk assessment procedures may well become less malleable as they become entrenched in both national and EC risk decision-making, now appears the appropriate time to stop and consider how we want the still fairly recently formalised risk assessment rules practically to operate, and whether any adaptations are required in order to steer risk assessment towards a model that more adequately responds to the many objectives (safeguarding human health, environmental protection, free movement of goods and market harmonisation) which the European Community simultaneously seeks to uphold.

Notwithstanding the present degree of undeterminacy, there are already some indications that EC risk assessment rules will lend themselves more easily to favouring exclusively scientific forms of risk assessment than mixed approaches. First, the methodology (or risk assessment “ingredients”), which both Commission Directive 93/67/EEC and Commission Regulation 1488/94 identify as being necessary to conduct reliable risk assessments, is clearly located within the realm of scientific expertise: methodological rules require measurements performed in laboratories, toxicity tests, estimates made through the extrapolation of observed dose-response relations in accordance
with statistical models, etc. Both the Commission Directive and Commission Regulation are, on the other hand, conspicuously silent on those aspects of risk assessment that we have come to identify as representative of the social impact of risks. The level of voluntariness with which the risks are assumed, the degree of familiarity, the immediacy or latency of effects, to name but a few factors, are nowhere mentioned as criteria to estimate the seriousness of various chemical risks. Perhaps, one could argue, this omission is due to the fact that the social impact of risks reveals itself only after the risks materialise, and therefore such considerations cannot be included in an ex-ante assessment. Although this argument might go towards justifying the absence of socially oriented considerations in risk assessment procedures for new substances (and, still, even for new substance it might be possible at least to make forecasts about the social impact of future risks), it fails to explain why such considerations, or risk assessment criteria, are equally absent in the risk assessment rules for existing substances.

Moreover, risk assessors' tasks are not limited to drawing up risk characterisations, but include making recommendations for risk management. This procedure, in addition to endowing scientific experts with the primary responsibility for the development of national and European chemical risk control strategies, appears to leave very little room for consideration of alternative criteria: regulatory authorities are presented with a more or less "finished product," in the form of a risk recommendation, which recommendation they can hardly challenge without calling into question the scientific authority of the experts they appointed.

A final -- and even somewhat alarming -- indication of the overwhelmingly science-oriented undercurrent in EC risk assessment is supplied by the fact that normative choices, when made, are usually not explicit, but rather embedded as a subtext in directives which, at first sight, seem non-normative and purely methodological. For example, we recall that the provisions relating to the dose-response assessment for mutagenicity, genotoxic carcinogenicity and skin sensitisation reveal a conservative slant: presence of the inherent capacity to cause such effects suffices, even when the dose-response relation cannot adequately be assessed. This risk-averse approach may well -- and justifiably -- correspond to a particularly high public concern regarding cancer and

582 Cf. ROBERT NILSSON et. al., o.c., pp. 308-310.
583 Cf. Section 1.2.3.
reproductive diseases, however it is significant that such concerns are not addressed openly. A normative choice to "err on the safe side" has clearly been made, however, in both the Commission Directive and the Commission Regulation this norm assumes the form of an instrumental, technical guideline added for the sole benefit of the experts who perform risk assessments on chemicals. Needless to add, the implicit anchoring of normative and/or policy choices in technical guidelines creates a risk that they might get covered under a "veneer of false precision."

Stepping out of the frame of risk assessment and moving to a more general level, the European Community's regulatory culture displays certain characteristics that lend additional credibility to the prediction that harmonised risk assessment procedures might become fixed in an almost exclusively science-oriented mould. In a 1997 paper, I explored tendencies in European Court decisions increasingly to emphasise the importance of scientific evidence as a basis for EC-level regulatory decisions (particularly when these decisions are within the competency of the European Commission) as well as for national restrictive measures taken with an eye to the protection of health and safety or, with lesser frequency, the environment. The European preoccupation with science as a basis for decision-making is at least partially explained by concerns about the legitimacy of EC regulation, as well as by the quest for international standards (or norms) for the development and evaluation of both positive and negative market integration measures; standards which the Member States, in spite of having different national concepts of regulatory normativity, can all recognise as valid and acceptable. Scientific "soundness" is one, perhaps the one validity criterion around which agreement can be forged on an international scale. As Christian Joerges (1997) puts it: "[B]y resorting to scientific expertise, legal systems subject themselves to 'external' validity criteria. By the same token, through a reliance on scientific assessments, they overcome their built-in parochialism; the legal system becomes entitled to a recognition of its position beyond its own borders."

Summarising, the wording of the risk assessment documents themselves, as well as the fact that they operate in a European, politically heterogeneous environment and have been developed against the backdrop of a concern for the international acceptability of decision-making criteria, suggest that Member

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States’ risk assessment procedures performed in accordance with the Directive (or risk assessments produced by national rapporteurs in compliance with the Commission Regulation) will display an overwhelming emphasis on scientific procedures and leave little room for a more balanced, or mixed, approach towards risk. Mixed approaches may nonetheless be preferable in that they are probably better attuned to the objectives of accountable and responsive health and environmental protection, and are better capable of integrating -- rather than dissimulating -- problems of uncertainty in risk decision-making (see above). Thus, we discern a tension between the drive towards uniformity (in the shape of internationally acceptable decision criteria), which is in turn propelled by the market harmonisation rationale, and the need for both flexibility and case-by-case specification, which characterises decision-making under conditions of uncertainty. This tension is reminiscent of the one discussed in Chapter II, where industrial interests in across-the-board, uniform reporting requirements for all notifiers of chemical substances, which can be dispensed with through the submission of a single, comprehensive technical dossier (the "lump-sum approach") are in certain instances (particularly with respect to environmental risk reporting) at cross-purposes with the advantages, from an informative and educational point of view, offered by case-specific, gradual and long-term data submission approaches.

3. **EC Risk Assessment Reform**

The foregoing conclusion suggests that EC risk assessment procedures might benefit from reform efforts to enhance their openness to more qualitative, non-statistical and socially informed approaches to risk. The most obvious way of doing so, obviously, would be through the adoption of amendments to Commission Directive 93/67/EEC (new substances) and Commission Regulation N° 1488/94 (existing substances). Such amendments could stipulate that, prior to determining the risk characterisation, national risk assessors and national rapporteurs are to take into account non-quantifiable dimensions of chemical risks, including the degree of voluntariness with which exposed parties assume the risk, the familiarity with this or similar chemical risks, the likelihood of occurrence versus scale of harm ratio, and, perhaps most importantly, the need for expedient decision-making.

The above proposal naturally begs the question: how do risk assessors,
rapporteurs and other experts involved in assessment procedures become aware of this “social dimension”? In my opinion, a more integrated approach to risk assessment could be achieved by creating more room for deliberation in risk assessment processes. We have seen that, at present, the risk assessment stage provides limited access for outside inputs. Notifiers of new substances may include a preliminary risk assessment in the technical dossier, and national risk assessors may solicit their opinion on proposed risk recommendations. However, national regulations may just as well preclude the latter option. No opportunities are foreseen for non-industrial interest groups, such as environmental groups, public health action groups and consumer groups, to make their view on particular risks known. Considering the pivotal role that risk assessment is to play in risk management decision-making, as repeatedly confirmed in Commission communications and the preambles of all three risk assessment documents (Commission Directive 93/67/EEC, the Existing Substances Regulation and Commission Regulation N° 1488/94), the lack of concern for deliberation in risk assessment is unsettling.586

Therefore, I would argue that the most pressing reform for the European Community to consider, should aim to ensure that a variety of interests and viewpoints are represented in risk assessment processes. To this end, EC authorities might, for instance, map out a procedure that risk assessors and rapporteurs have to follow, first, to make themselves aware of the social dimension of risk; second, to take this dimension into account in the stage of risk characterisation; and, third, to document how the social dimension has played a role in establishing the risk characterisation and subsequent risk recommendation. Furthermore, one might envisage a requirement to the effect that risk recommendations be communicated to affected parties and public interest groups, and a comment and reply period be foreseen. Alternatively, taking into account local differences in regulatory and administrative practice, the European Community might set out general guidelines for public

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586 One might argue that the public viewpoint is more appropriately introduced at the stage of risk management, and that, hence, it is not risk assessment but rather risk management decision-making that should be made more transparent and deliberative. However, as will be reiterated in Section 1.3.1 of Chapter IV, it may be far more difficult for public interest groups to make their opinion count at the stage of risk management than at the stage of assessment, irrespective of the content of this opinion. This is related to the phenomenon that risk assessment results, and particularly scientific risk assessment results, no longer reflect the uncertainty inherent in the process. In other words, risk managers tend to treat risk assessment results as factual information, and are therefore less open to approaches that, in their opinion, contradict scientifically
participation in risk assessment, and delegate the actual task of developing corresponding deliberative procedures to national authorities.

Either way, there can be little doubt that the reform process will be difficult and time-consuming. Nevertheless, in light of the importance of the objective, and the added advantages that a more open approach to risk assessment might bring in terms of public acceptance of EC risk control measures and, ultimately, European decision-making generally, the latter consideration does not negate the need for reform, but rather underscores its urgency.
INTRODUCTION

Imagine the following scenario. The researching staff at Chemplus NV, a company based in Belgium, has engineered a new chlorine-based substance which it intends to market under the catchy brand name “Chlorplus.” Consequently, Chemplus has notified the substance to the Belgian competent authorities (the Ministry of Health and Environmental Hygiene) submitting a thick technical dossier covering all the data requested, including physico-chemical properties and test results. The dossier, received by the Belgian authorities and passed on to the European Commission for distribution to the other Member States, indicates that highly concentrated doses of Chlorplus, when inhaled by laboratory mice, cause breathing difficulties. *Prima facie*, there are no indications of carcinogenicity. Ecotoxicity tests reveal that biodegradability in water is relatively low, but otherwise there are no clear signs of environmental harmfulness. A preliminary risk assessment points at a small, but non-negligible risk of respiratory ailments caused by inhalation of small doses of Chemplus over extended periods of time, and a quantitative assessment produces a mortality rate of 4/1,000,000 over a period of 10 years.

Armed with this -- incomplete -- information, Belgian regulatory authorities (or those situated in other Member States or at the EC level) face a number of different options. They can simply ignore the information supplied because it is too voluminous or complicated and, consequently, abstain from regulatory action. Alternatively, they can study the information submitted and conclude on the basis thereof that the risk represented by Chlorplus is negligible and does not warrant regulatory intervention. Or they can decide that there is no cause for immediate action, however that, should further information reveal that the preliminary risk assessment might have been overly optimistic, this position should be reviewed. Finally, they can decide to impose regulatory restrictions, with varying degrees of severity ranging from conditions for use of Chlorplus to outright bans on the substance. Whichever course regulatory
authorities choose to follow, even if it ends in a decision not to deal with the information at hand, it inevitably compels them to enter into the area of risk management.587

Risk management: the determination of what to do about (at least partially) identified or identifiable risks.588 Admittedly, it is not possible -- or even useful -- to draw clear-cut boundaries between risk management and the stages that precede it: both the phases of information gathering (or risk identification) and risk assessment contain managerial aspects; they are present in, for instance, the selection of data to take into account when measuring the harmful effects of a substance, or in the significance accorded to different extrapolation models.589 However, for practical reasons I will continue to use the term “risk management” in this Chapter to refer to the decision-making process that takes place after risk identification and risk assessment have been (or should have been) performed. Taken together, the three pillars of identification, assessment and management form the core of risk regulation.

This Chapter examines how EC legislation seeks to direct and accommodate risk management decisions relating to the production, marketing and use of chemical substances. To facilitate such examination, it is useful first to get acquainted with thoughts and proposals that have been launched throughout the past twenty years, with the aim of improving legislation on environmental and health risk management generally. Some of these proposals were introduced in the first Chapter, as desiderata for risk-oriented decision-making. They will be recapitulated and discussed in conjunction with other forms of regulatory criticism and suggestions for reform, which allows an analysis of the differences and overlaps in regulatory critique as well as in prescriptions for regulatory improvement.

Subsequent to this overview, I will turn to a more detailed analysis of risk management for chemical substances (which falls under the heading of substance-oriented management), followed by an evaluation of the “modernity” of the incumbent regulatory framework. This evaluation includes an assessment of the extent to which ideas for regulatory reform are reflected in chemical risk control measures, and a discussion of the regulatory framework’s ability to cope

587 ROGER SMITH & BRIAN WYNNE, o.c., p. 8.
with problems of uncertainty. I will argue that, although efforts have undeniably been made to modernise chemical regulation, EC legislation is still too much prone to hide or disregard uncertainty, particularly for those risks threatening the environment.

Going back to our Chemplus example, the Belgian authority in charge might decide, on the basis of the intrinsic properties of the substance, the assessment results submitted by risk assessors and their ensuing advice, that Chorplus represents too many health risks to be admitted into circulation, and that production of the substance should cease. This is what is called a "culling technique," in which regulatory authorities straightforwardly prohibit the sale or use of products (or, as the case might be, processes) that, in their opinion, do not meet minimum social performance standards.\textsuperscript{590} This "allow-or-withdraw" approach — which is also used in European legislation, most notably in Directive 76/769/EEC on marketing and use restrictions for certain dangerous substances\textsuperscript{591} — is most appropriate for products, where engineering incremental changes to improve social performance (for instance reduced toxicity or, in the case of Chlorplus, reduced effects on the respiratory system) is often impossible without changing the essential performance characteristics that made the substance marketable.\textsuperscript{592} To implement a culling technique, regulators need to draw an imaginary line (or threshold), separating those substances that meet social performance requirements, and therefore can be sold and used legally, from those that fall foul of the line. As the discussion below will bear out, how this line gets drawn is one of the most controversial themes in risk management.

Culling is but one of many techniques environmental regulatory authorities deploy to manage and control health and environmental risks. As mentioned, it is particularly suited for the control of marketable products.\textsuperscript{593} However, in those instances where pollution (causing health effects and/or environmental deterioration) is a side-effect of industrial activity or

\textsuperscript{590}CHRISTOPHER ARUP, o.c., pp. 48-49 on screening systems. RICHARD B. STEWART (1981), "Regulation," o.c., p. 1267 & 1282.
\textsuperscript{592}RICHARD B. STEWART (1981), "Regulation," o.c., p. 1267.
\textsuperscript{593}ANDREAS THEUER (1996), "Risikobewertungsmodelle," o.c., p. 121.
consumption, different strategies are called for. Take, for example, the emission of polluting substances from factory chimneys into the air, or discharges of toxic waste into water. To combat the risks resulting from air and aquatic pollution, regulatory bodies often resort to standard-setting: they determine the maximum amount of polluting substances allowable in air or water, whereupon polluting industries have to adapt their production processes or install cleaning mechanisms in order to stay below the regulatory maximum threshold. This approach was followed, for example, in EC legislation on water pollution: Council Directive 76/464/EEC calls for the establishment of limit values (determined by both the maximum concentration of a substance permissible in a discharge into water and the maximum quantity of such a substance as a unit of weight of the pollutant) for chemical effluents and compounds which, because of their toxicity, persistence and bioaccumulation, had been included on a "black list" of polluting substances.\(^5\)\(^9\)\(^4\) These limit values were subsequently published in a 1986 Directive and ensuing amendments, destined to be adopted and implemented in all but one Member State.\(^5\)\(^9\)\(^5\)

The selection of substances requiring emission standards may be determined on the basis of known physico-chemical properties and toxicity measurements, as happened for the substances included in List 1 of Council Directive 76/464//EEC, and may involve consultation with international organisations. Alternatively, the results of quantitative risk assessments may be used as cut-off points. The German Länderausschuss für Immissionsschutz (LAI), for example, determines concentration limit values for carcinogenic air pollution.

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\(^5\)\(^9\)\(^4\)Council Directive 76/464/EEC of 4 May 1976 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, OJ L 129/23 (1976). See J. MCLoughlin & E.G. Bellinger, o.c., p. 47. The substances on the black list (List 1 in the terminology used in the Directive) were chosen from a list of 1500 substances. The initial substances selected were the ones on which all the Member States could agree that they were most hazardous. Later, another 122 substances were selected, of which 14 were subsequently excluded. The final list contains 129 substances, including, \textit{inter alia}, mercury, cadmium, DDT and PCP (pentachlorophenol). See also Eckard RehBinder & Richard Stewart (1985), "Environmental Protection Policy" (Vol. 2) in Capellucci, Seccombe & Weiler (gen. eds.), Integration Through Law. Europe and the American Federal Experience, Walter De Gruyter, Berlin - New York, pp. 63-64; Nigel Haigh, o.c., pp. 70-74.

\(^5\)\(^9\)\(^5\)Council Directive 86/280/EEC of 12 June 1986 on limit values and quality objectives for discharges of certain dangerous substances included in List 1 of the Annex to Directive 76/464/EEC, OJ L 181/113 (1986). All but one Member State committed to adopting the maximum emission standards promulgated by the EU Council. The one exception, the United Kingdom, opted instead for quality objectives, meaning that rather than conditioning industrial activity on compliance with emission standards, the determinant criterion is whether the water in which polluting substances are discharged, meets pre-set purity and quality standards. See RehBinder & Stewart, o.c., pp. 63-
pollutants on the basis of carcinogen risk assessments and estimated mortality rates. Limit values or maximum concentration standards are set at a level where the expected risk (calculated on the basis of the hazardous properties of the pollutant, the dose-response relation and anticipated exposure) is deemed acceptable or negligible. For example, in the USA carcinogenic air pollutants for which the calculated individual mortality rate has been assessed at maximum 0.000001 (i.e., on a population of 1 million people, one person is expected to die as a result from life-long exposure to this particular carcinogen) are deemed to fall under the de minimis threshold. For substances the assessment of which produces a greater mortality rate, emission limits need to be set so that, as an overall result, the individual risk rate will drop to or below 0.000001.

Instead of setting emission and concentration limit values, regulatory bodies may seek technology-based solutions to health and environmental risks. The BAT (Best Available Technology) and BATNEEC (Best Available Technology Not Entailing Excessive Cost) strategies are well-known examples of such technology-based environmental controls. In the words of Ackerman and Stewart (1986), the operative principle of the BAT strategy is the following: "[I]f an industrial process or product generates some nontrivial risk, the responsible plant or industry must install whatever technology is available to reduce or eliminate this risk, so long as the costs of doing so will not cause a shutdown of the plant or industry".

The three regulatory approaches to risk management (culling, setting of limit values, and BAT or BATNEEC) differ from each other in that the measures they propose focus on different links in the industrial production chain. Chronologically speaking, product-oriented culling techniques might claim to intervene at the earliest stage, since they pre-empt production (or the continuation of production) of substances and products that are deemed to entail a higher than acceptable risk. Following the production chain, the next measures are technology-based control mechanisms, such as BAT, that aim to

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65; NIGEL HAIGH, o.c., pp. 71-72.
597 DAVID A. WIRTH & ELLEN K. SILBERGELD, o.c., p. 1864.
598 WILFRIED KUEHLING, o.c., p. 113.
599 Cf. the German "Stand der Technik." See THOMAS MANN, o.c., pp. 180-185.
improve production processes and provide for a cleaner technology. Finally, emission standards concentrate on the media in which polluting substances are discharged; mainly air and water. To comply with maximum values for discharges, industrial plants might opt to install cleaner, less waste-producing production techniques, or they might prefer to install additional cleaning mechanisms (e.g., water purification installations) at the end of the production chain. The latter technique, which leaves both production and production processes unaffected, is called end-of-the-pipe technology.\footnote{Cf. RICHARD B. STEWART (1981), “Regulation,” o.c., passim.}

On the other hand, the three risk-management techniques have a number of characteristics in common. First, they all involve some form of standard-setting, whether social performance standards (culing), production standards (BAT) or emission standards.\footnote{McCLOUGHLIN & BELLINGER, o.c., p. 47; BRADFORD C. MANK, o.c., p. 297.} For the techniques to work, regulatory bodies are required to draw lines between what is acceptable and what is not, and these lines become the pivotal point of orientation for health and environmental decision-making.\footnote{ALON ROSENTHAL, GEORGE M. GRAY & JOHN D. GRAHAM, o.c, pp. 322-338.} Second, in each of the above-mentioned instances, substantive decisions are made by the regulatory authorities and imposed on industry (a top-to-bottom approach). In addition to making the rules, regulatory authorities are responsible for compliance control. Third, even though regulatory bodies are unquestionably the ultimate and formal decision-makers, all three approaches involve a great deal of deference to and reliance on scientific and technological expertise, whether to determine the state-of-the-art in technology, to assess the risks related to the release and use of new products, or to measure the current level of air and water pollution and establish limit values. Finally, each of these techniques imposes uniform requirements on industry; there is little room for differentiation according to, for example, the location of industrial plants, or the individual ability of enterprises to adapt to new environmental requirements.\footnote{RICHARD B. STEWART (1995), Markets Versus Environment?, Jean Monnet Chair Papers, The Robert Schuman Centre at the European University Institute, pp. 4-5.}

These four characteristics (standard setting, top-to-bottom approach, reliance on expertise and uniformity) typify a form of environmental regulation that has been labelled "command-and-control" regulation. The reasons for the choice of name are obvious: regulators command a certain behaviour, and consequently control whether rules are complied with. Thus, culling, emission
standard-setting and BAT requirements are all examples of command-and-control regulation. In the area of environmental regulation, command-and-control is the most frequently used, tried and tested regulatory technique. The approach offers a number of undeniable advantages: substantive standards leave little room for interpretation or doubt, which guarantees a high degree of clarity and legal certainty, and compliance is relatively easy to control.\textsuperscript{605} It is equally undeniable that substantial accomplishments in health and environmental protection have been reached following command-and-control methods. However, over the last 15 years command-and-control rules have been exposed to harsh criticism,\textsuperscript{606} and proposals have been launched (and, in certain instances, taken up) to replace command-and-control regulation with mechanisms that – so critics of command-and-control approaches claim – are less intrusive, more efficient, more flexible and/or democratic, and more finely attuned to the regulatory objectives envisaged.\textsuperscript{607} In the following sections, I will take a look some of the main objections levied against command-and-control regulation, and discuss proposals for regulatory reform.

2. **The Trouble with Command-and-Control**

After the regulatory zeal that reigned throughout the 1970's,\textsuperscript{608} during which period a great number of landmark environmental and health regulations were adopted in both Europe and America,\textsuperscript{609} the late 80's and 90's could be...
characterised as the age of discontent with traditional forms of regulation. Particularly in America, numerous publications attract the reader's attention with catch-words such as regulatory failure, red tape, paralysis, inefficiency, and regulatory inconsistency. The European Community equally experienced a need to modernise traditional command-and-control regulation, as the 1985 New Approach to Technical Harmonisation (which condensed the role of EC regulatory bodies in the field of product harmonisation to the formulation of essential requirements, while the task of detailing technical standards was delegated to private standardisation bodies), and the emergence of cooperation-based legislation, testify. More recently, EC initiatives on legislative and administrative simplification underscore the need for more strategic, coherent and flexible forms of regulation, not in the least in the area of environmental policy.


MICHAEL KLOEPFER & THOMAS ELSNER, o.c., p. 965; JÖRG LEIMBACHER, o.c, p. 123; RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c, p. 60; ANTHONY OGUS (1994), Regulation," o.c, pp. 7, 10.


Cf. HANS-HEINRICH TRUTE, o.c, p. 950.
This criticism has most frequently been voiced in literature on economic instruments for environmental regulation, written by scholars such as Bruce Ackerman, Richard Stewart, Cass Sunstein and, in Europe, David Pearce. The second critique, which was preliminarily explored in Chapter I, is inspired by contemporary developments in law and sociology, in particular the growing body of scholarship pertaining to risk and uncertainty in modern society, and questions the capability of established techniques effectively to regulate complex problems. German authors are well represented in this domain, as evidenced by the writing of, for example, Gerd Winter, Karl-Heinz Ladeur, Christian Koenig and Gotthard Bechmann.

In the following paragraphs, I will sketch the main arguments against command-and-control as developed in these two branches of criticism. It will soon become apparent that, although the language deployed is typical of the different disciplines from which they draw inspiration, the two display remarkable overlaps. Moreover, the explanations sometimes complement each other. Nevertheless, as will be shown below, the second critique implies a more radical level of criticism of the traditional tenets of legal decision-making than the economically-oriented one. Correspondingly, the proposals for reform suggested by critics pertaining to the first group differ substantially from reform proposals that accompany the second line of critique.

2.1. First critique: command-and-control regulation is inefficient

Efficiency-oriented critiques of command-and-control regulation in the first place take issue with the uniformity of standards -- whether technology, emission or, to a lesser extent, product standards -- typical of this style of regulation. Allegedly, the adoption of uniform standards, and their universal enforcement in different industrial facilities and industry branches, results in

615 Cf. GÜNTHER TEUBNER (1993), Law as an Autopoietic System, o.c., p. 73: "[i]n the debate on regulation, 'regulatory failures' are frequently attributed to a 'mismatch' of regulatory instruments (for example, command and control regulation) and the internal logic of the regulatory field (orientation towards economic utility)". See also CASS SUNSTEIN (1991), "Administrative Substance," o.c., p. 627: "[s]ocial regulation is pervaded by strategies that have unanticipated systemic consequences, that deal with the symptoms rather than the causes of social problems, that direct attention to the wrong places, and that are insufficiently sensitive to the pressures that they impose on regulatees and the private sector".
616 See Chapter I, Heading 2.
economic inefficiencies and sub-optimal environmental outcomes. As Richard Stewart (1995) puts it: "[U]niform command and control requirements are economically quite wasteful because they ignore variations among facilities in the cost of reducing pollution, and also ignore geographic variations in pollution results". The reasoning behind this argument is, by now, well-trodden: it will be much more expensive to adhere to, for example, an emission standard for sulphurdioxide for one company than for another, depending among other factors on the industrial activity and the state of technology. In fact, the resources spent by the former company to attain the regulatory pollution standard, might be deployed to greater environmental effect elsewhere. Or, in Stewart's words: "[A] more cost-effective strategy of risk reduction could free enormous resources for additional pollution reduction and other societal purposes". As to geographic variations, the European Community was confronted directly with this argument in the Council negotiations leading up to the adoption of the 1976 Water Pollution Directive, where Britain contended that, because of geographical differences (presence of many estuaries and short, fast-streaming rivers in the UK opposed to long, slow rivers on the continent), a uniform level of emissions would result in a higher tolerance of aquatic pollution in the other Member States than in Britain. Britain therefore argued, successfully as it turned out, for the adoption of environmental quality standards as alternatives to emission standards.

Additional efficiency-based arguments against command-and-control focus on flaws in regulatory practice: following a command-and-control approach, regulatory authorities tend to impose disproportionate burdens on new products and processes, thereby stifling innovation. Although this is not

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617 Cf. GABRIELE BRITZ (1997), "Umweltrecht im Spannungsverhältnis von ökonomischer Effizienz und Verfassungsrecht," Vol. 30, Die Verwaltung, N° 2, p. 187; RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 81. Paul Kirchhof (1988) traces the lack of flexibility and resulting inefficiency back to a strict separation between regulator and regulatee, which is typical of top-bottom approaches such as command-and-control. PAUL KIRCHHOFF, o.c., p. 103.


619 As a rule, it is easier to introduce modifications and improvements in developing technologies than in mature technologies.


622 Britain was the only Member State that opted the quality standards; the others adopted emission standards. See NIGEL HAIGH, o.c., section 4.8-3 to 4.8-6.

an inherent flaw of command-and-control sensu stricto, it is highly conceivable that, in practice, command-and-control does indeed tend to favour the old over the new. A culling technique, for example, can much more easily be applied to new products before they enter the market (through product screening) than to existing products that are already circulating and need to be recalled, or phased out if a complete recall would lead to market disruptions.

A further shortcoming of end-of-the-pipe controls, which frequently are imposed following a command-and-control style of decision-making, is the lack of consistency between hazard and risk decisions taken in different regulatory areas (for instance water policy, waste treatment, air pollution prevention). Furthermore, command-and-control is said to be incompatible with consistent and intelligent regulatory priority-setting. According to Stephen Breyer (1993), regulatory bodies tend to suffer from “tunnel vision,” meaning that they “zoom in” on singled out, substantive problem areas and regulate them to the hilt, long past the point where regulatory expenditures still generate commensurate health and/or environmental benefits. The absence of an overall, strategic and coherent programme with priorities for health and environmental regulation results in haphazard agenda-setting, with agency priorities more closely reflecting “[p]ublic rankings, politics, history or even chance than the kind of priority list that environmental experts would deliberately create”.

A last and interesting argument against command-and-control regulation -- in particular regulation through the imposition of technology-based standards -- is that it is fundamentally undemocratic. Although this argument is not based on efficiency considerations, a number of proponents of a more market-sensitive approach to regulation have incorporated it into their attacks on command-and-control. They argue that, where Best Available Technology is embraced as the overarching objective, health and environmental standards become a function of scientific and technological feasibility, which is in turn determined by experts and regulatory authorities, joining forces in a “remote

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625 Ibid.
626 Ibid., p. 20.
627 STEPHEN BREYER, o.c., pp. 11-29.
bureaucratic process". The highly specialised, technical content of the considerations on which regulatory decision-making is based, renders this process intransparent and inaccessible to public scrutiny.

2.2. Second critique: command-and-control regulation is static

The second critique equally challenges the rigidity of command-and-control regulation, however in identifying regulatory failures it moves beyond efficiency considerations and addresses the general inability of command-and-control to take into account the dynamics of scientific, technological and social change that characterise contemporary society. We recall that the implementation of command-and-control regulation to a large extent hinges on standard-setting (product, emission- and technology-standards) and boundary-drawing. In other words, it involves the creation of stable, uniformly applicable cut-off points that determine the acceptability/unacceptability -- in legal terms, the legality/illegality -- of the products and/or industrial activities under scrutiny. Products that fall foul of the legal/illegal distinction have to be modified or, more likely, taken out of circulation; processes that do not meet the pre-established standards need to be adapted up to the point where they successfully transgress the legal/illegal boundary. In this context, health and environmental standards demarcate the crossing-line between the legal and the illegal.

The above observation implies that, in order to set standards, legislative as well as regulatory authorities need two types of information. First, they should have a general conception of what constitutes an acceptable, and therefore allowable (legal) state of affairs for the purposes of health and environmental protection. This conception is mainly experience-based: it

630 Note, however, that Stephen Breyer, who does challenge current command-and-control approaches for their lack of efficiency and coherence, does not advocate a more democratic form of decision-making, but rather emphasises the need for better technocratic decision-making.
632 Or, in the case of voluntary standard-setting, non-governmental organisations and private entities.
633 Cf. RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 82, relating to the protection of the environmental status quo: "das Prinzip der ökologischen Bestandsschutz (zielt) ersichtlich auf den Schutz des vorgefundenen
rests on knowledge concerning existing technical processes, concerning past industrial accidents, their causes and their effects on health and the environment, on experience relating to the relative tolerance of the population for polluting activities, and on many other factors. Referring to experience, regulatory bodies recreate an approximate picture of "normality"; a relatively stable idea of what a healthy and environmentally sound society should look like.634

The second type of information relates to the product, process of activity for which regulatory action is being contemplated. To evaluate whether, for example, the discharge of industrial by-products into water will disturb or on the contrary fit into the general, experience-based view of "normality" (in other words, whether it constitutes an acceptable or unacceptable intrusion on the aquatic environment), regulatory authorities obviously need to know whether this discharge would affect the health of people and/or the environment.635 Additionally, they need reliable information on the anticipated seriousness of expected health and environmental effects. Finally, they need detailed information on the relation between abatement techniques (for instance, the establishment of a maximum emission level) and the corresponding reduction of strain on the environment.636

The second critique of command-and-control, to which I will hereinafter refer as the "knowledge-based critique," contends that the above-sketched framework for decision-making on which command-and-control regulation relies, is no longer able to come to terms with the challenges posed by scientific and technological innovation, and their subsequent introduction into society. First of all, in areas characterised by rapid scientific and technological development, the information necessary to determine relevant standards often is lacking, and only becomes available after novel approaches, techniques or products have been tried out in practice. In the first Chapter, I gave the example of genetic and biotechnology, two areas where new scientific discoveries can be introduced into society at an extremely high pace, without having to go through
a long stage of conversion into technological processes.637 While genetically engineered vegetables are already produced, and are ready for marketing, a great deal of uncertainty remains, relating to both the potential benefits as well of the risks generated by such products.638 As we have seen in Chapters II and III, the same is true for chemicals. Scientific tests and assessments may provide initial information relating to anticipated health and environmental effects, however in most cases they are anything but conclusive.639 Hence, critics claim, traditional command-and-control regulation is unable to respond to the uncertainties that accompany scientific and technological developments; its binary mode of reasoning -- making determinations of acceptability or unacceptability and adopting regulatory measures for those products, processes or technologies which do not meet the "acceptability threshold" --- does not supply the tools that are necessary to regulate effectively in areas of uncertainty.

Furthermore, the above portrayal of legal decision-making failure is still overly simplistic to the extent that it treats the uncertainties that accompany innovating products and processes as "incidents" or aberrations that -- at least temporarily -- defy determinations of acceptability against a generally recognised backdrop of normality.640 Yet one could argue that rapid scientific and technological change creates uncertainties of a systemic rather than peripheral nature, which not only call into question our ability to measure the acceptability of "new" activities and products, but moreover erode the concept of a reliable reference point, in the form of a generally recognised and understood body of practice, against which individual activities and products are assessed.641

In circumstances of systemic uncertainty, practices of substantive standard-setting and boundary-drawing become random and ineffectual. Additionally, the implementation of traditional command-and-control techniques

637 Chapter I, Heading 2.1. See generally HERIBERT BICKEL, o.c., pp. 169-190.
638 THOMAS P. REDICK, WILLIAM A. REAVY AND DIRK MICHELS (1997), "Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: an Alternative Path within the Biosafety Protocol," Vol. 4, The Environmental Lawyer, N° 1, p. 6: "[G]MOs include plants and animals that are engineered to be resistant to particular herbicides, diseases or insects. The ecological impacts of GMOs are unknown to a large degree, and scientists from various disciplines differ in their views on the potential impacts that GMOs pose to biodiversity". Also ARNO SCHERZBERG, o.c., pp. 486-490.
639 See, e.g., Section II.2.2(b) of Chapter II, and Section II.1 of Chapter III.
640 Cf. FRANZ KOHOUT, o.c., p. 76.
in areas characterised by partial knowledge and incomplete information may engender problems of over- and under-regulation, phenomena to which I alluded in Chapter III.\textsuperscript{642} Under-regulation occurs where novel practices, techniques and products fall outside the established legislative and regulatory scope, and therefore remain unregulated until the risks become manifest, at which point irreversible (and, with the hindsight of knowledge, avoidable) damage may already have been done. Over-regulation, in turn, happens when the absence of conclusive information on the relative safety of a new practice leads to the adoption of restrictive regulatory measures, which may or may not be warranted to abate a generally recognised but thus far underdetermined risk.\textsuperscript{643}

2.3. \textit{Linking diagnoses to prescriptions}

The economic efficiency-oriented and the knowledge-oriented critiques share common characteristics in that they both identify discrepancies between the rationales that drive the legal and regulatory system on the one hand, and those that determine technological, scientific and industrial development on the other. According to efficiency-oriented critics, the problem is mainly one of conflicting normative paradigms: legal rules and regulations -- aimed towards safety, controllability and certainty -- are imposed upon a framework primarily concerned with profit-making and economic growth.\textsuperscript{644} A lack of understanding of, or identification with, the market forces that fuel economic development results in the enactment of rules that are inefficient, wasteful and, according to economic criteria, flawed. Knowledge-based critiques, in turn, emphasise the tensions between (static) legal norms, expressed in a binary code of legal/illegal distinctions, and the complex, dynamic and rapidly changing character of the environment which rules and regulations seek to govern. In other words, whereas efficiency-oriented critics point at a clash between two different sets of norms, knowledge-based criticism centres on a mismatch of norms and facts (or, regulation and environment).\textsuperscript{645}

\begin{footnotesize}
\begin{itemize}
\item Sicherheitsanforderungen\textsuperscript{*} gehe\textsuperscript{*}.
\item \textsuperscript{642} See Section II.2.1 of Chapter III.
\item \textsuperscript{644} KLAUS KÖNIG, o.c., pp. 354-355; DIETER CANSIER, o.c., 642.
\item \textsuperscript{645} See generally GÜNTHER TEUBNER (1993), \textit{Law as an Autopoietic System}, o.c.,
\end{itemize}
\end{footnotesize}
In their analysis of regulatory failures and weaknesses resulting from the perceived conflicts or mismatches, there is again some overlap between efficiency- and knowledge-based critiques. Both hold that strict adherence to command-and-control techniques exacerbates problems of random agenda-setting, lack of consistency and overall planning in health and environmental policy development, and insufficient flexibility of regulatory measures. Furthermore, efficiency- and knowledge-based critics agree that command-and-control obstructs innovation, either because of the imposition of overly stringent rules or because of the complete absence of regulation to give a context to new developments. Correspondingly, reform proposals derived from either the efficiency-based or knowledge-based critique, are compatible to the extent that they seek to promote added flexibility and regulatory coherence, as well as the stimulation of innovation.646

However, the different takes on the underlying causes of inadequate regulation (inefficiency or complexity) are reflected in different opinions on how to implement regulatory reform. Efficiency-oriented critics will favour reforms that leave a greater scope for decision-making on the basis of economic considerations, for example, through the introduction of cost-benefit standards for health and environmental regulation, through deregulation, the adoption of economic instruments (see below) and devolution of decision-making to economic rather than regulatory actors.647 It is their belief that, within a generally defined context of health and environmental protection goals, private parties operating according to market principles are often able to manage hazards and risks in a better, a more efficient way than regulatory authorities.

Knowledge-based critics, in turn, would question whether the mere redistribution of decision-making power to private entities is sufficient to correct regulatory failures, since private entities are just as much encumbered by uncertainties and complexity as public authorities. Economic instruments do little to manage or narrow knowledge gaps pertaining to health and environmental risks; similar to command-and-control regulation, they remain beholden to the presumption of availability of sufficient information and experience on which to base decision-making. In contrast, reform proposals flowing from the second strand of critique start from the assumption of

646 MICHAEL KLOEPFER, o.c., p. 1125.
647 Cf. KLAUS KÖNIG, o.c., p. 350; GÜNTER TEUBNER, o.c., p. 105.
incomplete information and partial knowledge, and aim to modernise (rather than downscale) the regulatory framework so that these conditions no longer obstruct, or even paralyse, decision-making. To this end, they seek to strengthen the self-learning capacities of law and regulation, to facilitate and structure decision-making under conditions of uncertainty through the introduction of procedural instead of substantive requirements and standards, and to create room for both experimentation with different control and management measures and ex-post correction of previously made rules and decisions ("Nachbesserung").

With regard to the involvement of third parties in decision-making processes, the knowledge-based critique stresses information exchange and cooperation rather than delegation of competencies.

Clearly, regulatory reform along either efficiency-oriented or knowledge-based lines entails a reconceptualisation of regulatory decision-making and administrative practice. However, whereas economic efficiency-driven reforms as a rule relegate regulation and administration to the backseat in favour of market mechanisms, regulatory and administrative bodies operating in a framework that has been attuned to the exigencies of uncertainty and complexity would have different, but no less demanding and essential responsibilities than those implementing command-and-control regulation. In fact, considering the need for flexible problem-solving, experimentation and ex-post correction, their responsibilities and decision-making authority might be boosted instead of curtailed.

3. Health and Environmental Regulation Reform Proposals

In the sections below, I will take a look at some of the reform proposals that were launched during the past decade, and that seek to improve, complement or supplant the traditional command-and-control regime. The first collection of proposals is aimed primarily at improving risk decision-making performed by regulatory and administrative bodies, whereas the second, third and fourth are geared towards devolution of decision-making capacity to alternative social actors (the public, industry).

Following an overview of each

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648 Chapter I, Heading 3.4(c).
649 RAINER WOLF (1996), "Der ökologische Rechtsstaat," o.c., p. 84. Cf. MARIUS AALDERS, o.c., passim.
650 Note that the first group of proposals equally contains some forms of "mixed" decision-making (deliberative and informal or cooperative decision-making). However,
reform proposal, I will briefly discuss whether and how suggested reforms respond to the different kinds of criticism levied against command-and-control regulation.

3.1. Improving regulatory and administrative decision-making

In recent years, a number of suggestions have been made for institutional and procedural changes in order better to equip regulatory and administrative bodies in risk decision-making. For instance, in "Breaking the Vicious Circle," US Supreme Court Justice Stephen Breyer's seminal work on risk regulatory reform (1993), the author makes an ardent plea for better educated, thoroughly trained and more knowledgeable administrators.651 Convinced that many of the failings of contemporary risk regulation (such as random agenda-setting, inconsistency of risk management decisions taken by different regulatory agencies, and disequilibria between the cost of regulation and resulting health and environmental improvements)652 can be traced back to institutional shortcomings within the regulatory apparatus, he argues for the creation of a centralised administration group, composed of the cream of the crop of experienced civil servants and gathering under its wings a high level of scientific and technological expertise.653 This administrative elite could monitor and assess the quality of risk management decisions made by regulatory agencies, and further decision-making through the elaboration of uniform assumptions and high quality risk analysis models.654 Moreover, the centralised group might strengthen coordination by creating an overall risk agenda that "[h]elps to prioritize different programs, and different activities within programs, and that looks for tradeoffs among programs that will lead overall to improved health or albeit of a mixed nature, such decisions are still forged within the institutional framework of regulation and administration, which is not the case for the reforms discussed under sections 3.2, 3.3, and 3.4.

651 STEPHEN BREYER, o.c., pp. 59-79.
652 Ibid., pp. 10-29.
653 Similar reforms are considered in Europe. In 1995, the United Kingdom consolidated the former functions of the National Rivers Authority and Her Majesty's Inspectorate of Pollution, as well as responsibilities which were previously assumed by local authorities or the Department of the Environment, in one Environment Agency for England and Wales. Through this consolidation, the UK hopes to achieve a higher level of efficiency, less duplication and greater consistency of approach across all pollution types and environmental media. WILLIAM HOWARTIIH, o.c., pp. 201-202.
654 STEPHEN BREYER, o.c., pp. 65-66.
Breyer’s suggestions for institutional reform, in particular the establishment of a centralised expert group of administrators roughly formatted along the lines of the French Conseil d’Etat, have run the gamut from praise to contempt in academic, administrative and industrial circles. While many agree with the need for an overarching, coordinating mechanism for different areas of risk regulation, opponents take issue with the elitist, technocratic nature of Breyer’s “administrative superpower.” Furthermore, Breyer’s emphasis on the importance of scientific expertise in decision-making gives rise to some of the same objections as encountered in Chapter III relating to scientific risk assessment. Finally, in light of the knowledge-based critique explored above, and particularly taking into account the enormous complexity of health and environmental problems which confront us today, one might question whether it is in any event feasible for one centralised institution to come to terms with the overwhelming diversity of information, to grapple with unavoidable knowledge gaps and come up trumps with coherent, rational and cross-agency risk regulation policy lines. Perhaps it is simply too much to ask.

As an alternative to Breyer’s administrative elite, authors such as Henning Friege (1987) and Harald Schäfer (1987) propose to make regulatory and administrative decision-making processes more deliberative, ensuring participation by administrators, scientific experts and different interest groups. Yet proposals for deliberative (or representative) risk decision-making, desirable as they may be from a legitimacy point of view, might be difficult to reconcile with the objectives of coherence as well as flexibility. There might be little scope for public authorities, acting on their own or in concert with regulated parties, to experiment with different risk control techniques if their

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655 Ibid., p. 67.
656 See generally DAVID A. WIRTH & ELLEN K. SILBERGELD, o.c., pp. 1857-1895; ADAM M. FINKEL, o.c., pp. 295-381.
658 See Section II, headings 2.2, 3 and 4 of Chapter III.
660 However, for a more optimistic view on the level of expertise in regulatory circles, see PAUL KIRCHHOF, o.c., p. 100.
adoption depends on the consent of a variety of interest groups representing a range of conflicting interests. To avoid regulatory paralysis, systems where participation takes the shape of public consultation, such as the framework laid down in the Swedish Environmental Protection Law, might be preferable to those where regulatory action hinges on co-determination. However, as Bo Carlsson’s study of regulatory decision-making in Sweden (1995) suggests, public concerns may be dismissed all too easily by regulatory authorities when weighed against countervailing scientific arguments and economic considerations. In light of the foregoing, it would perhaps be more fruitful to integrate multiple viewpoints and interests at an earlier stage in the decision-making chain, for example during the stage of risk assessment, as suggested in the last part of Chapter III.

In his description of the tasks which the centralised administrative expert group would undertake, Breyer hints at the development of (more or less formalised) procedural standards for regulatory decision-making, as well as the development of overarching agendas and priority lists for risk regulation. Of a somewhat less controversial nature than institutional reform proposals, ideas for the development of procedural guarantees for regulatory and administrative decision-making have been well received and explored in the literature and actual proposals on regulatory reform. First, there is undeniably a move towards greater transparency in decision-making: regulatory and, increasingly, administrative authorities are required to reveal, to lay open the process that led to the adoption of a rule or regulation, to expound on the rationale underlying decision-making and to allow public disclosure of this information.


Ibid., pp. 484-489.


STEPHEN BREYER, o.c., p. 67.

CAROL HARLOW, o.c., pp. 3-6; SUSAN ROSE-ACKERMAN (1994), “Environmental Policymaking,” o.c., p. 36; KLAUS KÖNIG, o.c., p. 351.

Parallel to the requirement that regulators and administrators lay open decision-making processes, there is a growing expectation that these bodies will rely on generally identified and validated types of information and decision-making methodologies to guide them in the adoption of rules and regulations. I have previously mentioned the requirement, laid down in Article 130R of the EC Treaty, that in preparing its environmental policy, the Community shall take account of available scientific and technical data. In the area of chemicals control, this provision has been specified further through the introduction of EC risk assessment legislation (see Chapter III and below), which -- in principle at least -- conditions the adoption of chemicals risk reduction measures on the integration of risk assessment information in regulatory decision-making. Yet another methodology aimed to improve the effectiveness and efficiency of regulatory and administrative action is cost-benefit analysis, which is equally listed in Article 130R as one of the parameters to take into account in the preparation of Community environmental policy. In risk regulatory terms, the application of cost-benefit analysis is generally understood to mean that regulatory intervention is appropriate only where the improvements (or prevention of deterioration) to health and/or the environment are proportionate to the costs of regulation. While most people agree that some balance should

European Court of Justice, the Court annulled a scantily reasoned Commission decision, thereby sending an implicit but undeniable message to the Commission that it should better structure and document its decision-making process. C-41/93, France v Commission, [1994], ECR, 1-1829. See Section II.3.1 of this Chapter. Interestingly, Carol Harlow warns against the dangers of transparency and the procedural rights which the public may infer from it. CAROL HARLOW, o.c., pp. 18-19: "[M]ore recently, the area of administrative discretion has been eroded by requirements of transparency; for instance, the formulation of reasons and open expression of policies as rules, a dangerous process which may create entitlements in the shape of 'legitimate expectations,' whether substantive or of legal process, is not yet clear. Rule-making procedures, previously relatively exempt, have also begun to be formalised. Transparency has led to demands for formal rights of consultation and participation, strongly protected in the United States by a jurisprudence built on the American Administrative Procedures Act. The lesson from America is, however, that the interface between these supposedly separate areas of administrative activity is highly problematic, creating a substantial cost in litigation and delay."

669 Article 174 ToA.


671 Article 130R of the EC Treaty (Article 174 ToA): "[I]n preparing its policy on the environment, the Community shall take account of: (...) the potential benefits and costs of action or lack of action (...)"

672 CASS SUNSTEIN (1996), "Health-Health," o.c., p. 1534; W. KIP VISCUSI (1996),
exist between the expenditures of regulation and its impact in terms of health and/or environmental gains, virtually no one fully agrees on where to draw the line. In other words, it is extremely difficult to create a consensus on the "worth" of human life and the environment, which is necessary as a counterweight to the costs of regulation. In order to bypass such extremely complex and contentious calibrations, recent reform proposals have introduced new, more sophisticated risk decision techniques, which are essentially modifications of cost-benefit analysis but can usually be achieved without requiring the odious conversion of human and environmental resources into monetary units. For example, the health-health tradeoffs proposed by Cass Sunstein (1996) compare the number of lives saved by following one regulatory option with lives saved under alternative regulatory schemes. Other decision-making mechanisms, described by W. Kip Viscusi (1996), include cost-effectiveness analysis (a weaker version of cost-benefit which only requires a showing that, in order to reach the set health or environmental goal, the least costly option has been chosen) and comparative risk assessment.

The above-described standards for regulatory and administrative decision-making may certainly contribute to the objectives of increased efficiency, consistency and coherence formulated by the efficiency-based critique. They furthermore evidence a more proceduralised approach to decision-making, since the emphasis shifts from the substantive content of decisions ("what is decided?") to the methodologies and processes deployed to...
reach plausible decisions ("how are decisions made?"). However, deployment of scientific data and methodologies such as cost-benefit analysis and comparative risk assessment is conditioned upon the availability of sufficient information pertaining to the risks to be regulated. These standards therefore do not address the main concern voiced by the knowledge-based critique, which revolves around problems of uncertainty.

According to the knowledge-based critique, regulation would be better equipped to contend with problems of uncertainty if it incorporated elements of planning and flexibility, and operated following a procedural rather than substantive rationale. Planning, we recall from Chapter I, aims to infuse some strategy into decision-making, so that the limited resources and information available are put to the best possible use, and directed towards the most pressing problems. The EC Directive on environmental impact assessment (EIA) is a good example of this brand of strategic, planning-oriented legislation: pursuant to the Directive, research into the environmental ramifications of new installations becomes part of industrial policy and developmental planning. The information produced through this kind of research not only gives regulatory bodies, industrial planners, developers and third parties an insight into potential risk areas; it can also enable the development of a range of monitoring and control options which may be included in subsequent licenses and authorisations, options that might not have been available had the environmental risks been discovered only after the installation or enterprise became operational. Priority-setting (for existing substances) is another example of a measure encouraging strategic decision-making. Priority lists constitute long-term agendas for planned further research and the gradual introduction of control measures pertaining to selected substances (selected on the basis of admittedly incomplete information), thereby transcending the level of on-the-spot crisis management.

To imbue the regulatory framework with sufficient flexibility, proposals have been launched to "temporalise" law, meaning that law should stimulate in-built opportunities for review and correction, and to create room for regulatory

677 Chapter I, Heading 3.4(d).
678 Cf. Latin's remark at fn. 673.
681 See Section II.3 of Chapter II.
experimentation and open-endedness. Exemplifying the latter, I refer to the brief discussion on the procedure set up to solve intra-EC disputes concerning requests for additional information pursuant to notification of new substances. The discussion addressed the concern that the relatively heavy and slow Commission procedure, designed to adjudicate disagreements between competent authorities of different Member States, might constitute a deterrent for these authorities to ask additional information in the first place. The analysis ventured that perhaps the absence of this fixed but cumbersome “last resort” might have prodded national authorities to look for less formalised and more adaptable and manageable problem-solving techniques, which would ultimately result in superior information production and exchange mechanisms.

The concepts of precaution, planning and self-learning through legislation have opened up extremely interesting perspectives for the future of health and environmental law. Yet, while they are undoubtedly worthy of further exploration, it is necessary to realise that their introduction in legal and regulatory practice will require considerable effort and will entail complex legal and practical challenges. First, the development of a legal framework that incorporates elements of long term planning necessitates a serious exercise in premeditation and coordination. At the same time, it has to avoid adopting a comprehensive rationality, and retain sufficient flexibility for experimentation and correction. These are by no means easy tasks for the already heavily burdened legal, regulatory and administrative apparatus. Furthermore, the “temporalisation of law,” implemented through the introduction of review opportunities, ex-post correction and temporary authorisations, may well clash with established legal principles of legal certainty and legitimate expectations. In this context, Rainer Wolf (1996) points out that “[t]he more the learning capacity of law is strengthened through mechanisms of review and correction ("Nachfassen und Nachbessern"), the stronger becomes the tension with legal certainty, which may be perceived as a guarantee for “not-having-to-learn”.”

The reconciliation of flexibility with legal certainty, which may require the reformulation of either (or even both) of these concepts, therefore presents itself as one of the most pressing issues confronting contemporary health and environmental law.

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682 See Section II.2.1 of Chapter II.
683 Ibid., translation from German text.
684 See Section 1.1 of Chapter V.
3.2. Information as a management tool

Instead of trying to improve the way in which regulators and bureaucrats conduct and implement risk management, one might consider taking decision-making responsibilities away from public authorities and allocating them to entities that are perceived as more rational, more open to innovation, or more efficient. Each of the following proposals implies a shift in risk management decision-making power.

As a first option, one might try to bypass regulatory decision-making through a direct transfer of responsibility to the parties which health and environmental regulation traditionally seeks to protect: the public, consumers, workers, etc. Members of the public, whether individually or organised in interest groups (the latter will probably prove more effective), might exert immediate pressure -- using either a voice or exit strategy -- on those parties the activities of which are deemed too risky, to cease such activities or modify their behaviour. To fulfil this role, however, the public clearly needs information on the health and environmental risks to which they are exposed, as well as on the parties who create and benefit from these risks. Hence, access to health and environmental information functions as a regulatory tool in that it raises public awareness, informs and thereby enables public action against health threatening and environmentally polluting activities.

The European Community's awareness of the regulatory relevance of information was confirmed most resoundingly by the adoption of the 1990 Directive on public access to environmental information. Even earlier, the 1985 Environmental Impact Assessment Directive stipulated that information


687 McLoughlin & Bellinger, o.c., p. 31 & p. 136.


relating to requests for development consent and the actual impact assessment must be made available to the public, which moreover must be given an opportunity to express its opinion on the project concerned. Furthermore, EC workers' health and safety legislation views adequate information to workers on the risks to which they may be exposed, and on precautions to take in order to avoid or diminish these risks, as an essential building block in any risk prevention and reduction policy on the work site. Framework Directive 89/391/EEC established as a general principle that employers have to supply workers with information and training on the safety and health risks they are likely to be exposed to, and on the appropriate protective measures. Additionally, workers (or workers' representatives with specific functions in protecting the health and safety of their colleagues) should have access to reports on risk assessment drawn up or commissioned by the employer, to lists and reports on occupational accidents, and to information supplied by inspection bodies and agencies (for more information, see below at Section II.1.2). Finally, eco-labels and risk- and safety-labels (for instance, the obligatory labelling on dangerous preparations and biocides) inform consumers about the health risks and environmental (un)friendliness of consumer products. Shoppers are thus able to make an informed choice as to which products to purchase, thereby sending signals to manufacturers indicating, for instance, a greater demand for "green" washing powders.

Supply of health, safety and environmental information as a risk management strategy offers a number of advantages. To the extent that informed consumers, workers, interest groups and neighbours of polluting facilities take their fate in their own hands and act upon the information provided -- for instance by exerting public pressure, refusing to buy environmentally unfriendly products or, if necessary, undertaking legal action to enforce their rights to health and a clean environment -- the strategy is self-

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693 In countries such as Germany and The Netherlands, the right to a clean environment has been elevated to constitutional status. VEERLE HEYVAERT (1998), "Access," o.c., p.
implementing; its success does not depend on the existence of a heavy set of rules and by-laws or on the vigilance of public authorities.\textsuperscript{694} It also responds to the previously mentioned allegations that regulatory decision-making is overly centralised, undemocratic and elitist, since it hands risk decision-making back to the public rather than letting it depend on judgements made by bureaucrats, scientists and technological experts.\textsuperscript{695} Moreover, certain authors claim that enhanced risk communication would help to bridge the gap between laymen and experts with regard to the perception of risks: according to this view, an educated public would make risk estimations that are closer to expert risk evaluations.\textsuperscript{696} This approximation of lay and expert opinions would result in a greater acceptance of regulatory decision-making.\textsuperscript{697} Thus, information supply and decision-making by public authorities would not only be complementary, but even mutually reinforcing risk management strategies.\textsuperscript{698}

On the other hand, risk management through information supply has its limitations. Collective action problems, excessive transaction costs and geographic diffusion of interests can thwart even the best-informed and -intentioned communities. It is furthermore questionable whether public pressure, revealed consumer preferences and the threat of private litigation would in any event be sufficient to keep polluting industries in check and guarantee an acceptably high level of health and environmental protection. Also, information is a capricious commodity; it is difficult to predict how it will be received or how much information should be supplied to reach maximal effect.\textsuperscript{699}

\textsuperscript{56. Cf. LEIGH HANCHER, o.c., p. 13, on the juridification of risk assessment and management.}
\textsuperscript{694}McLOUGHLIN & BELLINGER, o.c., p. 31 & 136.
\textsuperscript{695}PAULETTE L. STENZEL, o.c., p. 508.
\textsuperscript{696}GOTTHARD BECHMANN (1993), Risiko und Gesellschaft, Westdeutcher Verlag, pp. 257-259.
\textsuperscript{697}CHRISTIAN KOENIG (1994), "Internalisierung des Risikomanagements durch neues Umwelt- und Technikrecht?" Neue Zeitschrift für Verwaltungsrecht, p. 941.
\textsuperscript{698} The argument implicitly accepts the assumption that there is such a thing as an "actual" risk, which can only be measured by experts and is juxtaposed to lay "perceptions" of risk. If only the public were fully informed and educated, it would realise that its perception of risk is flawed and embrace "actual" risk evaluations performed by experts. The validity of this assumption has been challenged by authors such as Kristin Schrader-Frechette and, more strongly, Ulrich Beck. See KRISTIN SCHRADER-FRECHETTE (1991), Risk and Rationality, o.c., pp. 78-79, 83, 95-98; ULRICH BECK (1993), "Politische Wissenstheorie," o.c., p. 306: "[D]ie Nichtakzeptanz wissenschaftlicher Risikodefinition ist nicht etwas, was man der Bevölkerung als "Irrationalität" vorhalten könnte, sodem verweist genau umgekehrt darauf, daß die kulturellen Akzeptanzprämisse, die in technisch-wissenschaftlichen Risikoaussagen enthalten sind, falsch sind."
\textsuperscript{699} JOSEE VAN EIJNDHOVEN, ROB WETERINGS, COR WORRELL, JOOP DE BOER, JOOP VAN DER PLIGT & PIETER-JAN STALLEN (1994), "Risk Communication in The
The value-added of more information apparently has a ceiling: on labels, for example, too much information might deter consumers from reading any.\textsuperscript{700} Moreover, even if consumers had an unlimited capacity for information-processing, there still are certain product characteristics that can only be revealed through consumption and use, and that therefore cannot be indicated or summarised on even the most extensive label.\textsuperscript{701}

Practical limitations aside, risk management through information supply does not resolve all the ailments from which command-and-control was said to suffer. Different interest groups are just as capable of making inconsistent and incompatible risk management choices as different ministerial departments. In fact, the lack of central planning and intelligent across-the-board priority setting would become even more pressing if risk management were completely handed back to the public. Additionally, risk management through public voice and exit strategies would not necessarily result in more efficient outcomes. On the contrary, certain areas monitored by well-organised and assertive interest groups might be subjected to excessive health or environmental standards, whereas others that speak less to the public's imagination, or that predominantly affect the less affluent members of society, could be neglected.

In conclusion, risk management might certainly benefit from a sustained and, where required, improved supply of risk-related information to the public. However, as a management tool it appears in itself insufficient to reach and maintain the high levels of health and environmental protection which modern states, and the European Community (see Article 130r of the EC Treaty),\textsuperscript{702} seek to attain.\textsuperscript{703}

\textsuperscript{700}Not surprisingly, this shortcoming was emphasised by, \textit{inter alia}, Stephen Breyer, who favours improved regulatory decision-making over redistribution of decision-making powers. See STEPHEN BREYER, o.c., p. 56. Cf. HOWARD LATIN, o.c., pp. 224-226. \textsuperscript{701}PETER CARTWRIGHT (1995), "Product Safety and Consumer Protection," Vol. 58, \textit{Modern Law Review}, N° 2, p. 225. \textsuperscript{702}Article 174 ToA. \textsuperscript{703}Cf. PAULETTE L. STENZEL, o.c., p. 510: "[P]roviding the public with information about risks involved in the use of a product is not a substitute for government regulation. Rather, risk communication can serve as an important supplement to regulation (...)"
3.3. *Economic instruments: a combination of democratic determination and market allocation*

Probably the most popular and certainly the most discussed of the new ideas for health and environmental regulation is the incentive-based regulatory strategy, which advocates a flexible and market-oriented approach to risk management.704 As indicated above, economic instruments most directly aim to respond to efficiency-oriented critiques of command-and-control regulation. Numerous manuscripts have been written on economic instruments, such as tradeable permits and pollution taxes, explaining their underlying philosophy, their contributions to regulatory theory and practice, and their implementation.705 Succinctly put, economic instruments aim to improve (or maintain) a high level of health and, primarily, environmental quality by giving polluters a stake in this objective.706 As a rule, the stake consists of the financial rewards attached to the sale of pollution permits by companies which have "cleaned up" their technologies and therefore no longer need such permit, or of lower tax payments.

From a risk decision-making point of view, incentive-based regulation involves a multi-layered division of decisional responsibility. The "big issues" (i.e., how much pollution should generally be allowed; what overall level of health and environmental quality should be attained; the level of pollution taxes to be levied), so the most prominent authors in the field propose, should be settled democratically, through parliamentary decision-making.707 Cass Sunstein (1991), for one, asserts that it is much more feasible for the public, and Parliament, to form a conception of the general level of protection they want, than to grapple with the technical details and specifications that characterise, for instance, technology-based approaches.708 By giving Parliament the final say in the overall acceptable level of pollution, economic instruments purport to be

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704 CASS SUNSTEIN, "Administrative Substance," o.c, p. 633.
706 Cf. JÖRG LEMBACHER, o.c, p.125.
more democratic than command-and-control regulation.

Once health and environmental goals are agreed upon, it is left to administrators to draw up, issue and auction pollution permits, or, alternatively, to adapt or introduce new ecological taxes in order to reach the generally decided taxation level. Possibly, there is also a role for administrators in prioritising industrial activities for which marketable permits should be made available. However, technical, micro-level decisions on which technology to implement, or how much waste to produce, are no longer made within the walls of public offices, but are taken by the polluting industries themselves. They decide, for example, whether it is economically advantageous to upgrade their technology in order not to exceed the pollution levels specified in their pollution permits, or to pay more taxes, or alternatively whether the option of radically changing their production processes and selling off pollution permits to companies with less innovation opportunities is most attractive. Thus, as long as the democratically determined goals are met, enterprises are free to select the most appropriate means.

In this framework, the role of public authorities and administration is of a facilitating and advisory rather than regulatory nature.\textsuperscript{709} Caught between the general decision-making level, which is played out in Parliament, and applied risk management choices, made by industry, their task is to connect the two levels of decision-making by devising and maintaining a regulatory framework that creates scope for economic incentives and diversity in implementation, to offer advice and information to regulated parties, and to monitor whether industrial options taken pursuant to economic incentives are capable of meeting the objectives for health, safety and environmental protection set out by Parliament.\textsuperscript{710}

\textsuperscript{709} Cf. WILLIAM HOWARTH, o.c., p. 206.

\textsuperscript{710} The tradeable permit-system offers a clear illustration of the facilitating function of public authorities in the implementation of economic instruments. Tradeable permits confer pollution rights, and may be purchased and sold by industrial enterprises according to their "pollution needs." Parliament decides on a generally permissible level of pollution (which should ideally be gradually reduced) and confers to regulatory bodies the task of issuing and selling a commensurate number of pollution permits. When companies wish to trade pollution permits, this happens through the mediation and under supervision of the competent regulatory authority. Cf. NATHALIE BOUCQUEY (1994), "Hot Spots," o.c., p. 49. In addition, regulatory bodies retain the duty, which was also theirs under command-and-control schemes, to control whether enterprises are not overstepping their pollution rights. Thus, regulatory authorities assume the roles of auctioneer, mediator, supervisor and controller of the implementation of management decisions taken by industry in compliance with publicly promulgated health and environmental targets.
Economic instruments boast greater efficiency than command-and-control regulation because they afford industry sufficient flexibility to implement environmental objectives in the most cost-effective way. Furthermore, incentive-based approaches are said to spur innovation since, by achieving continuing reductions in pollution and/or waste, companies are able to increase their profits (by paying less taxes or selling permits). Moreover, one could argue that by relieving regulatory bodies of the time-consuming and technically demanding tasks of deciding on emission limits and prescribing technology-based solutions, they will better be able to perform coordinating, planning and priority-setting tasks. Finally, the greater democratic virtues of incentive-based regulation have already been brought to attention.

Undoubtedly, economic instruments offer many opportunities to improve or complement traditional risk regulation. The increased flexibility offered by incentive-based regulation may result in risk management that is more dynamic and adaptable to changing circumstances, knowledge and experience. However, in areas characterised by scientific uncertainty, economic instruments might be less appropriate. A trading system for pollution rights, for instance, presupposes that information on polluting substances, activities, processes and/or products is abundant, available and reliable. If not, companies would not be able to assess how many "units" of pollution rights they needed to purchase. However, as we have seen in the case of chemical substances, such information might be scarce, and knowledge on polluting effects of the release of chemicals into the environmental is usually incomplete. The system of tradeable "risk rights" for chemicals and pesticides, proposed by Bruce Ackerman and Richard Stewart (1986), would appear only to function for chemicals and pesticides the health and environmental effects of which are reasonably well-studied and understood. For those substances that are still hidden in the mists of uncertainty, however, the approach offers no ready solutions.

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712In the same vein, see CASS SUNSTEIN (1991), "Administrative Substance," o.c., p. 633: "[A] focus on ultimate ends also promotes coordination and rationality in regulation, by giving government an incentive to attend to appropriate risk levels in different areas, and by bringing a salutary measure of structure and sense to risk regulation."
713BRADFORD C. MANK, o.c., p. 313.
714Ibid., p. 298.
715BRUCE A. ACKERMAN & RICHARD B. STEWART, o.c., p. 1349.
3.4. Internalised risk management

The fourth approach has in common with the previous one that it delegates micro-decisions on how to implement risk management in practice to industry. However, instead of emphasising the economic perks that should persuade polluting enterprises to adopt a more environmentally friendly and healthy behaviour, this approach stresses self-responsibility of industry in the pursuit of health and a clean environment. Thus, the fourth approach starts with a conception of industry as an active, responsible institution with a capacity for self-regulation, rather than one that merely reacts, whether to coercive rules (command-and-control) or economic signals (client or consumer behaviour, and economic instruments). As in the case of economic instruments, internalised risk management systems place greater emphasis on regulatory bodies' facilitating and mediating responsibilities than on the individualised promulgation of environmental rules and regulations. In recent German literature, the tasks of regulators and their contribution to internalised risk approaches have been defined as “context-steering.”

To clarify the concept of internalised risk management, it is perhaps easiest to give an example of a legal instrument that aims to encourage industry to introduce self-regulatory and -monitoring structures within its own enterprises: the European Community's eco-management and -audit (EMAS) Regulation. The EMAS Regulation invites companies to register one or more

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718 TERENCE DAINTITH (1995), "European Community Law and the Redistribution of Regulatory Power in the United Kingdom," Vol. 1, European Law Journal, N° 2. p. 150; JOZEF FALKE, o.c., p. 69. An industrial facility can also derive competitive advantages from adhering to an internalised risk management system (such as positive image-building, greater willingness of suppliers and insurance companies to enter into contract with the enterprise, etc), however these are of an indirect nature, as opposed to the direct economic advantages of paying lower taxes or selling pollution permits. Cf. MATTHIAS PREUSS-SCHMIDT, o.c., p. 186.
719 ibid., p. 185: "[K]ontextsteuerung." Also HANS-JOACHIM KOCH, o.c., p. 218.
720 Council Regulation (EEC) N° 1836/93 of 29 June 1993 allowing voluntary participation by companies in the industrial sector in a Community eco-management and audit-scheme, OJ L 168/1 (1993). The EMAS Regulation is an example of internalised risk management for environmental purposes. However, attempts have equally been undertaken to introduce internalised approaches in the area of health and...
of their sites in a Community eco-management and audit scheme, with the objective of reaching environmental standards that go above and beyond the regulatory threshold.\textsuperscript{721} The first important aspect to note about the EMAS Regulation is that it is voluntary; companies located within the EC are not forced to participate in the scheme.\textsuperscript{722} For those wishing to take part, the Regulation outlines general directives and procedures, rather than substantive rules, which should be adopted by the respective companies.

As to general directives, EMAS aims to improve the environmental performance of industrial companies by the following means: (1) the establishment and implementation of environmental policies, programmes and management systems by participating companies, in relation to their site; (2) the systematic, objective and periodic evaluation of the systems' performance; and (3) the provision of information on environmental performance to the public (Article 1 of the EMAS Regulation). A company participating in the EC EMAS scheme needs to complete a number of steps. First, the company has to adopt an environmental policy.\textsuperscript{723} The Regulation stipulates that such policy must be aimed at improving the environmental performance of the company beyond the levels specified by law, taking into account the BATNEEC standard.\textsuperscript{724} Within these constraints, however, the company is free to determine the actual content of the policy. Subsequently, the company must conduct an initial review of the site to be registered in order to assess the environmental performance of the company as it stands (Article 3(b) of the Regulation). This initial review covers a wide range of activities having a potential effect on the environment, and includes issues of production, design, selection of raw materials and energy safety protection, for example, in the UK Health and Safety at Work etc. Act of 1974. See TERENCE DAINTITH, o.c., p. 69 etc.

\textsuperscript{721} Recently, the Commission finalised a Proposal to extend the scope of EMAS to include non-industrial organisations, such as firms and public and private institutions. See Proposal for a Council Regulation (EC) allowing voluntary participation by organisations in a Community eco-management and audit scheme, OJ C 400/7 (1998).

\textsuperscript{722} At the time of adoption of the 1993 Regulation, there was talk of making EMAS compulsory. However, the results of the first revision indicate that the voluntary approach will be maintained in the foreseeable future. In fact, the preamble of the 1998 Commission Proposal reaffirms that "[o]rganisations should be encouraged to participate in EMAS on a voluntary basis." Cf. JUAN XIBERTA (1994), "The Eco-Management and Audit Scheme," \textit{European Environmental Law Review}, March issue, p. 87.

\textsuperscript{723} Article 3(a) of the EMAS Regulation.

\textsuperscript{724} JUAN XIBERTA, o.c., p. 87; DIETER SELLNER & JÖRN SCHNUTENHAUS (1993), "Umweltmanagement und Umweltbetriebsprüfung ('Umwelt-Audit') - ein wirksames, nicht ordnungsrechtliches System des betrieblichen Umweltschutzes?" \textit{Neue Zeitschrift für Verwaltungsrecht}, N° 10, p. 930.
sources as well as transport, processing and emission of harmful substances.\textsuperscript{725} Thus, the review lays the foundations for a cradle-to-grave approach to environmental management.\textsuperscript{726} The third step consists of the implementation of the company's environmental policy through the introduction of an environmental programme for the site, together with an environmental management system applicable to all the activities of the site (Article 3(c) of the Regulation). Again, the programme as well as the management system are developed by the company itself. Step four is the actual eco-audit, which checks the environmental performance of the company against the objectives to which it is committed (Article 3(d)). For each site audited, an environmental statement must be prepared (step five).\textsuperscript{727}

All steps described thus far take place within the company. They constitute the core of internalised risk management. To control whether companies with registered sites have properly implemented the prescribed procedures, the Regulation furthermore requires an external verification of each step of the internal procedure, and a validation of the environmental statement by an accredited body of independent verifiers (step six).\textsuperscript{728} Validated environmental statements are to be submitted to the competent authority, and disseminated "as appropriate" to the public (step seven).

Internalised management's greatest contribution to risk management lies in the added flexibility it allows. Compared to command-and-control regulation, it leaves industrial undertakings a broader range of choice on how to achieve environmental improvements, which fosters cost-efficiency and diminishes the risk of incompatible or self-defeating requirements. Moreover, internalised management does not appear to have the potential detrimental effects on technical and/or scientific innovations that frequently accompany the gradual tightening up of limit values and BATNEEC standards in command-and-control regulation.

Furthermore, internalised risk management is the most educational of the discussed approaches, at least from the point of view of industry. Whereas economic instruments raise environmental consciousness to the extent that they are financially attractive, self-regulating approaches might go beyond immediate

\textsuperscript{726}JUAN XIBERTA, o.a, p. 87.
\textsuperscript{727}Article 3(f).
cost-benefit considerations, and ideally result in the development of management patterns that systematically take into account health and environmental issues. The potential for flexibility coupled with systematic self-observation, self-learning and correction ("Beistürung") inherent in internalised risk management creates a window of opportunity for integrating partial knowledge and uncertainty into health and environmental policies.

On the other hand, one might wonder whether this positive, responsible and active portrayal of industry is not overly optimistic, or even downright naive. Having been made responsible for the development of health and environmental programmes, can we really trust industry, the traditional "enemy" of green values, to incorporate objectives that, in certain instances, might force it to forego economic profits in the public interest? Undisputedly, industry's awareness of health and environmental concerns has increased, and the willingness of certain companies to participate in voluntary programmes, such as the "Responsible Care" programme for the chemical industry, demonstrates an eagerness to shed the image of industry as a ruthless, strictly profit-oriented institution in favour of a more nuanced picture of industry as a profit-seeking yet responsible enterprise. And yet, it is significant that this awareness came.

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729 See, for example, the observations in the Report of the Robens Committee (1970-1972) on the system of health and safety regulation in the United Kingdom, to the effect that apathy was the dominant factor in accidents, and that the way forward was not through ever more regulations and inspectors but through self-regulation, shared responsibility and voluntary action. HEALTH & SAFETY AT WORK, Report of the Committee 1970-1972, Cmd 5034 (1972), para. 13, 28, 255.

730 JOZEF FALKE, o.c, p. 69.

731 MATTHIAS SCHMIDT-PREUSS, o.c, p. 173: "Kontrolle der Kontrolle."

only after a wave of health and environmental regulation. Furthermore, even when industry associations (such as the European chemical industry association CEFIC), which usually are the engines behind the development of self-regulatory schemes, are sincere in their intentions to improve health and environmental performance, they face the same problems of monitoring compliance and enforcement as those experienced by public authorities. In fact, compliance and enforcement problems may grow even worse in the case of self-regulation, since self-regulation agreements are entered into on a voluntary basis, and industry associations generally do not dispose of, or are wary of using, coercive tools to force recalcitrant members into compliance.\textsuperscript{734}

Lastly, it is questionable whether internalised risk management scores better on the democracy front than command-and-control regulation. Critics of eco-audit systems, for instance, argue that auditing simply trickles down to the substitution of the judgement of one group of public experts (members of scientific committees commissioned by the government, health and safety inspectors, etc.) by that of experts working in and for the private sector. Internalised management systems may bypass the public even more than traditional regulation, due to their potential to hide risks and deflect public attention, so that a number of fundamentally political issues never reach the political arena.\textsuperscript{735}

In light of these considerations, it is not surprising that internalised risk management has been welcomed as a way to improve rather than supplant more traditional forms of risk regulation. The EMAS Regulation, in fact, gives evidence of similar caution: it intends to improve companies' environmental performance beyond legally defined boundaries, but does not waive companies'...

\textit{Resources Institute}, pp. 285, as an example of a publication that strives to cast a "greener" image of industry. \textit{Relating to eco-auditing and image-building, Cecilia Kye (1995) remarked that "environmental auditing also raises doubts as to the genuineness and usefulness of the end information provided to the public. Some industrial sectors are eager to use eco-auditing to (...) improve a tarnished public image. CECILIA KYE (1995), "Environmental Law and the Consumer in the European Union," Vol. 7, Journal of Environmental Law, N° 1, p. 51.}

\textsuperscript{734} \textit{NEIL GUNNINGHAM, o.c., p. 69: "[E]xperience in North America (...) and indeed the U.K., suggests that such action (termination of association membership in case of failure to comply with the Responsible Care scheme) is extremely unlikely, there being no documented case of a company's membership being so terminated. This probably reflects the philosophy of the relevant industry associations. As a senior member of the U.K. Chemical Industry Association (CIA) has put it, "you can't get acceptance just by jamming things down people's throats," and arm twisting is likely to remain a very rare feature of Responsible Care."}

\textsuperscript{735} \textit{MATTHIAS SCHMIDT-PREUSS, o.c., p. 175; LEIGH HANCHER, o.c., p. 11.}
obligations to meet regulatory requirements and standards.\textsuperscript{736} Additionally, the existence of a regulatory framework remains necessary in order to achieve overall coherence and priority-setting in health and environmental policy, transcending the level of management decisions taken in individual companies.

\textsuperscript{736} WOLFGANG HOFFMANN-RIEM, o.c., pp. 607-614.
SECTION II - CONTROLLING CHEMICALS: EXERCISES IN SUBSTANCE-ORIENTED RISK MANAGEMENT

As the uses for chemicals in industry and everyday life proliferated, and substances and residues were released into environmental media following numerous different pathways, the need became apparent for a substance-oriented, systematic approach to chemicals and chemical risks. By the late 1980's, EC environmental legislation that involved some aspect of the control of dangerous substances had developed into a virtually impenetrable patchwork of different regulations, directives and decisions addressing water pollution, air pollution, product safety, dangerous industrial activities, etc. In a 1987 article, Konrad von Moltke listed all existing EC legislation and proposed actions (in 1987) on cadmium. The list contained no less than 21 (!) different directives and decisions, each covering one or other aspect relating to the production, marketing, use, release or disposal of cadmium. One could hardly ask for a more eloquent illustration of the need for an encompassing, substance-oriented approach. Moreover, it became increasingly apparent that, by focusing on one environmental medium at the time, end-of-the-pipe regulation did not allow adequate management of the risks associated with chemical substances. Many substances migrate from one environmental medium to the next, often assuming changing chemical compositions. Effectively managing such risks called for a cross-media approach.

Recalling the previous Section on styles of risk management, it should furthermore be mentioned that, irrespective of the particular technique deployed, management of health and environmental risks through substance-oriented regulation in itself was considered a more modern, progressive form of risk regulation than technology-based or media-oriented regulation because it took as point of departure the substances that cause adverse health effects and environmental harm, instead of focusing on the health and environmental

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consequences of a vast and highly differentiated range of industrial and consumption activities.\textsuperscript{740} Culling techniques, for instance, intervene at the very beginning of the production chain and are aimed at \textit{ex ante} risk prevention rather than \textit{ex post} risk reduction or compensation.\textsuperscript{741} This observation might help to explain why, in his critical analysis of command-and-control regulation, Richard Stewart reaches far more damning conclusions on the subjects of technology-based approaches and emission standards than on culling techniques.\textsuperscript{742}

Summarising, the need both to rationalise health and environmental legislation and to cope with cross-media pollution, and the growing preference for legislation that sought to prevent rather than amend health and environmental problems -- which preference attained quasi-constitutional status in 1987 as one of the environmental policy principles listed in Article 130R of the EC Treaty (the prevention principle)\textsuperscript{743}— led to the adoption of a considerable amount of legislation professing a substance-oriented approach to risk management. Most of these instruments (the Notification Directive, the Existing Substances Regulation, the risk assessment documents, Directive 76/769/EEC on market restrictions) have already been mentioned in previous Chapters.\textsuperscript{744} Within the framework of this Section, they will be re-examined in light of the post-assessment management (or control) measures they contain.

Additionally, many health and safety laws were enacted specifically to address the use and control of dangerous substances in the workplace. This variety of substance-oriented legislation will also be discussed. Furthermore, a number of EC instruments focus on particular substances or groups of substances, such as cosmetics, detergents, food additives, pesticides, etc. Since my study aims to focus on the general (or “default”) legal framework for chemicals rather than on specialised legislation, EC legislation pertaining to

\textsuperscript{740}\textsuperscript{VICKI NORBERG-BOHM et. al., o.c., p. 7.}
\textsuperscript{741}\textsuperscript{HANS-WILHELM SCHIFFER & KILIAN DELBRÜCK, o.c., p. 1002; CASS SUNSTEIN (1991), "Administrative Substance," o.c., p. 632: "[R]ather than imposing complex technological requirements on pollutants as they exit the tailpipe, it would be best to eliminate lead and other dangerous substances before they enter the tank. Pollution prevention, rather than technological fixes, should guide environmental policy."}
\textsuperscript{742}\textsuperscript{RICHARD B. STEWART (1981), "Regulation," o.c., \textit{passim}.}
\textsuperscript{743}\textsuperscript{Article 174 ToA. See Mr. H.G. SEVENSTER (1992), Milieubeleid en Gemeenschapsrecht. Het interne juridische kader en de praktijk, \textit{Kluwer-Deventer}, pp. 110-111.}
\textsuperscript{744}\textsuperscript{Recall that it is practically impossible and even undesirable to draw strict boundaries between the stages of risk identification (Chapter II), assessment (Chapter III) and management (Chapter IV).}
such specialised sectors will not be discussed in detail. Nonetheless, some references to specific substance and product legislation are made. The last part of Section II is dedicated to the legal principles and rules directing chemical risk management under conditions of uncertainty. It asks how the European Community approaches situations where the risks are not clearly defined, and questions the adequacy of existing approaches.

1. **Managing Hazards: Actions based on Classification**

Let us once more revisit Chlorplus. Independent of the decisions regulatory authorities make on a case-by-case basis, there are a number of legal obligations that Chemplus NV, and subsequent users of Chlorplus, are bound to uphold in order to render the health and environmental hazards relating to the production, use and disposal of Chlorplus manageable. The first of these obligations consists of the duty to determine whether Chlorplus should be classified as a dangerous substance, and to establish the appropriate classification.

1.1. *Hazard management through classification*

In Chapter II, I discussed classification as one of the requirements that creates information gathering duties for manufacturers and/or importers of chemical substances.\(^{745}\) We recall that the European Commission is involved in a continuous effort to draw up harmonised classifications for dangerous substances,\(^{746}\) and that, for those chemicals that have not yet received a uniform classification, manufacturers and importers are required to attach a provisional classification. In addition to an instrument to stimulate information production, the classification of dangerous substances (i.e., substances that are so classified) and preparations is one of the foremost chemical hazard management tools deployed in European legislation.

Classification constitutes a pivotal selection mechanism on which health and environmental regulation hinges: a number of the EC-promulgated rules -- covering product-oriented and media-oriented legislation, as well as laws directed at enterprises and employers -- refer back to the classification system

\(^{745}\)See Section II, 2.3(a) of Chapter II.

\(^{746}\)Through amendments of Annex I of the Notification Directive.
and prescribe safety measures and/or restrictions for certain classes of dangerous substances. For example, the Seveso II Directive imposes a broad spectrum of safety requirements, including the development of a general safety policy and an emergency plan, for enterprises that work with dangerous substances.\footnote{Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, OJ L 10/13 (1997).} In part, these substances are mentioned by name, however the Directive equally contains a catch-all clause that extends its scope to all substances classified in particular categories listed in the Notification Directive (e.g., very toxic, highly flammable, dangerous to the environment in combination with the risk-phrase "very toxic to aquatic organisms;" see Annex I, Part II of the Directive).

In the area of workers' health and safety, the 1990 Directive on carcinogens requires that carcinogenic substances be replaced by innocuous or less dangerous substances.\footnote{See Section II.1.3 below.} In Article 2, the Directive defines carcinogens as substances or preparations that, pursuant to the harmonised classification system, must bear the risk phrase R 45 'may cause cancer.'\footnote{Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).} Furthermore, even in instances where classification according to the Notification Directive is not expressly referred to, the given classification of a substance as, for instance, "highly toxic" or "flammable" may target this substance for future regulation (emission standards, market restrictions, etc).

Considering these important ramifications, it is understandable that chemical producers strive to obtain the most favourable classification for the substances and preparations they market. The determination of harmonised classifications frequently forms the subject of protracted negotiations between the Commission and industry.\footnote{Interview with Mr. Jorge Costa-David, DG XI, the European Commission, June 1996.} In practice, this leads to considerable backlogs in the Commission's work,\footnote{For some 4500 existing and new substances, harmonised classification and labelling has been agreed upon. These substances are published in Annex I of the Notification Directive (situation at the end of 1998). We recall that there are over 100000 chemical substances in circulation. Cf. Commission Working Document of 18 November 1998, Report on the operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93, Directive 76/769/EEC, SEC (1998) 1986 final.} and implies that, for many substances and preparations, regulatory authorities have to rely on the provisional classifications established by industry.
1.2. **Hazard management through information supply**

Together with classification, labelling (and packaging; see below) requirements form the oldest core of EC chemicals control measures. As early as 1967, Council Directive 67/548/EEC provided that dangerous substances should be marked with danger symbols (a skull, a flame, a black cross printed on an orange background, etc.) and risk and safety phrases.\(^{752}\) Uniform labelling rules serve the dual purpose of market integration and consumer warning and protection. Throughout the years, the labelling scheme was extended to cover pesticides (1978) and, as of 1988, dangerous preparations generally.\(^{753}\) The latter extension indicates that, by 1988, consumer protection had gained weight as an EC legislative goal, since consumers are most likely to be exposed to dangerous chemicals in the form of preparations, such as insect repellents and household cleaning products. Significantly, the 1988 Dangerous Preparations Directive equally introduced safety data sheets, which created scope for more extensive, product-specific information, allowing industrial users better to control the risks inherent in the use of chemicals.\(^{754}\)

In general, industrial user and consumer warning duties are well-covered in EC chemicals legislation, apart from one regrettable oversight: whereas the Notification Directive gives a classification and corresponding danger symbol for "substances dangerous to the environment," the Dangerous Preparations Directive thus far does not provide warnings on environmental risks. Eco-labels can give consumers some indication as to which products are environmentally friendly, but eco-labelling schemes are far from comprehensive. In the absence of an eco-label, consumers are presently unable fully to integrate "green values" into their shopping behaviour. Hopefully, a forthcoming amendment to the Dangerous Preparations Directive will rectify this shortcoming.\(^{755}\)

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\(^{752}\) *Cf.* Chapter II, Section II.2.3(a).


\(^{754}\) In 1992, the requirement to attach safety data sheets was extended back to dangerous substances. *Cf.* Chapter II, Section II.2.3(b).

In addition to the general labelling and warning duties in the Notification and Dangerous Preparations Directives, which fall on the manufacturers and/or importers of chemicals, information duties are imposed on industrial users of chemicals, with the aim of informing and thereby protecting people who are at risk of being exposed to these substances. Affected parties may be employees working at industrial plants, or people living in the vicinity of an industrial site. Thus, Council Directive 80/1107/EEC on worker protection from risks related to exposure to chemical, physical and biological agents at work, as well as the more recent framework Directive 89/391/EEC on workers' health and safety (the arrangements of which are further detailed in, inter alia, Directive 90/394/EEC on carcinogens at work, and Directive 98/24/EC on chemical agents at work), establish that employers must supply workers with information and training on the safety and health risks they are likely to be exposed to, and on the appropriate protective measures. Additional measures cover the use of safety and warning signs at work (Directive 90/394/EEC), and the marking of containers and pipes used for dangerous substances (Directive 92/58/EEC on minimum requirements for the provision of safety and health signs at work). Finally, Directive 98/24/EC on chemical agents stipulates that, in the event of "accidents, incidents and emergencies," workers have to be alerted as soon as possible (Article 7).

Alongside employers' information supply duties, there are indirect preparation to the environment, which enables ensuing labelling. Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, OJ L 327/8 (1980). This Directive was one of the earliest EC health and safety instruments laying down information supply, training, health monitoring and other safety requirements, as well as rules relating to exposure limits (see below). However, many of the safety precautions detailed in the Directive were non-binding; as long as national measures taken in implementation of the Directive were consistent with the need to protect public health and the environment, Member States were free "[t]o determine the extent, if any, to which each of the measures provided for in Articles 4 and 5 (limitation of the use of chemicals, establishment of limit values, use of warning signs, record keeping, informing workers where limit values are exceeded, etc.) is to apply, taking into account the nature of the agent, the extent and duration of the exposure, the gravity of the risk and the available knowledge concerning it, together with the degree of urgency of the measures to be adopted" (Article 4(2) of Directive 80/1107/EEC). Only a few requirements, namely those applicable to chemicals the hazards of which are well-known (e.g., asbestos, lead, mercury), were compulsory. Directive 80/1107/EEC will be repealed in May 2001, when Council Directive 98/24/EC on chemical agents at work enters into effect. Directive 98/24/EC continues the tradition of indicative occupational exposure limits. However, it does create opportunities for the imposition of more compelling obligations on the Member States. Article 10 of Directive 89/391/EEC; Article 11 of Directive 90/394/EEC; Article 8 of Directive 98/24/EC.
information rights, granting workers or their representatives access to reports on risk assessment, to lists and reports on occupational accidents, to detailed information relating to preventative and protective measures, and to information supplied by inspection bodies and agencies (see above).\textsuperscript{758} In fine, it should be mentioned that the 1989 Framework Directive, the Carcinogens Directive and the Directive on chemical agents additionally establish a workers' right to be consulted and to participate in decision-making pertaining to health and safety issues at work.\textsuperscript{759} Although this right is fairly minimal, and does not guarantee anything beyond a right to sit in on and be heard at meetings, it does grant workers a somewhat greater facility to act on hazard and risk information than consumers have at their disposal.

Information supply to people living in the vicinity of a plant where dangerous substances are used, or who are otherwise likely to be affected, is covered in the Seveso II Directive. Article 13 requires that information on safety measures and the requisite behaviour in the event of an accident is supplied to persons liable to be affected. Furthermore, this information, as well as the establishment's safety report, should be made publicly available on a permanent basis. As a minimum, the information should provide an explanation, in simple terms, of the activities conducted at the site, data concerning the dangerous substances used and their hazardous characteristics, information relating to the nature of major-accident hazards and to the establishment's emergency policy.\textsuperscript{760}

Finally, before turning to other hazard management mechanisms, it should be pointed out that EC-developed information systems can and frequently are supplemented by national measures. For example, the German Regulation on Dangerous Substances requires of employers that they list all dangerous substances with which employees come into contact in a Dangerous Substances Register ("Gefahrstoffkadaster").\textsuperscript{761} The Register offers employers...
and inspectors an overview of the substances used in the work place, and thus constitutes an important instrument in the evaluation of internal substance-balances and -movements.762

1.3. Hazard management through safety measures

In addition to information requirements, EC legislation specifies a number of safety measures that must be respected by those marketing or dealing with dangerous substances.

1.3(a) Packaging

A safety precaution applicable to all dangerous substances and preparations is packaging: both the Notification Directive and the Dangerous Preparations Directive specify packaging requirements which manufacturers and importers have to respect in order lawfully to market their products. Thus, Article 22 of the Notification Directive (and corresponding Article 6 of the Dangerous Preparations Directive) insists, inter alia, that packaging should be so designed and constructed that its contents cannot escape, that fastenings should be solid and allow repeated opening and closing without the content escaping, and that the materials used in packaging should be resistant to the substance they contain. Of particular importance, most notably for preparations which are more likely to be used in individual households than substances, are the requirements that packaging of substances and preparations sold to the general public and labelled "very toxic," "toxic" or "corrosive," must be equipped with a child-resistant fastening and bear a tactile warning of danger.763 Furthermore, we recall that safety data sheets equally contain a number of safety prescriptions, addressed at professional users of substances and preparations, to reduce the risks relating to the use of chemicals.

762MICHAEL AU, o.c., p. 94
1.3(b) Safety measures in the work place

Packaging rules are the most substance-oriented of safety precautions; they are valid for all chemicals that are provisionally or pursuant to a harmonisation procedure classified as dangerous, irrespective of the use or uses they will be put to. However, the bulk of safety precautions relating to the use of dangerous substances can be found in workers' health and safety legislation. We find, inter alia, provisions for the training of workers so that they are better equipped to deal with health and safety risks arising in the work place, requirements for risk assessment in the work place, health surveillance, periodical examination and monitoring of workers who are or have been exposed to dangerous substances, and exposure limits.

Two lists of indicative exposure limits for certain dangerous substances have been drawn up by the Commission, advised by the Scientific Committee for Occupational Exposure Limits to Chemical Agents. It is important to bear in mind that, pursuant to Directive 80/1107/EEC, Member States are not bound to adhere to the letter of these limit values. As is the case for many of the safety measures laid down in framework Directive 80/1107, it is at the Member States' discretion to determine whether, and to what extent, specific rules should be enforced at the national level (see fn. 756). The situation will change when Directive 98/24/EC on chemical agents at work, which repeals Directive 80/1107/EEC, enters into force. Directive 98/24/EC incorporates the

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764 It should be noted that there are also numerous safety precautions to be observed during the transport of dangerous substances. However, transport issues being a study subject in their own right, these will not be discussed in the present analysis.
previously established sets of indicative limit values, but curtails the Member States’ discretion to the extent that: “[F]or any chemical for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice” (emphasis added).\footnote{767} In other words, Member States will no longer be free to decide not to adopt a national limit value after a Community indicative limit value has been established. Additionally, Article 3(4) of Directive 98/24/EC introduces the possibility of adopting binding Community limit values. For these values, “[M]ember States shall establish a corresponding national binding occupational exposure limit value based on, but not exceeding, the Community limit value.”\footnote{768}

Finally, Article 6(2)(g) of the 1989 framework Directive introduced the substitution principle as a safety measure in EC health and safety legislation, listing the requirement to "replace the dangerous by the non-dangerous or less dangerous" among the general obligations of employers.\footnote{769} This principle is reiterated in the implementing Directives on carcinogens and chemical agents.\footnote{770} The Carcinogens Directive, for instance, provides that "[T]he employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as technically possible, by a substance, preparation or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health and safety." Where such replacement is not technically possible, the carcinogen should be manufactured and used in a closed system (Article 5(2)). Alternatively, if working in a closed system proves technically infeasible, the level of exposure of workers must be reduced to as low a level as is technically achievable (Article 5(3)).

\textbf{1.3(c) Accident prevention and management policies}

A last type of safety prescriptions to be examined are measures of a more general and procedural nature which, instead of imposing specific safety rules on manufacturers, importers or employers, require the development of a general safety policy for those undertakings that deal with dangerous substances.

\footnote{767} Article 3(3) of Directive 98/24/EC. \footnote{768} Article 3(5) of Directive 98/24/EC. \footnote{769}\textit{Cf.} MICHAEL AU, o.c., p. 241. \footnote{770} Article 5(2) of Directive 90/394/EEC; Article 6(2) of Directive 98/24/EC.
Requirements of this nature are not substance-oriented sensu stricto, but lean closer to site-oriented, self-regulatory and internalised forms of industrial hazard management. Nevertheless, since the use of dangerous substances within an undertaking determines whether operators are required to implement these general safety prescriptions, it is appropriate that they should be discussed within this framework.

The EC legal instrument containing such broadly defined, procedural safety requirements is, of course, the Seveso II Directive. This Directive, which was promulgated in December 1996 and should be implemented in the Member States by the beginning of 1999, extensively amends its predecessor, the 1982 Seveso Directive. The history leading up the adoption of the latter Directive is well-known: it was adopted in response to the industrial disaster that occurred in Seveso, Italy, in 1976. Toxic substances, including dioxin, escaped from a factory in Seveso, and spread over the Italian countryside, with disastrous results. The Seveso disaster was, moreover, not an isolated event: similar accidents at Flixborough (UK), Beek (The Netherlands) and Velbert (Germany) all confirmed the concern that, in many undertakings, existing control systems against major hazards were inadequate.

The Seveso Directive strove to improve both the preventative and remedial side of safety management within undertakings where dangerous substances are used, with the aim of reducing the risk of major accidents. The Seveso II Directive embraces the same objective, however, when comparing the two documents, it is interesting to note how, in the interval between 1982 and 1996, the Community's approach to safety management has evolved.

In a nutshell, Seveso I required of manufacturers dealing with dangerous substances in their undertakings that they should "take all measures necessary to prevent major accident hazards and (to) limit their consequences for man and

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774 Although, providentially, no immediate fatalities were recorded, more than 600 people had to be evacuated and as many as 2000 were treated for dioxin poisoning. Many animals had to be slaughtered, and hundreds of acres of land decontaminated. BARRAT & ENMARCH-WILLIAMS, o.c., p. 195.
775 RÜDIGER BREUER, o.c., p. 211.
the environment." To attest compliance with this command, manufacturers were to prove to the competent authorities of the Member State in which their company was located, that they had indeed (1) identified existing major-accident hazards; (2) adopted the appropriate safety measures; and (3) provided the people working on the site with information, training and equipment to ensure their safety (Article 4). Furthermore, if certain categories of dangerous substances, specified in the Directive, were used, manufacturers had to draw up and submit a safety report, as well as an on-site and off-site emergency plan.

The more recent Seveso II Directive, in turn, equally requires of operators that they "take all measures necessary," however it infuses some structure into this provision by stipulating that operators should draw up a major-accident prevention policy (MAPP), in accordance with the guidelines (referred to in the Directive as principles) detailed by the Community in Annex III of the Seveso II Directive. The guidelines prescribe, _inter alia_, that the MAPP should state the operator's overall aims and principles of action, and, significantly, that the safety management system should include the part of the general management system that covers the organisational structure, responsibilities, practices, procedures and resources for determining and implementing the MAPP. Seveso II in other words seeks to connect safety measures to broader management concerns, thereby embedding (or internalising) management for dangerous substances into the overall management of establishments and installations.

Similar concerns to integrate safety management into the overall management and exploitation are reflected in Article 9's requirement that safety reports demonstrate "that adequate safety and reliability have been incorporated into the design, construction, operation and maintenance of any installation, storage facility, equipment and infrastructure connected with its operation which are linked to major-accident hazards inside the establishment" (emphasis added). Integration of safety management considerations even surpasses the level of the individual firm: Article 12 provides that "Member States shall ensure that the objectives of preventing major accidents and limiting the consequences of such accidents are taken into account in their land-use planning."
policies and/or other relevant policies."

The differences in approach between Seveso I and Seveso II could be interpreted as signposts of a growing awareness, within European Community institutions, of a need to move beyond crisis or disaster management towards long-term integrated risk management for dangerous substances.

2. **Managing Risks: From Scientific Probability to Legal Certainty**

So far, the discussion of substance-oriented management techniques has stayed conspicuously silent on the issue of risk assessment. And yet, as we learned in Chapter III, risk assessment was singled out by European Community institutions as a predominant tool on which to base health and environmental decision-making for chemicals. How can we explain the discrepancy between the importance attached to risk assessment, which was confirmed in the Risk Assessment Directive and Regulation as well as in general EC documents on health and environmental policy (such as the Dobris Report), and the relative scarcity of references to risk assessment in risk management instruments?²⁷⁸

To gain insight into this issue, it is essential to remember that most of the health and safety legislation discussed above dates from earlier times than the risk assessment provisions. Risk assessment methodology was not created in a vacuum, but introduced into a pre-existing legal system that was firmly based on classification; a system that conditions regulatory outcomes upon the identification of *intrinsic properties* of the substance (toxicity, corrosivity, flammability, etc.)²⁷⁹ As explained in Chapter III, the determination of intrinsic properties corresponds to the first stage of risk assessment; the *hazard* given decisive economic power in the technical operation thereof (Article 3 of Seveso II).

²⁷⁸ See, e.g., the preamble to Commission Regulation 1488/94: "Whereas the results of a risk assessment should be the principal basis of decisions under appropriate legislation to reduce the risks arising from manufacture, transport, storage, formulation into a preparation or other processing, use and disposal or recovery of existing substances". In workers' health and safety legislation, mention is made of risk assessments, however this refers to risk assessments made in the work place where chemical substances are used (discussed further below); not the general risk assessments made pursuant to Commission Directive 93/67/EEC or Commission Regulation 1488/94.

²⁷⁹ See Annex VI.1.1. of the Notification Directive: "Classification aims to identify all the physico-chemical, toxicological and ecotoxicological properties of substances as well as the physico-chemical and toxicological properties of preparations which may constitute a risk for handling or normal use." Packaging and labelling rules, for example, apply to all substances which have been classified as dangerous. Classification equally determines which establishments, where chemical substances are used or stored, need to comply with the requirements of Seveso I and, as of 1999, Seveso II.
identification stage. A complete risk assessment, however, additionally requires a dose-response assessment, an exposure assessment and a risk characterisation that takes into account the results of the three foregoing stages. Compared to classification, which centres on intrinsic properties, risk assessment could be said to embody a more contextual approach to health and environmental hazards, which is more sensitive to exogenous and (to some extent) social risk factors.

Hypothetically, the adoption of the Risk Assessment Directive and Regulation could have spurred EC institutions to overhaul the chemical management framework, and to replace the established classification system for dangerous substances according to their intrinsic properties, with new categories developed on the basis of risk characterisations (incorporating intrinsic properties, dose-response relations and exposure). In Section I.1. of this Chapter, I have offered a few examples of national chemical management measures that are based on the results of quantitative risk assessments. The European Community, however, apparently has no intention to implement such a systematic change; recently adopted legislation in the area of chemicals management indicates that, in the foreseeable future, classification according to intrinsic properties will remain the fundamental framework for chemical management decisions.

Hence the discrepancy: although the European Community has formally "pledged allegiance" to risk assessment, classification remains the predominant basis for decision-making and management. The European Community has sought to overcome this discrepancy by integrating risk assessment information into the classification mechanism. Moreover, some of the most recently adopted chemical management documents do indeed mention risk assessment, and require that competent authorities “take risk assessment into account” when implementing health and environmental protection strategies. The following sections map out the relation between risk assessment and risk management for

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780 Cf. Introduction to Chapter III, Heading 1.
781 Cf. Section II.2 of Chapter III.
782 See Section I.1 of this Chapter on risk reduction strategies followed by the German Länderausschuß für Immissionsschutz and USA carcinogenic air pollutants policy.
783 See, for example, the Seveso II Directive and recently adopted amendments to Directive 76/769/EEC, which are discussed in Section 2.2. below. It should however be noted that Directive 98/24/EC on chemical agents at work does “soften” the classification-based approach, stipulating in Article 2 that a chemical can be hazardous for the purposes of said Directive, even if it has not been classified as such following the Notification or the Dangerous Preparations Directive.
chemical substances, a relation that, for the time being, is still quite precarious and underdetermined. Based on the sparse indications offered in existing legal documents, the analysis attempts to trace the contours of the European Community's understanding and deployment of risk assessment as a normative concept.

2.1. Modifications to classification, packaging and labelling

While maintaining a predominantly classification-, and therefore hazard-based system of health and environmental management, the European Commission (who was responsible for the adoption of Directive 93/67/EC on risk assessment for new substances) tried to introduce risk assessment into decision-making processes via the backdoor. To this end, the Commission resorted to a simple but elegant technique: Article 2(2)(e)(i) of Commission Directive 93/67/EC provides that the recommendations for risk reduction, which may be issued after a risk assessment has been completed, may include "[modifications to the classification, packaging or labelling proposed by the notifier in the notification." Thus, instead of directly informing the risk decision-making process, risk assessment informs classification, which in turn determines the application of hazard management measures. In other words, through the indirect influx of risk information, hazard management turns into risk management.

While this example of pragmatic problem-solving by the Commission may be commended on its simplicity and ingenuity, it is questionable whether it will also prove effective. First, the provision limits modifications to provisional classifications, suggested by the notifier in the technical notification dossier. This implies that, once a harmonised classification has been reached, modifications on the basis of risk assessment information are no longer possible. It is furthermore puzzling that the Existing Substances Regulation, and accompanying Regulation (EC) 1488/94, do not provide that risks assessments could be used to modify to classifications, even though many of the substances listed in the EINECS (which were on the market before September 1981) have not yet been incorporated in the harmonised classification system.

Furthermore, reading the provision on modifications in combination with Articles 4(2)(i) and (ii) of Directive 93/67/EC, a vicious circle becomes apparent.
The latter Articles stipulate:

"(i) if the test appropriate to hazard identification in relation to a particular effect or property has been conducted and the results have not led to classification of the substance in accordance with Directive 67/548/EEC, the risk assessment in relation to that effect or property need not include the actions at paragraph 1(a) and (b) (dose-response assessment and exposure assessment) and the conclusion at Article 3(4)(i) shall apply (the substance is of no immediate concern and need not be considered again until further information is available), unless there are other reasonable grounds for concern; and

(ii) if the test appropriate to hazard identification in relation to a particular effect or property has not yet been conducted, that effect or property shall not be considered in the risk assessment unless there are other reasonable grounds for concern".

Hence, as a rule risk assessments will only be performed for substances that already have been classified as dangerous according to their intrinsic properties. On the other hand, if the hazard identification stage -- which also constitutes the first stage of risk assessment\textsuperscript{784} \textsuperscript{785} -- results in non-classification, or if no hazard identification has been undertaken, the second and third stages of risk assessment (which are necessary to inform the fourth and final stage of risk characterisation) will not be performed, unless there are reasonable grounds for concern. It is not difficult to discover the circularity inherent in this type of requirement: for risk assessments to be conducted (in the absence of classification), there needs to be a reasonable ground for concern. Concern will usually be the product of indications and data suggesting that a substance may pose a non-negligible risk. Moreover, the reasonableness requirement suggests the existence of a \textit{prima facie} burden of proof on the part of the competent authority in charge of commissioning risk assessments. However, when no hazard identification or preliminary assessment has been performed, it is unlikely that these indications, data and documents substantiating a reasonable concern would be available. The situation is reminiscent of the procedural deadlock paralysing the US Environmental Protection Agency under the TSCA, which similarly conditions testing upon prior demonstration of an unreasonable

\textsuperscript{784} See Section I.2 of Chapter III. 
\textsuperscript{785} See above.
risk.\textsuperscript{786}

For all practical intents and purposes, the reach of the modification provision therefore appears restricted to pre-existing but provisional classifications. And even here, the question remains whether it is possible to incorporate risk assessment information into classifications in a meaningful way, without distorting the hazard data. As mentioned before, risk assessments essentially provide a context, an environment to hazard identifications.\textsuperscript{787} It is difficult to see how this context can be fully reflected in a system that refers only to intrinsic properties and operates with neatly divided categories, such as "flammability," "toxicity," and "corrosivity." For example, we recall from Chapter II that the determination of toxicity levels (divided in the categories "harmful," "toxic" and "very toxic") happens on the basis of the median lethal dose.\textsuperscript{788} To prevent that different notifiers would classify the same substance differently, doses have been quantitatively standardised. In the absence of further clarification from Community authorities, it remains extremely unclear how risk assessment information could be integrated without altering or even distorting pre-established toxicity limits. Moreover, risk assessment data such as exposure assessments do not lend themselves to standardisation and quantification as easily as lethal dose tests. Consequently, integration of risk information might erode uniformity, thereby weakening one of the prime objectives of classification. Ironically, the category which is probably best able to absorb risk assessment information is the most vaguely defined and underdetermined one; the "dangerous for the environment" category. Unfortunately, risk information relating to ecotoxicity is generally only capable of giving very precursory indications of future environmental harm, which calls into question its suitability as a basis for classification and ensuing environmental decision-making.\textsuperscript{789}

2.2. \textit{Directive 76/769/EEC on market restrictions}

One area of chemicals risk management that is certainly intended to be informed by risk assessment, are the restrictions on the marketing and use of chemical substances imposed in Council Directive 76/769/EEC and ensuing

\textsuperscript{786} See Section II.2.2(b) of Chapter II.
\textsuperscript{787} Cf. GERD WINTER (1994a), "Regelungsmaßstäbe," o.c., p. 914.
\textsuperscript{788} See Section II.2.3(a) of Chapter II.
\textsuperscript{789} See Section II.1 of Chapter II.
amendments. In essence, the Directive lists substances that may not be used for certain purposes (for instance, a 1983 amendment to Directive 76/769/EEC provides that polybrominated biphenyls (PBB) may not be used in textile articles intended to come into contact with the skin);\textsuperscript{790} that may only be used in limited quantities (a 1991 amendment stipulates that pentachlorophenol or PCP may not be used in a concentration equal to or greater than 0.1\% by mass in substances or preparations placed on the market);\textsuperscript{791} or that may only be sold to specific categories of users (carcinogens, mutagens and substances toxic to reproduction may only be sold to professional users).\textsuperscript{792}

Risk assessments form a valuable source of information to determine which substances should be added to the restrictive list; they allow regulatory bodies to screen chemicals even before the substances are marketed, and to prohibit market access or, if risk assessments are performed after marketing has begun, to pull back those substances and compounds that pose an unacceptably high risk to man and the environment (the culling technique). This function of risk assessments was expressly confirmed in Article 11(3) of the Existing Substances Regulation, which reads: "[O]n the basis of the risk evaluation and the recommended strategy (by the national rapporteur),\textsuperscript{793} the Commission shall decide, where necessary, to propose Community measures in the framework of Council Directive 76/769/EEC (...)" Also, even before the risk assessment Directive and Regulation were adopted, one of the amendments to Directive 76/769/EEC (the 1991 PCP amendment) stated in its preamble that, in its development of a strategy for chemicals used in the preservation of woods, the Community would base this strategy on: "[i]nformation supplied to it by the Member States and in particular on the assessment of the risks for man and the environment (...)" (emphasis added).

Yet, when we look at the most recent amendments to Directive 76/769/EEC, which were adopted after the entry into effect of the Risk Assessment Directive and Regulation, we are still at a loss for references to the

latter instruments. The 14th and 16th amendments to Directive 76/769/EEC, adopted in 1994 and 1997 respectively, lay down a restrictive framework for the marketing and use of carcinogens, mutagens and chemicals toxic to reproduction, whether sold in their pure form or in preparations. The amendments only refer to classification, not risk assessment. This may be due to the fact that substances which display carcinogenic, mutagenic or teratogenic (i.e., toxic for reproduction) properties receive special treatment within the EC chemicals control scheme (see below). Hopefully, future amendments dealing with different categories of chemicals will shed more light on the EC's use of risk assessment in the determination of market restrictions.

2.3. Other areas

In addition to market restrictions, risk assessments are intended to inform health and environmental risk control measures contained in other pieces of EC legislation.

2.3(a) EC legislation covering specific groups of substances and preparations

First, risk assessments are used in authorisation schemes for specific groups of chemicals, such as pesticides and biocides. The risk assessment methodology prescribed in, for example, the 1991 Council Directive for the marketing of pesticides (the "Pesticides Directive"), closely corresponds to the ones found in the Risk Assessment Directive and Regulations. Moreover, in contrast to the Notification Directive, both the Pesticides and Biocides Directives

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793 Cf. Section II.3.3 of Chapter II and Section I.3 of Chapter III.
provide harmonised rules for authorisation (hence, for risk decision-making) of new products. These rules provide valuable information on the European Community's approach to and evaluation of risk, an issue that will be explored in greater detail in the following section.

2.3(b) Workers' health and safety

Risk assessments are part of workers' health and safety legislation. As early as 1978, the Council stressed the importance of establishing a common methodology for the assessment of the health risks connected with the physical, chemical and biological agents at work. Subsequent EC legislation launched requirements for employers whose workers came into contact with such substances to perform risk assessments (focusing in particular on the anticipated exposure of workers to risk-creating substances), to use the results of these assessments in the determination of risk control measures, and to keep risk assessment records available for public inspection. These assessments are of a different nature than the ones drawn up in accordance with the Risk Assessment Directive and Regulation: they are contextually determined by the staff characteristics and working conditions in each particular enterprise.

Directive 98/24/EC on chemical agents does obliquely refer to risk assessments made pursuant to the Notification Directive and Existing Substances Regulation, stipulating that: "[T]he employer shall obtain additional information which is needed for the risk assessment from the supplier or from other readily available sources. Where appropriate, this information shall comprise the specific assessment concerning the risk to users established on the basis of Community legislation on chemical agents" (emphasis added).
Interestingly, the definitive text differs substantially from the way it figured in the drafting stages of the Directive. In the Amended Proposal the corresponding provision read: “[T]he employer shall be in possession of an assessment of the risks concerning safety and health drawn up in a Document, hereinafter referred to as the “safety and health document”, which shall be kept up-to-date.

The safety and health document shall identify any risk at work arising from the intrinsic properties of the agents, alone or in combination, the level of exposure and the circumstance of work involving chemical agents and record in particular:

- an assessment of the risks incurred by the workers in any activity involving chemical agents, and that a competent person has carried out this assessment; where a chemical agent has been subject to a specific evaluation concerning the risks for its users as part of a process of authorization for placing on the market, the risk assessment shall take into account the results of that evaluation;

(...)” (emphasis added).

Compared to the Amended Proposal, the final text could be said to reduce the potential impact of previously made, general risk assessments: employers only have consider such information when they deem it appropriate. Moreover, it does not indicate to what extent -- if any -- general risk assessment results constrain employers in the choice of risk control measures. Neither is it clear whether there is any scope for employers to challenge the validity of test results and estimations. The upshot is a system that creates but very tenuous links between information production and risk management requirements. This, in turn, implies that risk management measures might create economic

- any occupational exposure limit values or biological limit values established on the territory of the Member State in question,
- the effect of preventive measures taken or to be taken,
- where available, the conclusions from any health surveillance already undertaken.”

On the other hand, the Directive does cover all risk assessments made on the basis of Community legislation, not just, as the Amended Proposal suggested, those that were drawn up in the course of an authorisation procedure. The formulation in the Amended Proposal could have led to all sorts of dilemmas. For example, would the absence of public intervention into marketing of notified chemical substances constitute an authorisation, implying that the risk assessment dossier submitted during the notification process needed to be taken into account by employers drawing up on-site risk assessments, or would the term “authorisation” only cover positive administrative decisions? Following the latter interpretation, the requirements in the Amended Proposal would have weighed comparatively heavier on employers located in Member States with the most extensive authorisation schemes for chemicals.
inefficiencies, caused by sub-optimal use of costly information.

2.3(c) Air quality control

Finally, risk assessments are integrated into recent EC initiatives on air quality control and water policy. Council Directive 96/62/EC seeks to foster the development of an overall strategy for air quality management and control, with the ultimate goal of maintaining or, where necessary, improving air quality within the European Community.\(^8\) To this end, the Directive sets out guidelines for the selection of health and environmental objectives for air quality, common methods and criteria for the evaluation of air quality, and information gathering and supply arrangements.\(^1\)

Although the Directive generally aims to give Member States a broad range of discretion in the implementation of air quality objectives, it does provide for the determination of uniform limit values for air pollution by the European Commission. Pursuant to Article 4 of the Directive, the Commission is first to concentrate on the establishment of limit values for a pre-defined group of 13 polluting substances, covering well-known culprits such as lead, sulphurdioxide and carbonmonoxide. In addition, the Commission should submit proposals for limit values for other, thus far unspecified polluters to the Council, where it appears that the deleterious effects of these substances on human health and/or the environment should be prevented, eliminated or reduced. For the selection of these substances, the Commission may, inter alia, rely on risk assessment methods.\(^2\) The provision is, mildly put, non-committal: it neither obliges the Commission to take risk assessments into account, nor does it give any indication on the role and weight to be attributed to risk assessment in selection procedures.

2.3(d) Water policy

The amended Commission Proposal for a framework for Community action in the field of water policy is rather more informative on the use of risk

\(^1\) Article 1 of Directive 96/62/EC.
\(^2\) Annex III of Directive 96/62/EC.
assessment in decision-making. Similar to Directive 96/62/EC, the Water Policy Proposal establishes overarching, broadly formulated guidelines to support a variety of water quality protection initiatives. In many respects, the Water Policy proposal represents European environmental law-making at its most modern. It aims to provide a centrally planned, long-term strategy for water policy development, while leaving local authorities a wide range of discretion in the choice of implementing measures (thereby ensuring a sufficient degree of flexibility). At various points, it emphasises the need for prioritisation, periodical review of regulatory and administrative decisions, transparency, institutional cooperation, legislative coordination and coherence, and regulatory differentiation to take into account different local circumstances. It furthermore seeks to take into account efficiency considerations by explicitly allowing the use of economic instruments, where appropriate, and insisting on the integration of cost-effectiveness considerations into risk decision-making.

The Proposal is also quite revelatory because it illustrates the role of risk assessment in risk decision-making with greater detail than found in any preceding measure. Risk assessment is mentioned both in the context of national and European water policy development. According to Article 13, Member States are to ensure the establishment of a programme of measures designed to reach environmental quality objectives for water. This programme must contain a number of "basic measures," including, inter alia, "[i]mmediate review of all relevant authorizations, among which discharge permits, followed by action based upon the level of risk involved" (Article 13(3)(d)(iii), emphasis added). More revealing, however, are the guidelines for Community action, which are listed in Article 21 of the amended Proposal. The relevant provisions of Article 21 are rendered in full text below:

"[A]rticle 21

Strategies against pollution of water

1. The Council establishes specific measures against pollution of water by individual pollutants or groups of pollutants which constitute an

803 Amended proposal for a Council Directive establishing a framework for Community action in the field of water policy, COM (97) 614 fin. 97/0067 SYN.
804 The goals of the Water Policy Proposal are a) the prevention of deterioration of aquatic and terrestrial ecosystems and the promotion of sustainable water use for fresh surface waters, estuaries, coastal waters and ground water; and b) compliance with international obligations pertaining to territorial and marine waters (Article 1).
805 These quality objectives are listed in Article 4. They essentially detail the overall goals set out in Article 1, and impose deadlines for achievement.
acceptable risk for the environment.

2. By 31 December 1998 at the latest, the Commission submits a proposal containing a first priority list of substances. The priority of substances for which measures should be adopted, it determined on the basis of the risk for the aquatic environment, which risk is determined by:

a) a risk evaluation pursuant to Council Regulation (EEC) 793/93 or

b) a targeted risk evaluation (following the method of Regulation (EEC) 793/93) which is exclusively aimed at aquatic eco-toxicity and toxicity for man via the aquatic environment,

or, if that is not realizable within the given term,

c) a simplified risk assessment procedure, particularly taking into account:

i) data concerning the intrinsic hazardous properties of the relevant substance, in particular its aquatic eco-toxicity and toxicity for man via aquatic exposure; and

ii) information obtained from the monitoring of widespread environmental pollution; and

iii) other demonstrated factors which may indicate the possibility of widespread environmental pollution, for example the scale of production or use of the substance concerned, and the usage patterns.

The Commission shall review this priority list by 31 December 2004 at the latest, and thereafter regularly every six years, and shall submit proposals where necessary.

3. In the preparation of proposals, the Commission takes into account the recommendations of the Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds, the Member States, the European Parliament, the European Environment Agency, Community research programmes, international organisations of which the Community is a member, European industrial organisations which also represent small and medium-sized enterprises, European environmental organisations and other information submitted to its attention.

(...)

5. For those substances appearing on the priority list, the Commission submits proposals for measures to restrict the predominant sources of relevant emissions. In doing so, the Commission shall take account of both product- and process-related sources, and will pursue a combination of measures which is cost-effective and proportionate. (....)"

The above guidelines offer important insights into the Commission's and - - if the Water Policy Proposal is adopted without all too drastic changes -- the
Community's approach to risk. In the next section, I will attempt to draw some preliminary conclusions on Community risk decision-making, based on the indications given in the Water Policy Proposal and other relevant measures.

2.4. *Searching for the normative foundations of EC risk decision-making*

However reluctantly supplied, the indications in the Risk Assessment Directive, as well as references made in other EC documents pertaining to risk management, make it possible to at least partially trace the contours of a normative body of rules which appears to guide the European Community in its risk decision-making. Below, I list some of its determinant characteristics.

First, EC legislation displays a special concern for carcinogenic substances and, to a slightly lesser extent, mutagenic substances, as well chemicals that may be toxic to reproduction. We recall from Chapter III that risk assessment for these categories of substances embraces a particularly conservative methodology: it operates on the assumption that, for such substances, there is no safe dose, however minimal. The mere determination of an inherent capacity for carcinogenicity, mutagenicity or toxicity for reproduction is sufficient to support a conclusion that risk reduction measures should be taken.\(^{807}\) The higher degree of caution respected vis-à-vis these three substance groups is furthermore reflected in the 14th and 16th amendments to Directive 76/769/EEC. Without exception, chemicals classified as carcinogens, mutagens or reproductive toxins are subjected to stringent marketing and use restrictions, fortified by a complete ban on the sale of such substances to non-professional users. Finally, it is no coincidence that the elaboration of the workers' health and safety Framework Directive 89/391/EEC started with the adoption of the Carcinogens Directive.\(^{808}\) Rather, it reflects a deliberate decision to grant priority to health risks from carcinogens before other chemical (or biological) agents, a decision that was already confirmed in the 1978 Action Plan on health and safety at work.

Turning to the general framework for chemical risk decision-making, the European Community does not appear to aim for a zero level of risk. Apart from the obvious point that the objective of a zero risk level would be incompatible

\(^{806}\) The Existing Substances Regulation.

\(^{807}\) Chapter III, Section 1.2(c).

\(^{808}\) Directive 90/394/EEC, see above.
with the validity of a statement that a substance is of concern, but that new information need not be supplied in the immediate future (which is one of the possible conclusions in risk assessment reports), this observation is supported by the risk standards laid down in Directive 98/24/EC on chemical agents at work. Articles 6(1) and 6(2) of the Directive put forth that: "[T]he employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum (...) Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment (...), the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk (...)" (emphasis added). The option to reduce instead of eliminate risks to workers points at a willingness, on the part of the EC legislator, to accept a residual or de minimis risk, below which threshold risk reduction measures are technically infeasible or unavailable.

A similar willingness to accept a de minimis risk level transpires from EC legislation on pesticides. Council Directive 91/414/EEC establishes a harmonised authorisation procedure for pesticides, providing inter alia that a pesticide may only be authorised if it is sufficiently effective and has no unacceptable effects on plants or plant products, no unacceptable influence on the environment and, in particular, no harmful effect on human health, animal health or ground water.809 Again, the use of the term "unacceptable," and the use of different standards implying a higher level of stringency for human and animal health, as well as ground water (unacceptable influence v. harmful effect), implicitly confirm the acceptance of a residual risk. Furthermore, it is clear from the wording of Article 2(13) of the Directive, which defines the concept of integrated pest control, that the economic costs of risk reduction measures should be taken into account, and that use of chemical plant protection products should not be suppressed to a level where the economic ramifications of such measures, in terms of reduced plant production yields, prove disproportionately negative.810 Finally, the pursuit of a zero risk objective

810 Article 2(13) defines integrated control as: "[t]he rational application of a combination of biological, biotechnological, chemical, cultural or plant breeding measures whereby the use of chemical plant protection products is limited to the strict minimum necessary to maintain the pest population at levels below those causing economically unacceptable damage or loss" (emphasis added).
would, in addition to being a logical impossibility,\textsuperscript{811} run counter to the risk strategies adhered to in most of the Member States.\textsuperscript{812}

The third identifiable characteristic of EC risk decision-making is closely connected with the second: in evaluating the appropriateness of risk control measures, Europe intends to take into account cost/benefit considerations.\textsuperscript{813} Twenty years ago, the Council issued a recommendation on the methods of evaluating the cost of pollution control, in which it stated that "[t]he cost evaluation is intended to determine the size of the burden to be born by the economy as a whole or by individual sectors of industry where specific measures are taken by the authorities to protect the environment, to provide data on the most cost-effective ways of reducing pollution and, under certain conditions, to help to determine quality objectives and/or emission standards".\textsuperscript{814} The Recommendation thus primarily embraced the soft version of regulatory cost/benefit analysis, but also left the door ajar for the reception of hard cost/benefit principles in risk decision-making. As discussed before, the soft version of cost/benefit centres on cost-effectiveness, and aims to ensure that health and environmental objectives are accomplished at the lowest regulatory expenditure possible. The objective of cost-effectiveness is therefore closely related to that of proportionality, which generally prescribes the attainment of regulatory goals by the least intrusive means.\textsuperscript{815} Both principles are reiterated in the Water Policy Proposal, at section 5 of Article 21.

Following the hard version, cost factors should help to determine not only the most suitable instrument for intervention, but also whether regulatory intervention is appropriate \textit{per se}. The possibility of applying the hard version in EC health and environmental decision-making was confirmed in Article 130R of

\textsuperscript{811} Cf. Chapter I, heading 3.3.
\textsuperscript{813} TURNER J. SMITH JR, o.c., pp. 276-277.
the EC Treaty: "[I]n preparing its policy on the environment, the Community shall take account of (...) the potential benefits and costs of action or lack of action" (emphasis added).816 In secondary legislation, the Pesticides Directive explicitly states that the economic costs of risk reduction measures should be taken into account (see above). In more covert terms, the Article 10(3) of the Existing Substances Regulation calls for an analysis of the "[a]dvantages and drawbacks" of substances for which control measures have been recommended.817 Finally, we saw in Chapter III that economic considerations have also played a role in determining the stringency of market restrictions: the phasing-out of PCTs (polychlorinated terphenyls) followed a two-step approach because an immediate ban would have had caused disproportionate economic disruption.818

The recent introduction of priority-setting techniques (in the Existing Substances Regulation and the Water Policy Proposal) indicates a growing interest on the part of the EC to integrate comparative approaches into risk decision-making. So far, the efforts made in this direction are very modest. The Existing Substances Regulation, for one, only introduces priority setting for data gathering activities, but makes no direct reference to comparative risk assessment as such, i.e., the technique of ranking health and environmental risks in accordance with the risk characterisations flowing from standardised assessments in order to determine the substances for which risk reduction measures are most pressing.819 Furthermore, the criteria for prioritised data gathering are very generally defined. Article 8(2) of the Regulation stipulates that "[f]actors to be taken into account in drawing up priority lists are:

- the effects of the substance on man or environment,
- the exposure of man or the environment to the substances,
- the lack of data on the effects of the substance on man and the environment,
- work already carried out in other international fora, and
- other Community legislation and/or programmes relating to dangerous substances".

These widely defined criteria, in addition to the relatively loose

816 Article 174 ToA.
817 TURNER J. SMITH JR, o.c., p. 279.
819 Cf. Chapter III, Section II.3.
requirement that they should be “taken into account,” leave the Commission, which draws up priority lists in consultation with the Member States,\textsuperscript{820} with a broad margin of flexibility. The Water Policy Proposal takes comparative methodology one step further: it specifically refers to the results of risk assessments (“risk evaluations”) as a basis for priority-setting, and deploys the much more forceful language of “priority lists being determined by risk evaluations,” which leaves far less room for the Commission to deviate from the ranking that is informally imposed by risk assessors (usually scientific experts) and reflected in the different risk characterisations (stage four of risk assessment). The formulation of Article 21 of the Water Policy Proposal therefore suggests a shift towards a more explicitly science-based and standardised form of comparative risk assessment in EC decision-making.

Perhaps to counterbalance the formal and deterministic tone of the previous requirement, Article 21 of the Water Policy Proposal provides in consultation with a widely drawn circle of institutions and interest groups. The Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds, the Member States, the European Parliament, the European Environmental Agency, Community research programmes, international organisations of which the Community is a member, European industrial organisations which also represent small and medium-sized enterprises and European environmental organisations may all directly submit recommendations to the Commission. In the Existing Substances Committee, by contrast, interest groups are not directly involved in the committee procedure, and therefore need to rely on the intermediacy of the Commission and/or national representatives to make themselves heard officially. On the other hand, given the greater deference paid to science-based risk evaluations in the Water Policy Proposal, it remains to be seen on which of the two priority lists interest groups will be able to exercise the greatest influence (if any).

In summary, the general framework for EC risk decision-making pertaining to chemicals displays the following aspects:

\begin{itemize}
  \item acceptance of a residual risk;
  \item openness to both the soft and the hard version of cost/benefit analysis;
  \item growing interest for comparative risk assessment; and
  \item recent emphasis on direct participation, although firm commitments are
\end{itemize}

\textsuperscript{820} Following a contre-filet procedure set up in Article 15 of the Existing Substances Regulation.
scarce.
Within the general framework, a niche is carved out for carcinogens, mutagens and substances toxic to reproduction, which are deemed per se dangerous and for which a much lower risk tolerance level is assumed.

3. Managing Uncertainties: A Precautionary Tale

Relying on scientific measurements (classification) as well as tests, estimates and standardised prediction methods (risk assessment), the hazard- and risk-based approaches used in contemporary chemical control seek to substitute experience as a basis for decision-making by a new, differently generated and gathered type of knowledge. Thus, hazard- and risk-based decision-making could be viewed as a functional equivalent to former danger- and causation-based approaches.

However, throughout this study we have come to appreciate that even the most sophisticated scientific assessments and models are usually not capable of delivering foul-proof results; outcomes of risk assessments range from highly plausible to inconclusive.\textsuperscript{821} Whereas it may be possible to relieve remaining uncertainties through immediate further testing, it might equally be the case that additional information gathering would require a long-term investment. Risk assessors -- or the respective competent authorities they work for -- might have different opinions on the relevance, reliability and interpretation of identical test results.\textsuperscript{822} Public authorities, in turn, might have widely diverging views on which risk levels (or indications) warrant intervention, and which do not.\textsuperscript{823} Finally, even when all parties involved agree on the existence of a risk sufficiently great to warrant intervention, an immediate regulatory solution may not always be at hand.

In sum, between determinations of “clearly safe - no intervention required” and “clearly dangerous/risky - intervention X required,” lies a vast grey zone that cannot readily be enlightened through the application of hazard or risk assessment techniques. In light of these limitations, it becomes paramount to ask what the European Community’s stance is on problems of

\textsuperscript{821} Furthermore, we should not forget that vast numbers of chemicals, marketed before the adoption of the risk assessment Directive, have not even been subjected to a fully-fledged risk-assessment.
\textsuperscript{822} FRANZ KOHOUT, o.c., p. 157.
\textsuperscript{823} French and German public authorities, for example, disagreed about the risk related
uncertainty.

3.1 Devolution of decision-making

Before 1992, the EC's policy relating to substances and products posing insufficiently revealed, uncertain risks was relatively straightforward: in areas of doubt, the Community as a rule refrained from intervening and left the issues to be resolved by the Member States individually.\textsuperscript{824} Considering that the adoption of most Community legislation requires at least a qualified majority in the Council,\textsuperscript{825} it is easy to see how scientific and technological uncertainty could obfuscate the legislative process. In the absence of conclusive scientific evidence, Member States were free to pursue national health and environmental policies according to their own discretion. This attitude was principally enshrined in a number of decisions taken by the European Court of Justice, which allowed Member States to uphold trade barriers for purposes of health and environmental protection in cases of insufficient evidence and/or lack of scientific consensus.\textsuperscript{826}

\textsuperscript{826} A seminal case in point is the Eyssen decision (Officier van Justitie v Koninklijke Kaasfabriek Eyssen BV, Case 53/80 [1981] ECR, 409). The facts of the case are the following: the Dutch government prohibited the presence of a food additive called nisin in cheese. This prohibition only applied to cheese sold on the domestic market. Although the nisin prohibition clearly constituted a trade barrier, and even one discriminating between domestic trade and export, the Court decided that the Dutch rule was justifiable on the basis of Article 36 of the EC Treaty (Article 30 ToA). In its judgement, the Court acknowledged the difficulties international organisations were facing in assessing the risks relating to the use of nisin, and reasoned that this scientific uncertainty might explain different national views on the harmfulness of the substance. It further referred to different dietary habits in the various Member States, indicating that in a country where cheese is consumed in great quantities, such as the Netherlands, concerns about food additives in cheese might assume a more pressing character, justifying the difference in treatment between cheese destined for the Dutch market and cheese for export. The rule which links scientific uncertainty to national discretion in policy decision-making, was reconfirmed in later Court decisions, such as the Sandoz and Van Bennekom cases [174/82, Sandoz BV [1983] ECR, 2445; 227/82, Van Bennekom, [1983] ECR, 3883]. The Sandoz decision furthermore made clear that Member States' discretion to take protective measures restricting the free movement of goods would also be respected in cases where scientific research was being undertaken, but insufficiently advanced to be conclusive: "[A]ccording to the observations submitted to the Court, however, scientific research does not appear to be sufficiently advanced to be able to determine with certainty the critical quantities and the precise effects "(of vitamins consumed in large quantities).
The deference owed to national discretion in the pursuit of health and environmental policies is reflected in Article 130T of the EC Treaty, which stipulates that the adoption of EC measures to further environmental objectives "shall not prevent any Member State from maintaining or introducing more stringent protective measures" (the opt-up clause).\(^{827}\) A similar clause was inserted in Article 100A (Maastricht version), which governs the approximation of national laws, regulations and measures affecting the establishment or functioning of the common market.\(^{828}\) Article 100A(4) provides: "If, after the adoption of a harmonization measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions. The Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States" (emphasis added).

Interestingly, when Germany relied on this clause to maintain more stringent restrictions on the use of pentachlorophenol (PCP) than the ones listed in Directive 91/173/EEC,\(^{829}\) the Commission decision authorising Germany's derogation from the Community system was challenged by France on the grounds that the decision failed to meet the necessity and proportionality tests under Article 100A(4).\(^{830}\) The case went to the European Court of Justice, which decided that, indeed, the Commission had insufficiently reasoned its decision -- a duty which it has pursuant to Article 190 of the EC Treaty \(^{831}\) -- and accordingly annulled the decision.\(^{832}\) Thus, the Commission was sent back to drawing board. In September 1994, it issued a Decision re-authorising Germany to maintain its ban.\(^{833}\) Only, in contrast to the first authorisation, the second one went into great detail justifying the grounds for the exemption and arguing

\(^{827}\) Article 176 ToA. See LUDWIG KRÄMER (1993), "Environmental Protection," o.c., p. 113.
\(^{828}\) Article 95 ToA.
\(^{831}\) Article 253 ToA.
its compatibility with the substance and procedures of Community law.\footnote{834} Although the second authorisation still met with some protest and discontent,\footnote{835} it does now appear that it will remain uncontested. In the mean time, the Commission has issued a similar PCP exemption for Denmark, and other exemption seeking countries are awaiting a response from the Commission.\footnote{836}

The tribulations surrounding the use of Article 100A(4)'s opt-up clause are indicative of a number of factors complicating health and environmental regulation at the EC level. First, the PCP case uncovers latent tensions between market harmonisation and environmental differentiation. Whereas the Article 130T provision allowing Member States to opt up from purely environmental measures comes with no strings attached,\footnote{837} the Court has conditioned divergence from market harmonisation objectives pursuant to Article 100A(4) upon adherence to procedural and substantive standards. In other words, the Member States and, in its confirmation of diverging measures, the European Commission, have a much stronger duty to substantiate opt-ups when these might weaken the functioning of the common market. This "giving reasons requirement" has recently been confirmed in the Treaty of Amsterdam, which renumbers Article 100A(4) as 95(4), and adds two new provisions. Thus, Articles 95(4) to 95(6) now read as follows:

\[*[4]. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36,\footnote{838} or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after
the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether they are a means of arbitrary discrimination or a disguised restriction on trade and whether or not they shall constitute an obstacle to the functioning of the internal market (emphasis added).

The wording of the new version resolves some of the issues that used to complicate application of Article 100A(4). Whereas in the Maastricht edition, it remained unclear whether opt-ups covered new as well as existing national measures, the Amsterdam version clearly confirms the possibility of national derogations from the Community framework through adoption of new measures as well as through maintenance of previously enacted national provisions. While this gives the opt-up clause a broader scope of application than a restrictive interpretation of Article 100A(4) of the Maastricht Treaty would have warranted, national divergences from harmonising measures are on the other hand limited through the introduction of stricter procedural requirements for the approval of opt-ups. A reasoning requirement is explicitly confirmed for both existing measures and national provisions introduced after the adoption of a harmonisation measure. In the latter case, Member States are to substantiate divergences from the Community framework on the basis of new scientific evidence, and by documenting a problem specific to the Member State, which moreover manifested itself after the adoption of the harmonisation measure.

Following this requirement, it is possible to envisage scenarios where a Member State has legitimate grounds to diverge from the Community measure, but is not in a position to do so. During negotiations and analysis of a Community proposal to introduce a harmonising measure, a Member State might become aware of a particular national situation which makes the introduction of this measure problematic. However, since Article 100A provisions are adopted by qualified majority voting, this State might be outvoted in the Council. After adoption of the harmonising measure, the Member State will not be able to opt up, because its specific problem (a) was not addressed in existing national measures, and (b) did not arise after the adoption of the Community measure. In its present form, the opt-up clause fails to cover such situations.

The insertion of the words "or reject" in paragraph 6 further underscores the Commission's duty seriously to examine the grounds put forward by the
Member States, and suggests that derogations from the Community framework should not be granted as a matter of course. As to Commission verification of national notifications, it is important to note that the requirement to examine whether national measures constitute disguised trade restrictions has been supplemented by a much vaguer and more encompassing one, namely a verification of whether the national measures impede the functioning of the internal market. At this point, it is difficult to say whether this insertion will effectively widen or narrow the scope for opt-ups. If paragraph 6 is interpreted literally, saying that both conditions have to be fulfilled simultaneously to warrant a rejection (i.e., a national measure is a disguised trade restriction and will have an actual adverse effect on the internal market), this may slightly extend the scope for approvals. If, on the other hand, a finding that a national measure would present an obstacle to the functioning of the single market alone would be sufficient to reject the notification, this could seriously limit opportunities for opt-ups.

Thus, while the Amsterdam version does resolve some of the outstanding questions pertaining to the application of Article 100A(4) under Maastricht, it raises a host of new ones. Hence, the tug-of-war between market harmonisation and environmental differentiation, which is the undercurrent propelling conflicts under Article 100A(4), is anything but decided.

Second, a close reading of the PCP case hints at another, more insidious problem. At several points, the 1994 Commission decision (second confirmation of the German ban) indicates that Germany esteems the health risks emanating from PCP more serious than, for example, France.\textsuperscript{839} The disagreement between the two countries appears not so much due to insufficiency of scientific information, as to conflicting opinions relating to the value of different types of scientific and science-based information. Here, uncertainty and discrepancies in national treatment of similar health problems are more closely connected to scientific controversy than to scarcity of scientific data. As science progresses and requirements to subject products, processes and activities to scientific testing and analysis multiply, it becomes more and more likely that problems of uncertainty will be expressed in terms of controversy, disagreement between experts, and conflicting scientific models. Other than emphasising that national

\textsuperscript{839} The fact that France had ceased PCP production before the adoption of the Community measure, whereas Germany is Europe's biggest producer of PCP, might have contributed to its more optimistic attitude vis-à-vis PCP's health risks. ROBERT D. SLOAN & PASCAL CARDONNEL, o.c., p. 46.
regulatory decisions should take into account the results of (international) scientific research, the European Court thus far has given but scant indications on how scientific controversies, resulting in different national risk policies (and, hence, in trade barriers), should be resolved.  

For example, in the 1982 Commission v. Ireland case, the Commission argued that the Irish ban on the import of poultry meat from Member States that permit vaccination against the Newcastle disease was an unpermissible barrier to trade. The Commission’s argument was based on statistics indicating a low and further decreasing incidence of the Newcastle disease in the Community. Ireland retorted by submitting veterinary studies showing that, in countries where vaccination was permitted, the virus still subsisted, although masked by the effects of vaccination. In its reply, the Court decided in favour of the Commission, referring back to the offered statistics and their trustworthiness. It did not explain, however, why the studies handed in by the Commission were more reliable than those submitted by Ireland. Possibly, the decision might be interpreted to mean that, in case of controversy, the Court will be disinclined to uphold a measure that obstructs the project of EC market integration. However, so far the EC’s position on issues of scientific controversy remains insufficiently clarified.

3.2. The precautionary principle in the Maastricht Treaty

Until 1992, the European Community would as a rule stay out of issues shrouded in uncertainty, and leave them to national discretion. However, with the adoption of the Maastricht Treaty, a new principle found its way into Article

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842 Interestingly, similar battles over the validity of conflicting scientific assessments and expert opinions are now replicated at the international level. During the past years, the EC has been fighting a losing battle to legitimise its import bans against US-produced beef, which contains hormones. European and American scientific experts and policy makers disagree about the dangers attached to the use of hormones in products destined for human consumption. In dispute resolution, the World Trade Organisation (WTO) ruled against Europe, which nonetheless still refuses to import US beef. See “European Communities – Measures Affecting Meat/Livestock and Meat Products (Hormones)” Cases WT/DS26/AB/R and WT/DS28/AB/R. See also fn. 988.

843 Cf. C-17/93, Van der Veldt, [1994], ECR, I-3537. A similar reasoning might have persuaded the WTO to rule against the European Union in the beef hormone case.
which potentially heralds a change of approach in EC environmental policy making: the precautionary principle. Until its incorporation in the Maastricht Treaty, the precautionary principle had been developed mainly in German law, where it was deployed to broaden the scope of environmental protection to encompass actions against those dangers and risks that are either too temporally or spatially remote, or that cannot be established with a sufficient degree of probability to fit within the traditional danger-based (or even the newer risk-based) framework.

Significantly, even after more than twenty years of experience with the precautionary principle and its application in practice, its precise portent and meaning remain debatable, as German legal students and scholars readily acknowledge. This is even more so for precaution as a European law principle. Beyond the minimum consensus that precaution embodies the idea that taking regulatory measures to prevent possible risks may be legitimate, even in the absence of conclusive scientific evidence on causal relationships or on the extent of anticipated damage, opinions on its scope and interpretation differ substantially within and among the Member States. Britain, for example, apparently gives a narrower interpretation to the concept of precaution than the one developed in Germany. The fact that, thus far, European Union
institutions (in particular the Council, the Commission, the European Court and the European Environment Agency) have done little to clarify the meaning of precaution as an EC law principle, only adds to the confusion.

Precautionary approaches have, *inter alia*, been associated with adherence to best available technology (BAT) or best available technology not entailing excessive costs (BATNEEC) standards. Here, precaution is linked with the development and promotion of cleaner technologies, and emphasises technical, engineering solutions to health and environmental problems.851 BAT standards are said to loosen the ties between causation-based requirements for the demonstration of harm and regulatory intervention, because: "[T]hey require pollution to be reduced, not because harm can be demonstrated, but simply because it is technologically and economically feasible to do so. Thus, they do not depend on evidence of cause and effect relations between pollution activities and environmental harm."852

For substances and products, an equivalent of the BAT/BATNEEC standard can be found in the substitution principle, which warrants the systematic replacement of dangerous substances by, on the face of it, safer ones. We recall that the European Community has embraced the substitution principle in its treatment of carcinogens and, more recently, chemical agents

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Environmental Strategy presented to Parliament, September 1990, Cm 1200, pt. 1.18. The 1994 *Duddridge* decision, taken by the UK Queen's Bench Division, furthermore indicates that neither the statements in the White Paper, nor the incorporation of the precautionary principle in the EC Treaty, should be viewed as creating binding standards for government action. With respect to the White Paper, Justice Smith ruled that "[i]f the Government announces a policy which it intends to adopt without being under any obligation to do so, it must be entitled to define the limits of that policy in any way it wishes." Incorporation of the precautionary principle in the EC Treaty does not alter this prerogative, since "Art 130r (of the EC Treaty) does not impose an obligation upon the Secretary of State to consider his duties (pursuant to national legislation) in light of the precautionary principle." *R v Secretary of State for Trade and Industry ex parte Duddridge*, UK Queen's Bench Division, judgment of 4 October 1994, rendered in Vol. 2, *Journal of Environmental Law*, N° 2, pp. 224-244 (with comment by David Hughes). *Cf* Section II.4.3 of Chapter V. *See also* NIGEL HAIGH (1994), "The Introduction of the Precautionary Principle into the UK," in TIMOTHY O'RIORDAN & JAMES CAMERON, o.c., pp. 229-242.

851 This is the interpretation generally adhered to by German bureaucracy, and has to a considerable extent been taken over at the EC level. SONJA BOEHMER-CHRISTIANSEN, o.c., p.50.

852 DANIEL BODANSKY (1994), "The Precautionary Principle in US Environmental Law," in TIMOTHY O'RIORDAN & JAMES CAMERON, o.c., p. 221. On the other hand, it should be mentioned that, within a BAT framework, the adoption of progressively more stringent standards becomes a self-legitimating process, which implies that there will be less ground for revision and *ex-post* improvement of regulatory decision-making. This, in turn, results in reduced self-learning capacities of regulatory structures aimed towards the adoption and enforcement of BAT standards.
generally.\textsuperscript{853}

For product- and substance-oriented regulation, compliance with the precautionary principle may furthermore be reflected in the adoption of conservative assumptions and broad safety margins. A conservative assumption is, for example, the assumption that, if a substance administered to test animals in concentrated doses causes cancer, there is no safe dose at which the substance can be inhaled or ingested without producing a risk of cancer. As to the calculation of safety margins, let us assume that a substance has a “no observable adverse effect level” (NOAEL) of 1 mg/kg.\textsuperscript{854} This means an intake of the substance at levels below 1 mg/kg does not cause any observable harm. However, to err on the side of caution, regulatory authorities might decide to set the maximum allowable daily intake (ADI) at a level that is 10, 100 or even 1000 times lower than the NOAEL.\textsuperscript{855} The greater the difference between the NOAEL and the ADI, the broader the margin of safety (or, the higher the level of precaution).

A more radical reading of precaution suggests that the application of the principle should entail a reversal of the burden of proof for the authorisation of industrial activities, processes and substances. Parties seeking to introduce new and risky substances or practices into the environment, should be required to provide conclusive evidence of their safety. In the absence of sufficient scientific data to back up the moving party’s claims of safety, regulatory authorities should refuse to authorise the substance or practice at issue.

This interpretation of precaution has met with considerable controversy. Industrial enterprises, particularly those active in new and developing industries, vehemently argue against the presumption of danger, and stress that an across-the-board reversal of the burden of proof would paralyse production and have disastrous effects on economic competitiveness. It is difficult to assess whether the consequences of a full reversal of the burden of proof would indeed be as apocalyptic as industry claims, however it stands beyond reason that industry’s ardent resistance against this approach seriously hampers its political viability.\textsuperscript{856} Moreover, it is undeniable that, legally, a universal reversal of the

\textsuperscript{853} See also the discussion at point 3.3 below.
\textsuperscript{854} This means that the substance produces no observable adverse effect when ingested in quantities below 1 mg per kg. Cf. Ch III, Intro, 1.
\textsuperscript{855} In US pesticide registration procedures, for example, the NOAEL and ADI usually differ by a factor of 100. GEORGE M. GRAY & JOHN D. GRAHAM (1995), “Regulating Pesticides,” in JOHN D. GRAHAM & JONATHAN BAERT WIENER, o.c., p. 176
\textsuperscript{856} Cf. TIMOTHY O’RIORDAN & JAMES CAMERON, o.c., p. 23: “[t]he European Union is
burden of proof would clash violently with one of the basis principles embodied in the concept of the "Rechtsstaat," namely that one should be free to do what does not harm others, and that harm should be proven before this freedom is curtailed. If, on the other hand, the burden of proof were only reversed for newly developed products and processes, this would disproportionately favour the maintenance of existing ones, which might be disadvantageous from an economic as well as a health and environmental viewpoint.

Hence, reversal of the burden of proof is usually suggested for targeted categories of substances or activities that are considered dangerous per se. For example, the fourth amendment to the German Regulation on Dangerous Substances (1993) introduced a general prohibition on worker exposure to chemical compounds with N-nitrosamine. Tests had indicated that 90 per cent of all examined N-nitrosamine substances were carcinogenic. Thereupon, the German regulator opted for an across-the-board prohibition. Exemptions can only be obtained upon submission of scientific evidence attesting the non-carcinogenicity of specific compounds.857 The prohibition thus provokes a reversal of the burden of proof for a limited range of products, illustrating at the same time that this type of precaution is itself implemented with due caution.

A fourth approach to precaution advocates a general reduction of stress on health and the environment, with or without there being concrete indications of potential harm.858 This approach has also been expressed in terms of "safeguarding of ecological space."859 For similar reasons as the ones discussed above, practical implementation of this version of the precautionary principle is as a rule limited to targeted categories of practices or substances.860 In substance-oriented legislation, reductions of health and/or environmental stress caused by specific groups of substances are frequently effectuated through a replacement rule, ordering that, where feasible, "safer" substances should be substituted for target substances.861 European Community legislation

deeply ambivalent about precaution. At the environmental protection end, there is much sympathy for the principle, particularly because of the need for cross-border compliance. But at the "top" end of strategic policymaking there is far less enthusiasm with much greater emphasis on promoting growth and excessive stimulation in a recession-prone European economy". Also JOHN S. APPLEGATE (1992), "Worst Things First," o.c., pp. 283-284.

857 MICHAEL AU, o.c., p. 241.
858 THOMAS KIENLE, o.c., p. 872.
859 TIMOTHY ORIORDAN & JAMES CAMERON, o.c., p. 17.
860 Thomas Kienle (1996) gives the example of reducing the emission of oestrogens in water. KIENLE, o.c., p. 872.
on health protection in the workplace includes a replacement rule for carcinogens. Attractive as this strategy may sound, intelligent application of replacement rules is fraught with difficulties, as will be further discussed in the following Section.

Finally, according to authors such as Wolfgang Köck, Karl-Heinz Ladeur and Olivier Godard, the adoption of a precautionary approach should most of all be linked to the previously discussed modern risk management concepts of planning, experimentation and revision of rules. Wolfgang Köck (1996) considers that a precautionary approach requires that risk regulation takes into account "[t]he danger of incorrectly assessing dangers." In other words, a precautionary approach should be aimed at strengthening the regulatory apparatus' ability to control the outcomes of its own operations, through the continued and targeted gathering of new information, through monitoring and the development of regulatory strategies to improve or amend regulatory decisions ex-post. In a similar vein, Godard (1997) argues: "[p]recautionary action is not intended to support a definitive commitment or prohibition, but presumably a transitory one. Since the real limits of nature are unknown, our regulatory measures should be looked upon as experiments which have to be controlled and analysed, as is done for scientific experiments in order to improve our knowledge. Then, we must develop regulatory measures which allow future progress in knowledge to be welcomed. This means maintaining a sufficient reversibility of rules." Of all approaches to precaution discussed, this last one places the strongest emphasis on procedural instead of substantive modernisation of the legal and regulatory framework.

### 3.3 The precautionary approach exemplified

Going over the range of EC regulatory instruments for the control of chemicals, a number of approaches could be qualified as precautionary according to the various definitions provided. This is most noticeably the case for carcinogens, as well as mutagens and reproductive toxins. As discussed, assessment techniques for these substances incorporate conservative assumptions, and across-the-board restrictions apply for their marketing, sale

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864 OLIVIER GODARD, o.c., p. 72.
and use (14th and 16th amendment to Directive 76/769/EEC).865

Pursuant to workers' health legislation, employers are to replace carcinogens by less dangerous substances, in so far as it is technically possible.866 The substitution principle embodies a precautionary approach: we should not require exhaustive evidence before banning a substance; the existence of an alternative substance that, on the basis of available information, appears less dangerous, suffices. While the substitution principle is one of the most dynamic and progressive elements of the European Community's chemicals control policy, it is nevertheless necessary to be aware of the risks of substitution. Intelligent substitution calls for a comparison between risks, which is an extremely difficult and precarious undertaking.867 The relative risk attributed to substances may differ substantially, depending on whether one focuses on the immediate or long-term effects, the health effects on workers or the safety for the general population, the effects on health or on the environment, etc. This does not even take into account the varying potential of substances for synergy with other chemicals, which may result in a prima facie safe substance causing much greater health or environmental damage than a targeted dangerous substance, when it is used in combination with certain other chemicals. Not surprisingly, the development of a workable, sufficiently sophisticated and equitable system for chemical risk comparison is generally considered one of the most challenging, even daunting tasks which lay ahead for regulatory authorities in the years to come. As we have seen in Section II.2.4. above, the European Community is only now making its first hesitant steps in this direction.

In light of the complexities of comparative risk assessment, and the high probability of occurrence of countervailing risks,868 one might question the wisdom of the present replacement requirement, which is imposed on employers individually without being linked to any more centralised and broadly informed efforts to at least draw up guidelines for comparative assessments. Conceivably, employers will focus mainly, if not exclusively, on those substances causing acute rather than chronic health effects on small but identifiable groups of workers. Hence, they might be prone to replace dangerous but controllable...

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865 See Section II.2.4 of this Chapter.
866 See Section II.1.3(b) of this Chapter.
867 ANDREAS THEUER (1996), "Risikobewertungsmodelle," o.c., p. 129; BRADFORD C. MANK, o.c., p. 283.
868 Cf. JOHN D. GRAHAM & JONATHAN BAERT WIENER, o.c., pp. 1-41.
substances by chemicals the effects of which are latent, more diffuse and more
difficult to trace, not knowing whether the net result of their actions will be a
higher, or a lower level of protection.\textsuperscript{869} Even more predictable is the
replacement of chemicals creating health risks, however remote, by substances
that pose environmental risks. The 1998 Directive on chemical agents at work
actively encourages this approach. It excludes substances and preparations
"which only meet the criteria for classification as dangerous for the environment" from its definition of hazardous chemical agents.\textsuperscript{870} Consequently, when an
employer replaces, say, a corrosive substance by one that is only dangerous for
the environment, she has according to the letter of the Directive substituted a
non-hazardous for a hazardous substance. And this even in cases where the
potential harm to the environment is substantial and acute, whereas the risk to
health is relatively small and easily contained by other means.

Additional precautionary approaches in the regulation of chemicals are
the previously discussed priority-setting schemes, which aim to strengthen the
basis for strategic decision-making and long term planning, and certain
monitoring and review provisions applicable to specific chemicals. These groups
of measures represent a more procedural style of precaution: they emphasise
learning and \textit{ex-post} correction of interventions. However, what was said about
priority setting equally goes for monitoring and review procedures: the EC
framework is quite rudimentary, and there is substantial scope for clarification
and improvement. Monitoring continues to be used more for compliance control
than learning purposes, with requirements often only attaching to substances
that are already known to pose certain dangers to health or the environment.\textsuperscript{871}
Furthermore, new instruments such as the 1996 Integrated Pollution Prevention
and Control Directive focus on release monitoring, \textit{i.e.}, tracking of quantities and
types of industrial emissions, but do not cover monitoring of effects of various
emissions on the environment. So far, private duties for monitoring of effects
only exist for employers vis-à-vis employees who are exposed to chemicals in the
work place. As to review procedures, they are foreseen for pesticides and
biocides, which require an authorisation review (possibly followed by an
authorisation renewal) at least every ten years.\textsuperscript{872} However, the organisation of

\textsuperscript{869} Cf. CASS SUNSTEIN (1996), "Health-health," \textit{o.c.}, pp. 1541-1542.
\textsuperscript{870} Articles 2(i) and (ii) of Directive 98/24/EC.
\textsuperscript{871} See, \textit{e.g.}, Article 6 of Council Directive 96/62 of 27 September 1996 relating to air
\textsuperscript{872} See Articles 4(4) to (6) of Directive 91/414/EEC, and
periodical as well as incidental review procedures is left to the individual Member States; there are no EC stipulations relating to either the thoroughness or swiftness of review mechanisms. No systematic review procedures exist for other types of chemicals; there is only the general requirement that notifiers alert competent authorities of new, relevant information, a requirement that is in itself regrettably vague.
SECTION III - EVALUATION

Briefly, before turning to the overall evaluation of EC risk regulation in Chapter V, it is useful to highlight a few aspects of the risk management techniques discussed above.

1. How Modern is EC Risk Regulation: A Mixed Review

Analysing existing risk management techniques, as they have been enacted in European legislation, against the backdrop of the regulatory reform proposals listed in Section I, it becomes clear that EC legislation has at least attempted to integrate certain modern elements and ideas into its health and environmental risk control policies. Few would dispute that European institutions have understood that information supply and warnings can affect industrial user and consumer behaviour, which in turn sends signals to manufacturers. When it comes to the development and control of labelling requirements for dangerous substances, few, if any, information schemes are as sophisticated as the European Community's.

There is also a growing awareness of the role that access to information and participation can play in the development of risk policies. In Europe, this awareness is probably sharpened by the "democratic deficit" that plagues European Union decision-making generally. Opening up decision-making processes to public assessment and consultation is not only a tool for risk policy reform, it is also a strategy to strengthen Europe's democratic credentials and to legitimate measures taken by European institutions, particularly the European Commission. Hence, the general objective of softening the elitist, bureaucratic image of EU institutions might play a greater role in the adoption of provisions guaranteeing, for instance, interest group participation and deliberative decision-making in priority setting for aquatic pollutants, than the specific concern of coping with uncertainty in risk decision-making. It could be said that, in this scenario, EC risk policy reform rides the coattails of EU

democratisation efforts.

Furthermore, EC health and environmental law is increasingly characterised by a desire to move beyond crisis management and lay down a framework for long term risk reduction policies. The Seveso Directive, enacted in 1982, was one of the first legal instruments reflecting a philosophy that risks should be approached strategically, and that risk management should form an integral part of industrial management, not an externally imposed burden. The Seveso II Directive, which amends the original, strengthens precisely those strategic and planning-oriented aspects of the 1982 version. The compulsory risk internalisation schemes mapped out in the Seveso and Seveso II Directives are flanked by voluntary, self-regulatory initiatives, such as eco-management and audit. One of the best-known, and allegedly most successful self-regulatory programmes was developed by and for the chemical industry: the Responsible Care Programme. This Programme has been hailed (most fervently in industrial circles) as representative of a new generation of entrepreneurship, one that adopts a more responsible approach to production and seeks to reconcile profit-seeking with the imperatives of a healthy and green environment. Responsible Care has been said to serve as a blueprint for other industrial sectors that plan to internalise risk management into their business processes.874

In sum, it is undeniable that EC authorities in charge of health and environmental regulation have made some effort to "modernise" their approach, to develop a regulatory framework that is more responsive to those problems that traditionally bedevil attempts at chemical risk control, such as invisibility and latency of effects, cross-media migration of pollution, uncertainty and rapid change. Nevertheless, there are grounds to be wary of the eagerness with which the Community (or, in the case of self-regulation, industry) at times announces breaks with tradition and new approaches. They may be more symbolic than real. It is telling that the core provisions in, for instance, the Integrated Pollution Prevention and Control (IPPC) Directive, which is said to epitomise the new approach to environmental regulation, still revolve around the adoption of limit values for emissions (Article 9(3) of the Directive).875 The establishment of limit values is not exactly a revolutionary approach, and only makes sense for well-studied and understood substances and technologies.

874 See NEIL GUNNINGHAM, o.c., pp, 59-62.
Admittedly, the IPPC Directive also contains more "dynamic" provisions, such as Article 13 requiring that issued permits are reconsidered and updated periodically, however those conditions are phrased is such a vague and general manner that they do not actually constrain national licensing authorities. If a Member State were so inclined, it could easily dispense with its obligations by periodically re-rubberstamping previously granted permissions. Conceivably, such broad and vague provisions, as well as ambitious statements in preambles, do more to better the EC's reputation as a defender of the environment, than effectively to improve health and environmental protection in Europe. Similarly, provisions on consultation with experts and interest groups, as foreseen in the Water Policy Proposal, may be devised to fill in the democratic deficit rather than the information and certainty deficit (see above). This synergy might enable the Community to kill two birds with one stone, however it might just as well lead to a situation where formal compliance is valued over effective compliance, and interest group inputs are officially welcomed but practically ignored. If the EC seriously considers modernising its approach — and the Member States' approach — to health and environmental protection, general "pledges of allegiance" are probably insufficient.

In the area of chemical control specifically, a lot of work remains to be done. As I mentioned, the European Community's best efforts in modernising health and environmental regulation have been performed in the area of information supply. While the establishment of elaborate information duties is, in itself, laudable, it is important to remember that, as a regulatory measure, information supply is quite a "soft" instrument, and that its utility is limited for a number of reasons. First, various authors have suggested that there is a point

876 Article 13 provides:
* "[1]. Member States shall take the necessary measures to ensure that competent authorities periodically reconsider and, where necessary, update permit conditions.
2. The reconsideration shall be undertaken in any event where:
• the pollution caused by the installation is of such significance that the existing emission limit values of the permit need to be revised or such new values need to be included in the permit;
• substantial changes in the best available techniques make it possible to reduce emissions significantly without imposing excessive costs;
• the operational safety of the process or activity requires other techniques to be used;
• new provisions of Community or national legislation so dictate."
877 The insertion of qualifiers such as "substantial" and "significant" leave Member States an ample margin of discretion for deciding when reconsideration is necessary. Moreover, the Directive does not give any indication about the procedures to be followed in reconsideration (open or closed, written or informal), or the level of scrutiny to which permits should be subjected.
of diminishing returns for information supplied on, for example, packages and labels.\textsuperscript{878} EC institutions should bear this in mind when considering the introduction of new labelling requirements, and avoid the temptation of simply adding on requirements that are symbolic rather than effective. Second, it is difficult to warn users and consumers against uncertainty. EC labelling rules stipulate that experimental substances should bear the generic "Caution - substance not fully tested" label. However, this gives no indication how caution should be exercised. Moreover, it is very well possible that substantial uncertainty remains after a substance has been "fully tested." The problems of warning under conditions of uncertainty most significantly limit the effectiveness of information supply pertaining to environmental risks, which are (as discussed in Chapter II) more complex, less studied and less understood than health risks.\textsuperscript{879} The shortcomings of information supply for environmental risks are further exacerbated by the relatively greater detachment of the recipients of the information. Readers may understandably take labelling information more seriously when it pertains to their personal health and safety, than when a more remote and vaguely contoured environmental harm is alerted to.\textsuperscript{880}

Development of procedural standards and guidelines for risk decision-making has been feeble: beyond indicating which comitology procedure should be followed in the event of delegated decision-making, very few indications are provided on how the Council, the Commission, or national competent authorities should structure and arrive at decisions pertaining to the appropriateness of regulatory measures for the control of chemical substances. We know that, theoretically, risk assessment results should be "taken into account." Various sources and legal provisions suggest that cost-benefit considerations should play a role. However, there is a significant lack of, first, documentation on how EU institutions use information such as risk assessments and cost-benefit calculations to arrive at regulatory outcomes,\textsuperscript{881} and, second, specific instructions to competent authorities located in the Member States on how to structure national (or regional) decisions. Some of the most recent initiatives in EC environmental law, particularly the Water Policy proposal, hold some promise in this regard: the instructions about priority setting methodology, for

\textsuperscript{878} See, inter alia, STEPHEN BREYER, o.c., p. 28.
\textsuperscript{879} HANS-WILLEM SCHIFFER & KILIAN DELBRÜCK, o.c., p. 1003.
\textsuperscript{880} Cf. STEPHEN BREYER, o.c., p. 35.
example, are more detailed and specific than in any preceding measure. Still, these are but the very humble beginnings of what will hopefully become a useful set of guidelines that will strengthen the procedural rationality of EC as well as Member States' law-making activities.

So far, economic instruments have not played a significant part in chemical control. It is obviously more difficult to devise economic incentives for manufacturers to reduce the risks inherent in the products they supply, than to encourage them to clean up production processes. Some advocates of economic instruments have toyed with the idea of introducing "risk rights" for chemicals and pesticides, an equivalent of the pollution rights allocated under tradeable permit schemes. The production of risky chemicals would be conditioned upon the acquisition of risk rights. Chemical manufacturers who succeeded in reducing the risks attached to the chemicals they market, would be able to sell off a portion of their risk rights and thus make a profit. It is an idea that merits further exploration, however, as economic instrument advocates acknowledge, the complexities of implementing such a scheme are daunting. To name but one complicating factor, it would require a calculation method for risks that is far more sophisticated than the ones presently available. Furthermore, economic instruments, we recall, do not perform adequately under conditions of uncertainty: we cannot trade what we do not know. Hence, the scope for risk permits seems limited at present.

With regard to strategic instruments such as priority-setting, monitoring and review, we recall that the EC legal framework is still in a rudimentary phase. Predictably, conversion towards long-term precautionary instruments will be laborious and time-consuming to implement. More alarming, however, is the ill-considered adoption of promising strategic principles, such as the substitution principle, that are far more complex than they appear. The introduction of such principles requires more forethought and coordination than has up to now been invested.

882 BRUCE A. ACKERMAN & RICHARD B. STEWART, o.c., p. 1349.
883 Interview with Daniel Dudek (Environmental Defense Fund), July 1995.
884 It might, on the other hand, be feasible to give economic incentives to users of chemical products to reduce risky activities. For example, one might develop a programme that taxes agro-industries on the use of pesticides. However, in order effectively to improve health and environmental protection, such strategies also require sufficient and reliable knowledge about the risks attached to chemicals, and about the availability and risks of substitute products or alternative techniques. If not, such programmes might result in negative risk tradeoffs, reducing instead of increasing the overall level of health and environmental protection.
Finally, risk internalisation by the chemical industry still has a way to go before it matures into a full-fledged regulatory, or self-regulatory, approach. "Responsible Care" is a positive initiative, but it struggles with problems of self-monitoring and compliance control. Seveso II has been adopted too recently for its impact to be known. The study of whether and to what extent internalised risk management contributes to better health and environmental protection is therefore a challenging task for the years ahead.

2. Health and Environment: Once Again, an Unbalanced Tandem

The risk control techniques in EC legislation are better suited for the prevention or reduction of health and safety risks than of environmental risks. Risk management rules thus display the same lop-sided structure as the framework for risk identification: their primary goal is the safeguarding of human health and safety, and risk control techniques are judged mainly on their effectiveness for human protection. If they are deemed sufficiently effective for the latter purpose, it is often assumed that they will also "work" for environmental risks. Unfortunately, that assumption may prove false on more than one occasion. We have discussed in Chapter II that pre-market testing is disproportionately crude for the revelation of environmental risks. With regard to risk management, we noted that the impact of information supply pertaining to environmental risks on industrial user and consumer behaviour is likely to be much smaller than the effect of health information on the same groups of people.

The emphasis on health risk management is further reinforced by, for example, the prioritised treatment given to carcinogens, and generally by the imposition of substitution requirements on employers, who are furthermore encouraged to rank environmental concerns much lower than threats to workers' health, even if the latter have a much smaller statistical chance of materialising. Obviously, there is nothing wrong with a high level of concern for health risks, or even for one health risk (cancer) in particular. However, in a world of limited resources and options for regulatory action, there may be serious drawbacks to compounding different categories of risk. When health and environmental risks are processed together through a regulatory selection mechanism that is particularly sensitive to health protection, environmental risks may systematically slip through the mazes of regulation. Hence, a need
may exist to correct in-built biases that are generally sound (we may principally rank health protection higher than environmental protection), but may in specific instances lead to unbalanced outcomes (for instance, where a substantial long-term environmental risk is substituted for a de minimis health risk). While most of the recently adopted EC legislation that affects risk decision-making for chemicals does not exacerbate the bias against environmental risks (for instance, the Existing Substances Regulation, the Air Quality Directive, the Water Policy Framework proposal), it nonetheless does little to prevent the occurrence of unbalanced outcomes.

3. **Creating boundaries of certainty**

As noted throughout our analysis of EC chemical control legislation, direct references to the concepts of either risk or uncertainty are remarkably scarce. In fact, the uncertainties that beset the study of chemicals and their interactions with man and the environment by and large remain hidden under the surfaces of risk management arrangements. Most importantly, the classifications according to which chemical substances and preparations are categorised in no way allude to the approximate, the preliminary character of the data on which they are based. Measurements and tests are done and re-done with at times different results; test readings are not always unequivocal; certain scientific models are embraced while others are set aside; data that are either too complex, too inconclusive or simply too ill-fitting are discarded or played down, observations are being artificially limited to a pre-defined period of time; appropriate classifications are being hotly debated between manufacturers and Commission officials, etc. And yet, the fifteen short and straightforward descriptors give no indication of this difficult and laborious process, or of the uncertainty of underlying data. Quite to the contrary, they create little islands of artificial certainty, upon which basis the regulatory framework is constructed.

It is hardly surprising that, within these boundaries of artificial certainty, principles such as precaution have difficulty taking root and acquiring practical significance. Those provisions that do implicitly acknowledge the precariousness and temporality of the “facts” underlying risk management decisions, and of the decisions themselves (such as provisions to the effect that on-site risk assessments should be reviewed when new information becomes available), seem quite isolated and unsupported. Usually, they are inserted into a pre-existing
framework without much apparent forethought on their precise meaning and scope, their enforceability, or their impact on risk management practice. Furthermore, as we discussed in Section II.2.1 of this Chapter, the classification system may have the unintended consequence of limiting the opportunities for integration of new information instead of expanding them. Only very recently, the Community has given a first signal that it might be converting towards a more open, less categorical approach to chemicals risk management. The recently adopted Directive on protection against chemical agents at work acknowledges that a chemical may be hazardous, and hence that regulatory measures might be necessary to contain the hazard, even if the this substance or preparation does not meet the criteria to be classified as dangerous.\footnote{See Article 2(iii) of Directive 98/24/EC.} The future will tell whether this provision truly heralds a new, more flexible and inclusive approach to the treatment of chemical risks, or whether it will remain an aberration in a classification-dependent regulatory framework.

The upshot is that EC legislation still has a long way to go fully to lay open the uncertainties inherent in information gathering, assessment and management of chemical substances. Only sporadically, the veil of artificial certainty is pierced. Admittedly, it would be unfair to portray this veil simply as an obstacle to more rational and dynamic risk decision-making. It also protects the legal system from the onslaught of new problems, dilemmas and conflicts that will emerge once uncertainty is indeed introduced and acknowledged in legal decision-making. The following and final Chapter therefore contemplates both the opportunities and drawbacks associated with a more thorough reform of the EC legal framework for chemical control, and subsequently asks whether and how such reform should be achieved.
CHAPTER V

RISK REGULATION

A Tale of Caution and an Agenda for Reform

INTRODUCTION

The previous Chapters mapped out what could be labelled the “regulatory life cycle” of chemical substances. The beginning of the cycle, enveloping the stages of hazard and risk identification and assessment, is characterised by a fairly unified regulatory approach: rules pertaining to information gathering and assessment for new and existing substances, as well as for specific groups of preparations such as pesticides and biocides, are tightly tailored along the same pattern. The risk assessment methodologies laid down for new and existing substances, for example, are virtually identical. By the time we reach the end of the cycle, the regulatory framework has branched out into a diversity of risk management measures, centring on the chemical substance or preparation itself (for example, market restrictions under Directive 76/769/EEC, or authorisation schemes for pesticides), the environment where dangerous substances are used (for example, regulation of industrial enterprises in the case of major accident hazards, or eco-audit and management), the medium into which substances are released (air, water and/or soil), targeted categories of people exposed (for instance, consumer protection through labelling, or the protection of employees exposed to chemical agents at work), or any combination of the above (such as the prohibition to sell carcinogens to non-industrial users).

Considering the multiplying structural complexity of chemical risk regulation as we near the end of the regulatory cycle, one might safely predict that, there, regulatory modernisation and reform would be most difficult to implement. In particular, the introduction of measures that aim to bolster the strategic, planning-oriented features of risk regulation, and of reforms that look to improve the overall coherence and consistency of the established framework, will be more arduous and complicated when the regulatory body in need of reform is dispersed over a variety of legislative documents and instruments, which are only loosely connected, sometimes overlap, and at other times contradict each other. It is therefore hardly surprising that, in our appraisal of
the reform efforts undertaken thus far by the European Community, the
parsimonious, concentrated risk identification and assessment provisions
"scored" relatively better than the multitude of risk management arrangements
that are scattered over many different EC Directives, Regulations, Decisions and
Proposals. Indeed, the move towards integration of risk and uncertainty, which
-- allowances made for inevitable imperfections -- seemed quite promising in the
Chapter on information supply, appeared to fizzle out somewhat in the stage of
risk management (Chapter IV). The latter stage continues to be dominated by a
danger-based, relatively impermeable classification system, which does not
provide sufficient opportunities for the efficient and effective use of different
types of information that are gathered before or acquired after the adoption of
risk reduction measures. Neither does it adequately accommodate the
introduction of strategic long-term decision-making procedures.\textsuperscript{886} Hence, future
reform efforts will need to concentrate predominantly on improving the
managerial aspects of risk regulation.

This does not mean, however, that the legal framework for data gathering
and risk assessment can no longer be improved upon. For example, with regard
to information gathering, we recall that the preference for one-stop-shop
approaches and standardised supply requirements may lead to sub-optimal
results, particularly for environmental hazard and risk data. The tension
between flexibility and temporalisation (which approaches better fit the purposes
of health and environmental protection) on the one hand, and uniformity and
finality (preferred by industry) on the other, is, indeed, the fundamental
dilemma that characterises chemical control regulation on the brink of
modernisation. As to risk assessment, although the foundations have been laid
down as Community standards, risk assessment still has to mature as an
integral part of EC risk regulation. At present, risk assessment prescriptions are
rather overly formulaic, and assessment results have not fully been absorbed in
risk decision-making processes (see below).

In this concluding Chapter, I will draw together the observations on risk
identification, assessment and management, and crystallise them into an overall

\textsuperscript{886} Cf. Dieter Murswieck (1991) on the regulation of technology generally: "[D]ie
klassische bürgerlich-liberale Perspektive der Beschränkung staatlicher Regelung der
Wirtschaftstätigkeit auf Gefahrenabwehr beherrscht noch immer das technische
Sicherheitsrecht. Und das heißt vor allem, das die Exekutive nicht zur Planung der
Technologieentwicklung, sondern nur zur Kontrolle der
Rechtmäßigkeit voraussetzungen im Einzelfall ermächtigt ist." DIETER MURSWIECK,
o.c., p. 153. See also FRANZ KOHOUT, o.c., p. 104.
review and critique of European Community risk regulation for chemical substances. I will then consider both the opportunities as well as the pitfalls of further regulatory reform, ending with some case-specific suggestions on how greater integration of risk and uncertainty into the EC legal framework might be accomplished.
SECTION I - THE LEITMOTIFS OF EC CHEMICAL REGULATION

Glancing over the evaluations of EC legislation pertaining to risk identification (Section III of Chapter II), risk assessment (Section III of Chapter III) and management (Section III of Chapter IV), it is easy to identify certain recurrent themes and challenges for the integration of uncertainty considerations in the legal framework.

First, tensions between market integration and health and environmental objectives spring up in many different shapes and forms. It is no exaggeration to claim that their resolution, or at a minimum their management, will be vital to the successful implementation of a regulatory framework that responds to the social, scientific, natural and cultural changes that are continually reshaping our world. Second, within the area of health, safety and environmental protection, a recurrent theme is the disproportionate potential for neglecting environmental risks. Third, there are at present insufficient connections, or links, between regulatory requirements and instruments to promote both cohesion and dynamic implementation. Finally, the analysis in Chapters II, III and IV has borne out that the EC legal framework for chemical control depends heavily on the cooperation of many different actors, including public as well as private entities, for its implementation. The effectiveness of EC risk regulation, and particularly the level of health and environmental protection afforded by risk regulation, will therefore to a considerable extent depend on the quality of the consultation, cooperation and participation schemes that are developed within the EC legal framework for chemical control.

1. Market v. Environment: Of Old Cures and New Diseases

Market and environment are age-old adversaries. Their conflicts are manifold, and often the resolution of one leads to the emergence of another.

In its most traditional and widely spread meaning, the "market v. environment" dilemma refers to tensions between the objective of free trade, which requires a non-interventionist policy and open borders to products and services from trading partners, and the protection of public values such as health, safety and a clean, healthy environment. The latter goal is most commonly achieved through regulation, which in turn restricts opportunities for
Trading partners may seek to alleviate this tension through the elaboration of standards for the legal and legitimate adoption of regulatory measures, such as criteria of proportionality, necessity and effectiveness. Alternatively, they may try to overcome the dilemma through the establishment of a uniform or harmonised regulatory framework for health, safety and environmental protection. The European Community, for example, relies on a combination of both methods to reconcile market integration with the furtherance of green values.

There are, however, other dimensions to the "trade v. environment" conflict, which cannot be resolved purely through the harmonisation of trade and/or environmental protection regimes. Franz Kohout (1995), for example, sketched the tension in terms of the inverse relationship between economic growth and environmental health. Economic growth can reduce the effectiveness of regulatory environmental standards. This is typically the case for emission standards: a maximum emission level established in 1984 may keep pollution at a sustainable level at the time of its adoption, however by 1994 there may be so many more polluting sources that the same emission level no longer succeeds in guaranteeing an acceptable level of environmental quality. This facet of the "trade v. environment" conflict could be managed by switching from emission and technology-based standards to health and environmental quality targets. However, it should be borne in mind that quality standards have their own effectiveness problems. It is, first, extremely difficult to grasp and determine an acceptable level of environmental health. Furthermore, the costs

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891 FRANZ KOHOUT, o.c., p. 78.
of controlling whether polluters comply with environmental quality objectives are very high, and grow exponentially with economic development, thus revealing yet another aspect of the "trade v. environment" tension.

In the preceding analysis of EC chemical legislation, we have repeatedly encountered a third variety of the "trade v. environment" dilemma; one that is perhaps less obvious, but by no means less pertinent than the previously discussed types. It is the tension between two divergent regulatory styles, one that responds better to business and industrial concerns, another that is more productive from an environmental protection perspective. The former incorporates the values of uniformity, certainty, finality and predictability; the latter is conducive to variability, flexibility, reversibility and openness. It is easy to see why industry generally prefers regulatory measures that espouse the former values. Uniformity of regulatory measures offers enterprises some assurance that competitors are not being dealt a better regulatory hand than they are. Certainty, finality and predictability of administrative decisions make them, from a business point of view, reliable factors (or "invariables") to be accounted for in managerial decision-making and planning. Why the opposing values of variability, flexibility, reversibility and openness are more productive to deal with health and environmental risks, particularly in conditions of high and/or enduring uncertainty, has been discussed elsewhere in the text.

Current EC regulatory measures as a rule emphasise uniformity rather than flexibility. In this regard, they accommodate the pursuit of industrial interests more than the achievement of environmental objectives. Preference for uniformity and finality reveals itself, for example, when we compare the detail and sophistication of initial notification duties to the sketchiness of updating requirements, as we did in Chapter II. In the third Chapter, the tension between uniformity and flexibility was identified as a likely undercurrent explaining why the EC increasingly leans towards a rather formal, science-based and standardised style of performing risk assessment. In Chapter IV on risk management, the tension, and its resolution in favour of uniformity, transpired

892 Cf. JULIA BLACK (1997), Rules and Regulators, Clarendon Press, Oxford, p. 28; and Section III.3. of Chapter II.
893 Cf. BRADFORD C. MANK, o.c., p. 287.
894 However, it should be noted that the costs of complying with identical regulatory standards may differ substantially between enterprises, depending on, for instance, the size of the facility, its location, the adaptability of incumbent production processes, etc. Cf. RICHARD B. STEWART (1995), "Markets," o.c., p. 18.
895 DIETER MURSWIECK, o.c., p. 153.
in the tendency to seal off areas of artificial certainty, and to use artificially constructed certainties (mainly assuming the form of pre-established classifications) as a take-off point for the development of regulatory control measures. And, as mentioned at the end of Chapter IV, the long-term arrangements that do exist, particularly the provisions on emissions release monitoring, are primarily designed for compliance control with fixed regulatory cut-off points (for instance, maximum emission standards), and much less for the creation of new information that could be relevant for future regulatory developments. In this regard, they, too, respond and contribute to a uniformity- and certainty-oriented regulatory style rather than a variable and flexible one.

Naturally, legislative and regulatory flexibility is not a magic formula to swipe all health and environmental protection shortcomings off the European agenda. There are a number of practical reasons why regulatory and administrative bodies might share industry's general preference for a uniform and certainty-seeking regulatory style. For one, fixed substantive standards, such as an across-the-board prohibition of substance X in any compound or preparation, require less interpretation and are therefore easier to impose than flexible ones stipulating, for instance, that use of the substance should not give rise to a risk of illness or death higher than one in one million.896 Or than a procedural standards demanding that any use of substance X should be reviewed and approved by an independent scientific committee, that the consent of workers exposed to X should be obtained and special insurance schemes drawn up to compensate workers who do experience deleterious effects from exposure. In other words, with flexibility in legislation comes administrative discretion, and with discretion, difficult choices.897 Particularly in the short term, national administrative bodies that are in charge of implementing Community and national law, might be less than enthusiastic about receiving instructions that look more like do-it-yourself kits than finished documents.

Additionally, attention has been drawn to the fact that compliance control with flexible requirements may be more difficult to organise and ascertain.898

896 Cf. ROBERT BALDWIN, o.c., p. 331.
898 On the other hand, compliance control with procedural prescriptions is, in principle, straightforward. Such control involves checking whether the appropriate steps were taken in a decision-making process, for example: was an independent committee of experts consulted; had an impact assessment been undertaken; were the costs and benefits of alternative regulatory options considered; was the preliminary decision made
This would not only complicate the task of public authorities, but also of third parties, such as environmental groups, who want to make use of recently acquired access to environmental information rights to monitor industry’s performance and the legality of its actions. Finally, flexible and variable requirements might be more amenable to certain forms of misuse than uniform requirements. Susan Rose-Ackerman (1994) warns that “variability in environmental statutes often takes the form of special treatment for certain classes of dischargers independently of their impact on the environment.” We could indeed imagine that the very uniformity and rigidity of traditional forms of regulation, such as command-and-control, erect a screen between regulatees and regulators, insulating the latter from undue pressure. Where flexibility introduces discretion, and decisions are treated as reversible in principle, opportunities and incentives are created for regulated parties to try and exert influence over decision-makers.

The reluctance to adopt a flexible, risk-oriented regulatory style, however, stems from more than practical objections alone. Fundamental concerns have been raised over the planning and strategic aspects of regulatory reform. To some, terms such as “strategic decision-making,” “priority-setting,” and “long-term monitoring” bear an uncomfortably close resemblance to the vocabulary deployed by Big Brother. Add “open-endedness” and “reversibility” to the list, and fears swell that this particular Big Brother might be the worst of its kind: a fickle dictator. Thus, regulatory reform irritates classic liberal notions of freedom of enterprise as an expression of individual liberty, and the absence in publicly known; did third parties have an opportunity to comment; is there a procedure for review of regulatory decisions; etc. Hence, if flexibility is tempered by proceduralisation, the control problem might be alleviated. But see Martin Shapiro (1996), who argues that procedural controls have a tendency to transform over time into more penetrating, substantive controls. MARTIN SHAPIRO (1996), "Codification", o.c., pp. 37-38.

899 See MONIKA BÖHM, o.c., pp. 196-197.
principle of regulatory constraints and controls.\textsuperscript{903} Its openness to informal, "soft" legal instruments,\textsuperscript{904} and its emphasis on temporalisation and reversibility, moreover challenge mainstream interpretations of legal certainty, legitimate expectations and public accountability.

Summarising, the further development and implementation of a new regulatory style will be neither an easy nor a painless process. In its infancy, it will give rise to many new implementation and control problem, as well as new variations on old problems, that will cause considerable controversy and call for strenuous efforts at problem-solving, and that may have law-makers, regulatory bodies, administrators, regulated industries and even interested third parties yearning back for the days when rules were clear-cut, uniform and final. The undeniable tension between most regulatory reform proposals and the classic liberal ideology upon which traditional and wide-spread notions of legality and fairness were constructed, will in all probability fuel vociferous allegations of illegality and unconstitutionality, allegations that will resound in academic circles, in the political arena, and in the court room. And yet, recalling the changed circumstances that led us to question the traditional framework in the first place, and given that the scientific, technological, social and cultural uncertainty that pervades our society cannot reasonably be treated as a temporary nuisance, regulatory reform is the most, perhaps the only rational option.\textsuperscript{905} Stubbornly sticking to tried and tested regulatory techniques would be tantamount to prescribing old cures for new diseases, even when they have shown not to work.\textsuperscript{906}

2. Health v. Environment: A Case of Bias and Amplification

At every stage of the regulatory life cycle, environmental risks have a greater chance of slipping through the mazes of regulatory attention than health risks. Existing data gathering and testing requirements may just about suffice to give rudimentary insights into health risks resulting from exposure to chemicals -- and even there, the results are plausible at best -- but they are woefully inadequate to predict environmental effects. Substantial improvements

\textsuperscript{903} Cf. DIETER MURSWIECK, o.c., p. 153.
\textsuperscript{905} Cf. Chapter 1 under Heading 2.
to the quality of available environmental risk information would probably require a thorough reconceptualisation and reformatting of chemical manufacturers' information supply duties (See Section III.2 of Chapter II). The next step, risk assessment, again follows dynamics that reduce the chances of environmental risks being singled out for regulatory control. Quantified risk assessment, for example, reduces the complexities of risk to the common denominator of increased human mortality, a measurement that is of little direct relevance to environmental risks. Risk management tools reflect deliberate policy choices to prioritise health threats, and particularly cancer threats, over environmental deterioration. Combining these factors, the odds that a chemical posing an environmental risk that cannot directly be related to a health risk will be subjected to regulatory restrictions, are very small indeed.

Each and every one of the above arrangements may be supported by a rationale that is, in itself, utterly defensible. Short term, pre-market testing may be the preferred method for gathering hazard and risk data because it is easier to standardise -- an aspect that regulated industries value highly (see above) -- and compliance with testing requirements is easier to verify than observance of long term monitoring arrangements. Moreover, testing results constitute a clearly identifiable starting point for decision-making, a point that by no means presents itself so clearly in the course of an extended, gradual and incremental reporting process. With regard to risk assessment, the added complexity that environmental risks introduce into the assessment process would in all likelihood be translated into better calibrated, more reliable assessment results, but it might make comparisons between different risks virtually impossible, and thus obstruct decision-making processes to determine which risks should be regulated. In risk management, the prioritised treatment of cancer risks and other human health threats over environmental concerns may very well reflect reasonable public preferences. Furthermore, the preferential treatment of cancer risks constitutes a rudimentary form of priority-setting. Priority-setting significantly contributes to rulemaking efficiency and consistency, which does not only improve the management of health risks, but arguably generates positive spill-over effects that are beneficial to risk regulation as a whole.

Nevertheless, even if at every stage of the risk regulatory process a good or at least a reasonable argument exists for maintaining the bias in favour of health risks, the regulatory process as a whole still produces outcomes that

906 Cf. FRANZ KOHOUT, o.c., p. 101.
disproportionately disadvantage environmental risks. I suggest that the regulatory failure to integrate environmental risks into decision-making processes is not so much a result of ill-conceived arrangements and shortcomings that manifest themselves at one particular stage in the regulatory life cycle, but is rather caused by the compounding effect of decisions made at every stage of the process, however sensible (or plausible) these decisions might be when considered individually. The regulatory bias in favour of cancer and health risks is not merely maintained at the stages of data gathering, assessment and management -- which would be in accordance with public preferences and policy programmes -- but is amplified at every step, and it is precisely the amplification that leads to disproportionate outcomes in the end.07

In this regard, the phenomenon of amplification is closely related to the concept of path dependency, a term used in economics and policy studies to describe the determining effect of previously made choices on available future options.08

In my opinion, it is possible for unintended amplification to occur because the existing EC regulatory system for the control of chemical risks is insufficiently open about the uncertainties and partial knowledge that characterise every stage of the regulatory cycle (see also below). Amplification is, in other words, related to law's tendency to create artificial certainties and use these as stepping stones for further decision-making. We recall the practice of classification, which essentially aims to condense all the information provided in technical dossiers --the narrative and descriptive parts, the physico-chemical measurements and testing results, the forecasts and predictions -- into fifteen easily manageable and understandable descriptors. As discussed in Chapter IV, these categories no longer reflect the uncertainties inherent in the classification process. Furthermore, our discussion of the use of risk assessment data for risk management purposes indicated that there is little scope for re-introduction in the assessment process of information that has been left aside (because of lack of knowledge, negligence, or intentionally) at the stage of classification. Risk

07 Cf. Wolfgang Hoffmann-Riem (1990) on "regulatory programming failures." Programming failures occur when selected rules are not suited to reach regulatory goals, or when these rules produce undesirable side-effects. Amplification could be classified a regulatory programming failure. WOLFGANG HOFFMANN-RIEM (1990), "Reform," o.c., p. 404.

08 Cf., e.g., JERZY HAUSNER, BOB JESSOP & KLAUS NIELSEN (1995), Strategic Choice and Path-Dependency in Post-Socialism. Institutional Dynamics in the Transformation Process, Edward Elgar, Aldershot, p. 6: "Path-dependency suggests that the institutional legacies of the past limit the range of current possibilities and/or options in institutional innovation."
assessment itself, it has been said before, introduced a new level of reductionism along parameters that, again, emphasise health over environmental risks. Finally, those environmental risks that do survive this double dose of reductionism, that are consequently classified as "dangerous to the environment" and possibly evaluated as substances that are "of concern" by risk assessors,909 are filtered into a risk management process that, overall, works better for the reduction of health risk than for the environment (Cf. Section III.2 of Chapter IV). The upshot is a regulatory framework in which environmental risks are systematically and disproportionately neglected.

3. **Missing Links**

The substantive complexity of the risks created by exposure to chemicals is matched by the structural complexity of the legal framework that sets as one of its main goals the protection of human health and the environment against these risks. EC law pertaining to chemical control has a pyramidal structure. At the top of the pyramid are the information supply and risk assessment requirements -- virtually identical for all substances -- at the bottom a variety of risk management prescriptions covering market restrictions, authorisation procedures for specific categories of chemicals, health and safety at work, air and water pollution, major accident hazards, etc.910 It would therefore perhaps be more appropriate to speak of a legal network than of a legal framework for chemical substances.

Without entering into the debate on whether it would be possible -- or indeed desirable -- to try and consolidate EC environmental law into one document,911 it should be mentioned that this network structure makes sense when we consider the main regulatory goal of information gathering instruments such as notification: to stimulate the production of a body of knowledge,

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909 Cf. Section I.2.c. of Chapter III.
911 The option of codification of areas of EC law that are presently dispersed over a range of documents, such as food safety law, is discussed in the 1995 "Molitor Report" on legislative and administrative simplification. See Report of the Group of Independent Experts on Legislative and Administrative Simplification, COM (95) 288 FINAL/2. See also CAROL HARLOW, o.c., pp. 3-25; KARL-PETER SOMMERMANN (1996), "Europäisches Verwaltungsrecht oder Europäisierung des Verwaltungsrechts - Inkonsistenzen in der Rechtsprechung des Europäischen Gerichtshofes," Vol. 111, *Deutsches Verwaltungsblatt*, No 6, p. 897.
however imperfect, that can facilitate ensuing decision-making processes. Rules and procedures to direct such decision-making processes may already exist, or alternatively may be drawn up at a later stage, by a different body than the authority that adopted the notification rules, and the actual decisions using the information produced in the notification process may be taken by yet another body. We can envisage how different parts and aspects of the knowledge generated through one set of rules are fed into a range of rule-based decision processes, thus creating a veritable web of interconnected rules. Similarly, classification -- which is determined following the rules laid down in the Notification Directive, using information generated in notification or reporting processes -- constitutes a pivotal point of connection to a variety of rules, such as major accident control requirements, health and safety at work conditions, and marketing restrictions.

The regulatory network that spreads around the concept of classification may be the most visible one in the area of chemicals control, but there are others. We recall, for instance, the EC organisation of quality control of information supplied in the notification process.912 The Notification Directive does not specify quality standards for information production and submission, but instead refers to good laboratory practice (GLP) standards set out in another EC Directive, which in turn refers to the 1981 OECD Decision on Mutual Acceptance of Data. Similar to classification, GLP standards function as a general "facilitator" for decision-making; their use transcends the context of individual testing procedures. In the case of GLP, its multiple utility obviously has much to do with the procedural quality of GLP standards: GLP verifies the circumstances in which testing takes place rather than the actual tests. In fact, I would argue that a proceduralised approach to law and regulation generally tends to stimulate the formation of networks, precisely because the rules it generates are (or should be) more adaptable to changing contexts than substantive criteria would be, and therefore can serve as a frame of reference for a greater diversity of decision-making processes.

Finally, legal and regulatory networks are very much part and parcel of European Community law. In light of the intricate division of legislative, regulatory and administrative competencies between European, national and regional authorities, different layers of rules and decision-making pertaining to

912 See Section II.2.4 of Chapter II.
one and the same regulatory issue are bound to develop. Take, for instance, the complex interplay between EC institutions and Member States in the data reporting procedure for existing chemicals, as discussed in Sections II.3.1 and II.3.2 of Chapter II. During the first reporting stage, manufacturers and importers of chemical substances, located in the Member States, supply information directly to the Commission. During the second stage, the Commission delegates the task of further data collection and risk assessment (for substances that have been prioritised based on the information acquired in the first stage) to national rapporteurs, who are acting as agents for the Commission (delegation rather than decentralisation) but are nonetheless appointed by the Member States. The assessments and recommendations made by nationally based rapporteurs can in turn be used to inform risk management decisions taken at the European level, (for instance, a Council decision to add a new market restriction to the list in Directive 76/769/EEC). The implementation and enforcement of EC-wide market restrictions are, again, left to the Member States. The number of laws, rules and decisions linked together in one risk control scheme -- by far not the most complicated one imaginable -- is indeed bewildering.

While the network structure might be the most logical — or even the only feasible — format for European chemical control legislation, it poses a number of challenges and difficulties. The effectiveness of a network depends on the quality of the "knots," in other words on the stability and reliability of the connections between different rules and procedures within the network. In the preceding analysis, we have discovered that the connections between different rules and requirements pertaining to chemicals often leave something to be desired. This is most clearly the case for EC legislation on risk assessment, which presently sits uncomfortably between data gathering and risk management. On the "input side" of risk assessment, we saw that the connections between classification and risk assessment are not particularly conducive to a free flow of information; data that is lost at the stage of classification in most cases cannot be retrieved for the purposes of risk assessment. This arrangement has two regrettable consequences. First, it

914 Cf. KARL-HEINZ LADEUR (1996b), "Die Zukunft" o.c., p. 515.
915 Cf. Section II.2.1 of Chapter IV.
impoverishes risk assessment, which is performed relying on less than all available information. Second, it limits the opportunities for risk assessment results to be fed back into classification.916 In other words, risk assessment cannot play a constructive role in the ex-post correction and improvement of classification decisions, even though these decisions are made on the basis information that, so experts and policy makers acknowledge, is incomplete and imperfect, and even though the correction of (provisional) classifications is legally recognised as one of the functions of risk assessment.917 In conclusion, the connections between the rules on data supply and classification on the one hand, and those relating to risk assessment on the other, are insufficiently flexible to allow feedback and a bilateral flow of information.

The “output side” of risk assessment does not appear adequately connected to other chemical control arrangements either. Heralded by Council and Commission alike as the principal basis for risk management decisions, risk assessment results thus far have kept a very low profile in EC measures that are oriented towards risk reduction. The only instrument explicitly to refer to risk assessment of chemical substances as performed in compliance with EC requirements, and to insist that risk assessment results be used as a basis for decision-making, is the Water Policy Framework Proposal, a document that is still to be adopted.918 The remaining scarce references to risk assessment, such as those made in EC legislation on air pollution and workers’ health and safety,919 are vague or non-committal.920 As to traffic flowing in the opposite direction (i.e., information generated during the stage of risk management that is fed back into the risk assessment process), although the provisions of the Risk Assessment Directive and Regulation do not explicitly discourage the use of such information in the assessment process, there are no clear-cut arrangements to ensure that information is made available,921 or that risk assessments are reviewed upon submission of new data.

918 Cf. Section II.2.3(d) of Chapter IV.
919 Cf. Sections II.2.3(b) and (c) of Chapter IV.
920 Risk assessment is, of course, prominent in the EC Directives on pesticides and biocides. However, in both cases the requirements for data gathering and supply, risk assessment and risk management (in the form of authorisation) are contained in one single document. Therefore, problems relating to connections between dispersed sets of rules do not immediately occur within these self-contained frameworks.
921 Other than the general updating requirements imposed on notifiers of new, and manufacturers or importers of existing substances (see Sections II.2.2(c) and II.3 of Chapter II).
In sum, the roots of risk assessment in data supply arrangements, as well as its branches into other pieces of Community legislation, still need to thicken. For the time being, a noticeable discrepancy remains between risk assessment’s formal status, and its use in legal and regulatory practice. Because of the weak, or altogether missing connections between risk assessment for chemicals and other links in the regulatory chain, precious information may get lost, and opportunities for learning through comparison and feedback are unnecessarily stunted. To avoid such developments (which in turn produce sub-optimal results for risk regulation), risk assessment should be invigorated, activated as a vital and central part of risk regulation. Reform should therefore include efforts to forge stronger, more flexible and more conducive gateways between the first, second and third stage of the regulatory life cycle.

The proposed “activation” of risk assessment as an integral and connected part of risk regulation may further the development of a risk regulatory dynamic that is more productive and resource-efficient than the present system. However, several caveats should be borne in mind. First, as risk assessment develops into a central part of the legal framework for risk control, new problems will undoubtedly emerge. Our discussion of the controversies surrounding the use of risk assessment as a basis for chemicals regulation clearly illustrated that risk assessment techniques are not universally accepted as a legitimate basis for regulatory decisions. Even among those who agree that contemporary risk regulation cannot do without some form of risk assessment, opinions differ widely as to the desired scope, the most reliable techniques and the relative weight to be attributed to assessment results in regulatory decision-making processes. Not surprisingly, controversies thus far have soared highest in the United States, where risk assessment plays a prominent, highly visible and active role in risk regulation. The relative quiet that accompanied the introduction of risk assessment in European Community law may therefore be a further indication that, up to now, the shift from a danger-based to a risk-oriented framework has predominantly been a palace revolution with little discernible impact on the day-to-day regulation of health and environmental risks. Hence, if the European Community does decide to invigorate risk assessment and give it a stronger footing in EC health and environmental law generally -- as some very recent pieces of EC legislation and legislative proposals

923 Cf. Section II of Chapter III.
indicate it might -- it would be well advised to re-examine the assessment rules adopted in 1992 and 1993, to consider the pros and cons of different styles and approaches to risk assessment, and to brace itself for the heated debates that, in all likelihood, will ensue.

The second caveat is a reminder of the indissoluble bond between risk and uncertainty. European Community institutions should be wary of converting risk assessment results into final and incontestable legal “facts.” In other words, awareness should be maintained throughout the regulatory life cycle that risk assessment is an approximate, not an absolute technique. The real strength of risk assessment resides in its capacity to uncover problem areas in health and environmental regulation and to give indications of the urgency of the matter, not in its accuracy as a quantitative mortality or morbidity measurement tool. Approaches that exclusively rely on mortality rates to determine whether regulatory intervention is warranted (e.g., if risk assessment indicates that the substance “Chlorplus,” when released on the market, will result in the death of at least four people on a population of one million, restrictive measures should be taken), and then again fall back on these same mortality rates to establish the required stringency of regulatory action (e.g., the concentration of Chlorplus in a chemical preparation has to be reduced to a level where exposure to this preparation will produce a mortality rate of less one in one million), credit risk assessment with a degree of reliability and certainty that the technique, thus far, does not deserve. Ideally, risk assessment results should open debates on regulatory intervention, not determine their outcome.

Furthermore, the value added to the regulatory process by risk assessment would be significantly reduced if risk assessment became treated as merely a “second level classification.” Classification, we have seen, contributes to the uniformity and finality of the regulatory process rather than to its flexibility and differentiation; certainty is valued over nuance. In this regard, classification could be considered an instrument that better responds to the demands of the market, than to environmental concerns (see above). Instead of repeating this bias (“amplification”), risk assessment results could play a vital role in restoring the balance. This could be accomplished if risk assessment embraced those qualities that classification lacks, in particular context-dependency, nuance, and openness to ex-post review and correction.
4. **The Involvement of Public and Private Actors in Risk Regulation**

The control of chemical substances is very much a joint effort. At every stage of the process, regulatory bodies -- situated at the EC, the national or the regional level -- have to invoke the help of industry to make regulation go forward. The analysis in Chapter II made it abundantly clear that manufacturers and importers play a crucial role in information gathering. The rules relating to risk assessment for new substances offer industrial enterprises an opportunity to include a preliminary assessment in the technical dossier for notification, which is used as a basis for the assessment performed by public authorities. As a rule, risk assessors will simply review the methodologies adopted in the preliminary assessment supplied by industry, and rubberstamp the document. Additionally, notifiers may have a chance to comment on the conclusions drawn by public risk assessors, and those comments are included in the summary report that maps out the risk assessment results.\(^{924}\) With regard to risk management, the involvement of industry in the respect and implementation of risk reduction measures is evident.

Moreover, the European Community increasingly displays a preference for regulatory frameworks that imply a high level of decentralised decision-making. The 1996 Directive on Integrated Pollution Prevention and Control, for instance, requires that local environmental authorities lay down maximum emission values at the level of the individual installation.\(^{925}\) This requirement creates a wide scope for industrial entrepreneurs to inform local authorities of the technological and economic particulars of each installation, and of the projected cost and feasibility of technological change. Their superior technical knowledge places them in an ideal position to negotiate with local authorities and significantly to affect -- some might claim, to determine -- the outcome of administrative decisions.\(^{926}\) The Seveso II Directive, as well as the EMAS Regulation, take decentralisation one step further: operators themselves are in charge of developing a risk management and reduction programme, and public authorities' tasks are reduced to those of inspection and review.\(^{927}\)

In addition to relying on input from industry, public authorities frequently

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\(^{924}\) See Section 1.2 of Chapter III.
\(^{926}\) Cf. LUDWIG KRÄMER (1997), Focus, o.c., p. 232.
\(^{927}\) Cf. Sections I.3.4 and II.1.3(c) of Chapter IV.
must invoke the help of independent scientific experts. Most obviously, risk assessments are not actually performed by administrators, but are handed over to national expert committees, which are usually chaired by university professors in one of the sciences relevant to risk assessment (e.g., biochemistry or toxicology). Decision processes relating to risk reduction measures rely heavily on scientific expert advise, whether these decisions are taken at the EC, or at the Member State level. To name but one example, some of the amendments to Directive 76/769/EEC on market restrictions explicitly refer to the opinion of the Scientific Advisory Committee on Toxicity and Ecotoxicity. Also, we recall that Article 130R of the EC Treaty requires that all available scientific and technical data be taken into account in the development of Community environmental policy. The integration of scientific expert opinions in policy decision-making is further promoted by the European Court of Justice as an important procedural parameter to assess the legality and legitimacy of risk regulatory decision-making.

Last and, in this case, least (see below) are the ultimate beneficiaries of chemical risk regulation: the public; non-industrial users of chemical substances and preparations; and people who are at a particular risk from chemicals used in industrial installations, either because they work there or are located in the vicinity of an installation. Their involvement is more remote: workers are entitled to chemicals hazard and risk information, and have limited participation rights in decision-making in the work place; other groups simply have access to information and can use this information to make their own risk management decisions (e.g., consumers deciding not to buy "Chlorplus" on the basis of labels and risk phrases) or to lobby political support for risk reduction measures.

The growing involvement of a variety of social actors in chemical regulation is not all that surprising. In fact, multi-party involvement was identified in the first Chapter as one of the telling features of a legal and

930 Article 174 ToA.
932 Cf Section II.1.2 of Chapter IV.
933 Multi-actor involvement is not restricted to chemicals regulation, but equally features in other areas of health and environmental policy. See, e.g., JEREMY RICHARDSON (1994), "EU Water Policy: Uncertain Agendas, Shifting Networks and Complex
regulatory framework in transition from danger- to risk-orientation. It does, however, raise new concerns. In particular, the diversification and change in the relationships between regulators, regulated parties, prospective beneficiaries of regulation and so-called “independent” or neutral parties involved in the regulatory process (typically expert committees consulted by administration), may influence the opinions, approaches and even objectives of any one of them. Changed relationships may even cause shifts in the balance of power between different parties involved in risk regulation. It therefore becomes essential to examine whether these new institutional constellations are still capable of producing equitable results for the purposes of health and environmental regulation. If it appears that the changed dynamics between the parties involved in, and affected by, risk regulation allows one, or several, of them disproportionately to influence regulatory outcomes, the European Community should consider creating new institutional guarantees for those parties that are disenfranchised, in order to restore the balance of power.

Applying the above considerations to the case of chemical control, it quickly becomes apparent where the tensions lurk. The chemical industry has an overwhelming influence on the development and implementation of risk reduction measures. Several factors collude to place the industry in a unique position of power vis-à-vis public authorities, the public, and even scientific experts. To list but a handful, the chemical industry is proportionately much better informed and much more knowledgeable about the chemical risks than the public authorities that are supposed to ensure the control of these risks. Any regulatory effort hinges on the supply of technically detailed and complex information, hence, on industry’s willingness to cooperate. Also, the chemical industry is its own main trading partner: the vast majority of man-made chemical substances are sold back to chemical installations. Expertise on the manufacture as well as use and disposal of chemicals therefore remains bundled within one industrial sector. Moreover, the importance of the chemical industry in the European economy makes it a political force to be reckoned with. Its

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934 See points 3.3 and 3.4(d) of Chapter I. Cf. HANS-WOLFGANG MICKLITZ, o.c., p. 697.
937 We recall, for instance, the protracted negotiations with the chemical industry that customarily accompany the European Commission’s determinations of harmonised classifications (see Section II.1.1 of Chapter IV).
political significance is bolstered by the fact that it is a highly unified and
organised industrial sector.\(^{938}\) Finally, its patronage of scientific research may
foster unspoken allegiances within the scientific expert community, whose
status of independence consequently becomes tainted.\(^{939}\)

The centrality of the chemical industry in risk control begs the question of
how “publicly conscious” public decision-making is. Provisions relating to data
supply, assessment and management create numerous opportunities for
industry to “capture” the attention of public authorities at the EC and Member
State level, and surreptitiously or overtly to push forward its own agenda.
Recent emphasis on public access to environmental information, and on (limited)
public participation in risk decision-making, represents an attempt to redress
the balance.\(^{940}\) Such attempts could and should be fleshed out further.

Thus far, little thought has gone into ensuring the effectiveness of access
to information, and the importance of stimulating genuine communication
between public and specific interest groups has largely been overlooked.\(^{941}\)
Certain commentators fear that broadly framed, passive information rights,\(^{942}\)
such as the general right of access to information kept by public authorities,
established in the 1990 Information Directive,\(^{943}\) have little practical value, but
are mainly symbolic gestures that pay lip service to the goals of transparency
and representation in public decision-making.\(^{944}\)

Similar concerns are raised in the context of participation: the
establishment of a basic right to be consulted (for instance, the right granted to

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\(^{938}\) One only needs to visit the “activities report” on the website of CEFIC, the European
business association for the chemical industry, to obtain an impression of the level of
professionalism, and of the significant resources that are undoubtedly contributed to
secure the smooth and efficient organisation of the chemical industry (see
http://www.cefic.be).

\(^{939}\) The chemical industry spends some 20 billion EURO on research and technological
development in Europe each year. See CEFIC (1998), Position Paper on the Fifth RTD

\(^{940}\) See, e.g., MARTIN EIFERT, o.c., p. 544.

\(^{941}\) Ibid., 548.

\(^{942}\) Information rights are passive when those who possess the information need simply
to make the information available on request, but have no specific duties to ensure that
information is created, made understandable and effectively communicated to the
“Passieve Openbaarheid in het Milieurecht,” Milieu en Recht, N° 4, p. 146.


\(^{944}\) See, e.g., JULIA BLACK (1998), “Regulation as Facilitation,” o.c., p. 652; ARNO
workers to participate in decision-making on health and safety issues at work,\textsuperscript{945} or the requirement in the Water Policy Framework proposal that, in the preparation of risk reduction proposals, the Commission takes into account the recommendations of, \textit{inter alia}, the European Environment Agency and European environmental organisations) does little to guarantee that such input will actually make a difference for the formulation of risk control measures. Admittedly, mandatory legal requirements are but a poor substitute for a genuine political willingness to have a range of different interests represented and heard in public decision-making processes. However, precisely because of the limitations of law, it is all the more necessary to try and reach the best possible results with the limited means available.

\textsuperscript{945} See Section II.1.2 of Chapter IV.
SECTION II - REFORM: THE ACCEPTABILITY OF ERROR

The reform agenda that emerges from our overview in Section I is the following. First, the present balance between the certainty and flexibility afforded by the legal framework needs to be reassessed, and more emphasis needs to be placed on the latter. Second, a special effort is necessary to increase the visibility of environmental risks in legal decision-making and to counteract the effects of amplification. Finally, legal reform should strive to stimulate communication. This refers both to communication between rules, which seeks to ensure that the knowledge produced through the application of one set of rules becomes relevant and furthers the functioning of another, and communication between the parties involved in decision-making. The latter aims to achieve that information and participation rights reach their maximum utility within the boundaries of the politically and practically feasible.

1. General Comments

Below, I will make a number of practical suggestions for legal reform that might contribute to the above-listed objectives. Predictably, the suggestions are accompanied by a disclaimer. Perfection is a lofty goal, but it should not blind us to the inescapable fact that no amount of legal reform and innovation is going to produce the “perfect” legal system. First, law’s prowess as a social innovator is rather limited.946 Even if it were theoretically possible to conceive of a legal system that would protect us against every environmental and health risk in existence, it is highly questionable whether it would be politically or economically feasible to enact and implement such a system.947

Second, and more specific to the case of chemical regulation, it is not even theoretically possible to conceive of a legal system that guarantees perfect outcomes. Even if each of the reform proposals that follow were fully adopted and strictly carried out, the resulting legal framework would not safeguard decision-makers -- whether public authorities, members of the judiciary, scientific experts, industries, interest groups or consumers -- from the possibility of error. In fact, the most basic assumption underscoring the entire

947 In fact, many would question the desirability of attaining an absolute guarantee of safety on philosophical or psychological grounds.
preceding analysis, namely that uncertainty is an inherent rather than incidental feature of health and environmental decision-making, challenges the very possibility of a perfect, foul-proof legal framework to secure health and environmental protection against chemical risks. What is aspired to is rather the development of a legal system that optimises the circumstances under which decisions are reached, that minimises risks of irreversibility and that allows decision-makers to learn from previous, imperfect solutions. Legal reform furthermore seeks to devise mechanisms that would help to overcome the dichotomy between legal certainty and flexibility. To quote Albert Reiss (1989), what is at stake is "[t]he acceptability of error."  

A third and final consideration to be taken on board before launching into reform proposals, is that the philosophy that underscores these proposals, and indeed the entire preceding investigation, is itself open to criticism. As I suggested at the end of Chapter I and in the discussion on "market v. environment" dynamics, sceptics fear that the added flexibility and open-endedness will unravel rather than loosen the legal system for health and environmental protection, and that the rules generated by such a system would not be clear or "hard" enough to merit the qualification of law. Others are concerned that proceduralisation would disconnect law as an ordering principle from ideas of fairness, equity and justice, concepts that have a much stronger ethical connotation. In their opinion, procedural rules are too vulnerable to manipulation: unjust outcomes in regulatory or administrative decision-making might all too easily be justified on the basis that the appropriate procedures were followed. Alternatively, there are those who consider proceduralisation's dependence on cooperation and multi-party involvement in the regulatory process as a weakness. Like flexibility and open-endedness, dependence on cooperation would excessively dilute the coercive power of law.  

The rebuttal, which has also been mentioned before, is that confronted with a traditional legal system that clearly is not attuned to problems of risk and uncertainty, and in the absence of an equally or more promising alternative strategy, it would be unwise to reject experiments with proceduralised, flexible

949 See Section I.1 of this Chapter.  
951 See MONIKA BÖHM, o.c., pp. 196-197.  
and cooperation-oriented legislation off-hand. The primary objective of reform efforts is not to supplant incumbent frameworks, but rather to extend the law to areas that were previously beyond its grasp. The aforementioned criticism can play a positive role in this exercise. Most importantly, it gives an indication of the kinds of problems that will arise when reform proposals are put into practice. Awareness of potential weaknesses facilitates targeted monitoring of reform implementation and effectiveness. It enables legislative as well as regulatory authorities to anticipate alternative approaches and correction mechanisms, and to act swiftly when revisions prove necessary.

Finally, the fact that reform proposals neither hold out to be, nor are received as a final, exhaustive and ready-made fix for the shortcomings of traditional causation- and danger-based approaches, conveys a message about the most sensible way of implementing reform. The reform suggestions listed below lend themselves to temporalised implementation. As more experience with flexible styles of legislation and regulation becomes available, aspects of planning, open-endedness, communication and proceduralised decision-making can gradually move towards a more central position in European health and environmental law.

2. **Rebalancing Health and Environmental Risk Control**

The first reform proposal centres on efforts to counteract the previously discussed effect of amplification, and hence to redress the balance of regulatory attention for health and environmental risks respectively.

In my opinion, reform efforts to restore this balance will be most fruitful if they predominantly address the first stage of chemical risk regulation; the stage of data gathering. This is because, first, it is at this initial stage that the building blocks for later action are created; a correction introduced at the stages of risk assessment and/or risk management will do little good if the vast majority of environmental threats remains undetected. Furthermore, if the effects of amplification were countered strictly at the risk management level, this would give the public a misleading impression about regulatory priorities. Without full information about the particulars of chemical risk identification and assessment processes -- and especially about the bias against environmental risks embedded in these processes -- the public might reasonably assume that a bias in favour of environmental risks in risk management measures (say, a
substitution rule for products that are classified as dangerous to the environment) implies that decision-makers attach greater importance to the pursuit of a clean environment than to good health. One can easily imagine that this impression would upset a great many people, and that the explanation that "we were merely trying to rectify a bias introduced earlier in the process" would be greeted with undisguised suspicion. Reform proposals that in the first place target data gathering would, I believe, better reflect what risk regulation ideally aims to achieve: a more reliable information basis for risk decision-making which is representative of the values and priorities that society holds dear. The foregoing does not imply that there is no room at all for rebalancing in the area of risk management. It does, however, create priorities among reform efforts.

How can data gathering requirements be balanced in order to be more sensitive to environmental risk detection? As discussed in the last Section of Chapter II, the answer apparently does not reside in the introduction of yet another battery of short or medium term laboratory tests. More relevant for the detection and evaluation of environmental risks is information that is accumulated over time; that is based on observation instead of prediction. Furthermore, bearing in mind the enormous difficulties attached to the reproduction of ecosystems in an artificial environment, observations will be more reliable when they are the result of a study of natural (in this context, non-artificial) ecosystems.

The foregoing suggestions entail, first of all, a shift in risk identification methodology: the emphasis migrates from bioassays, extrapolation and prediction to epidemiology, measurement and induction. They also precipitate a qualitative change in the data supply commitments of manufacturers and importers: whereas, under existing data supply arrangements, short-term and pre-marketing commitments dominate, the focus would shift to long-term post-marketing data gathering activities. Thus, environmental information supply would transform from a pre-condition to marketing into a condition for responsible marketing.

2.1. Updating questionnaires

A number of approaches can be followed to create more space for long-term commitments in the EC legal framework for chemical control, ranging from

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953 This option is further explored sub 3 below.
relatively modest ones to more complex and far-going adaptations. For example, it would be fairly simple for EC institutions to invigorate notifiers' and reporters' updating requirements -- which are already part of their existing commitments -- by designing an updating questionnaire. The European Chemicals Bureau, for instance, should have the necessary expertise to draft such a questionnaire. This document could then be used as a blueprint by national competent authorities, who distribute these updating questionnaires to the chemical manufacturers and importers (and, possibly, the main industrial users of dangerous substances) located within the Member State, and recall the completed forms after a pre-set term has elapsed.

The Notification Directive could easily be amended to provide a legal framework for the EC-wide distribution and collection of questionnaires. All it would take is a mandatory requirement for Member States to ensure that their competent authorities distribute and collect such questionnaires (preferably developed on the basis of an EC blueprint). Possibly, such amendment would include a provision requiring competent authorities to forward collected questionnaires to the Commission, which could use the information contained therein to improve its centralised chemical data sets and inventories.

The updating questionnaire has several advantages. Most importantly, it would give some “backbone” to the updating and reporting provisions in the Notification Directive and the Existing Substances Regulation, which at present are very vaguely defined. It would also considerably facilitate the task of national regulatory authorities to control compliance with these requirements. In all likelihood, the initial investment costs in the development of a blueprint would be quite modest, as would the marginal costs of periodically revising the questionnaire. The benefits in terms of improved environmental information supply, on the other hand, could be substantial. As a regulatory instrument, the updating questionnaire therefore appears to have a favourable cost/benefit ratio. Finally, a periodically re-appearing questionnaire might be a valuable tool to foster a more long-term attitude towards health as well as environmental risks within the management of chemical corporations. Such attitude might in turn make industrial enterprises more amenable and better adapted to other forms of strategic and flexible health and environmental regulation.
2.2. *Engineering standards and biomarkers*

The European Community might consider the adoption of a basic set of engineering standards for chemical substances and preparations. Specifically, such standards might require that the necessity to monitor substance flows be taken into account at the designing stage, and that every reasonable effort be made to engineer substances that are easily traced and recognised in natural ecosystems.

Alternatively, it might be worthwhile to consider creating a legal obligation for chemical manufacturers to pair the production of a new substance or preparation with research, or assistance to research, in biomarkers. Such a requirement could be justified as an extension of the polluter pays principle, since the development and refinement of monitoring techniques could be classified as a "cost" created by pollution. In other words, chemical manufacturers and importers would not be required to undertake monitoring themselves, but to facilitate the conditions under which monitoring takes place.

Both the development of monitoring-oriented chemical engineering standards and biomarking are activities that take place at the frontiers of science and technology. It might therefore be premature to introduce engineering standards or biomarking provisions into law at this stage. Nevertheless, in light of their remarkable aptitude as detection instruments for environmental risks, and the promising reports from scientific corners on their potential for improving both the availability and reliability of information from monitoring, the eventual introduction of these (or similar) requirements is an issue more than worthy of further exploration.

2.3. *Imposition of monitoring duties*

The previous section hinted at a third approach to redress the balance between health and environmental information supply arrangements: the direct

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954 Biomarkers are biochemical, cellular and physiological parameters that can be used as diagnostic screening tools and indicate the level of exposure of ecological habitats to environmental pollutants, or the effect of pollutants. The great advantage of biomarkers is that they can be used for retrospective rather than prospective risk identification studies. In other words, they are used in monitoring, not in predicting exercises. See, e.g., BRENDA SANDERS (1990), "Stress Proteins: Potential as Multitiered Biomarkers," and GLENN W. SUTER II, "Use of Biomarkers in Ecological Risk Assessment," both in JOHN F. McCARTHY & LEE R. SHUGART (eds.), Biomarkers of Environmental
imposition of ecological monitoring duties on chemical industrial enterprises. This approach takes the complexity of reform to a higher level. Monitoring arrangements are more complicated to translate into legal commitments than the preceding suggestions since their effectiveness to a large extent hinges upon coordination and cooperation between chemical installations. As a general matter, given how time-consuming and expensive monitoring is, and how broad the potential scope of monitoring efforts, avoiding duplication is paramount. Hence, a framework for legal reform should supplement monitoring requirements with the establishment of sophisticated communication and information exchange mechanisms between monitoring data suppliers.

Communication becomes all the more crucial when we consider that, to be relevant for the purposes of risk assessment and management, monitoring information needs to combine data covering a vast range of aspects. To interpret monitoring results, we need, for instance, information concerning the design, composition and physico-chemical properties of chemical substances and preparations to which ecosystems are exposed. Additionally, we need information about how these chemicals are released into the environment, at what stage of the production chain release occurs, whether they are released in solid, liquid or gaseous form, in which combinations they are released and into which media. We need information about how substances, particles and compounds can be transported, whether they mutate, whether synergies occur, and which circumstances are most conducive to mutations and synergies. We need information about the make-up and regenerative capacity of ecosystems, about the presence of biomarkers, about the environmental quality of locations prior to exposure, about whether there have been quality changes after exposure, about alternative causes of such changes (e.g., weather conditions, changes in land use), about the potential for macro-level ecological ramifications of micro-level mutations, etc. A challenging list, to say the least.

What makes this list particularly daunting is not so much the quantity of information that need be amassed, but the variety of sources it involves. Chemical manufacturers, for instance, may have the details about the composition and characteristics of the substances they produce, but they are not necessarily the ones who process these substances, or emit chemical residues from these substances into the environment. Neither are they necessarily aware of environmental conditions, or of the uses made of natural

resources that have been exposed to dangerous substances (or waste from dangerous substances) originating from their installations. The performance of environmental quality monitoring therefore requires a coordination of data gathering and supply activities by, to name but a few, chemical manufacturers, industrial users, transporters and disposers of chemicals, consumers, a variety of scientific experts, environmental research institutes, science foundations, public education and public administrative bodies, etc.

Given the level of organisational complexity, it is hardly surprising that the few private monitoring duties that have made their way into EC law thus far concentrate on discharge rather than environmental quality monitoring.\textsuperscript{955} This does not imply, however, that environmental quality monitoring with the purpose of environmental risk detection is completely out of the question. The chemical industry (comprising manufacturers as well as industrial users) is, after all, probably the best organised and most cohesive industry in Europe; it is conceivable that communication and coordination networks between actors located at different segments of the chemical industrial chain be established, and that a code of practice be developed to structure and direct data exchanges. By the same token, it might prove possible to develop communication networks between industrial and non-industrial suppliers of monitoring information.\textsuperscript{956}

Considering that the majority of the practical complexities and challenges of maintaining such communication networks for environmental quality monitoring will only be revealed once the system takes off, and that, similarly, the most appropriate problem-solving options may only become apparent within the context of an actual (rather than anticipated) problem, this might be an occasion where open-ended rules are most productive.\textsuperscript{957} In practical terms, the European legislature might deliberately constrain itself to formulating basic environmental quality monitoring obligations, indicating which entities need be involved in the information network, and mandating the parties involved in monitoring to set up coordination and communication structures between them. Conceivably, initial legal provisions might set a certain time frame (say, five years) during which the regulatory addressees are expected to develop the mechanisms which they consider most appropriate for ensuring compliance with

\textsuperscript{955} Cf. Section II.3.3 of Chapter IV; WILLIAM HOWARTH, o.c., p. 226.
\textsuperscript{956} For example, through the intermediacy of CEFIC, the chemical industry association, which could function as a communication bridge between the industry, research institutes, environmental organisations and public authorities.
\textsuperscript{957} See Heading 3.4(c) of Chapter I.
their monitoring duties, and to experiment with problem-solving mechanisms. When the trial period elapses, their self-regulatory effort could be evaluated by a multipartite committee comprising representatives of, *inter alia*, the Commission, representatives of national government and administration, the parties involved in the information exchange and communication networks, and public interest groups. The committee would review the experience of parties involved in the effort, discuss and evaluate the effectiveness of the emerged monitoring arrangements, highlight problem areas and determine how the thus far rudimentary legal framework should be fleshed out to support monitoring arrangements, and where formal obligations or prohibitions are necessary to correct recurring communication failures or bottlenecks. This effort could be repeated periodically, so that over time, lacunas in the legal framework are filled.958

2.4. *Establishment of a European Monitoring Institute*

Open-endedness of rules, combined with self-observation and review, is one way of dealing with the organisational complexities and uncertainty inherent in the development of monitoring networks. The great advantage of this approach is that it stimulates direct and long-term communication between different actors who normally operate in distinct social spheres, and that it encourages creativity and flexibility in implementation. In fact, the level of flexibility is such that it might -- for the time being, at least -- turn into an impediment: the European Community and the Member States may not yet be ready to embrace a legislative approach that so radically deviates from tried and tested methodology. The proposal below is somewhat more traditional -- and, hence, perhaps more feasible in the short run -- in that it is more rule-dependent, and leaves a greater scope for interventions by public authorities.

The European Community might consider the establishment of a European Monitoring Institute, to which the tasks of gathering information, coordinating on-going monitoring efforts, and setting up new ones, are delegated. The functions that, in the previous proposal, came to life through communications in a network, would here adhere to a public institution. In this

958 This does not imply, however, that every voluntary arrangement developed within the coordination and communication network should eventually be cast in stone. The resulting monitoring system might well turn out a mix of mandatory and voluntary arrangements.
scenario, environmental information supply duties (imposed on manufacturers and importers of chemicals pursuant to the Notification Directive and the Existing Substances Regulation) might be translated into financial contributions to the Monitoring Institute, which invests received funds in European monitoring projects.

A positive feature of this approach is that the rules to determine the required level of contribution could be designed to stimulate innovation and give incentives to notifiers and reporters to develop "greener" chemicals, or substances that are easier to manage and control. For instance, notifiers might benefit from a lower contribution rate if they have integrated monitoring considerations into chemicals engineering and design stages, and consequently come up with products that are more easily traceable in the environment. Or, if they have linked research into chemicals to research into corresponding biomarkers. It would furthermore be possible to set up a programme for partial reimbursement for producers (and, possibly, industrial users) of substances for which monitoring data indicate that they are environmentally benign. This would make polluting and toxic substances relatively more expensive, which could spur research into greener products. We might even envisage a contribution scheme that operates on the assumption that man-made chemicals and their residues will have some effect on the environment, and therefore as a rule levies contributions, but allows potential contributors to disprove this assumption in individual cases. Hence, on those rare occasions where laboratory tests do produce conclusive evidence, this option would not be foreclosed.

Additional advantages of the institutional approach suggested above are that it allows economies of scale to develop, which might be more difficult when the responsibility for monitoring is parcelled out over a variety of actors. And, assuming that the jurisdiction of a European Monitoring Institute would span across the European Community, this would accommodate the establishment of transfrontier monitoring networks, a task that might be far more complicated for entities that are registered or located in one Member State. Bearing in mind the cost of monitoring, the frequent and chronically understudied occurrence of synergic effects between substances coming from different sources and emitted into diverse media, and the often transboundary nature of pollution caused by chemicals, these are considerable benefits. Finally, information produced under the auspices of a public, European institute might have a higher degree of
credibility than monitoring results issued by the chemical industry, particularly in environmental and public interest circles.

On the down side, the efficiency benefits gained from economies of scale and scope might be squandered on the maintenance of bureaucratic machinery. Without going too deeply into the pros and cons of institutionalisation generally, it is a familiar argument that institutions tend to favour routine over creativity (or, uniformity over flexibility). There may be less scope for ad-hoc problem solving -- and, hence, learning from trial, error and experience -- in an institution than within a network. Again, the tradeoff seems to be whether the added structural backbone afforded by the institutional approach (in other words, the certainty) weighs up against the potential for sub-optimal outcomes related to reduced flexibility. For the time being, the answer might be a resounding “yes.” Nevertheless, as regulators, regulated bodies and third parties alike become more familiar with flexible approaches -- after all, the introduction of monitoring requirements that allow fine-tuning and ex-post correction of contribution rates is already more flexible than strict adherence to uniform testing requirements -- a switch to a network- and coordination-based style might be contemplated.

2.5. Combined data gathering and assessment approaches

A variation on the theme of the previous proposals is the development of an environmental risk control technique that bridges the stages of data gathering and risk assessment. The following proposal is slightly less sweeping than the two preceding ones in that it conditions the imposition of monitoring duties on the crossing of a de minimis risk threshold.

The regulatory treatment of carcinogens, mutagens and reproductive toxins constitutes a valuable source of inspiration for the development of this proposal. The latter substances have in common with environmentally harmful chemicals that they are difficult to discern on the sole basis of laboratory tests. To summarise but a few of the complicating factors: symptoms frequently have long latency periods; relevance of animal test results for humans, as well as extrapolation methods, are extremely controversial; the fluctuating influence of factors external to the exposure to a particular chemical (such as concurrent or subsequent exposure to other chemicals, genetic make-up, climate) confounds
dose-response predictions, etc. However, at various instances in the regulatory framework, the bias against the detection of, say, carcinogenic properties that results from the complexities of data gathering and testing, is deliberately counteracted by measures that enhance both the visibility and the relevance of carcinogens in the regulatory framework. Most significantly for our present purposes, the difficulties of constructing plausible dose-response relationships -- normally an indispensable link in risk assessment processes -- is neutralised by the introduction of the conservative assumption that, essentially, there exists no level at which a carcinogen can be presumed safe.

A similar technique might be devised to balance the low visibility of environmental risks in risk assessment: the establishment of a de minimis risk threshold that would "trigger" monitoring duties. In other words, the environmental risk threshold would trigger an evaluation that the substance is of concern, and additional information should be generated through monitoring. This would require no more than a refinement of the evaluative options already provided in EC risk assessment legislation. During the monitoring period, the substance might be marketed under the label "Caution - substance being monitored for environmental damage;" a label similar to the "Caution - substance not fully tested" label attached to experimental chemicals. Upon completion of the monitoring term, a review could be conducted to determine whether monitoring results, in combination with other available information, indicate that the substance does not cause significant environmental harm and the provisional label can therefore be removed, whether the monitoring period needs to be renewed, or whether the provisional label should be replaced by a permanent warning of environmental harmfulness, and additional restriction measures considered.

Finally, it should be pointed out that, in developing such a "triggering" mechanism, EC legislative bodies should take care to incorporate the proper incentives to encourage innovation and greener products. This implies, first,
that the mechanism should be introduced for existing as well as new substances (in fact, one of the great advantages of monitoring is that it occurs post-marketing, and can therefore be undertaken for old as well as new substances). Second, the Community might want to consider granting some form of compensation to distributors of chemical substances who have fulfilled their monitoring obligations, especially when those monitoring results indicate that the substance poses no significant threat. Compensation could be provided, for example, in the shape of a temporary exclusive distribution right, which the manufacturer or importer could deploy to recoup the investment made in monitoring. Conversely, if there are more than one manufacturer/importer per substance, information sharing systems could be set up during the monitoring period. Hence, the lower value of shared exclusive distribution rights would be balanced by lower, because shared, investment costs in monitoring.

3. Towards Long Term Risk Management

The second set of reform proposals is aimed at overcoming the dichotomy between certainty and flexibility that bedevils risk regulation. With these proposals, we arrive at the heart of the regulatory matter. Indeed, in one way or another, the basic tension between these seemingly irreconcilable objectives is the undercurrent of virtually all controversies and of the most heated debates surrounding issues of risk regulation. It is therefore not without trepidation that I introduce some modest suggestions towards flexible, but reliable risk management.

In my opinion, the ideological and practical gap between certainty and flexibility could be narrowed significantly through the development of a positive, more long-term oriented interpretation of legal certainty. Rather than the ability to rely on the finality of self-standing regulatory decisions, legal certainty for regulatory addressees would be expressed in terms of awareness of the medium and long-term perspectives of regulatory policy, and in terms of an assurance that, when changes and corrections at the individual decision level are being considered, parties affected by these changes will be alerted at the earliest possible time, and will be granted opportunities to be involved in the deliberation process. This approach to legal certainty compensates for the lack of finality of the substance of individual decisions by the presence and reliability of a “big

picture," coupled with firm procedural guarantees.

3.1. Reversibility of regulatory decisions

The alternative approach to regulatory policy will require certain adaptations within the chemical industrial community. More than ever, manufacturers as well as industrial users of chemicals will need to incalculate the reversibility of the regulatory decisions that constitute the backdrop for their business conduct. One should not forget that, under current EC legislation, the chemical industry already has to accommodate a certain degree of reversibility. Authorisations for the marketing of pesticides, for instance, should be granted for a maximum term of ten years, subject to renewal. Moreover, they may be reviewed at any time if there are indications that the conditions for authorisation are no longer satisfied. In the future, this scheme will be extended to include biocides. Furthermore, it is not uncommon for emission standards to be ratcheted up over time, or for marketing restrictions to be made more stringent as more scientific information concerning their effects becomes available. The difference between incumbent regulatory approaches and more flexible, reversible regulation is therefore, first, one of degree: the proportion of rules and decisions subject to review and modification would augment.

A second difference is that, under a certainty-oriented framework, rules and regulations usually evolve from less to more restrictive over time. This is, of course, because regulatory interventions require (perhaps not entirely but still reasonably) conclusive proof of damage, and, generally, this proof is produced and collected gradually. Hence, as more evidence becomes available to substantiate cause-effect relations between chemical substances and health or environmental damage, corresponding regulatory restrictions will both tighten and increase. In a risk and precaution-oriented framework, on the other hand, regulatory restrictions do not necessarily follow a similar linear and incremental pattern. Since the ties between cause and effect are loosened, and regulatory decisions may be taken on less than complete information, regulatory review of such decisions may as well result in a relaxation of existing conditions and restrictions. This might, for instance, be the case with the imposition of monitoring duties, which may be loosened as more monitoring data are made available.
The latter difference might, in fact, facilitate the acceptance of a higher degree of reversibility by the chemical industry. Reversibility is not unlike risk: it presents a threat and an opportunity at the same time. Just as business strategies, investment and insurance schemes can be differentiated according to the level and kinds of risk involved in an industrial undertaking, it might be possible to incorporate, or at least accommodate, the reversibility of regulatory decisions into business planning. For instance, an industrial installation that has adopted an environmental management and audit scheme would be in a good position to produce new relevant information on the impact of industrial processes on health and the environment, and to monitor, evaluate and learn from the impact of incumbent rules and regulations. Hence, this installation might better be able to anticipate regulatory reviews and predict likely outcomes. This would both strengthen its negotiating position vis-à-vis regulatory authorities and other parties involved in review processes (see below), and would give it a competitive advantage over installations that conform to rather than anticipate regulatory change.

Admittedly, the ideas developed above are still very rudimentary. The reconciliation of regulatory reversibility and industrial practice is a project that will require an enormous amount of time and effort; much more than can be dedicated within the confines of this Chapter. However, this Chapter does aspire to supply some workable suggestions that might further this reconciliation. The first, mentioned above, is to select an internal business management strategy that can make the most out of reversibility. The second, which will be developed below, is to balance the higher level of uncertainty that reversibility creates, with the establishment of an overall, long-term chemical risk reduction programme.

3.2. An agenda for chemical risk reduction

How to develop a long-term programme for regulatory action towards risk reduction in the area of chemical substances? And, which entity should primarily be in charge? Tackling the last question first, a strong case could be made that, in spite of recent controversies, the European Commission would be the most appropriate, and best qualified institution for this task within the European context.966 Not only does the Commission have the right of initiative

965 See Articles 4(4) to 4(6) of Directive 91/414/EEC.
966 Cf. STEPHEN BREYER & VEERLE HEYVAERT (1999, forthcoming), *Institutions for
for EC legislation, it is also the Community's chief strategist: one of the Commission's tasks, which is gradually increasing in importance, is the establishment of a yearly plan for Community action. In light of the strong strategic overtones of priority-setting, this exercise would most naturally be classified as an extension of the Commission's planning activities for the furtherance of the European Community. Moreover, the Commission already has some limited experience in the area of strategic risk decision-making, acquired through the composition of five consecutive Environmental Action Programmes (see below). Furthermore, the European Commission arguably bundles the highest level of scientific and technical expertise, and has access to a range of outside sources of expertise. It is probably the institution most experienced with setting up broad-based consultation and coordination processes, experience that will prove extremely valuable to increase the legitimacy and effectiveness of risk reduction priority lists (see below).

As alternative candidates, we might consider one of the fairly recently established regulatory, quasi-regulatory or advisory agencies, for instance the European Environment Agency, the Agency for Health and Safety at Work, the European Medicinal Agency, or the European Chemicals Bureau. However, I would argue that, at this point in time, none of these institutions has the required experience and breadth to assume such a pivotal task. Moreover, a decision to delegate priority-setting for chemical risk reduction to one of the aforementioned agencies would raise the even more difficult question of which is best suited to the task. Obviously, difficult questions, too, can be answered, however the added complication of deciding between agencies forms an additional practical argument in favour of leaving the task with the Commission.


How to develop priority-lists? Above, I mentioned the Commission's existing practice of drawing up strategic Environmental Action Programmes. These grant some rudimentary insight into the Commission's priorities for risk regulatory action over a period of, approximately, five years at a time. Obviously, the scope of Action Programmes is very broad, and the areas for prioritised action are quite generally and vaguely indicated. The current Fifth Environmental Action Programme therefore by no means provides sufficient information to draw up a more detailed and specific EC regulatory programme for chemical risk reduction.969

To develop a more detailed ranking system, the Commission could rely on comparative risk assessment (CRA) to compose a priority list for regulatory action on chemicals. As we discussed in Chapter III, CRA is not a magic formula for rational risk regulation, and comparative assessment techniques need to be applied and evaluated with due caution. Yet, even the staunchest critics of comparative risk assessment tend to be painfully unenlightening when it comes to advocating alternative methods to prioritise among chemical risks, methods that ideally would be more productive, accurate and equitable than comparative risk assessment. Arguably, the most reasonable approach for the Commission to follow in establishing a risk reduction priority list would be to deploy CRA as a technique for priority-setting, but to balance its results through the inclusion of non-quantifiable, more reflective considerations (such as equity considerations, or taking into account the level of familiarity and corresponding degree of public acceptance of a particular risk). In other words, CRA would be an important, but not a determining factor in priority deliberations.

Additional factors to be considered would include the previously mentioned equity and public acceptance considerations, cost-benefit and cost-effectiveness calculations, and not in the least, forecasts about future technological developments.970 The latter offer important guidance on whether substances (and compounds of substances) under evaluation are likely to be phased out by technological change, whether their market share will remain approximately the same, or whether demand is expected to increase significantly because these substances or compounds play a vital role in new and developing

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970 See also Heading 4 below.
technologies. Finally, priority-setting exercises could take stock of (and eventually adjust) the balance between health and environmental risks targeted for prioritised risk reduction measures. The inclusion of considerations of this nature would enable regulatory authorities to verify -- in an admittedly rudimentary way -- whether, at the end of the day, risk identification and assessment reforms are translated into a more balanced distribution of regulatory attention. If an investigation, conducted in the course of priority-setting, indicated that regulatory action based on the proposed prioritised agenda would result in the reduction of health risks, but would have extremely limited ramifications for the environment, then this would send a signal that further efforts are needed to increase the visibility of environmental risks during the stages of risk identification and assessment. Hence, the goal of “further improvements to information gathering and assessment techniques for the purpose of environmental risk detection” could be included on the priority list. The objective is, again, to create and enhance a regulatory “memory” that stretches beyond the scope of individual, case-by-case decision-making.

3.3. Coordination and communication

It will come as no surprise that, to be effective, the organisation of a priority list for risk reduction will require intense coordination efforts on the part of the European Commission. The added certainty that regulated parties (as well as third parties affected by risk regulation) derive from the existence of an EC priority list could easily be undermined if Member States would continue to undertake regulatory activities inconsistent with the general directions set in the priority list. The Commission would therefore be well advised to solicit widespread support for its priority-setting activities.

The most obvious way to go about this, would be to consult representatives from regulatory bodies that are charged with risk regulatory functions in the Member States. Possibly, national administrations might draw inspiration from the priority-setting activities undertaken at the European level, and use the European model as a frame of reference for the development of complementary national risk reduction programmes. Securing the support of the administrations from the Member States for prioritised targets for European regulatory action might furthermore dilute the risk that, once prioritised areas for risk reduction are translated into concrete legislative proposals (say, further
amendments to Directive 76/769/EEC), these proposals would not pass through the Council, or the Parliament. Finally, we should not forget that national regulatory authorities are the main entities responsible for the implementation and enforcement of Community health and environmental law. Hopefully, their involvement in the development of an overall risk reduction strategy would increase both their understanding and acceptance of EC regulation as a source of law, which could in turn promote more efficient and effective implementation of Community legislation.

It almost goes without saying that, in addition to coordinating with public authorities from the Member States, the Commission should create opportunities for the by now familiar stakeholders (industry, public, environmental and consumer interest groups, and outside experts) to take part in the priority-setting process. Representative deliberation would not only consolidate the authority of resulting priority lists, it would also improve the quality of the lists, since each of the above-listed parties have relevant information to contribute to the priority-setting process. Thus, industrial representatives will have important information on the technologies and substances that are likely to become more widely spread in the future, and those that are on their way out. Public interest groups could gather and submit information on risk awareness, risk aversion and public perception of different kinds of threats; environmental interest groups might be particularly interested in monitoring the health-environmental ratio in proposed reduction programmes.

Broadly based involvement in priority-setting exercises might furthermore constitute an opportunity to double-check whether participation mechanisms in the stages of risk information gathering and assessment function adequately. For instance, the level of discontent of one, or several, of the consulted parties with a proposed priority list might be interpreted as prima facie evidence that existing consultation and participation provisions in the EC regulatory framework for chemicals need to be reassessed. Hence, in addition to offering guidance concerning areas for future decision-making, priority-setting

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971 Although, it should be mentioned, the ties between national regulators and the European Parliament are weaker than those between regulators and the Council.
972 Cf. John Applegate (1992), discussing priority setting in the US context. Applegate suggests that the EPA would draw up the initial risk reduction programme, on a mandate from US Congress, and then subject it to public comment. JOHN S. APPLEGATE (1992), "Worst Things First," o.c., p. 310.
973 See headings 3.5. and 5 below.
constitutes an act of regulatory self-observation and -evaluation, capable of producing information that may strengthen both the substantive and the procedural rationality of decision-making processes.

3.4. The legal status of priority lists for chemical risk reduction

Finally, we should touch upon the issue of the appropriate status of Commission-made priority lists for chemical risk reduction. Should they be made legally binding (for instance, through their adoption by the Council in the form of a Council Regulation), or should they be advisory in nature? The most obvious, albeit somewhat unsatisfying, answer is: "Ideally, somewhere in between." EC priority lists should marshal sufficient authority to function as a reliable source of regulatory information for the chemical industry, and thus to serve as a counterweight to the increased reversibility of individual decisions. Also, they should be considered sufficiently authoritative by regulatory authorities located in the Member States to be taken into account in the development of national risk policies. On the other hand, they should not be so binding that they become, themselves, non-revisable and irreversible, thereby undoing the higher level of flexibility that priority lists were intended to enable in the first place. In sum, priority lists for chemical risk reduction would in all probability join the ranks of a growing body of European "soft law"; authoritative yet not mandatory, instructive yet not cast in stone.974

The latter statement might appear more condemning than is intended; it seems to relegate priority lists to a legal no man's land. However, I would argue that the European Community has more experience, and probably greater aptitude, in making soft law work, than any other governance structure. It is one of the European Community's inevitable missions -- some would call it a predicament -- to reconcile different levels of governance, to strike a balance between the involvement of regional, national, European and even international authorities in the development, implementation and enforcement of health and environmental policy.975 We need only think of the complex and far-reaching debate on subsidiarity -- a debate that has spread its tentacles into the realm of EC environmental law -- to be reminded of the undeniable fact that balancing authority between the European and the Member State level is a serious and

974 Cf. FRANCIS SNYDER, o.c., p. 218.
975 Cf. STEPHEN BREYER & VEERLE HEYVAERT, o.c.
difficult matter. Moreover, as we have seen in the case of notification of new substances, the development of EC-wide policies not only requires Member States to accept a (partial) transfer of competencies to European bodies, it furthermore implies that a Member State may see itself constrained by determinations made by the national authorities of other Member States.

One of the side-effects of the constant need for balancing acts between different sources and layers of authority is, I believe, that European institutions have developed a certain creativity in the choice and development of both hard and soft legal instruments, principles and practices to further the reconciliation (or harmonisation) of European and Member States' policies without overly upsetting national sensibilities. For instance, the famous principle of mutual recognition, first introduced by the European Court in its seminal Cassis de Dijon ruling, posits that any product lawfully produced or marketed in one Member State should in principle be allowed to circulate freely on the Community market. It creates a presumption in favour of free trade, but with an escape clause attached: Member States seeking to rebut the presumption can do so, provided they prove that, in their specific case, a national mandatory requirement having a restrictive effect on EC trade is warranted on the basis of, for instance, documented health and safety concerns. In other words, mutual recognition enables the development of a system that obviously favours the European level, and the pursuit of an EC objective (free trade), over the Member State level and the protection of national objectives through mandatory product regulation. However, the principle is flexible enough to allow a rebalancing of

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977 See Section II.2.1 of Chapter II.

978 Cf. FRANCIS SNYDER, o.c., pp. 197-225.


980 See, inter alia, PAUL CRAIG & GRÁINNE DE BURCA, o.c., pp. 604-608; SEBASTIAN
the merit of European and national objectives in specific cases, which equally entails a rebalancing of European and Member State authority.

Mutual recognition has also been incorporated in secondary EC law. In particular, the EC Pesticides Directive, as well as the recently adopted Directive on Biocides, lay down a system of mutual recognition of marketing authorisations for plant protection and biocidal products. In principle, a product that has been authorised in one Member State should qualify for authorisation in any of the others. However, as in the context of Cassis de Dijon, the objective of EC market integration (expressed in the EC-wide validity of authorisations) is kept in check by the countervailing objective of safeguarding Member State prerogatives to regulate trade conducted within its borders (when it deems such constraints in the national public interest). This is most notably the case for pesticides: a marketing authorisation granted by one Member State is not automatically valid throughout the EC. Pesticide traders must apply for authorisation in each Member State for which they seek market access. Moreover, applicants carry an initial burden of proof: their application must be substantiated with documentary evidence to the effect that "agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable" in the Member State that has already authorised the product, and in the State where authorisation is sought. Here, mutual recognition does not establish a presumption of conformity. In fact, its main practical purpose is to prevent Member States from compelling applicants to repeat tests and analyses already carried out in connection with previously obtained authorisations in different Member States.

It is not my intention to go deep into the reasons why the mutual recognition doctrine was given a relatively weak interpretation in the case of pesticides. Suffice it to say that pesticides are considered per se dangerous products -- indeed their very purpose is to attack small components of ecosystems -- and that this classification imparts particular urgency to Member States' insistence on their prerogatives to protect the health and environment of

FARR, o.c., pp. 10-12.


982 The balance in the Biocides Directive is slightly more tilted in favour of market integration. See Article 4 of Directive 98/8/EC.

983 Article 10(1) of Directive 91/414/EEC.
However, I do wish to draw attention to potential breadth of mutual recognition schemes: they are able to incorporate and support differently calibrated balances of power between sets of objectives, rules and sources of authority.

Perhaps, an approach that operates following similar dynamics as the ones activated by the principle of mutual recognition, could give sufficient “bite” to a chemical priority list, without casting it in stone and thus undermining its flexibility. In practical terms, this would imply that, if the European Community considered introducing risk reduction measures relating to substances or compounds that do not figure on the priority list covering the relevant time period, detailed reasons would have to be supplied to support this decision. Conceivably, deviation from the priority list would trigger an intensive negotiation process -- comparable to, for instance, the “notice and comment” period respected for informal rule-making in the United States985 -- between regulatory authorities and interested parties. Negotiation would not only aim to forge consensus on the acceptability and necessity of deviating from the priority list (or absence thereof), but could even touch on issues of (partial) compensation of those who relied on information in, or reasonably inferred from, the priority list to develop business or action strategies. Furthermore, as all Community decisions, decisions on risk reduction measures deviating from the priority list would be subject to review by the European Court of Justice.

In this manner, the Court could play an important and productive role in finding a workable equilibrium between the desirable levels of flexibility and stability of the regulatory framework for chemical control. Similarly, in the absence of Community legislation, the Court could incorporate priority lists into its decision-making on the legality of mandatory requirements, developed within the Member States, in light of Articles 30 and 36 of the EC Treaty986 For instance, a national regulation restricting the concentration of Chlorplus in, say, wood paint, might be presumed in conformity with Article 36 if Chlorplus figures on the EC priority list for chemical control. Conversely, if Chlorplus were not prioritised, it would initially be up to the restricting Member State to prove that the locally established concentration limit for Chlorplus in wood paint does

986 Articles 28 and 30 ToA.
not constitute an illegitimate trade barrier, adopted predominantly for protectionist reasons. Moreover, if the European Court ends up agreeing with the restricting Member State, this might send a signal to EC regulatory authorities (in particular, the Commission) that the priority list should be reviewed and the incorporation of Chlorplus considered. Thus, judiciary and regulatory processes might usefully inform each other.

3.5. **Procedural guarantees**

I mentioned before that concerns about the potential randomness of flexible regulatory decision-making could furthermore be allayed by procedural guarantees. Procedural guarantees refer, first, to participation rights (see also above). Rules have a higher chance of being accepted when the regulated parties (mainly industry), as well as those who are in some way affected by regulatory decisions (for instance, employees working in a chemical installation; people living in the vicinity of a chemical plant; the public generally in its relation to the environment; consumers; etc.), are involved or represented in the rule-making process. Analogously, changes to rules have a better chance of being accepted when the regulated parties, as well as those affected by regulation, are involved or represented in the rule-changing process. We will come back to the issue of regulatory reform through the reinforcement of participation rights further in the text.

The second type of procedural guarantee consists of the assurance that, when regulatory decisions are being considered, certain types of information are included, certain methodologies followed, and so on. Essentially, it comes down to the assurance that certain quality standards for regulatory and administrative decision-making are complied with. What these standards might be, and how they would affect decision-making under conditions of uncertainty, is the topic of the following section.

4. **Quality Standards for Regulatory and Administrative Decision-Making**

A third possible way to make the legal framework for chemicals more responsive to problems of uncertainty, would be to adopt standards for administrative decision-making. As we have learnt from Chapter IV, this
proposal is not entirely original: several commentators have posited that, when administrative substance is complex or underdetermined, structuring decision-making processes may yield more productive results than imposing substantive outcomes. Moreover, it is possible to detect the humble beginnings of standards for administrative decision-making in the practice of European environmental law: Article 130R of the EC Treaty, we recall, stipulates that, during the preparation stages, Community acts on the environment must take account of available scientific and technical data, and the potential costs and benefits of action or lack of action.\textsuperscript{987} It continues that preparation should include consideration of the economic and social developments of the Community as a whole and the balanced developments of its regions. As a refinement of the first requirement, it has been suggested that decision-makers should take into account risk assessment. Chapters III and IV recounted that risk assessment, following the methodology laid down in Commission Directive 93/67/EEC (risk assessment for new substances) and Commission Regulation (EC) 1488/94 (existing substances), was heralded as the predominant basis for future risk management actions (even if subsequent legislation reveals little of the impact risk assessment has had so far).\textsuperscript{988}

While the practice of administrative standard-setting (in other words, of procedurisation) still needs to mature considerably, it is undeniable that there is a growing preoccupation with the quality of legislative drafting of Community documents. This concern was voiced, \textit{inter alia}, during the 1992 Edinburgh Summit of the Council of Ministers, and later echoed in the Molitor Report.\textsuperscript{989} The concern is matched by a corresponding desire to infuse some structure -- aimed to secure greater transparency, reliability and, ultimately, procedural

\textsuperscript{987} Article 174 ToA.

\textsuperscript{988} It is interesting to note in this context that risk assessment’s status as administrative procedural standard has recently been confirmed at the international level. In the previously mentioned US & Canada v. EC Beef Hormone case, the Dispute Settlement Bodies of the World Trade Organisation (of which the United States, Canada, the European Union and many other states are member) decided that Europe’s decision to follow a restrictive policy with regard to the use of beef hormones, and the sale of animals treated with hormones, needed to be substantiated on the basis of a risk assessment. Absent that, the Dispute Settlement Bodies found the European Community’s policy to ban certain hormone treated beef products contrary to its obligations under the GATT. See “European Communities – Measures Affecting Meat/Livestock and Meat Products (Hormones)” Cases WT/DS26/AB/R and WT/DS28/AB/R; cf. fn. 842.

fairness into EC decision-making processes. Hence, the Commission has responded with a rather impressive set of guidelines and standards to improve the quality of legislative drafts, generally reflecting the same ideas as those launched at Edinburgh and in the Molitor Report.\textsuperscript{990} In sum, the present climate at the European Community level appears favourable to the continuing pursuit and elaboration of ideas of proceduralisation and, in particular, standards for administrative decision-making.

Encouraged by the generally benign climate for procedural standard setting, I will suggest a few additional standards that could contribute to the quality of regulatory and administrative decision-making, particularly for decisions taken under conditions of uncertainty. The two standards can be applied both at the level of regulation and individual decision-making. They are, first, the requirement that opportunities for regulatory review be taken into account in decision-making processes, and, second, that public authorities consider the varying potential of regulatory options for additional knowledge production. Before giving some more detail about the two proposals, it should be emphasised that, as with cost-benefit considerations and risk assessment, the suggestion that these factors should be taken into account does not imply that they should determine regulatory outcomes. Their main purpose is to enrich, and thereby improve, deliberative processes.

4.1. Consideration of opportunities for review

The first administrative standard requires law-makers and/or regulatory authorities to take into account the need for review opportunities prior to the adoption of a rule or regulation. While devising a general rule or a decision, decision-makers should bear in mind that this rule, or the individual decisions taken in application of the general rule, may need to be revisited and revised at a later stage.

Ideally, this consideration should resonate in the structure, scope, and implementation style of rules and decisions. It might, for instance, result in a preference for legislation that incorporates reporting duties pertaining to the implementation of the very rules adopted, or that foresees periodical reviews to

assess the effectiveness, practicality and, possibly, the efficiency of the incumbent legal framework. The 1993 EMAS Regulation provides a practical example of this approach: Article 20 stipulates that "[N]ot more than five years after the entry into force of this Regulation, the Commission shall review the scheme in light of the experience gained during its operation and shall, if necessary, propose to the Council the appropriate amendments, (...)"991 And indeed, by late 1998, a Proposal for a Regulation that widens the scope of the 1993 instrument was finalised by the European Commission, and submitted to the Council.992

Consideration of the need for review opportunities might, furthermore, lead to a prevalence of gradual implementation schemes, and to a relative increase of individual decisions that are subject to renewal, such as the newly introduced temporary authorisations for marketing and use of biocides.993 Finally, it might result in the redefinition of impact assessments to include an assessment of the reversibility of the environmental or socio-economic harm that could result from an authorisation or its refusal.

4.2. Productivity of rules

A second, and related, proposal for a quality standard for the improvement of administrative decision-making processes, is the requirement that the productivity of a rule or regulation be taken into account in the development of a risk reduction strategy. In this context, productivity refers to a rule's potential for the production of new knowledge and information. In other words, when deliberating the adoption of a general rule or administrative decision, public authorities should consider its potential for the creation of new information, and ceteris paribus follow the approach that fosters the highest level of knowledge production.

A practical example might clarify this standard. Let us assume that risk

assessment and preliminary health monitoring data suggest that Chlorplus, when used in high concentrations in industrial settings, might pose a significant risk to workers. In particular, there might be a relation between exposure to Chlorplus and asthma. However, as so often in risk regulation, the factual basis is tentative. Confronted with this information, the competent regulatory authority decides to prohibit the use of Chlorplus in industry. Leaning towards a literal and substantive interpretation of the precautionary principle, it considers that, although evidence is inconclusive, workers are potentially exposed to a significant risk and concludes that this potential warrants the imposition of a ban on Chlorplus.

Deserving as this decision may be for other reasons (for example, it might have been taken after consultation with a wide variety of interest groups; serious efforts might have been undertaken to gather and use all available scientific and related data in the decision-making process; or the decision may be very timely), the ban will not score highly when measured against the criterion of information productivity, since manufacturers who no longer use the substance will be unable to produce new knowledge pertaining to the banned substance. Under conditions of uncertainty, this is a serious shortcoming, particularly when we take into account that the substance introduced to replace Chlorplus may pose alternative (and potentially more severe) risks. If the competent authority wishes to favour a more information productive risk reduction strategy, it might, for example, stipulate conditions for use (such as use of Chlorplus in a closed system, use of personal protective equipment by workers exposed to the substance, regular health checks focusing on those health effects Chlorplus may be associated with, and/or the adoption of an insurance scheme for compensation of workers affected by Chlorplus) and announce that the decision on a ban on Chlorplus will be reviewed in five years. The interval between the initial decision and the planned review would create a time span for manufacturers to gather evidence to dispel the health concerns surrounding Chlorplus, which evidence would further inform the review process. If additional findings point in the opposite direction, manufacturers might use the time span to prepare a conversion to an alternative technology, which would facilitate the implementation of the ban once it enters into effect.

The latter example should not lead us to conclude that, under conditions of uncertainty, the most information productive regulatory option must necessarily prevail. The objective of productivity might be overridden by other
concerns. For instance, if additional research is highly expensive, and acceptable alternative production techniques are available, a ban might prove more recommendable on the basis of cost-benefit considerations. It is important to repeat that the chief objective of standards for administrative decision-making is to structure decision-making processes, to provide guidance on the ingredients that should go into deliberative processes, and not to dictate their outcome. Consideration for the productivity of rules is such an ingredient; its weight, however, is to be determined within the context of decision-making.

4.3. Level of application

Before turning to the last set of proposals for risk reform, we should briefly reflect on an outstanding, thorny issue: at which level of authority should quality standards for decision-making be introduced?

Within the framework of the study, which focuses on the European Community level of legislation and regulation, the most obvious answer would be to follow the beaten track and build on the existing standards for decision-making in Article 130R of the Treaty.994 Conceivably, a provision could be added to the effect that, in preparing its policy on the environment, the Community shall take account of “the need to review environmental decisions and the continuing need for new information.” Additionally, the Commission might expand on its previously published set of guidelines to improve the quality of legislative drafting (see above).995

The problem with this approach is that, while Article 130R applies to the preparation of Community acts,996 the bulk of risk regulatory decisions pertaining to chemicals is still taken at the Member State level. Hence, a thorough reform of risk regulation through the introduction of quality standards for decision-making can be achieved only if these standards also penetrate the national level.

EC decision-making standards can trickle down to the level of national administration following different paths. First, regulatory and administrative bodies in the Member States may decide to emulate the example set at the European level, and adopt EC standards for national decision-making

994 Article 174 ToA.
995 Cf. CHRISTIAAN TIMMERMANS, o.c., pp. 1244-1245.
996 Article 174 ToA.
procedures. European institutions might foster the exemplary function of EC decision-making processes, for example by giving a broad interpretation to the reasoning requirement contained in Article 190 of the EC Treaty.\textsuperscript{997} By documenting the steps leading up to a Community decision (for instance, the adoption of maximum concentration levels for pesticide residues), EC institutions could create valuable procedural knowledge for local administrations.\textsuperscript{998} Statements of reasons could, furthermore, prove highly valuable to flesh out newly adopted principles of EC law. The precautionary principle, for instance, might be imbued with greater practical significance if preambles to EC environmental legislation (or summary statements attached to legal documents) would indicate where and how this principle has played a role in shaping legal and regulatory requirements.

Yet, while opportunities for “example-setting” and administrative coordination between the Member States are certainly worth exploring,\textsuperscript{999} we should be wary of overestimating both the influence and appeal of EC standards at the level of national administration. The British Duddridge decision illustrates the ambivalence of national administrative and judicial authorities towards EC decision-making standards.\textsuperscript{1000} The case raised the issue of whether decisions made by the British Secretary of State should comply with the precautionary principle, as understood in Article 130R of the EC Treaty.\textsuperscript{1001} In reply, the Court stated unequivocally that: “[a]rticle 130R does not impose an obligation upon the Secretary to consider his duties under the precautionary principle.”\textsuperscript{1002}

An alternative path for EC quality standards to reach the national level is

\textsuperscript{1000} R v Secretary of State for Trade and Industry ex parte Duddridge, UK Queen’s Bench Division, judgment of 4 October 1994, rendered in Vol. 2, Journal of Environmental Law, N° 2, pp. 224-244. Cf. Section II.3.2 of Chapter IV.
\textsuperscript{1001} Article 174 ToA.
\textsuperscript{1002} Cf. fn. 1000. It is particularly interesting that this case occurred in the United Kingdom which, according to Jürgen Schwarz, in one of the Member States where administration is most open to European influences. See JÜRGEN SCHWARZE, o.c., p. 885.
via the European Court of Justice. Through the medium of Article 30/36 rulings, the Court has elaborated and clarified a number of procedural standards — most famously the proportionality principle — that should be respected by the regulatory bodies of the Member States. However, it is questionable whether, in its review of national regulatory decisions, the Court would venture beyond the most basic standards necessary to ensure the legitimacy and legality of decisions that may restrict intra-Community trade, and include standards, such as the consideration of review opportunities and the productivity of rules, that are essentially aimed at qualitative improvement and optimisation of decision-making.

The remaining option is to enforce EC quality standards for decision-making by means of secondary Community legislation. This approach would probably guarantee the greatest level of consistency and penetration. However, an across-the-board harmonisation of national decision-making procedures in the areas of health and environment — areas in which the EC does not have exclusive competence — would almost certainly be perceived as an excessive encroachment on national sovereignty; one for which the Community to date lacks the required authority. In this regard, it is interesting to note that the Risk Assessment Directive, while strongly advocating reliance on risk assessment results for national decision-making in its preamble, does not introduce an explicit obligation for Member States to do so in the Articles of the Directive.

What would be feasible, on the other hand, is for the European Community to elaborate the procedural requirements that the competent authorities in the Member States should respect in authorisation and review procedures for categories of chemical preparations that fall under an EC-wide authorisation scheme. The most familiar examples are pesticides and biocides. The Biocides Directive, for instance, provides the foundations for the introduction of nationally applicable decision-making standards: Annex VI of the Directive lays down common principles for the evaluation of dossiers for

1003 Article 28/30 ToA.
1005 Furthermore, even if the Court were so inclined, we should not forget that the scope for judicial reform of administrative procedures depends on many variables, such as the number of cases brought before the European Court, and the reception and interpretation of Court decisions by Community institutions as well as Member States.
1006 The preamble reads: "Whereas the results of a risk assessment should be the principal basis of decisions under appropriate legislation to reduce the risks arising from the placing of substances on the market" (emphasis added).
biocidal products, including a few procedural decision-making principles. These principles could be expanded upon to offer a fuller, more detailed set of administrative quality standards. The introduction of quality standards in specific areas of national decision-making would be less "tidy" than an across-the-board harmonisation of administrative procedures. Yet, precisely because of this untidiness, it might create greater opportunities for experimentation, self-learning, review and self-adaptation within national administrations, potentially outweighing the disadvantages of a fragmented introduction.

5. Communication

The final set of reform proposals is aimed at strengthening the potential for communication within the legal framework for chemicals. Communication refers, first, to communication between rules and transmission of information from one legal or regulatory system to another. The preceding analysis indicated that, while the existing European Community rules constitute a quite powerful engine for information production, this information is not always successfully reintroduced into the regulatory machinery. We recall the example of risk assessment results, which do not yet resonate sufficiently in risk management instruments.

Several steps could be undertaken to improve the communication flow between rules. Obviously, regulators and administrators should do their homework: in the preparation of rules and individual decisions, they should at the very least become aware of the varieties of information at their disposal, including information produced in compliance with Community legislation. To structure the regulatory information-gathering process, it might prove very

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1007 Directive 98/8/EC of the European Parliament and the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123/1 (1998). At present, the quality standards for administrative decision-making that can be inferred from Annex VI relate predominantly to the integration of risk assessment and cost/benefit considerations. Section 63 of Annex VI states: "[I]n the decision-making process the Member State shall take into consideration the following:

- the results of the risk assessment, in particular the relationship between exposure and effect,
- the nature and severity of the effect,
- the risk management which can be applied,
- the field of use of the biocidal product,
- the efficacy of the biocidal product,
- the physical properties of the biocidal product,
- the benefits of the biocidal product."

1008 Cf. Chapter I under Heading 3.4(c).
useful if public authorities were requested to document this procedure, indicating which sources of information were considered and, possibly, which ones were rejected. Such an exercise in transparency would benefit regulatory addressees and interested third parties, who would be better able to assess the legality and legitimacy of decisions pertaining to them. However, it would equally constitute a procedural guarantee for the decision-makers themselves, and it would significantly augment the informational value of the pending rule or decision. Here again, the European Community could play an exemplary role, for instance, by attaching an easily accessible, summary statement of reasons to decisions taken within the framework of Directive 76/769/EEC on market restrictions for dangerous chemicals.1009

Furthermore, the EC legal framework itself might be reviewed, with an eye to the modification of provisions that obstruct the integration of certain types of information in risk decision-making. Most importantly, the classification-based system for risk management decisions might be opened up to allow decision-making on substances or preparations that do not fit into the pre-established danger categories, but nonetheless raise significant health or environmental concerns. Modification might be as simple as adding a phrase such as "or other (non-classified) substances of concern." Significantly, as discussed in the previous Chapter, the recent Directive on the protection of workers against chemical agents suggests that the European Community may indeed be inclined to switch from the rather static classification-based system to a more flexible approach.1010

The second type of communication to be considered is, of course, communication between the parties that are (or should be) involved in risk

1009 Suggestions of this kind might raise the concern that all this added transparency and openness will land Europe in "American situations," where regulatory agencies are so tightly shackled to procedural requirements that it becomes virtually impossible to undertake any kind of positive regulatory action. It is undeniable that administration should seek to maintain a healthy balance between discretion and accountability. However, we should not forget that the United States and Europe have different administrative and judicial traditions, which most probably makes them prone to different kinds of "excesses." The fact that heavy procedural requirements may contribute to regulatory paralysis in the United States therefore does not necessarily imply that increased transparency would result in a similar deluge in Europe. Cf. STEPHEN Breyer & Veerle Heyvaert, o.c.; Veerle Heyvaert (1997), "The Changing Role," o.c., pp. 2-9; Ronald Brickman, Sheila Jasanoff & Thomas Ilgen, o.c., pp. 74-99.

decision-making. As stated before, the intensified cooperation between public authorities and industry that is precipitated by the conversion to a risk-oriented legal framework, necessitates a reconceptualisation and rebalancing of information and participation rights for other actors involved in or affected by risk regulation. Most significantly, it invites us to consider the opportunities for the public, generally or through representation by interest groups, to contribute meaningfully to risk decision-making. In particular, I would suggest that this discussion should go beyond the formal creation of public access embodied in, for instance, the 1990 Directive on access to environmental information. Increasingly, the quality of the communication that information and participation rights seek to establish, should be taken into consideration.

Concerns for the quality of communication emerge, for instance, in the context of labelling. As labelling duties grow more extensive, the question of how to avoid an information overload, which would ultimately discourage consumers from taking labels seriously, becomes pressing. Quality concerns are equally raised in relation to public access to environmental information, where the absence of a duty, borne by public authorities and industry, to make environmentally relevant information accessible and understandable, severely limits the public utility of this information.1011 Finally, the quality of communication is at stake in the elaboration of participation rights. As we have seen, recent Community initiatives, such as the Water Policy Framework Proposal, contain the hopeful beginnings of a more deliberative model of decision-making. While the attempt to give the public, via interest group representation, a voice in decision-making may be well-intentioned, the timeliness and efficacy of such general consultation arrangements is questionable. Confronted with a hermetic presentation of scientific “facts,” which were constructed outside the reach of public intervention, dissenting voices may all too easily be muted. As suggested previously, public consultation could therefore be more productive at the stage of risk assessment, before the factual basis for decision-making has been consolidated. In sum, if quality considerations do not become part of the legal dialogue on public rights to information and participation, this dialogue might unfortunately end with the sound of one hand clapping.

SECTION III - CONCLUDING REMARKS

In conclusion, I would like to recall the objectives that my study aimed to achieve. A first objective was to explore a new and stimulating direction in legal theory, one that advocates the development of a risk-oriented, proceduralised approach to legal decision-making. Perhaps, my interpretation and presentation of this approach might, in turn, constitute a basis for future discussion and analysis. Thus, this thesis will hopefully contribute to the expansion of its own source of inspiration.

Furthermore, the study sought to clarify the challenging and intricate legal framework that supports the control of chemical risks in Europe, an area that is unfortunately understudied and, often, erroneously cast aside as “strictly technical” and of little legal relevance.

The overriding objective, however, was to illustrate the old saying that there is nothing as practical as good theory. This is, first of all, borne out by the substantive analysis: increasingly, European Community legislation introduces and incorporates decision-making techniques and requirements that are compatible with a risk-oriented approach. Reference to the theoretical framework may therefore enable us to understand, explain and conceptualise new trends in health and environmental legislation; to make sense of changes that, otherwise, might appear arbitrary. Moreover, while the preceding study focused on chemicals, the explanatory and interpretative power of the theory can be exported to other areas that are characterised by uncertainty, such as the control of genetically modified organisms, or nuclear power. Most importantly, the theoretical framework offers us new lenses through which we can critically assess existing legal and regulatory arrangements, and scrutinise areas of tension or “regulatory failure.” Ultimately, a different look may help us find new solutions.
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PRIMARY SOURCES

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