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Europe After 1992
New Regulatory Strategies

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DEPARTMENT OF LAW

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Chapter I

The Institutional Setting: Is There a Regulatory Deficit in the European Community?

1. Harmonisation as a Vehicle for Community Intervention

One of the most striking features of regulatory techniques used in federal States is their diversity. "Traditional" legislation is only one of them: grants-in-aid or other incentives can be used by federal government, to convince Member States to follow its guidelines, and specialised agencies be set up to channel their action.

Thirty-five years after the coming into force of the Treaties of Rome, such flexible opportunities remain far more limited in the European Community setting. Harmonisation -- or, in the language of the EC Treaty, "the approximation of such provisions laid down by law, regulation or administrative action in Member States" (Article 100) -- has remained the primary form of action. The Community adopts a legislative act, which is subsequently transposed by the Member States into their own legal order, and applied by their own administration. The EC has occasionally provided guidelines for implementation by the Member States requiring them for example, to collect specific data or to mutually inform each other of decisions adopted in a given field. Yet, if one overlooks those important powers enjoyed by the Commission in competition or anti-dumping policies, the Community has never significantly departed from its traditional mode of *decentralised administration*.

Why did the framers of the Community treaties choose to limit the Community to interventions of a legislative type? There is no clear cut answer to such a broad question: the legislative history of the EEC Treaty is not yet accessible to study, and it is far from certain that the issue was addressed at the time the Treaty was negotiated. This notwithstanding, several factors can be tentatively combined to explain this situation. All relate to the same basic reality: the Community has been endowed with limited powers.

This is true as regards legislative competences. Even prior to the Maastricht Treaty, there was no doubt that the Community, just as any international organisation, enjoyed only those powers conferred on it, by the treaties. By formally establishing that

> "[T]he Community shall act within the limits of the powers conferred upon it by this Treaty",

Article 3B of the Treaty on European Union only raised to the level of formal treaty commitments that which was widely held to be a general principle of Community constitutional law, known as the principle of attributed powers ("compétences d'attribution"). Even those generic provisions, such as Articles 100 or 235 are - in principle at least - limited in scope.

This element clearly impinged upon internal market policy. Article 100, for instance, suggests that the Community is supposed to act only if, and to the extent that, national regulatory policies have an adverse effect on the establishment of a unified market. It was therefore proper to limit its intervention to a mere harmonization of national provisions, rather than endowing it with more substantial means of action. The emphasis on harmonisation of national provisions can thus be seen as an institutional reflection of the peripheral importance of social regulation in the Community

context. Indeed, Community lawyers tend to insist that the use by the Community of its competences should be such that it will not completely pre-empt Member States's competence in the area of social regulation[1]. Hence, inter alia, the strong insistence on the resort to directives, which must be transposed by national authorities into their legal orders, and which thus leave them, in theory at least, a certain leeway as to the methods by which their objectives are to be achieved[2].

Harmonisation must also be seen in relation to the role of Member States in the Community system. As is known, the Community is a far less autonomous body than any federal government. Member States still largely control the legislative process; they are responsible for the implementation of most Community acts. The delegation to an autonomous body of important administrative powers, was likely to be resented as being too intrusive as it would alter the delicate balance of power between the Community and its Member States. Concerns of this nature undoubtedly played a role in the definition of the duties that were assigned and of the means that were granted to the Community. Suffice it to state that an enormous growth in its activities notwithstanding, and despite the frequent complaints one hears about the "ever-increasing Brussels bureaucracy", the Community Administration, with a staff of some 10 000 officials is still, in numbers at least, no more than the administration of a medium-size European city. The approximation of national laws had the great advantage of enabling the Community to intervene in a

[1] See for instance the debate in Fallon and Maniet (1990) regarding product safety.

[2] Article 189 of the EEC Treaty. Member States sensitivity on this issue was confirmed by the adjunction to the Single Act of a declaration inviting the Commission to make use of directives in its proposals pursuant to Article 100A whenever harmonisation involves the amendment of legislative provisions in more than one Member State.

number of areas, without at the same time depriving the Member States of any possibility to act.

Likewise, the Community has limited financial resources and the major part of these are devoted to a voracious agricultural policy, leaving only limited room for manoeuvre in other areas. It seems clear in any event that the principle of attributed powers makes it impossible for the Community to use its spending power beyond its sphere of legislative competence (Lenaerts, 1990, 223)[3]. All this makes it difficult for the Community to systematically employ the "carrot-and-stick" approach which is familiar to most federal governments.

2. Harmonisation and its Shortcomings

Most reviews of Community policies are essentially lengthy catalogues of legislative provisions. However, a problem-oriented approach reveals a number of flaws, the origin of which can be traced to the particular profile of Community acts of intervention.

The difficulties which surround the harmonisation process are well-known. Decision making is slow and cumbersome because of the ever-growing complexity of the subjects covered and of the necessity of consensus. The adjustment to technical progress is difficult (Dashwood, 1983). Moreover, harmonisation is carried through with recourse to an instrument - the directive - which must be transposed by Member States into their domestic legal orders.

[3] See for instance the common position adopted in October 1991 by the Council of Ministers as regards the proposed directive on general product safety, or Directive 83/189 establishing a system of murual information on technical regulations adopted at national level (OJ L 109/8 of 26 March 1983).

This often results in huge bottlenecks at the implementation level; it may also explain the attention given by Community bodies to formal compliance, namely the adoption by national legislatures of the measures prescribed by the directives, rather than to the substantive observance of their provisions. Although the Commission has repeatedly stated its intention to go beyond transposition and to systematically monitor administrative application, it is not apparent whether it is well equipped to so do. Lastly, this two tier legislative process means that the Community is deprived of any direct power over those firms and other private actors who are the true addressees of social regulation, since it does not have the power to attach direct sanctions to the violation of Community norms and thus to enforce them.

All these elements clearly curtail the overall efficiency of the Community's regulatory action. Another problem is the lack of flexibility inherent to such a system. As indicated above, the harmonisation process was primarily dominated by market integration concerns with a corollary emphasis on uniformity. This tendency was further aggravated by the fact that the Community, being generally deprived of an administrative power of its own, has often found it necessary to make recourse to very detailed directives in order to ensure their uniform application. It is not altogether clear whether such a process might adequately cope with the variety of situations existing within the Community. True, it has been shown that even in its current stage of development, Community law possesses a wide range of techniques that provide an important measure of flexibility (Ehlermann, 1984). Yet, for a variety of reasons, not all difficulties can be anticipated nor accommodated in a complex and fairly inflexible legislative phase (Scharpf, 1988). Very often one might only then properly assess and weigh up the various interests involved during the process of the application of a norm to a concrete situation. The regulation of

pharmaceutical products offers an example of just such a situation: although national rules pursue similar objectives, their application differs widely from country to country because of existing divergences between medical and regulatory cultures (Kaufer, 1989).

Naturally, where one does not wish to place market integration in jeopardy, this plea for flexibility should not be seen as an open invitation to grant further discretionary powers to the Member States. But this issue must eventually be addressed: otherwise there is a real risk that Community regulation will aggravate an already serious implementation problem, it being insufficiently sensitive to the variety of situations with which national regulators have to deal.

Modern constitutional theories have stressed the changing functions of the second branch of government (administration) both in the welfare state and the regulatory state. Administration does not merely comprise the execution of legislation: the more comprehensive executive tasks become, the more sophisticated administrative techniques are needed. As we shall see below (Chapter II), in the whole area of risk control and management, administrators are often entrusted with policy-making functions. Hence the efforts of the Community to write detailed directives which include provisions on the "quality" of regulatory bodies (independence, expertise, staffing). But in several areas, the Community's lack of administrative competences is a serious obstacle to achieving Community objectives.

Put together these elements are responsible for what one might term the Community's "regulatory deficit": the Community is present in an evergrowing number of areas, but by virtue of institutional constraints, its action is at times sub-optimal.

3. The Single Market Programme: New Openings and New Problems

To a large extent, the internal market has acted as a catalyst upon the above-mentioned problems. On the one hand, the programme was largely conceived as a *legislative exercise*: the White Paper, released by the Commission in 1985, listed around 300 measures to be adopted by the Community by the end of 1992. As most of these acts were adopted in the form of a directive, it was to be foreseen that this would give rise to problems at the implementation level. The problem came to the fore right on cue in 1988, when the Commission realised that only a handful of directives had been duly implemented by all Member States.

At the same time, awareness of regulatory problems had clearly grown in Community circles in the few years prior to the launching of the internal market programme. Several features of the new approach suggested by the Commission aimed to provide a remedy to the shortcomings of the earlier approach. The emphasis laid upon the mutual recognition of national regulations and standards and that laid on the delegation of quasi-legislative powers to private standardisation bodies, were conceived as alternatives to a cumbersome rule-making process. As a result, the White Paper suggested restricting harmonisation to the laying down of basic health and safety requirements (Commission, 1985, 18). It was also expected that this new approach would increase the range of choices available to consumers, thereby creating proper competition among national rules. The assumption was that this process will facilitate technical and regulatory adjustment and eventually lead to convergence around one or a few

basic models. Thus, ex-ante harmonisation would be, in part at least, replaced by a market-driven process, resulting ultimately in spontaneous adaptation (Prosi, 1990).

Yet, in spite of its many advantages, mutual recognition cannot be seen as a panacea. It cannot be suitably adapted to all types of product, nor can it deal with all regulatory problems (Siebert, 1990, Majone, 1991). It puts legal certainty at risk, as distinct national regulations must coexist. National administrations sometimes find it difficult to identify what their legal obligations are[4]. Moreover, mutual recognition of national rules is not always sufficient: divergences in national administrative practices at the level of licensing or of certification, may hamper free movement. In fact, more than being regarded as a regulatory technique, mutual recognition may be seen as an integration instrument which creates pressures in favour of the removal of trade barriers. Thus, how exactly regulatory intervention is to be conducted at Community level largely remains an open question.

4. The Lessons of Maastricht

This is not the place to engage in a detailed assessment of the Treaty on European Union. Yet it is worth pointing out that - irrespective of what its ultimate fate will be - the Treaty contains two important political signals, which have been further developed in the ensuing ratification debates. Both are of direct relevance to our concern.

[4] In response to this kind of concern, the Commission has started to publish communications setting out the legal situation in various sectors of the economy.

i. The Member States are not prepared to accept an unlimited expansion of Community competences.

A number of elements indicate their reluctance in this respect. After lengthy debates, they have adopted the three pillar structure suggested by the Luxembourg Presidency, which can only be read as a refusal to "communitarize" foreign policy and immigration matters. Even in the Community sphere, the new competences established by the Maastricht Treaty in fields such as education, culture, public health or consumer protection are replete with reservations: the Community can encourage cooperation among the Member States, support and supplement their action, but harmonisation of the law of the Member States is often excluded. Thus, the impression is that the main object of many new provisions is not so much to legitimize Community' intervention in a number of fields in which it was already present, but somehow to make sure that it would not go beyond certain limits. Naturally, this impression is only strengthened by the inclusion of the much vaunted subsidiarity principle in the Treaty. Even if there are reasons to doubt that Article 3B as it currently stands could be readily used by the Court of Justice, it is clear that it entails a powerful message, one directed at Community institutions: Member States will oppose any move that appears to threaten the current balance of power.

ii. The Commission has been weakened.

The Commission clearly won "the battle of the Single Act". Many of its proposals were adopted by the intergovernmental conference. The endorsement of the internal market programme enabled it to dominate the Community's agenda for much longer than had its predecessors. Thanks to the development

of majority voting and the establishment of the cooperation procedure, it played a central role in relationships between the Council and the Parliament.

In contrast, it reaped a meager harvest in Maastricht. Not only were most of its proposals (generalisation of majority voting, new hierarchy of norms, implementation powers) postponed or rejected, but its institutional status was weakened. One cornerstone of its power, the right of initiative, has been watered down in monetary policy where it only enjoys the right, sometimes shared with the European Central Bank, to put forward "recommendations" which are not protected by the unanimity rule (previously contained in Article 149). It is also bound to play a lesser role in the new co-decision procedure. Furthermore, some declarations attached to the Treaty (declarations on transparency and access to information, on the cost-benefits evaluation of Commission proposals) suggest that its legitimacy has been questioned -- a fact which is amply confirmed by the harsh statements on the "appointed bureaucracy" heard in the ratification debates underway in several Member States.

5. The Post-1992 Challenge

The above elements indicate that the Community will be facing a awkward challenge in the years to come.

On the one hand, there are reasons to suggest that the harmonisation of laws, as it has so far been employed, is not sufficient to establish and regulate "an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured" (New Art. 7B), and that other types of Community intervention should be envisaged. On the other hand, the outcome of the intergovernmental conferences has provided ample evidence that national

governments were not prepared to accept a substantial alteration of the balance of power between the Member States and the Community.

One is therefore forced to walk a tight rope. True, implementation problems have now gained the status of a political problem, as shown by the *ad hoc* declaration appended to the Maastricht Treaty, which leaves room to hope that the Member States might be convinced that some changes are needed in order to achieve the objective they endorsed in 1985. Yet, as things stand, it seems unlikely that they will accept any major initiative which questions their implementation powers. All proposed solutions to the regulatory deficit should therefore give due consideration to this basic political reality.

Chapter II

From Internal Market Policy to Risk Regulation

Prompted by its Internal Market programme, the Community has already moved beyond its traditional legislative policies. Its recent activities are by no means restricted to the establishment of a legislative framework ensuring the free movement of goods and the availability of services throughout the Community. Instead, as Member States regulation has been found to be restrictive of trade in the Community, it has either fallen or has required standardisation. Thus the Community has been forced to develop measures which either standardize or substitute national provisions. Recent policy programmes have thus become more comprehensive and legislative techniques have changed profoundly. In the first section we addressed the institutional framework of these changes and the challenges they pose. In this part of the paper we are first going to supplement these deliberations by approaching the regulatory tasks the Community faces from another angle. The complementary starting point is sought in the "object" of the Community's activities. The so-called risk problem, namely the growing concern for protection against safety and environmental hazards needs to be, and is in fact, taken into account in the policies and the legislative framework which aim at the completion of the Internal Market. By focusing on this background, additional aspects of the Community's tasks can be more clearly identified and the problems and prospects for further improving the EC's regulatory performance better elaborated.

1. The Impact of the Risk Problem

"Risks" are an unavoidable side effect of societal activities and modern techniques of production. Risks are deliberately taken because of expected benefits. Deliberate risk taking presupposes both an interest in such benefits and a capacity to detect risks and to control them to a degree that seems socially acceptable. The gathering of information on risks, the establishment of bodies responsible for risk assessment, the entrusting of officials with the task of taking action in emergency cases form the core elements of modern safety legislation throughout industrialised societies. But the impact of the risk problem reaches further. The need to assess and control safety and environmental risks has not only generated specialised legislative reactions but is today influencing policy-making on a much broader scale.

1.1. Legislation or Policy?

A telling indicator for the omnipresence of safety and environmental concerns is the recent appearance of the Community's Communication on industrial policy [COM (90) 556] together with the Green Paper on European standardisation. Both documents strongly underline that the taking into account of safety and environmental concerns and the promotion of stringent standards should not be seen as a threat to the independence of the economy, but rather as a means whereby its long term competitiveness might be furthered. Similar deliberations play an important role in other related fields such as certification policies and measures aiming at voluntary commitments of enterprises, such as the draft regulation on ecological auditing [COM (91) 459]. This is not to suggest that the growing awareness of the risk problem in so many policy initiatives renders specific safety legislation and risk management activities

superfluous. It would, however, be both unfeasible and unproductive to attempt to provide for risk regulation within the general framework of the establishment of the Single Market. Risk only arises as a result of economic process. It would not be possible to pre-judge exactly which risks will arise and to pre-determine standards and mechanisms to deal with them. To attempt do so is in fact to put the brakes on the economic process. Thus re-active and free standing regulatory policies are required. Logic, however, demands that these structures do not upset the primary purposes of the Community, the completion of the internal market and the formulation of industrial policy. Risk regulation must enhance and not stifle economic progress.

1.2. General Features of Product Regulation and Safety Legislation

Product safety legislation initially focused upon particular dangerous machinery, then on broader product categories such as foodstuffs and medicinal products and gradually became all-encompassing. For this very reason the Community, in its efforts to overcome barriers to trade, had from the outset to tackle safety issues. With the adoption of the New Approach to technical harmonisation and standards in 1985 the link between market integration and safety policies was formally recognised. The New Approach shares a number of important characteristics with generals trends of modern safety legislation in industrial societies.

i. Flexibility

Safety is a normative concept. To confirm the safety of a product means that its attendant risks are judged to be acceptable. The assessment of products has to take a broad set of factors into account. The foreseeability of risks and

the capability of coping with risks change over time. Legislators therefore tend to resort to general clauses to delegate the concrete safety assessment to non-legislative bodies and to provide for procedures which allow an adjustment in safety requirements.

ii. Expertise and social considerations

Any responsible safety judgement requires the integration of expertise into assessment procedures. The type of expertise needed depends upon the risks concerned. For many mechanical products, expertise can be provided by engineers. The more sophisticated the product, the more refined the techniques of risk detection and evaluation must become. Risks to health and the environment often require scientific expertise from various disciplines (chemists, toxicologists, pharmacists etc.). Resort to engineering and scientific expertise does not, however, change the normative status of risk assessment. It is simply not enough to leave the assessment of risks to experts. There must, in the light of the the normative element inherent to risk assessment, be some external judgement as to the social acceptability of the risk evaluation provided, and the risk management suggested by experts. Whilst the legal system must integrate scientific judgements on the one hand, it must also pay regard to such social, normative evaluations on the other. This necessarily leads to co-operative arrangements. The structuring of such arrangements is one of the key issues of safety regulation.

iii. Legislation, administration and judicial control

The regulation of risks does not fit into classical notions and differentiations made between legislation and administration, politically

responsible and non-governmental bodies. Firstly, risk regulation blurs the distinction between legislation, administration and judicial control. Legislation cannot but define objectives and adopt general clauses. As a result the administrative branch must accept new responsibilities. Secondly, this development is accompanied and necessitated by an opening up of the legal system to non-governmental actors, to experts and to non-legal criteria.

The political and legal systems cannot exclusively rely on their own resources and specifically legal criteria. Expertise is needed in preparing legislation, within the administration and at the implementation stage. At the same time, the integration of expertise inevitably implies an opening up of the system of government to non-governmental actors - and their interests. The traditional distinctions made between the powers and competences of legislation, administration and the judiciary are distorted by the use of general clauses, which delegate decision-making competences to the administration and the judiciary. Administrative bodies are entrusted with the task of particularising or developing standards or rules and with their enforcement in specific situations and individual cases. Those authorities invested with the power to issue rules or standards *and* to take individual decisions are thus unavoidably constrained to make policy choices. Such functions might then only gradually be distinguished from legislative actions.

Judicial control of such decisions cannot restore the rule of law. Courts are neither equipped to second-guess the regulatory process in its full complexity, nor do they possess the legitimacy to take those policy decisions which legislators have delegated. There are only two options available. Courts may identify particularly sensitive policy areas in which legislative responsibility must not be delegated at all. But in general they will neither refer regulatory

Role of Courts

tasks back to the legislator nor try to check whether the substantive content of regulatory decisions is correct. Judicial control must instead concentrate on procedures and their rationality, on guaranteeing participatory and individual rights, on the adequacy and fairness of interest representation and the existence of the balanced consideration of expert opinions.

1.3. Specific Difficulties at the Community Level

At the Community level the development of regulatory policy-making through legal procedures, shares all the general characteristics and problems outlined above. However, the Community's legal system is distinct and the problems it faces are more complex than those of national systems.

i. Expertise, cultural traditions, trade interests

Experts act within professional and scientific communities. These communities share the broader values and cultural traditions of the society to which they belong. Arriving at consensus within an international setting is therefore more difficult than within nation states. Divergences are less likely where the expertise needed is strictly scientific and truly international scientific communities already exist. It would, however, be premature to assume that this condition be generally fulfilled. The field of engineering in particular, possesses diverse professional traditions. Agreements on technical standards, consensus on the methods of testing out certification and on the acceptance of individual decisions taken can be difficult to achieve.

Consensus building is further complicated where economic interests are at stake. Even if all participants in the decision-making process agree in

principle that national economic interests should be irrelevant, cost-benefit assessments may vary simply because of the differing socio-economic conditions which necessarily and legitimately influence safety assessments.

ii. Administrative resources and competences

As indicated in the introduction, regulatory policy at the Community level has traditionally, and in many areas still does, focus on rule making. In preparing legislation, in carrying out those rule-making competences delegated to it, the Commission depends upon the proliferation of expertise within national administrations. This factual dependency is inextricably linked with institutional constraints. The Community lacks genuine administrative competences in the field of social regulation, which would empower it to directly enforce its decisions. The responsibility for implementing decisions taken at the Community level rests with the Member States. The more the Community turns to very general rules, the more difficult it becomes to ensure the uniformity of their substantive implementation within the Member States. An assessment of specific situations within the Member States involves both the application of a given rule or standard and the interpretation of this rule or standard in the light of broader legislative objectives. This alone leads to great diversity in the choices which individual decision-makers take. But the particular characteristics of risk regulation further aggravate this situation. It is in fact the function of risk regulators to react to new examples of risk and thus to continually develop new standards as new problem arise. For this system to be effective as a whole, however, new standards set in relation to new risks must be communicated back to a central authority and out again to other decentralised risk evaluators. The Community, however, neither posseses the technical nor the administrative resources to run such a system smoothly and effectively.

2. How Regulatory Policies Should be Constructed

The involvement of the Community in risk regulation requires policies that reflect the complex characteristics of the risk problem.

- *Technical and scientific expertise must be provided at all stages of the legislative process and its implementation.* This expertise is neither readily available nor can it easily be generated. The "Europeanisation" of expertise upon which a mutual recognition of risk assessments and consensus building may be built, presupposes the setting up of an infrastructure which not only ensures continuous cooperation between the Community and national administrations, but also an ongoing involvement of those communities of experts on which national administrative authorities rely.

- It is the job of experts to transform their special knowledge and experiences into practical suggestions. This transformation does not take place in isolation. It is embedded in a normative and social process in which experts represent, articulate and respond to broader societal experiences and demands. This embeddedness of risk assessments *justifies in principle participatory rights in, and the openness of, risk assessment procedures*. Public discourse on the risk problems in Europe is, however, still predominantly national. It is likewise difficult to conceive of the representation of social interests at the European level. For the time being the European consumer and environmentalist organisations remain relatively weak, whereas trade unions have been more active in their organisational efforts. These differences between the internationalisation of science, the gradual Europeanisation of expertise and political processes which are still bound to national and cultural mores, need to

be taken into consideration when it comes to legitimising risk decisions at the European level.

- Regulatory policies at the European level aim, on the one hand, at the completion of the Internal Market, and need to be co-ordinated with industrial policy, safety at work, environmental and consumer policies. On the other hand, the impact of regulatory policies on national economies has to be taken into account. In view of the economic divergences within the Community, *it should not be taken for granted that regulatory measures have to be uniform and all encompassing*. Uniformity or equivalence of safety levels needs to be insured where products are marketed throughout the Community and safety interests must be protected through construction and production methods. But it seems questionable to impose advanced technologies on each and every region and product.

It is crucial for the design of legislative and implementation policies to realise and to recognise that risk regulation cannot simply be accomodated within traditional legal notions on legislative, administrative and judicial functions. It is likewise impossible to strictly distinguish between competences designed to realise the Internal Market and those which aim to protect health, safety or environmental interests and to adhere to models of executive federalism which assume that Member States simply execute rules adopted and decisions taken at the Community level. This is not to suggest that the present institutional structure of the Community should be neglected in the design of legislative and administrative policies. But these institutional issues need to be redefined in the light of the characteristic features of risk regulation.

3. Comitology and its Limits

At present, the regulatory responsibility for risk regulation rests with the Commission and a dense network of consultative, regulatory and management committees which is, in the field of technical harmonisation and standards, complemented by cooperative arrangements with European standardisation bodies. Comitology has developed gradually and in step with the ever increasing load of European regulatory legislation. The setting up of committees was not originally understood to be a technique of risk regulation in the modern sense. But the comitology system proved to be flexible enough to take on complex tasks by differentiating between various regulatory functions.

i. Differentiations

Typically a threefold subdivision can be observed which corresponds to the various aspects of regulatory policy-making:

- a policy-making level at which final decisions are taken;
- an interest group level at which traders and other social interests are represented;
- a scientific level at which experts bring in their specialised knowledge and experience.

This differentiated structure has obvious merits. It ensures that the various aspects of risk assessments are taken into account. It enables the Community to take advantage of the Member States' administrative experience and scientific

expertise. It ensures that cultural and economic divergences within the Community can be considered. The setting up of committees with differentiated functions presupposes that there is sufficient expertise available at the "political" level to make an informed judgement. Since the "political" committees themselves are composed of expert administrators from the Member States, which can eventually be accompanied by qualified experts, well informed judgements are, in principle, to be expected.

ii. Performance

The performance of the comitology system depends, however, on various conditions. Even if committees meet regularly and develop working routines and commonly shared assumptions, there are limits to the workloads they can handle.

Standardisation is one field where this constraint is particularly important. Expertise and standard setting is provided by the European standardisation organisations. The Commission's Green Paper emphasized the need to restructure the procedures of the European standardisation bodies so that standard setting becomes a genuine European project. Because of the growing importance of European standardisation the supervisory tasks of the Commission become ever more challenging. Standardisation mandates must be elaborated, priorities be set, the compliance of standards with the safety requirements of directives either be checked or, as the Commission for good reasons prefers, be ensured through participation of its own experts in the work of standardisation committees.

It is hardly conceivable that the enormous amount of standardisation work can in the long run be guided and controlled within the Comitology system. The supplementation of this system through the participation of Community officials, together with the admission of consumer organisations and trades union representatives to the standardisation bodies, already indicate that a genuine European scheme of standard-setting is emerging. In the future perspectives outlined in the Commission's Green Paper, standardisation work is a natural ally of industrial policy and serves as an incentive to further quality-oriented production strategies. Such perspectives do not by any means contradict regulatory objectives which focus upon the protection of safety and environmental interests. But the public responsibility for defining and controlling socially acceptable levels of risks cannot be left to standardisation alone. If standardisation evolves as a quasi-autonomous system, the complementary function of public risk management - the measuring of the social acceptability of risk - will have to be accomplished in an organisationally independent way.

iii. Implementation

The task of implementing Community rules and decisions rests with Member States. Implementation is simple and relatively easy to control where Community rules specifically address particular issues such as the acceptance or prohibition of chemical substances and food additives. In the case of more general rules and standards, however, it is difficult to determine the individual assessments which will be made by national administrations. The Community has reacted to these regulatory gaps by supplementing directives with provisions which aim to guarantee equivalent administrative practices and substantiate the administrative functions Member States must fulfil. Foodstuffs law and technical safety law are pioneering that development. In both fields, however, a need for

additional and more stringent control of implementation practices has been perceived and means to do this are envisaged, e.g. by establishing Community inspection services, by substantiating further the requirements national bodies have to meet and by establishing horizontal links between national bodies.

iv. The Delegation Issue

So far, practical considerations which militate in favour of an "approfondissement" of the Comitology system have been emphasized. It should not be forgotten that the performance of regulatory functions through committees raises delicate constitutional issues. It is often argued that risk regulation involves a political evaluation which cannot legitimately be made by annonymous committees. If this objection were justified, it would seem reasonable to restore political control either by giving preference to management or regulatory committees or by insisting on unanimous decisions wherever harmonisation policies intersect with policy fields in which the Community has no expressly defined competence. In our view, such a solution would be neither practically nor legally sound. The legality of the Committees' system has been accepted by the ECJ. But the maintenance of residual decision-making powers by the Council tends to jeopardize the continuity and rationality of regulatory policy-making. Insistence upon the competences of Member States and unanimity in decision-making endangers the "quality" of the Commission's harmonisation policies.

The delegation objection is misplaced because any type of risk regulation inevitably needs to resort to non-legal expertise and resources. The real issue is not "delegation" but the rationality and legitimacy of committee procedures. The legitimacy of risk regulation rests upon legislative mandates, the expertise and

political accountability of decision-makers, and judicial control. Improving the administrative infrastructure, providing procedural safeguards ensuring the quality of expertise, granting participation rights and public access to committee proceedings are more adequate ways to legitimise decision-making. Judicial supervision cannot aim to control the substantive correctness of regulatory decisions. Once the ECJ becomes fully aware of the nature of risk regulation, it will instead be forced to address the same issues that have plagued European and American courts, e.g. respect for procedures and rationality of decision-making.

Chapter III

Improving the EC's Regulatory Performance

1. Regulating the Regulators

The particular intensity of Community involvement in regulatory activities was not foreseen by the creators of European institutions. Many activities undertaken by the Community attempt to provide protection against health, safety and environmental hazards and to define the borderline between socially acceptable and unacceptable risks. As we have seen, however, this cannot be achieved through traditional legislative and judicial structures, whilst the mere monitoring of the implementation of Community provisions into national law simply does not suffice to guarantee an effective form of regulation. Attention should instead focus upon the co-ordination and control of those individual regulators whose function it is to continually define new standards. The Community must develop techniques and structures to fulfil this function.

From amongst the most often cited defects of the current comitology system, the following should in our view be addressed:

(i) the complexity and the ambiguity of the rules governing its functioning;

(ii) its lack of transparency;

(iii) the lack of coherence between certain sectoral policies.

Each of these issues will be tackled in this section of the report.

1.1. Streamlining the Regulatory Process

i. Because of its distinct characteristics the legal framework of risk regulation must specifically focus upon the rationality, fairness and legitimacy of decision-making. At the European level the following elements could be taken into account.

- Member States already contribute considerably to the preparation of regulatory decisions. There may be instances where relevant information is withheld because representatives of Member States feel that such information may be detrimental to their economic interests. Such attitudes would not be compatible with the duties imposed on Member States by Art. 5 of the Treaty. It might, however, be useful to clarify the Community's rights under that provision.

- Pertinent legislative and administrative provisions increasingly provide for public hearings prior to important regulatory decisions. Such hearings can only be considered if the issue really merits public debate. Rights to request public hearings should be considered for the European Parliament and eventually for regions particularly affected by Community decisions.

- Scientific committees such as the Scientific Committee for Food enjoy wide recognition and respect. This positive example confirms that acceptance of Commission decisions is in fact furthered by the quality of the Community's expertise. This example also suggests that selection procedures for the appointment of scientific experts and of interest representatives are important.

- Laying down procedural rules implies commitments that can be judicially reviewed without expecting the ECJ to second-guess the substantive validity of regulatory decisions.

ii. The Europeanisation of standardisation progresses rapidly. But national standardisation organisations still defend their positions and national standards will retain some importance. The readiness to mutually recognise national standards might be improved if the procedures of national standardisation organisations, including participation rights of non-traders and supervisory functions of administrations, were harmonised by a standardisation directive. Such an initiative would also help to clarify the Community's expectations as to the work of European standardisation organisations, which up to now are laid down in the general guidelines on cooperation.

iii. Safeguard clause procedures are means of correcting and updating the Community's regulatory rules and decisions. The right to initiate such procedures is restricted to the Member States. Safeguard clause procedures are, however, functionally equivalent to general rule-making and decision-taking activities at the European level. At present, the right to initiate such proceedures is held solely by the Member States. In other words, the centralised authority alone possess such a right. Those regulatory tasks at stake, however, are often performed by a lower level, i.e. in Germany by the Länder. To grant such bodies the right to initiate safeguard clause procedures would be in line with the subsidiarity principle.

iv. The most urgent task is the development of sophisticated legal techniques which oversee the on-going process of risk evaluation and standard

setting. Only in this way might the qualitative regulatory performance of the Member States be improved.

- One important step the Community is already taking is the definition of those requirements the competent authorities in the Member States must comply with.

- The ECJ has consistently held "that where cooperation between the authorities of the Member States makes it possible to facilitate and simplify frontier checks, the authorities responsible for health inspections must ascertain whether the substantiating documents issued within the framework of that cooperation raise a presumption that the imported goods comply with the requirements of domestic health or legislation" (case 124/81 [1983] ECR 203 at 249). The existence of such "horizontal" duties among Member States has expressly been confirmed by the ECJ on other occasions (cf. case 203/81 [1983] ECR 255 at 278). On that basis a wide variety of positive duties to cooperate could be developed. Member States could be asked to interact in a productive way, e.g. by informing each other about pending decisions or by providing and admitting evidence available in other Member States.

1.2. Improving Transparency: Towards an EC Administrative Procedures Act

The suggestions listed above aim to provide a legal framework which is clearly adapted to those changes now underway in administrative functions. The European Court of Justice has already had the opportunity to develop a number of general principles governing the action of Community bodies. By doing so,

it has paved the way towards the development of a distinct body of Community administrative law.

However, it could be argued that quite apart from their efficiency, the growth in the number of committees, the overlap of their activities, and the divergences between the rules governing their functioning creates a real lack of transparency. In such a situation, it is difficult for Community citizens to identify the body which is responsible for decisions which apply to them, and the legal remedies which are available.

A similar situation arose in the USA at the time of the New Deal, which saw, as is known, a dramatic growth in government intervention. The establishment of new specialised agencies, the functions of which were extremely complex and varied, created a need for rules to ensure they did not act arbitrarily or unlawfully. In the absence of a true administrative law tradition, the rules governing the federal administration had developed in a piecemeal fashion as they had been worked out in response to *ad hoc* needs. However, such an approach was deemed insufficient to cope with the changes under way. The *Administrative Procedures Act* adopted by Congress in 1946, aimed to legitimise the growth of federal bureaucracy by providing *a single set of rules* explaining the procedures to be followed by federal agencies and providing for judicial review of many of their decisions. In order to avoid any brutal rupture with the past, the Act had only a residual effect: in other words, the procedural requirements it contained were applicable only to the new agencies and then only to the exent that those statutes which established these agencies and the programmes they were to operate, did not themselves contain specific rules.

It is submitted that the Community could usefully draw on such a precedent. The enactment of an EC Administrative Procedures Act would of course provide the Community with a unique opportunity to decide what kind rules are more likely to rationalise decision making, to what extent interest groups should be given access to the regulatory process, or when judicial review is necessary. Even if it were to limit itself to the writing of existing practices into the law, such as the APA largely did, the adoption of a single set of administrative rules would at least provide for a hard core of provisions applicable to the developing regulatory process. Such a move would bear witness to the EC's unwillingness to allow an unregulated growth of the Community's administrative functions. As such, it would certainly be useful if, as we believe, the Community will be called upon to establish administrative agencies of its own in a number of areas (see below section 2.)

1.3 Improving Policy Co-ordination

General developments should prompt the Community to reconsider its regulatory priorities. We referred above (Chapter I) to the widespread feeling that in certain areas methods provided for more uniformity than is sometimes needed. A declaration attached to the Maastricht Treaty now invites the Commission to systematically undertake a cost/benefit analysis of its proposals, which suggests that sofar insufficient attention has been paid to this requirement. The net benefits of Community regulation, though difficult to quantify, are certainly large for all the Member States. At the same time, experience has shown that the process of regulatory decision-making suffers from a number of structural defects. Among the major shortcomings are the lack of rational procedures for selecting regulatory priorities, the absence of central coordination and oversight leading to serious inconsistencies across and within regulatory

programmes, and the insufficient attention paid to the cost-effectiveness of individual rules.

The patchwork character of Community regulation and the lack of incentives to search for economically efficient solutions are due in large part to political and institutional factors such as the complexity of Community policy-making, disagreements among Member States concerning priorities, the inadequacy of political oversight, and the need for the Commission to respond to national initiatives.

However, the shortcomings of Community regulation also have causes that are intrinsic to the regulatory process. While the scope of non-regulatory programs is constrained by the size of the Community budget, the costs of most regulatory decisions are borne directly by the firms, individuals and local governments who have to comply with them.

i. Defects of the regulatory process

A large proportion of Community programmes are regulatory in nature; that is, they attempt to correct some particular form of market failure: monopoly power, economic rent, excessive competition, inadequate consumer information, or negative externalities like environmental pollution and technological risks. Moreover, both the extent and the complexity of Community regulation are bound to increase with the completion of the internal market. It would be dangerous to overlook the real possibility that a greatly expanded body of Community regulation may reproduce some of the same political and economic defects that have weakened and distorted the regulatory process in countries like Canada and the United States. These defects are so serious that at the present

time many analysts speak of "regulatory failure" and support the ideology of deregulation.

The main structural shortcomings of the American regulatory process are inadequate political oversight by both Congress and the President, and economic inefficiency - in the sense that the same quantity of resources used to meet regulatory objectives could be reallocated to produce a greater level of benefits. Political oversight should be exercised at three different levels: at the highest level, in order to evaluate the total impact of regulation and to decide whether to spend directly through government expenditures or indirectly through regulation; at an intermediate level, in order to set priorities among different regulatory programs, both within agencies and across agencies; and at the lowest level, to evaluate and compare individual rules in terms of the benefits and costs they are expected to produce. In practice, regulatory oversight has largely been confined to the lowest level - the review of individual rules - and has been exercised by the executive branch.

The inefficiency of the present regulatory process is also well documented in the literature: striking differences in cost effectiveness both across and within regulatory programs and agencies; regulations that do not give incentives to firms and individuals to comply through the most cost-effective means available; wrong regulatory priorities; overlapping and partly conflicting rules; hard to explain differences in procedural requirements (in some cases regulatory decisions must be justified in cost-benefit or cost-effectiveness terms; in other comparable cases, federal legislation restricts or impedes administrative agencies from taking proper account of costs and benefits in their decisions).

The root cause of both economic inefficiency and inadequate political oversight, according to many analysts, is the absence of a regulatory budget procedure. Because the size of regulatory programs is not significantly constrained by congressional appropriations and by the level of tax revenues, as in the case of non-regulatory programs, the current regulatory process misses four steps central to bringing any expenditure process under control. First, neither the Executive nor the Congress systematically determine the overall level of regulatory activity in a given period. Second, no office in the executive branch or committee in Congress is responsible for systematically establishing regulatory priorities across government. Third, the Executive has not instituted any systematic process of submitting regulatory proposals to Congress. Finally, there is no central agency to audit regulatory programs. In short, no mechanism exists for regulation that requires policy-makers throughout the government to solve the two-level budget problem - how much to spend during a given period and then how to allocate this total amount among alternative uses - which is addressed by any government in its direct expenditure activities.

It is not difficult to find counterparts in Community regulation for many of the defects of the American regulatory system. If anything, some defects are even more serious in the case of EC rule-making. Thus, disciplined budget setting is even weaker since the burden of implementing Community regulation is carried by the governments of the Member States. Also, because of the absence of a central political authority, regulatory issues are dealt with sector by sector, with little attempt to achieve overall policy coherence. Even within the same sector it would be difficult to maintain that regulatory priorities are set in a way that explicitly takes into consideration either the urgency of the problem or the benefits and costs of different proposals. For example, the imbalance between water and air pollution control existing in Community environmental

policy can hardly be explained by differences in the seriousness of the relevant problems. The health and environmental effects of inadequate regulation of air pollution, as well as the impact of divergent national regulations on competition, are no less serious than in the case of water pollution.

Again, some product directives choose total harmonisation while others rely on optional harmonisation, without any obvious connection with the perceived seriousness of the relevant environmental or health risks. And the piecemeal procedure of the Commission in proposing new regulation has resulted in directives in areas where harmonisation is a low priority, while neglecting other areas which need a considerable amount of harmonisation.

ii. A useful analogy: The regulatory budget

If it is true that lack of budgetary discipline is a basic reason for the structural defects of the regulatory process, one should attempt to create control mechanisms similar to those traditionally used in the case of direct public expenditures. Following this line of reasoning, several analysts of the American regulatory process have proposed the introduction of a regulatory budget. In its basic outline the regulatory budget would be established by Congress and the President for each agency, perhaps by starting with a budget constraint on total private expenditures mandated by regulation, and then allocating the budget among the different agencies. By setting a budget constraint on mandated private expenditures, the regulatory budget would clarify the real costs to the economy of adopting a regulation and encourage costeffectiveness. The knowledge that agencies would be competing against each other would lead them to propose their "best" regulations in order to win presidential and congressional approval. Simultaneous consideration of all new regulations would permit an assessment

of their joint impact on particular industries and the economy as a whole. Finally, the placement of the regulatory budget decisions in the hands of Congress and the President would force them to assume responsibility for the overall magnitude and priorities of regulation.

The process would approximately work as follows. Before a regulation is even be proposed, it would be presented to a central clearing house within the executive branch - presumably the Office of Management and Budget - together with a preliminary analysis of its private mandated costs and benefits. The OMB would compare the proposal with other proposals made by the same agency and other agencies and together with those agencies would compile and then submit to Congress the government-wide proposed regulatory budget.

An important element of the congressional review process would be the creation of regulatory budget committees, charged with the task of evaluating the regulatory proposals and presenting a unified legislative package to the floor of each chamber. These committees, it is argued, would create a new set of congressional experts on the economics of regulation, just as the traditional expenditure budget committees have created a class of legislators with budgetary and general macro-economic expertise. Of perhaps greater importance, the regulatory budget committees would create a group of legislators interested in the overall consequences of government regulation to counteract the coalition between special interests groups and traditional authorising committees.

Regardless of how congressional deliberations are structured, the essential feature of the regulatory budget process would be the approval by the full Congress of both a total ceiling on all mandated private expenditures and individual ceilings broken down by agency or even by rule. The final stage of

the ideal budget procedure would be regular auditing and an effective sanctions mechanism for cutting back the regulation or disciplining the agencies in the event an authorised budget ceiling is exceeded.

Unfortunately, a number of serious technical difficulties have to be resolved before the regulatory budget could actually be implemented. First, it is not clear what the basis for establishing the size of the budget would be. Unlike the usual budget, there are no analogues to revenues and deficits that constrain the size of the regulatory budget. One possible solution of this problem would be to include in the budget all regulations that meet a cost-benefit test. Provided agreements is reached about the quantitative estimates, this would maximise the net benefits from regulation.

The second and more serious problem is that of estimating the full social cost of regulations, especially when the regulations restrict outputs or behaviour rather than merely requiring outlays for compliance. For this reason it has been suggested that experiments with the regulatory budget be tried at one or two agencies, preferably ones where the policy instruments rely more heavily on direct costs. If, for example, a company producing electricity is forced to add a scrubber to an existing plant, the costs can be estimated with little difficulty. In a dynamic framework, however, the situation becomes more complex. It may be difficult to anticipate changes in technology and, thus, changes in costs over time.

A third group of difficulties concerns the design of effective sanctions for noncompliance. Private mandated expenditures never show up in a regulatory agency's books. For this reason there is no simple way of keeping an automatic control on the agency's running out of regulatory appropriations. Thus, an

agency could overrun its regulatory budget without anyone knowing it, for there is no automatic way of debiting a private cost against the agency that mandates it. Still, costs could be estimated and debits entered to agency accounts.

In conclusion, none of the problems may be individually insuperable; but taken together they are sufficiently severe to make it unwise to propose the regulatory budget as a practical approach to regulatory reform. Nevertheless, because the budget is such a useful analogy for highlighting the defects in the current regulatory process, a promising approach consists in developing methods of regulatory oversight and control that incorporate budget concepts in a workable fashion.

iii. Possible directions for reform

A number of ad hoc mechanisms of coordination already exist on the American scene. What would be needed is a systematic survey and evaluation of the various types of coordinating mechanisms in order to determine to what extent they have succeeded in resolving jurisdictional problems and improving overall regulatory consistency.

In addition, it is worth pointing out that a number of instruments have potential for coordination, although they have not generally been viewed as coordinating tools. A significant example is the environmental impact assessment (EIA) recently introduced also into Community legislation. American experience under the National Environmental Protection Act (NEPA) suggests that EIAs have considerable potential as a successful coordinating mechanism. As is known, the NEPA requires all federal agencies to analyse the environmental effects of proposed actions and of reasonable alternatives to such

actions. From the viewpoint of coordination perhaps the most significant part of the requirements is the review and comment process. Because of its obligations under the NEPA and the Clean Air Act, the Environmental Protection Agency (EPA) is the only federal agency to comment on practically all impact statements. The review and comment period serves as an opportunity for inter-agency coordination since it assures active participation by all agencies involved.

One mechanism instituted by most Federal agencies (including the Departments of State, Treasury, Commerce, Agriculture, Defense, Energy, Interior, Health, Housing, Justice, Labor, and Transportation) to improve execution of NEPA responsibilities, has been the creation of special high level offices within the agencies. Such "NEPA offices" have apparently been most successful in coordinating interagency work on issues that cross agency lines, in providing information, and establishing contacts with state and local agencies and the public. NEPA offices that report directly to agency heads, or their deputies, appear to be the most effective.

To introduce a similar coordinating mechanism into the Community policy-making process (but also to implement the requirement that environmental considerations shall become part of all the other Community policies which was recently strengthened by the Maastricht Treaty) it would be useful to institutionalise an internal review procedure whereby the Directorate-General for Environment would comment on programme proposals made by the other Directorates-General (similarly Rehbinder and Stewart 1985). The coordination potential of the review procedure would be vastly increased if EIAs were not limited to individual projects, as in the present EC directive, but could be extended to cover groups of related programmes ("joint environmental impact assessments").

Despite their practical usefulness, administrative mechanisms of coordination and indirect methods such as the EIA are certainly not sufficient to ensure a correct choice of priorities and the overall consistency of Community regulation. Hence another focus of attention must be the issue of central coordination. One possible model, suggested by the analogy with the budgetary process, deserves special investigation: a *regulatory clearing-house* located at a sufficiently high level in the Community bureaucracy, possibly in the office of the President. Directorates-General would be asked to submit annually draft regulatory programs to the clearing-house for review. When disagreements or serious inconsistencies arise, the President or a "working committee on regulation" would be asked to intervene. By extending centralised control over the regulatory agenda of the Directorates-General, this review process would help the Commission shape a consistent set of regulatory measures to submit to the Council and the Parliament. The usefulness of the procedure as a tool of managerial control could be increased by coordinating the regulatory review with the normal budgetary review, thus linking the level of budgetary appropriations to the cost-effectiveness of the various regulatory programmes.

One key function of such a clearing-house system, in addition to providing for greater coherence would be to flesh out the concept of subsidiarity: only through the systematic review of the proposals put forward by the various Directorate-Generals will the Commission be able to determine when action by the Community is necessary.

This is not to say that Community intervention would sytematically be made more difficult. It might indeed be the case that a review process will lead to the conclusion that the goal of streamlining regulatory procedures and reducing their costs might only be achieved through the shifting of regulatory

responsibility from the national to the Community level. For example, since 1965 the Commission has been concerned with the harmonisation and unification of regulatory rules for the approval of new drugs and the mutual Community-wide recognition of national drug approvals.

However, experience has shown that the "multi-state drug authorization procedures" established under Directive 83/570[1] (and, more recently, Directive 87/22) have limited effectiveness. Differences between national schools of medicine, different attitudes toward the evaluation of risks and benefits, and differently perceived needs for new drugs tend to lead to different interpretations of applications for new drug approvals, despite the fact that they have been prepared according to a standardised European format.

It would be much more efficient to replace the cumbersome multi-state application procedure by entrusting the whole drug approval process to a central regulatory agency - the European Drug Agency. The establishment of such an agency would make a significant contribution toward shortening the drug approval process, reducing development costs, and lengthening the effective patent duration.

We have set aside questions of political and institutional feasibility. It would be naive to underestimate them. But however tight the constraints, they should not be allowed to obscure the fact that, in the perspective of a fully integrated European market and the consequent growth in volume and complexity of Community regulation, the question of regulatory reform can no longer be evaded.

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[1] OJ 1983 L332/1.

2. Structuring the Administrative Partnership

Legal commitments alone cannot guarantee productive cooperation. Such cooperation needs to be systematically encouraged and supported. This is why the creation of specialised bodies (agencies, bureaus, offices) should, in our view, be considered at the Community level. Prior to considering how this could best be done, it might prove useful to say a few words explaining the various forms of agency which operate in the United States. Having seen the American model we might then explain why Europe should develop *its own very distinct form of specialised bodies.*

2.1 The American Agency Model(s)

Before discussing the American model or, rather, the variety of American models of regulation by means of single-headed agencies or collegial boards and commissions, it seems useful to call attention to the distinction between regulatory *function* and the different *means* by which the function can be performed. The main justification of regulation is its capacity to increase the allocative efficiency of the market by correcting various types of market failure: monopoly power, insufficient provision of public goods, negative externalities, asymmetric information, and so on. In order to achieve these regulatory objectives, different countries have used different means. For example, in Europe nationalisation has been a historically important method of regulating natural monopolies in transportation and public utilities. Where these industries have been privatised, as in Britain, the regulatory function has been assigned to new administrative bodies, the "Regulatory Offices". In the United States, on the other hand, nationalisation having been rejected for political reasons, regulation

of natural monopolies was accomplished from the 19th Century onwards, by means of independent commissions.

Regulation can also be achieved by delegating regulatory responsibilities to private bodies, by reliance on legal remedies, by taxation, or by specialized agencies operating outside the central structure of government, as in the American case. Experience suggests that specialised and more or less independent bodies are the most effective means of regulating areas of economic and social life characterised by great complexity and a high degree of innovation. The evidence comes not only from the United States, but also from the recent proliferation of regulatory agencies in Europe (regulatory offices in Britain, autorités administratives indépendantes in France, amministrazioni indipendenti in Italy, etc.).

Despite these new developments in Europe, the century-old experience of the United States remains valuable because of the variety of methods that have been tried there. It is impossible to review here a history which, at the federal level, begins in 1889 (when the Interstate Commerce Commission was created on the basis of pre-existing models of state regulation). Our highly selective treatment attempts to clarify aspects of the American experience which are often overlooked.

The typical American agency has powers of rule-making, adjudication of individual cases, and enforcement. However, one also finds in American administrative history a weaker version, termed the "sunshine commission" because of its reliance on disclosure and public information ("regulation by information"). The outstanding example here is the Massachusetts Board of Railroad Commissioners created in 1869. This commission issued no orders that

the regulated industry was legally bound to obey, except for orders to produce information. Sometimes the Commission also specified the form the information had to take. For example, the agency often required railroads to submit data in standard accounting forms that would facilitate a comparative statistical analysis of different companies. Through its informal approach to regulation, the agency maintained a stable truce with the railroads, based on flexibility and cooperation.

It is interesting to note that even now the most successful agencies are precisely those which rely, to some extent, on the model of "regulation by publication". The best illustration is provided by the Securities and Exchange Commission. Nearly all American business executives are familiar with the agency because of the reporting requirements it enforces. These include the public disclosure of detailed informations about their companies and even disclosure of their own salaries and perquisites.

The strategy followed by the Massachusetts Board amounted to a reversal of the state's traditional railroad policy, which had produced a number of stringent laws that everyone then ignored. The Board, by foregoing the role of adversary, avoided the embarrassing impotence of the early railroad statutes. It also avoided the troublesome question of constitutionality in the delegation of legislative power to agency discretion.

This brings us to another aspect of the American regulatory experience: the independence of the agencies from the central structure of government, and the consequent issue of political accountability. According to some critics, the independence of the agencies implies a lack of political accountability to any elected officials. As Marver Bernstein wrote in 1955: "The dogma of independence encourages support of the naive notion of escape from politics and

substitution of the voice of the expert for the voice of the people ... The Commission has significant anti-democratic implications" (Bernstein, 1955: 293).

To evaluate these arguments, one must keep in mind that, in this context, independence means that the members of the regulatory commissions are appointed for fixed terms and cannot be removed by the president for reasons of policy disagreement. The commissions are certainly *not* independent of Congress. In fact, oversight by committees and subcommittees of Congress is usually exercised vigorously. The legislators have two powerful instruments of control at their disposal; an agency's organic statute, i.e. the law creating the agency, and budgetary appropriations. The statute establishes goals and objectives, sometimes in great detail, with deadlines for goal achievement and an indication of the instruments to be used. If Congress becomes displeased with agency operations it can pass amendments prescribing or proscribing certain agency activities (Reagan, 1987: 156). Recent empirical studies of the effectiveness of congressional control over the bureaucratic discretion of a major regulatory agency, the Federal Trade Commission (FTC), have found that FTC activity, measured by the distribution of its caseload, is in fact systematically responsive to congressional influence (Faith, Leavens and Tollison, 1987; Weingast and Moran, 1987). Similarly, the historical study by William Kovacic shows that the FTC, rather than ignoring prevailing congressional sentiment as some suggest, chose antitrust programs that were consistent with and responsive to the clearly articulated preferences of its oversight committees in Congress (Kovacic, 1987).

Budgetary appropriations constitute, of course, a basic control over an agency's ability to implement a statute, but, as Michael Reagan (1987: 157) points out, "for oversight purposes it is less the funding than the suggestions and

directives - given with increasing frequency in reports accompanying appropriation bills - that make the appropriation process the most powerful form of congressional oversight". Thus, an increasing body of evidence strongly suggests that, at least as far as congressional oversight is concerned, the political irresponsibility of regulatory agencies is largely a myth.

But presidential control of the agencies has also been progessively extended. Presidential authority to revise the funding requests of agencies and independent commissions and to combine them into a single executive budget for submission to the Congress, was legislated in 1921 and reinforced by the transfer of the Bureau of the Budget (now Office of Management and Budget) from the Treasury to the Executive Office of the President. Another very important instrument of control, is the power to appoint agency heads, commissioners and other top non-civil service personnel. The president's authority to determine who will chair the regulatory commissions was extended in the 1950s, and with some apparent success (ib.: 160).

The latest developments in presidential oversight emphasize procedural rather than substantive controls. In 1978 President Carter pushed the application of economic analysis to regulation by an executive order creating the Regulatory Analysis Review Group (RARG). Another innovation of the Carter presidency was the introduction of a "regulatory calendar", a biannual compilation of forthcoming federal regulations under consideration by the agencies. The calendar requirement was a useful step since, for the first time, the public and all the various government agencies had the possibility of knowing in advance what proposals were scheduled. The calendar was also designed to provide information about the benefits and costs of these proposals and hence the means for a rational evaluation of priorities among competing regulatory initiatives.

However, the reforms of the Carter period proved to be ineffective in influencing the behaviour of regulatory agencies, in part because as the administration's term wore on, the President's attention was increasingly diverted by non-regulatory issues (Litan and Nordhaus, 1983).

President Reagan abolished the RARG, and instead made the Office of Information and Regulatory Affairs (OIRA) in the OMB the institutional focus of presidential oversight. While President Carter had permitted, and in fact advocated, greater use of cost-benefit analysis in regulatory decisionmaking, Reagan's Executive Order 12291, issued in February 1981, required that all major regulatory decisions (i.e., those that impose costs of over $ 100 million per year) now be justified in cost-benefit terms. Despite the political motivation of the Reagan's reforms - the desire to curtail the scope of federal regulation - there are reasons to believe that cost-benefit analysis will continue to be viewed as an essential requirement for rational decisionmaking in regulation.

2.2. Why has the Agency Model been so Little Exploited in the EC?

Specialised bodies similar to US Agencies are rather rare at the Community level. Of the various structures established by the Treaties, only the European Investment Bank or the Euratom Supply Agency bear some similiarity to the American model. Whilst, as we shall see below, specialised bodies of various types are now being proposed in several areas, it is useful to understand why this evolution has been so retarded.

In the first place, it should be noted that nothing in the EC treaties provides for the creation of this kind of structure. Article 4 of the EEC Treaty, lists the various institutions operating at Community level and specifies that each

of them must act "within the limits of the powers conferred upon them by the Treaty". This has generally been read as a prohibition on the establishment of futher organs, to be overturned only following a Treaty revision (Lenaerts, 1992). As early as 1958, the European Court of Justice also indicated that the delegation of powers by Community institutions to *ad hoc* bodies not envisaged by the ECSC Treaty was possible only subject to strict conditions and that in any event, the delegation of broad discretionary powers was not permitted[2].

However, to state that the Community's institutional structure did not provide the kind of flexbility that was needed somewhat begs the question: why then did those who drafted the Treaty choose to limit the Community to certain types of intervention? Two factors can explain this choice.

The first is the role the Member States intended to play in the integration process. We have seen earlier (Chapter I.1.) that this largely contributed to the emphasis that was laid on an essentially legislative approach to integration problems through a cumbersome harmonisation process. This point might not be overstressed. The expansion of Community competences in the 1970s and the early 1980s, for instance, can only be understood with reference to the near total control Member States enjoyed over the policy-making process. In this way the Community appeared to be merely one additional instrument in their hands, rather than a usurping power. For this reason a mutation which in any federal system would have been at the expense of the component units, and thus

[2] Case 10/56, *Meroni*, [1957-58] ECR 157. It is generally held that although this ruling dealt with the fairly detailed provisions of the ECSC Treaty, its conclusions are *mutatis mutandis* applicable in the broader context of the EEC Treaty (Kapteyen and VerLoren van Themaat, Gormley ed., 1990, 121-122). But most of the agencies now proposed take power away from the Member States, rather than from Community institutions. The relevance of the *Meroni* precedent in this type of situation is therefore dubious.

opposed by them, was readily accepted by the Member States of the Community (Weiler, 1991).

However, this "neutral" character of the integration process will last only as long as Community intrusion into spheres which have been traditionally part of the Member States' competence is compensated for by representation of the Member States at all stages of the decision-making process. This concern has led to the establishment of expert committees, composed of Commission and Member States representatives, to assist the Commission in its executive functions.

Any departure from the comitology model of action is therefore likely to meet with strong resistence. In particular, the delegation to an autonomous body of wide-ranging law-making and enforcement powers similar to those enjoyed by American agencies, is likely to be resented by the Member states as too intrusive since it would alter the delicate balance of power which has presided over the growth of Community competences. Undoubtedly, concerns of this kind have played an important part in determining the functions granted to the newly established European Environment Agency, which is more concerned with research and data collection than with regulation per se.

Secondly, mention should also be made of those elements of European administrative culture which have certainly played a role, albeit a lesser one, in those developments under review. The creation of specialised agencies endowed with broad powers is far from a being traditional feature throughout Europe. On the contrary: regulatory functions are often assigned to ministries, or to the cabinet as a whole (Majone, 1989). Even in the realm of monetary policy, where the need for expertise is widely accepted, the recent debates over the creation

of a European system of central banks have clearly shown that most central banks do not enjoy the same degree of autonomy as does the Deutsche Bundesbank. Many of them are still largely dependent on decisions made by the Treasury. Governmental supervision and indirectly, Parliamentary monitoring of administrative action, are often regarded as pre-conditions for a democratic society. All this makes it rather unlikely that national governments will be willing to concede to Community bodies powers that they are rarely prepared to delegate to domestic bodies.

2.3. What Kind of Agency Might be Useful and when?

Given these premisses, one might wonder if the agency concept can be of any help at all at the current stage of institutional development within the Community. Politically, Member States seem unwilling to alienate further aspects of their sovereignty, be it in favour of autonomous organs. Legally, the delegation of law-making powers to independent bodies appears to go beyond what is permissible within the framework of the current treaties. What role, if any, can agencies conceivably play in such a context?[3]

The answer lies, in part at least, in the question itself: to be acceptable, Community agencies must pay due consideration to the above reservations. In other words, what is envisaged here is not a mere transposition of the American model. The establishment of specialised agencies should not be equated with the complete preemption by the Community of entire sectors in which the Member

[3] For the sake of simplicity we will retain the word 'agency', as it used in various Community texts establishing specialised bodies. Sight should not, however, be lost of the fact that the term agency might mean many things.

States have to date been active. Rather, the ambition of these bodies should be to *supplement and assist action taken by the Member States.*

Agencies could help to solve many problems which the present system cannot adequately solve, such as:

- providing expertise in preparing, carrying out, evaluating and coordinating Community policies;
- establishing links between national administrations and building up issue-centred expert networks;
- systematically informing decision-makers about projects carried out by, or on behalf of, competent authorities within or outside the Community;
- supporting those Member States with scarse administrative resources;
- monitoring implementation, and helping in the organisation of exchanges of experience;
- commenting upon practical experiences and helping to develop innovative regulatory responses.

By gathering information and providing for its exchange and by organizing expertise, agencies can hope to develop a real "communauté de vues" among national experts. By preparing policy decisions and providing assistance to Member States whose regulatory capacity is weaker, they can equally promote "une communauté d'action"[4].

[4] Functions of this kind have been entrusted to the newly established Environmental Agency (OJ L120/1 of 11 May 1990), and are envisaged in two drafts currently under discussion (draft regulation establishing a European Agency for the Evaluation of Medicinal Products, OJ C310/7 of 30 November 1991, draft regulation establishing an European Agency for Health and Safety at Work, COM(90) 564 final of 25 September 1991).

It is fair to say that some of these functions are already undertaken within the current comitology setting. Yet, the agency structure would present several advantages: greater stability, providing a much needed long term perspective, the possibility of more systematic action, etc. In addition, European agencies could play a crucial role in the public discourse on risk policies. For, despite the emphasis so far laid upon the necessity to "Europeanize" expertise, we should point out that risk assessment cannot and should not be understood as a task solely to be performed by to experts, operating in isolation from broader social developments, cultural traditions and values. Member States participation in the functioning of agencies, the involvement of unions, environmental and consumer organisations and the willingness and ability to disseminate information to interested actors, can all contribute to legitimising European policy-making.

Entrusting the Commission with such and similar tasks would not, in our view, be a valid alternative. The Commission's administrative structure is currently too weak to take over new functions and it is unlikely that the Member States would be willing to grant to it the additional means that would be necessary. In contrast, the setting up of what one could call a "quasi-agency" structure, pooling together the expertise available at national level, should elicit a more positive response.

True, the loose structure which is envisaged here would not suffice in highly regulated areas in which divergences in national administative practices are of decisive importance. Those regulations governing access to the pharmaceuticals market offer a good example of such a constellation: short of a common licensing system, a true common market for pharmaceuticals seems beyond reach. In such cases, the possibility of entrusting a specialised agency

with a *decision-making power* of their own ought to be considered[5]. Yet, in the light of the subsidiarity principle, a quantum leap of this kind should be initiated only when and if it appears that a centralisation of decision-making is necessary to find a remedy to an administrative impasse.

3. Implementation Plans

3.1. Some Reflexions on the US model

The establishment of specialised agencies is not commensurate with the centralisation of regulatory enforement. American regulatory federalism combines a variety of approaches and techniques to improve cooperation between the states and the central government in enforcing regulation. This is particularly true in the areas of environmental protection and health and safety at work, which form the core of "social regulation" and contribute a significant portion of the $510 billion which economic and social regulations are supposed to have cost the U.S. economy in 1990.

The main types of intergovernmental regulatory programs may be summarised as follows:

[5] This is more or less what is envisaged for pharmaceuticals although, formally, all legally binding decisions of some importance would be taken by the Commission upon a proposal presented by the Agency (see above, note 7). As indicated above (note 5), it is not clear that this kind of precaution, clearly inspired by the *Meroni* precedent, is indispensable.

Typology of Intergovernmental Regulatory Programs

Program Type	*Description*	*Major Policy Areas*
Cross-cutting requirements	Applies to most federal assistance programmess to ensure broad coverage	Non discrimination, environmental protection, grants managements
Cross-over sanctions	Threatens to terminate aid provided under one or more specified programmes unless the requirements of another programme are satisfied	Highway safety, environmental protection, health planning, handicapped education
Partial preemptions	Establishes federal standards, but permits states with federally approved plans to enforce standards	Environmental protection, natural resources, occupational health and safety, meat and poultry inspection

H&S in U.S.A. (O.S.H.A.)

This section reviews the nature and use of federally-approved state plans in the field of health and safety at work - an area of growing importance in the EC, for which it is important to assess the relevance of the American experience. The use of federally-approved state implementation plans in environmental regulation has been analysed by Richard Mott (Mott, 1990).

In 1970, when the Occupational Safety and Health Act (OSH Act) was passed, few American states had comprehensive laws dealing with safety and

health at work and fewer still had adequate programs to enforce them. The judgement of Congress that existing state laws were unable to provide meaningful protection to the nation's workers is evident in the legislative history of the Act. Above all, sponsors of federal legislation criticised the lack of uniformity among safety and health programs, which created competitive disadvantages and discouraged nationwide progress in this important area of social regulation. However, the OSH Act does not provide for the complete federalisation of occupational safety and health enforcement. The objective of assuring safe and healthy conditions at the workplace was to be reached, in part by "encouraging the States to assume the fullest responsibility for the administration and enforcement of State occupational safety and health laws", by means of federal grants and approved state plans (OSH Act Section 2(b)(11)).

The reasons for encouraging state participation were twofold. First, since it would take time to promulgate state standards and create a program for their enforcement, permitting the state safety and health agencies to continue to function would provide workers with at least some degree of protection during the interim period. Second, there were some states that had administered effective programs prior to the passage of the act. Concern was expressed during the legislative debates, that these services not be lost to the overall safety and health effort.

The OSH Act incorporates special mechanisms for utilising state resources. The most important of these are the provisions for *state plans* contained in Section 18(b) through to (g). While the Act generally preempts state enforcement once the federal government regulates, Section 18(b) provides that states desiring to regain responsibility for the development and

enforcement of safety and health standards under state law, may do so by submitting and obtaining federal approval of a state plan which meets the strict requirements set forth in Section 18(c), (see below). Approval of a state plan by the Occupational Safety and Health Agency (OSHA) permits the state to re-enter the field of occupational health and safety regulation.

In Section 18 Congress adopted an innovative regulatory approach, authorising the joint exercise of authority by state and federal agencies. Two points should be noted in this context. First, federal enforcement powers are not delegated to the states. Instead, Section 18 permits states with federally approved plans, to enforce state standards under the authority of state law, using state administrative and judicial procedures. Second, federal approval of a plan is not a single regulatory event; rather, it occurs in stages. Initial approval of a plan under Section 18(b) is granted if upon submission of the plan, OSHA finds that the plan meets or will meet the criteria set forth in 18(c).

During the period of initial approval, OSHA may exercise its enforcement authority concurrently with the state, with employers subject to inspection and citation by either authority. Initial approval is the most significant step in the plan approval process as it removes the preemption barrier and permits the state both to commence enforcement operations and to receive federal matching grants.

i. Criteria for State Plans

a. Standards

A state must provide for the development of state standards "at least as effective" as corresponding federal standards. In fact, the great majority of state standards under approved state plans are identical to their federal counterparts. Where states choose to develop their own standards, OSHA must evaluate the effectiveness of the state's rule-making procedure as well as the substantive content of the resulting standards. State standards that differ from corresponding federal standards must provide equal or better protection than their federal counterparts; moreover, the state must assure that subsequent judicial and administrative interpretations of a state standard do not compromise its effectiveness. The principal limitation on the standards-setting authority of those states with an approved plan is found in the "product standard limitation" of Section 18(c)(2). This provides that state standards, where applicable to products distributed or used in inter-state commerce, must be necessitated by compelling conditions and must not unduly burden interstate commerce.

b. Enforcement

Section 18(c)(2) requires state plans to provide enforcement of state standards at least as effective as federal enforcement. The remaining subparagraphs of this section contain criteria which emphasize the importance of state provisions that adequately provide for right of entry and inspection, funding and staffing and state reporting requirements. Enforcement procedures generally mirror those used in the federal system. Adoption of a

procedure manual, resembling the OSHA Field Operations Manual has been a required developmental step (see the section on the approval process, *infra*) in virtually all states, as has been the promulgation by the states of administrative regulations comparable to federal regulations, governing such matters as inspections, citations, penalties, review procedures and variances. Section 18(c)(3) requires state inspection rights to be at least as effective as those available to OSHA.

c. Staffing

Sections 18(c)(4) and (5) state that the Secretary of Labor (in whose Department OSHA is located) is to approve a state plan, only if it provides "necessary" qualified personnel and "adequate" funds to carry out enforcement functions.

Prior to 1978, OSHA had developed numerical staffing requirements or "benchmarks" for each state plan. These staffing requirements were challenged by the labor unions (AFL-CIO), on the ground that the benchmarks used by the Secretary of Labor were predicated on federal enforcement levels that were artificially low (the Secretary was accused of deliberately withholding a commitment to the provision of adequate resources until he knew the full extent of likely state participation).

Court proceedings ensued, culminating in a decision by the District of Columbia Circuit (AFL-CIO v. Marshall), that reversed the district court's grant of summary judgement in favor of the Secretary. The district court, on remand, issued an order directing the Secretary to develop a 5-year schedule for each state, to meet the "fully effective" staffing levels, taking into account

certain specified factors in each state, such as the number of employees and employers; the number of hazardous industries; the number of schedule inspections that should be conducted; the anticipated number of accident, complaint, and follow-up inspections required; and the number of inspections a compliance officer could perform.

ii. The Approval Process

a. Application

Section 18(b) provides: "Any State which at any time desires to assume responsibility for development and enforcement therein of an occupational safety and health issue with respect to which a federal standard has been promulgated under section 6 shall submit a State plan for development of such standards and their enforcement".

Once the governor of an interested state has designated an appropriate agency to formulate a plan, the state becomes eligible to receive federal funding for plan development. Each state plan must meet certain specified conditions before it will be given the Secretary's approval. Of greatest importance is that each plan must designate or create a new state agency to enforce the plan. There must similarly be procedures for standards promulgation and rulemaking and there must be provisions for enforcement and adjudication. State plans must also demonstrate the availability of adequate funding and the existence of a sufficient number of trained personnel.

b. Developmental Stage

For the first three years after initial approval, all state plans are considered to be "developmental". The most important feature of the developmental stage is that during this period the federal and state governments have concurrent jurisdiction.

During the developmental period the Secretary evaluates, monitors, and audits the state plan at least every six months. States with approved plans must submit annual activity reports and inform the public of its right to file written complaints during this three year period. This procedure is known as CASPA (Complaints About State Plan Administration). The information from these reports is used by OSHA to help determine whether a developmental plan should be rejected or certified as operational.

c. Operational Stage

When all developmental steps are completed, OSHA issues and publishes in the Federal Register, a formal notice of certification. This action signifies the beginning of the "operational" stage of the state plan. Theoretically lasting one to two years, the operational stage usually involves no federal compliance activity, but OSHA retains discretionary concurrent jurisdiction. During this stage there is also more intensive monitoring of the state plan by OSHA.

The entire approval process, of which the operational stage is the last step, is designed to lead to final approval, pursuant to section 18(e). When a

state plan is ready for this final authorisation, a notice is filed in the Federal Register. The public may submit any comments and if substantial objections to final approval are received, a formal hearing will be held. A final decision will then be issued within 120 days.

Once a state plan has been definitively approved, the Secretary may continue periodic monitoring to determine if the state plan has remained as effective as federal regulation. If the state plan has failed to maintain its high standards, the Secretary may begin proceedings to withdraw approval of the plan.

d. Modification

Most alterations to state plan come about as a result of an OSHA evaluation. The authority to review and approve the modifications to the state plan, formerly vested in Washington, is now delegated to the Assistant Regional Director.

The most important changes in a state plan are the addition and modification of standards. As federal standards are changed and added to, state plans must be constantly revised, so that the state plan remains "as effective as" federal regulation. While there is some leeway given in safety standards. OSHA requires that state health standards rigidly adhere to federal standards.

e. Rejection and Withdrawal

Any state plan submitted for initial approval failing to meet OSHA requirements may be rejected only after a formal hearing. If its plan is rejected, a state may demand a review of the Secretary's decision by filing a petition within 30 days with the U.S. court of appeals. for the circuit in which the state is located. The Secretary also may withdraw approval of a certified operational plan if a state fails to continue its management in a satisfactory manner.

Finally, a state may voluntarily withdraw its plan or any portion of it by notifying the Secretary in writing of its reasons for so doing. The notice of withdrawal must be accompanied by a letter terminating the application for any requested grants (there are two main types of grant: a) developmental or planning grant of up to 90 percent of a state's cost of preparing the plan; b) state operating grant, only available to states whose plans have been certified as operational. These grants may not exceed half of the state's total cost).

iii. The Future of State Plans

As of 1990 there were 21 states with approved state plans for private and public sector employees and two state plans (Connecticut and New York) covering only state and local government employees. California, Indiana, Maryland, Michigan, Minnesota, North Carolina, Oregon, South Carolina, Virginia and Washington are the most important states with approved state plans.

The reasons why more than half of the American states have decided not to submit state plans (and thus to be "federalised") are complex, but tend to be economic rather than political. With maximum federal operational grants of only 50 percent, instead of the earlier 90 percent for development, many states may find it increasingly expensive to keep the plan "as effective" as the federal OSHA. This is particularly true in the area of health hazard enforcement, where a greater federal emphasis will force states to hire more inspectors and to buy expensive monitoring equipment. Unless the funding formula is changed, economic reasons may cause states to withdraw plans voluntarily or to have their approval withdrawn by OSHA. Connecticut and Colorado have already done so. In California, it took a ballot initiative to restore Cal-OSHA to operational status. Few of the states with approved plans are large industrial states. Pennsylvania, New Jersey, New York, and Illinois voluntarily withdrew their applications and Ohio never submitted a plan. It is possible that as more agricultural health standards are adopted some of the smaller, agricultural states will also find that state plans are too expensive to maintain.

3.2. Could such a Model be Transposed at the EC Level?

Implementation plans have attractive features on several distinct levels:

- states retain the possibility to act if they see fit;
- in order for them to do so, they must meet precise standards;
- such a flexible solution takes due account of the fact that not all states enjoy a similar regulatory capacity; some of them need federal assistance in order to meet national standards.

In other words, implementation plans provide a possibility to reconcile two apparently conflicting trends: the desire to have high standards applied in a

uniform manner throughout the country, and the desire of the states to retain their responsibilities in a number of areas.

Yet, one must be aware that the overall efficiency of the system is conditional upon two important elements. Firstly, as regards the legal setting, the rule is that implementation of federal standards is taken care of by federal administration; state implementation remains an exception, subject to a special authorisation, which can be withdrawn at any time. Secondly, in administrative terms, the federal government has the technical capacity to take over the functions assumed by the states in cases where this proves necessary. The combined effect of these two elements is of course to give credibility to the threat of federal preemption.

The setting is of course radically different in the Commmunity. Far from being the exception, decentralised implementation tends to be the rule (see above). Yet, to require Member States to draw up an implementation plan and to set up the means that are necessary to make it operational would force them to address the implementation issue more systematically than is currently the case. They would need to identify the means - both human and financial - which will require mobilisation if the objective set at Community level is to be reached. Resources from the structural funds could be used to assist those Member States lacking sufficient resources to develop the requisite structures.

Naturally, incentives must be formulated which encourage Member States to comply with Community rules. Short of this, the concept of implementation plan would add little to the current practice. This, however, does not imply that the Community should be given the power to act on its own in case a Member State should fail to meet Community standards. Financial aid could be made

Mutual recognition

conditional upon national regulators' performance, and should be withdrawn where they fail to meet Community standards. Non-compliance might also result in the suspension of certain benefits attached to the single market: goods originating from a country which fails to meet Community standards might be subject to systematic controls in other countries, or even be denied entry to other national markets. As producers from these markets have an interest in access to foreign markets, it is likely that such a threat would provide a strong incentive to comply with EC rules. Where such incentives exist, it would not be necessary for the Community to intervene *in lieu* of defaulting Member States, which intervention would undoubtedly result in delicate institutional debates.

Yet it is clear that such a system can work only if the Community is technically equipped to assess the adequacy of implementation plans, to monitor the activity of national administrations, to provide guidance - all missions that, by its own admission, the Commission is currently not in a position to carry out satisfactorily, but *which could be entrusted to agencies organised along the lines we described above* (see point 2.3).

This notwithstanding, one could argue that the proposed scheme is *quite in line with the subsidiarity principle:* Member States would retain their primary responsibility in a number of areas, while the Community's main task would be to assist and supplement their action. In other words, it would be given powers of its own "only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States" (Art. 3B).

Chapter IV

Improving the EC's Enforcement Capacity

1. Introduction

Any discussion of potential improvements in the EC's enforcement capacity needs to be set in a broader context. This can be summarised by four remarks.

First, as is well-known, in every legal system there is a gap between the law on the books and the law in action. It would be very surprising if Community law were any different. The mere existence of such a gap should not necessarily be a cause for concern. What is more important is to concentrate on those which are problematic and capable of resolution. This involves an effort to map the gaps which exist; to explain why they exist; to identify those gaps which are likely to be more enduring or long-term characteristics of the Community system; and if possible to distinguish and identify those ideally less-enduring gaps which pose real problems for the operation of the internal market. This in turn invites reflection on the general purposes of the Community and its existing institutional structure.

Second, the enforcement of Community law is part of the more general conceptual domain of the effectiveness of Community law. Effectiveness may refer not only to enforcement but also to implementation, impact or compliance. There is no universally accepted definition of these terms, in particular with respect to Community law. Nor is there very much empirical research with

regard to Community law on these topics. It may be suggested, however, that it is most useful to conceive of effectiveness, implementation, impact and compliance, not as static phenomenona or fixed states of affairs, but instead as complicated, multi-directional processes of reaction and adaptation, potentially involving political and legal processes and changes in organisations.

Third, enforcement is often considered to be the same as implementation. The latter is, however, a much broader concept. The implementation of Community law may take many different forms. Even from the formal doctrinal standpoint we can distinguish at least seven types of implementation: (1) the enactment of Community policy into legislation by Community institutions; (2) the implementation of Community regulations by the Member States; (3) the transposition of Community directives into national law; (4) litigation in a national court based on a Community directive which has been recognised as having, or is argued to have, direct effect; (5) the interpretation by national courts of national legislation in the light of Community law; (6) the implementation of Community secondary legislation or of national transposing or implementing legislation, within or by the national civil service; and (7) the use of Community law by economic undertakings, other organisations and individuals, in the sense that they orient their behaviour in relation to Community law. For the present purposes, only (3), (4), (5) and (6) are deemed to be enforcement.

Fourth, the basic type of legislation for implementing the internal market programme is the directive. Two features of this type of legislation are pertinent here. On the one hand, directives involve a two-phase legislative procedure in which, following the enactment of the directive at Community level, Member States must transpose the directive into national law. On the other hand,

directives are designed to harmonise rather than replace national legislation, with the result that national transposing legislation may differ in each Member State. Leaving aside possible eventual modifications of these features, each of them currently raises a well-known problem of enforcement. On the one hand, Member States may not fulfil their legal obligation to transpose a directive into national law, either by failing to enact the transposing legislation, or by transposing a directive inadequately or partially. On the other hand, uniform application of Community law depends partly upon mutual recognition, partly upon national administrations, and partly upon litigation within national legal systems; its effective enforcement thus often depends ultimately upon national legal and political systems.

Against this background, the following paragraphs consider three means of improving the EC's enforcement capacity: (1) changes in the Commission's litigation strategy; (2) the role of private parties, in particular in litigation based upon directly effective Community legislation; and (3) possible new remedies.

2. The Commission's Litigation Strategy

Litigation by the Commission in the Community system has several distinctive features. First, the Commission initiates cases by both proactive and by reactive means, but the latter outnumber of the former by a ratio of approximately three to one and most complaints come from companies, not private individuals or other sources. Second, enforcement actions against Member States are based on Article 169 EEC, which provides a three-stage procedure, comprising two administrative stages and one judicial stage. The Commission has complete discretion in conducting such actions. Third, a very high proportion of enforcement actions are settled (or otherwise disposed of) out

of court: for every 100 complaints in 1990, the Commission sent 62.5 formal notices but only 16.4 reasoned opinions, only 5 were referred to the European Court and only 2.4 went through to judgment. Third, the Commission is a repeat player in the Community litigation system. In addition to its role under Article 169, it is a necessary intermediary in actions by one Member State against another under Article 170 EEC; it is a privileged applicant in actions for annulment under Article 173 EEC; and it intervenes as a matter of course in every reference for a preliminary ruling under Article 177 EEC. In addition to other advantages, the Commission can play for rules.

These elements suggest two preliminary conclusions.

First, as used by the Commission, negotiation and litigation are not alternatives; instead they are complementary. This is not merely to say that the main form of dispute settlement used by the Commission is negotiation, and that litigation is just an extension of this process. Rather, litigation by the Commission is essentially a part of continuing processes of negotiation, especially in view of the fact that the plaintiff and the defendants in enforcement actions are both repeat players involved in continuing relations. Consequently, the relations between negotiation and litigation should be analysed and used consciously as a matter of policy. Potentially at least, the Commission should be able to use litigation in a continuous, proactive as well as reactive way, so as to create counters, lay down conditions or establish frameworks for negotiation. In other words, it can convert litigation into a resource so that litigation is an aspect of its negotiating strategy. This will be even more important because the Maastricht Treaty, assuming that it is duly ratified, provides the possibility for lump sum or penalty payments for failure to comply with a decision of the European Court of Justice.

Second, the Commission should examine more systematically its use of litigation and consider the possibility of developing a litigation strategy. This would involve an analysis of the Commission's past and current practice of litigation, the elaboration of coherent strategies for going to court if this has not already been done, and consideration of the possibility of establishing a service or unit for monitoring the Commission's litigation practice. By virtue of its position in the Community system, the Commission should be able to concentrate not simply on winning individual cases, but also and more importantly, on using litigation to establish basic principles.

3. The Role of Private Parties

The role of private parties in the enforcement of Community law is crucial, first, because private parties supply most of the complaints to the Commission, and second, because the application of Community law relies essentially on the national law and legal institutions in the Member States as invoked by private parties. These facts were recognised in the 1985 White Paper, but their implications deserve further consideration.

Since the early 1960s the European Court of Justice has elaborated a specific way of increasing the role of private parties in the enforcement of Community law. It has gradually constructed what we can call a judicial liability system. In effect, it has established a liability rule providing that a plaintiff can seek relief from a government agency for specified conduct. The system is triggered by suits or complaints; the government agency need not of course be a court.

The European Court developed the elements of this judicial liability system in three overlapping stages. All involved litigation concerning Community directives. First, the Court established that, assuming certain conditions were satisfied, a directive could have direct effect, in the sense that it could be invoked by a private party against an organ of the state in a national court. Second, it laid down guidelines according to which national law, falling within the sphere of application of a directive, was to be interpreted by national courts in the light of the wording and purpose of the directive. Third and most recently, it decided that the full effectiveness of Community rules might be called into question, and the protection of enforceable Community rights would be weakened if individuals could not obtain compensation under certain conditions, where their rights were infringed by a breach of Community, law for which a Member State was responsible.

As a means of supervision and control, the creation of a judicial liability system is not unusual. However, the system which has been developed by the European Court has distinctive features. First, the liability rules have been established by the judiciary, rather than by legislature. Second, they have involved judicial decision and interpretation, not legislation. Third, they have been directed mainly at governments, rather than private organisations. Fourth, the specified conduct which is their target is 'procedural' rather than 'substantive', namely the failure of Member States to fulfil their Treaty obligations, in particular by failing to transpose Community directives into national law. Fifth, and consequently, the system is limited in scope: it is designed to achieve a specific aim, namely the correct transposition of Community directives. Sixth, the government agency from which relief may be sought is, in the last instance, the European Court, that is, the same agency that is the initial source of the liability rules. Seventh, the system itself relies on -

and thus strengthens - one of the key relationships in the Community's federal dynamic, namely the relationship between national courts and the European Court, in particular by breathing new life into the form of judicial co-operation envisaged by Article 177 EEC.

This discussion suggests at least four tentative conclusions; possible new remedies are dealt with later. First, though developed piecemeal by the European Court rather than systematically by the legislature, the judicial liability system should be recognised as a system. This implies a further analysis of the pertinence of its elements and the coherence of the whole. Second, it may be time to re-assess the current law that directives do not have 'horizontal' direct effect, that is, that a directive cannot be enforced between two private parties *inter se*. Third, though the implications of the *Marleasing* judgment are not entirely clear, the enforcement of Community law may be improved by greater, continuing attention to the role of national courts in interpreting national legislation in the light of Community law. Fourth, it may be suggested that consideration should be given to expressing some of the elements of this judicial liability system in legislative form. Recourse to courts can never be the principle means of enforcing Community law, and courts are often not the most suitable institutions for performing such functions. The judicial liability system elaborated so far by the European Court of Justice as part of the 'constitutionalisation' of the founding Treaties deserves further consideration in this light.

4. New Remedies

Joined Cases C-6/90 and 9-90 *Francovich* represents a fundamental change in Community constitutional law. However, this case is very recent, the

Court's judgment is expressed in general terms, and the longer-term implications of the ruling have yet to become clear. The elements which merit further consideration include the particular form of Community acts in question, the potential plaintiffs, whether the existence of a prior judgment against the Member State under Article 169, with regard to the same directive or other act, is a condition precedent to an action for damages, and the conditions laid down by the Court for such an action. They could be clarified in future cases, in which the Commission may wish to consider seeking statements of principle to resolve existing ambiguitities. In addition, the Court could be asked to declare expressly in future actions under Article 169 whether the conditions for liability have been satisifed. In the meantime the Commission may wish seriously to consider issuing an interpretative communication with regard to the judgment.

Another possibility which might be considered, is that of *'cross-over sanctions'*, in which the failure of a Member State to fulfil its Community obligations in one domain would be sanctioned by a sanction against that Member State in another domain. Such measures are provided in the ECSC Treaty, Art. 88, 3rd para., subpara. (a). This possibility was canvassed in a Commission staff paper to the 1991 Intergovernmental Conferences, but the serious practical and political difficulties which it involved were given a great deal of emphasis. Despite the related revision of Article 171 as a result of Maastricht, this possibility deserves to be reviewed.

Even though Community rights are to be enforced in national courts and according to national legal procedures, the European Court's jurisprudence has increasingly impinged on national legal remedies. It may be suggested that, in fact, it is beginning to contribute to the restructuring of national procedural systems. It is time to take stock of this situation, especially since differences in

national remedies affect the extent to which individuals can rely in practice, on rights derived from Community law. In addition, it may be suggested that further consideration should be given to the adoption of legislation designed to harmonise national systems of remedies for the enforcement of Community rights. Otherwise Member States fail adequately to fulfil their obligations under Article 5 EEC.

Conclusion

Making the Single Market Work

The success of the internal market programme lay in its apparent lack of ambition. The objective itself appeared to be a mere restatement of the traditional concept of the common market, which formed the core of the founding treaties. The White Paper programme did not entail any significant transfer of competences or of financial means to the Community. Nor did it require a radical institutionally reform. Yet, in part because of this apparently low profile, the internal market played a central role in the revival of Community fortunes in the 1980s.

As the completion of the internal market now approaches, it becomes evermore clear that the Community is called upon to deal with problems of a new nature. It is impossible to promote free trade without somehow paying attention to the risks inherent to economic activity. The Community's traditional means of intervention are ill-designed to address issues of this kind. At the same time, the involvement of the Member States in the pursuit of Community policies remains one of the cornerstones of the EC's institutional balance. The current system of decentralised implementation has enabled the Community to intervene in a growing number of areas without pre-empting all opportunities for intervention on the part of national administrations.

Making the single market work thus requires the setting up of a framework within which the Community might be able to fulfil new functions, without undermining the degree of control exercised by the Member States.

This result can be achieved with innovative instruments which will improve the Community's co-ordination and control functions, without presupposing a complete take-over of given tasks. Likewise, more emphasis should be laid on incentives than on sanctions.

1) Streamlining the regulatory process should be one of the priorities. This would involve systematically organising co-operation between the Community and the Member States, by better defining the tasks and duties of all actors. At the Community level, this could be achieved *inter alia* through the adoption of an EC Administrative Procedures Act. The need for horizontal co-ordination among the units responsible for various sectoral policies should also be acknowledged. Here an apposite response might take the form of a central clearing-house for new legislative proposals, which body would be given the task of controling whether Community action is necessary and determining what the priorities should be.

2) Implementation concerns should be addressed at the very outset of the legislative procedure. Implementation plans would greatly aid both in defining needs and in evaluating available resources; adequate incentives, both positive and negative, should encourage compliance by the Member States.

3) The Community's co-ordination and monitoring capacities should be strengthened by the creation of specialised agencies which pool together the expertise available at national level. The tasks of these bodies would in effect

be limited to assisting and, if necessary, supplementing the regulatory policies conducted at national level.

4) Lastly, as regards judicial policy, some thought should be given to the possibility of harmonising those judicial remedies available to private parties in cases of a violation of EC law. Generally speaking, however, more attention should be paid to the use of incentives rather than to concrete sanctions. Neither the Commission nor the European Court of Justice would be able to systematically address infringements of Community law. This should lead the Commission to revise its litigation strategy, and go to court only *in ultima ratio*, when no alternative is available, or a decision of principle is to be made by the Court.

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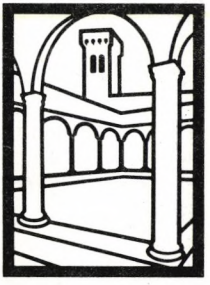

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