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Product Safety, Private Standard Setting and
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Fabrizio Cafaggi

**EUROPEAN UNIVERSITY INSTITUTE
DEPARTMENT OF LAW**

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FABRIZIO CAFAGGI

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Abstract

This essay deals with product safety and liability, looking in particular at the interaction between regulation, contract and civil liability. Risk definition, assessment and management in product safety has changed in the last 20 years, and a well recognised role is played by private actors both in standard setting, in monitoring and risk management concerning post sale duties. Post-market surveillance has become a crucial part of the risk management strategies, but the regulatory dimension has not been sufficiently linked with that of governance.

In the first part, I examine the current review of product safety at EU level with the proposed regulation on market surveillance and its relationship with the broader debate concerning better regulation.

In the second part, I show the increasing contractualisation of standard-setting concerning safety and product defectiveness, which influences both regulation and civil liability systems. In both cases, however, insufficient attention has been given to the implications of such a contractualisation for liability standards.

I then move to information duties in product safety and product liability and claimed that business models of the supply and distribution chain may be affected by the regulatory design concerning product safety. I contend that a reform of the General Product Safety Directive and Product Liability directive should promote the creation of more structured information networks, aimed at making information production and transmission concerning product safety more effective. Enterprises should be constrained by the safety goals, but they should enjoy discretion in choosing organisational models that best fit with their business models. In particular, the distinction between hierarchical and horizontal networks should be fruitfully employed to design default rules organising the information safety network. This would be particularly important for pan-European networks which have to coordinate enterprises operating in different legal systems with different institutional frameworks. I propose to introduce default rules concerning information networks that parties can adjust to their specific business models.

Private law and regulation interplay in the field of product safety. Not only it happens between administrative regulation and civil liability, as it has long been recognised, but also with contract law, given the increasing contractualization of standard-setting and the necessity to build contractual networks to implement monitoring of product safety in modern market economies. These examples suggest that the current approach to harmonisation of European Private Law is limited and does not reflect the necessity to coordinate different instruments to pursue unitary policy objectives: producing higher and more effective product safety in Europe at reasonable costs.

Keywords

Product safety - product liability - information regulation - self-regulation – network - governance

Product Safety, Private Standard Setting and Information Networks

Fabrizio Cafaggi

1. New regulatory strategies in product safety: Controlling private standard-setting and promoting safety in inter-firm networks¹.

Legal reforms concerning European product safety are under careful scrutiny². The European system, encompassing a liability (dir. 374/85/EC³, hereinafter ‘PL directive’) and a regulatory system (dir. 95/2001/EC⁴, hereinafter ‘GPSD’), has made important progress towards increasing safety levels and ensuring relative uniformity.

The product safety regime is currently under review⁵ while the third report on the Product liability directive was published in 2006⁶.

¹ This essay is part of a larger project focusing on a comparative analysis concerning product safety between EU and US. It was firstly presented at CLEF workshop, Florence, February 2008. I thank the participants for comments. Responsibility is my own. It is forthcoming in F. Cafaggi and H. Muir Watt, *Regulatory strategies in European private law*, Edward Elgar, 2008.

² See Proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products SEC(2007) 37 fin. The proposal, being a part of a broad package of measures to facilitate the functioning of the internal market for goods, was adopted by the European Parliament on 21 February 2008; see press release IP/08/276 available at <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/276&format=HTML&aged=0&language=EN&guiLanguage=en>.

³ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7.8.1985, p. 29.

⁴ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4

⁵ Commission proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products, cit.

The recent resolution of the European Parliament, of the 20th of May on EU consumer policy strategy 2007-2013 provides further indication, in particular, “*calls on the Commission to work with Member States to ensure that existing legislation is properly implemented and fully enforced by the Member States including by assessing the possibility of reviewing Directive 2001/95/EC on general product safety; recalls that the CE marking can be wrongly interpreted as a general indication of third-party testing or a mark of origin, but also that the Commission has been requested to present an in-depth analysis in the field of consumer safety markings, if necessary followed by legislative proposals*”. See par. 13, the complete text is available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2008-0211+0+DOC+XML+V0//EN&language=EN>.

⁶ See Third report on the application of Council directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, COM(2006)496 final. See D. Fairgrieve and G. Howells, ‘Rethinking product liability: A missing element in the European Commission’s Third review of the European Product Liability Directive’, in *Modern Law Review*, vol. 70, 2007, p. 962 ff., part. p. 972 ff.

Comparative research - though not covering the 27 MS - show that administrative practices in product safety regulation are significantly different⁷. Policy reform currently focuses more on market surveillance than standard-setting, moreover, in its review, the Commission underlines the need to improve market surveillance by reinforcing and extending existing instruments such as those defined in GPSD.⁸ The annual report on Rapid alert system for non-food consumer products (Rapex) shows that an increased number of notifications, and suggests that cooperation between industry, national authorities and European Commission is growing⁹.

Important changes in the standard-setting process concerning product design have taken place without adequately considering the structure of the industrial chain and its internal decision-making process¹⁰. In this essay, along the lines of the overall project, I consider the interaction between private law and regulatory dimensions from two relatively under-investigated angles. I will examine (a) one hypothesis of private law influence on regulation, in particular the case of contracting over standard-setting, and (b) one aspect of regulation affecting the structure of industry, in particular the formation of vertical networks along production and distribution chains.

Firstly, I shall address the effects of private (particularly contractual) standard-setting on the definition of 'defective product' in the liability domain and that of 'dangerous product' in the regulatory domain. Changes in regulation, specifically the increasing use of self-regulation and co-regulation promoted by GPSD in relation to technical standardisation, imply a greater participation of private actors in standard-setting. But how should their activity be performed? To whom should they be accountable? These changes do not only affect the regulatory dimension, but also the liability dimension to the extent that the standards employed to define a dangerous product may constitute a reference for defectiveness¹¹.

⁷ In some countries, like Germany, administrative discretion in risk assessment and control prevails over technical approaches. On the contrary, in Scandinavian countries a more technical approach prevails. See H.W. Micklitz, T. Roethe, *European Product Safety Legislation - A comparative study of legal frame and practice in Germany and Baltic Sea States*, p. 114 ff.

⁸ See Commission proposal 2007: "The proposals, following the Council's Resolution of 10 November 2003, have the objective to provide a common framework for the existing infrastructures for accreditation for the control of conformity assessment bodies, and market surveillance for the control of products and economic operators, by reinforcing and extending what exists and not weakening existing instruments such as the General Product Safety Directive which is very successful and effective." (p. 2)

⁹ See Keeping European Consumers safe, 2007 Annual Report on the operation of the Rapid Alert System for non-food consumer product, available at http://ec.europa.eu/consumers/safety/rapex/docs/rapex_annualreport2008_en.pdf.

¹⁰ But see the Resolution of the European Parliament on consumer policy strategy 2007-2013, cit., where the EP "Calls for measures to improve dialogue at EU level between consumer organisations and industry, to include all actors in the value chain; takes the view that a good dialogue, including the sharing of best practices, could reduce problems in the internal market".

¹¹ On the complementarity of regulation and liability see F. Cafaggi, 'A coordinated approach to regulation and civil liability: Rethinking institutional complementarities', in F. Cafaggi (ed.), *The institutional framework of European private law*, OUP, 2006, p. 191 ff. See also G. Spindler, 'Interaction between product liability and regulation at the European level', in this volume.

Two possible schemes can be defined:

- a) acceptance of the influence of regulatory standard in the liability domain, including those privately defined, or
- b) rejection of this influence and promotion of the separation between liability and regulation, claiming that functional complementarity can allow different standard-setting procedures affecting each other over and beyond the necessity for coordination.

Secondly, I look at the product safety directive, in particular the information duties and show that compliance with them implies the creation of inter-firm networks. These networks may take different forms and be designed according to the specific structure of the industry. The aim is not only descriptive but also normative. Not only I claim that safety regulation has a significant effect on the creation of networks among firms and indirectly on organisational forms, but I also advocate that this model should be expanded to include other features of risk control and management, thereby transforming an artificial hierarchical model into a more effective network model.

The paper proceeds in the following way. Section 1 is devoted to a general illustration of current debate about product safety regulation at EU level. Section 2 examines the role of private standard-setting on regulatory and liability strategies and their interplay. Section 3 analyzes the effects of regulatory strategies concerning information on the creation of networks, their shape and scope. Concluding remarks follow.

2. Product safety in the framework of regulatory innovation

Before embarking on a detailed analysis, it is useful to propose a brief survey of the main institutional and substantive changes recently considered at European level. On the one hand, the EU stressed the need for a more complex yet shared legislative process advocating the expansion of the Lamfalussy architecture¹². On the other hand, it has advocated the broader use of alternatives to legislation distinguishing between binding and non-binding instruments¹³. The general strategy aims at developing a new approach

¹² See the Commission staff working document - Instruments for a modernised single market policy - Accompanying document to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A single market for 21st century Europe, COM(2007) 724 final, SEC(2007) 1518, p. 8 ff. (hereinafter Instruments for a modernized single market)

¹³ See Instruments for a modernized single-market, cit., p. 11ff. "Four types of non-binding instruments can be distinguished:

- (a) Measures aiming at preparing policy action (legislative and non legislative) such as Green Paper and White Papers, other consultation documents (e.g. those prepared for internet consultations and Communications to gather views from stakeholders in preparation of initiatives
- (b) rules Measures aiming at clarifying the law and ensuring that EU rules are properly applied on the ground without changing the EU Acquis (technical guidelines, technical handbooks, interpretive communications)
- (c) Measures that contain normative elements such as Recommendations – specifically referred to by the EC Treaty and defined by the ECJ as measures adopted by EU institutions when they do not have powers under the Treaty to adopt binding measures or when they consider that is not appropriate to adopt more mandatory

to better regulation by combining the legitimacy demand, which triggered the White paper on governance¹⁴, and the effectiveness demand, which together have driven the Better law making/Better regulation policy¹⁵. General principles concerning better regulation have been defined at national level but so far have had little impact on sector specific regulation¹⁶. The role of private regulators has increased¹⁷. This is not primarily the effect of a transfer of regulatory power from public to private, rather it is part of a process of a new architecture where new regulatory powers have emerged and old ones have been redistributed¹⁸. This change suggests that the analysis should not be predominantly focused on the public/private divide but within private law devices between (private) regulation and liability and particularly on the forms of their institutional complementarities. The theoretical challenge is to analyze private regulation and liability, in this contribution civil liability, as concurring tools for risk regulation and risk management.

Safety of products is part of a broader strategy concerning risk regulation. The link between the principles of better regulation and its implementation for risk regulation has not been the pillar of EU policy. EU has not followed the path of institutional complementarity. There is no coordination between the regulatory and liability regime. The definitions of a safe product and product defect follow different logics that can hardly be explained in the framework of institutional complementarity. While the conventional view is that regulation defines minimum standards and liability increases safety standards, the definitions suggest that the opposite is true. Safety is defined as absence of risk or existence of minimum risk¹⁹. Defect is defined on the basis of consumer expectation and is generally associated to some rudimental risk-utility analysis, at least for design defect²⁰.

(d) Self-regulation and co-regulation instruments, such as Codes of conduct whereby the Commission asks industry to come up with solutions provided these do not contradict EU law and the Commission's policy objectives. Voluntary standard-setting can also be comprised in this category."

¹⁴ White paper on European Governance, Brussels, 25.7.2001, COM(2001) 428 final.

¹⁵ See Instruments for a modernized single-market, cit.

¹⁶ See for example in the UK the Principles of good regulation drafted by the Better regulation task force, available at <http://archive.cabinetoffice.gov.uk/brc/publications/principlesentry.html>.

¹⁷ See also the report on *Self-regulation practices in SANCO policy areas*, P. Van der Zeijden and R. Van der Horst, Zoetermeer, February 2008, where the current cases for self-regulation and co-regulation are presented, indicating also their effectiveness in terms of monitoring and compliance, p. 32 ff.

¹⁸ See B. Hutter, 'The role of non state actors in regulation', in F. Schuppert (ed), *Global governance, ed the role of non state actors*, Nomos, 2006; C. Scott, 'Self-regulation and meta-regulatory state', in F. Cafaggi, *Reframing self-regulation in European private law*, Kluwer, 2006, p. 131; J. Black, 'Tensions in the Regulatory State', *Public Law*, 2007, p. 58; R. Baldwin and J. Black, 'Really Responsive Regulation', *Modern Law Review*, 2008, Vol. 71, p. 59; F. Cafaggi, presentation at the European Economic and Social Committee, public hearing on *The Current State of European Self- and Co-Regulation*, 31st March 2008.

¹⁹ See art. 2 of GPSD, that defines as 'safe product': "any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons".

²⁰ See art. 6 PL directive, that provides: "A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product;

The reform path proceeds along parallel, yet independent, lines²¹. The current approach is that while the PL directive has general application, the GPSD only applies when no specific regime concerning product safety is in place. No coordination exists as to the definition of safe and defective product, thereby generating different standards; the same is true in relation to remedies, even if it is clear that the PL regime focuses on compensatory remedies, while the GPSD focuses on injunctive or interim remedies (such as product withdrawal and product recall). Even more difficult is the interaction in relation to information duties and post-sale duties.

Both in the field of product safety and liability, a separate strategy for trans-European groups and networks of firms and purely national ones does not emerge. No specific links are made to the Private international law regime in the Rome 2 regulation²².

The uncoordinated approach to product safety and product liability has prevented the definition of a coordinated strategy, aimed at improving institutional complementarity. This is particularly relevant for strategies of market surveillance where the focus seems to be entirely on regulation, while the potential effects on the liability regimes have not been sufficiently investigated. The absence of different regulatory approaches for purely national and trans-national groups and networks has created inefficiencies. Differences in regulatory regimes and practices may severely affect the ability to select one regime. This essay tries to show the importance of considering the interplay between regulation and civil liability especially in the context of pan-European networks.

The European Commission has devised a new general strategy to complement the specific measures concerning product safety and market surveillance²³. A proposed regulation has been recently approved by the European Parliament²⁴. One of the main purposes is the introduction of a complementary system of market surveillance based on national accreditation bodies empowered to assess conformity. The system envisaged defines national accreditation bodies; their nature and governance system. It also defines the relationship between accreditation and conformity assessment bodies. Finally it complements the measures of market surveillance designed by GPSD.

In relation to the accreditation of bodies concerned with conformity assessment, there are some features worth analysing: a) their non-profit nature and b) the introduction of an express principle of non-competition. The accreditation body, if not directly operated by public authorities, should be accredited as a public authority, operate on a not-for-profit basis, and should not perform activities or services usually provided by

(b) the use to which it could reasonably be expected that the product would be put;
(c) the time when the product was put into circulation”:

²¹ For a deep analysis of the interaction between the two aspects see S. Whittaker, *Liability for products – English law, French law and European Harmonisation*, OUP, 2005, and F. Cafaggi, ‘A coordinated approach to regulation and civil liability’, cit., p. 191 ff.

²² Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II), OJ 31.07.2007, L199/40.

²³ Proposal for a Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of the products, cit.

²⁴ European Parliament legislative resolution of 21 February 2008 on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037 – C6-0068/2007 – 2007/0029(COD)).

conformity assessment bodies²⁵. In other words, according to the non-competition principle, accreditation bodies can not compete among themselves and with conformity assessment bodies²⁶. European legislators explicitly want to avoid that any regulatory competition system will take place. Thus, they promote a cooperative model of mutual recognition.

In relation to the market surveillance system, the description of the different measures is aimed at reinforcing the mutual recognition approach and the cooperation among national authorities, while little attention is paid to modes of market surveillance and information gathering about serious risks concerning products already in the market. Furthermore, little is said about the relationships between the conformity assessment body and the enterprises, producers and distributors charged with monitoring and information duties. There is a serious risk that the new system will increase the costs of control without improving its effectiveness or, worse, that it might overburden certifiers and conformity assessment bodies with accreditation costs that will not produce any real effects on consumer protection against unsafe and dangerous products²⁷.

3. The effects of private activity in regulation and civil liability

3.1 The role of standard-setting in regulation and civil liability

Product safety should be conceived as an integrated strategy, combining regulation and liability²⁸. In a previous contribution I have tried to answer more general questions concerning the desirable complementarity between the two²⁹: how do these two

²⁵ See Art 4 Regulation on Market surveillance, General principles.

²⁶ see Art 6 Regulation on Market Surveillance, Principle of non competition:

“1. National accreditation bodies shall not compete with conformity assessment bodies

2. National accreditation bodies shall not compete with other national accreditation bodies.”

²⁷ See the step forward towards a better coordination indicated in *Questions and answers: Product safety activities and follows up the 2007 stocktaking exercise*, Memo/08/251, Brussels, 17.04.2008, where the Safety pack with industry has been proposed, which is a “voluntary agreement with the toy sector to boost product safety by following certain guidelines. These will include *sharing expertise*: in particular participating in the Commission’s evaluation of business safety measures in the toy supply chain with a view to investigating ways in which safety measures can be enhanced and continued cooperation regarding the implementation of such improvements; [...] *cooperation with national authorities*: working together to ensure that dangerous goods, and in particular counterfeit goods, can be identified and intercepted in time to ensure a high level of consumer safety”.

²⁸ The debate concerning the regulatory functions of private law in general, and specifically on civil liability is in place. Different streams of scholarship advocate such a function. Typically this is the approach of law and economics, see G. Calabresi, *The Costs of Accidents*, Yale University, 1977; S. Shavell, ‘Liability for Harm versus Regulation of Safety’, *J Legal Studies* (1984) 357; Id., ‘A Model of the Optimal Use of Liability and Safety Regulation’ [1984] *Rand J Econ* 271 ff.; Id., *Economic Analysis of Accident Law*, Harvard University Press, 1987; J. Landes and R. Posner, *The Economic Structure of Tort Law* (1987); R. Ackerman, ‘Tort Law in the Regulatory State’, in Schuck (ed.), *Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare* (1991), at 80 ff. This approach has also been endorsed by the socio-legal studies movement see H. Collins, *Contract law*, Lexis Nexis, 2004; C. Parker, C. Scott, N. Lacey, and J. Braithwaite, *Regulating Law* (2004). Critiques of this approach are made by some tort scholars. See, e.g. J. Stapleton, ‘Regulating Torts’, in *ibid.*, at. 122 ff.

²⁹ See F. Cafaggi, ‘A coordinated approach to regulation and civil liability’, *cit.*, p. 191 ff.

strategies (regulation and liability) interact when standards are set? As an empirical matter, do they constitute completely separate spheres or do they overlap? Normatively speaking, if they already interact, is the coordination satisfactory or should it be improved?

In this essay, I focus on some specific questions concerning the influence of private regulation in standard-setting on civil liability and regulation³⁰. Standard setting in both product safety and liability should be conceived as a process not as a product. Standard setting concerning product safety is linked to risk assessment which should be determined according to the available technical and scientific knowledge, given the uncertainty about risks associated to products. The same product may be deemed safe at time 0 and become unsafe at time 1. In the case of liability, there is a time dimension. The defect has to exist before the product is put into circulation³¹. No liability, under the directive, can be found if the defect could only be discovered after the product was put into circulation. The development risk defence under art. 7 lett. e) of the PL Directive allows the producer to plead exclusion of liability if the defect could not have been discovered before the product was put into circulation³². It should be pointed out that the state of scientific and technical knowledge does not correspond to that used in the industry, but more broadly that available in the scientific community. The reference point is the scientific not the business community.

This approach has several consequences to choose the effective regulatory strategy: it emphasizes the dynamic structure of standard setting and the need for responsiveness, it implies a liability system for defective standard setting different from that to be used for a defective product. Standard setting should be scrutinized according to specific criteria. A defective standard, thus, should not be evaluated similarly to a defective product.

In product safety, Europe has moved from input or design standard to performance or output standard³³. The former are still used in specific fields such as drug and food. This change has contributed to partial convergence between regulation and liability. In product liability, the definition of defective product is based on consumers'

³⁰ On the definition of private regulation see F. Cafaggi (ed.), *Reframing self-regulation in European private law*, Kluwer, 2006. For a governance perspective on product standards see H. Schepel, *The constitution of private governance : product standards in the regulation of integrating markets*, Hart, 2005.

³¹ On the differences between the two directives see F. Cafaggi, 'A coordinated approach to regulation and civil liability', cit., p. 191 ff.

³² See *Commission v. England*, Case C-300/95, ECR I-2649:

"In order for a producer to incur liability for defective products under directive 85/374, the victim does not have to prove that the producer was at fault; however, in accordance with the principle of fair apportionment of risk between the injured person and the producer set forth in the seventh recital in the preamble to the directive the producer has a defence if he can prove certain facts exonerating him from liability, including that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered. Whilst the producer has to prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, without any restriction as to the industrial sector concerned, was not such as to enable the of the defect to be discovered, in order for the relevant knowledge to be successfully pleaded as against the producer, that knowledge must have been accessible at the time when the product in question was put into circulation".

³³ For this distinction see A. Ogus, *Regulation: legal form and economic theory*, Oxford, 2004, p. 168 ff.

expectations³⁴. No specific references are made to private standard-setting and expectations that can arise. The debate has focused more on the role of alternative designs than on the safety expectations of consumers coming from privately defined standards developed through codes of conduct³⁵. There is a clear divergence between the definition of dangerous product and that of defective product in this respect³⁶.

The regulatory approach adopted in GPSD is framed under the proportionality principle and favours the adoption of codes of practice both at European and national level³⁷. The use of private standard setters, especially in relation to technical standardisation, is promoted and its interplay with market surveillance has recently been revised³⁸. The framework is to be completed by reference to technical standardisation and the new approach which has given significant importance to mutual recognition of safety standards³⁹.

As to the interaction between standard-setting in regulation and civil liability at least two general points should be made. The first is concerned with the role of regulatory compliance as a 'coordination mechanism' between civil liability and regulation⁴⁰. The second is related to the impact on civil liability of private regulation either as an alternative or as a complement to public regulation⁴¹.

When standards of manufacturers' conduct are defined by administrative entities they certainly influence the standards employed in civil liability. Often, analogous principles operate for strict liability and for negligence, although judges tend to be stricter with non-compliance in strict liability and less severe with compliance in negligence.

The general rule, common to most legal systems, is that compliance with administratively defined standards does not exclude liability while a violation generally

³⁴ See Art 6 PL directive that provides:

"1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) the presentation of the product;
(b) the use to which it could reasonably be expected that the product would be put;
(c) the time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation."

See S. Whittaker, *Liability for products*, cit.; C. Castronovo, 'La responsabilità civile', in *Manuale di diritto privato europeo*, in C. Castronovo and S. Mazzamuto (eds.) Giuffrè, Milano, 2007, p. 213 ff. part. p. 226 ff..

³⁵ In the Third report the Commission has drawn attention to different interpretations of defect given by national Courts. On these questions see D. Fairgrieve (ed.), *Product liability in comparative perspective*, Cambridge University Press, 2005.

³⁶ See F. Cafaggi, 'A coordinated approach to regulation and civil liability', cit. p.

³⁷ See Art 4, 8, 11, 12, 13 of GPSD.

³⁸ See in this volume G. Spindler, 'Interaction between product liability and regulation at European level', p. 00

³⁹ See in this volume M. Audit, 'Impact of the mutual recognition principle on the law applicable to products', p. 00

⁴⁰ In general regulatory compliance is seen more as an enforcement than as a coordination device, concentrating on the question of whether compliance with administrative regulation is sufficient to exclude liability.

⁴¹ While here I am focusing on the definition of defect, in particular design defect the potential impact of private regulation is much broader.

implies liability⁴². This is also the approach at EU level, both in relation to specific products and to general product liability⁴³. These principles have been hotly debated, suggesting that regulatory requirements should become the civil liability standards thereby introducing a regulatory compliance defence⁴⁴. The introduction of a regulatory compliance defence may move the litigation from producers to regulators, if safety standards were lowered or inappropriate⁴⁵. But the current divergences among MS in relation to state liability for defective standards are much wider than those harmonised in the PL directive⁴⁶. In addition, public regulators, if bearing the overall liability burden, may become sensitive and over regulate, thereby hindering product innovation. The rejection of the defence of regulatory compliance is perfectly defensible under the institutional complementarity approach; less defensible if liability and regulation are considered functional equivalents rather than complements.

Somewhat similar though not identical rules are used for technical standards, publicly produced. Compliance with technical standards does not exclude liability⁴⁷. Non-

⁴² See for the UK, Regulation on general product safety 2005, on which see D. Fairgrieve and G. Howells, 'General product safety- a revolution through reform?', *Modern Law Review*, vol. 69, p 59; P. Cartwright, 'The regulation of product safety', in G. Howells (ed), *The law of product liability*, Lexis-Nexis, 2007, p. 695 ff.

For France, see art. 1386-10, 'A producer may be liable for a defect although the product was manufactured in accordance with the rules of the trade or of existing standards or although it was the subject of an administrative authorization', see B. Cazeneuve, *La responsabilité du fait des produits*, Dunod, 2005, 78, J.S. Borghetti, 'Contrats et responsabilité. La responsabilité des fournisseurs du fait du défaut de sécurité de leurs produits', *Revue des contrats*, 2006, p. 835.

For Italy see F. Cafaggi, *La responsabilità del produttore*, Cedam, 2003, cit. p. 995. For the case law concerning drugs see Cass. N. 8069, 20 luglio 1993, and Cass. n. 1138, 1 february 1995: "le imprese farmaceutiche le quali intervengono nel ciclo produttivo di gammaglobuline umane, sono responsabili per colpa grave dei danni derivati in caso di contagio conseguite all'uso del farmaco ove, pur avendo ottemperato alle disposizioni normative vigenti non dimostrino di avere impiegato ogni cautela idonea ad impedire l'evento".

For the U.S, see Restatement third on Products liability § 402 (a).

⁴³ See C. Hodges, *European regulation of consumer product safety*, OUP, 2005, 21 ff. See for pharmaceutical products see M. Mildred, 'Pharmaceutical products: the relationship between regulatory approval and the existence of a defect', *European Business Law Review*, 2007, p. 1267 ff.

⁴⁴ In Europe see the third report, COM (2006) 496 final, 14.09.2006, p. 11. In the US the Supreme Court has recently issued a judgement *Riegel v. Medtronic, INC*, n.06/179, WL 440744, 20 february 2008, reviewing the relationship between administrative regulation and tort law; see on these questions C. Sharkey, 'Products liability pre-emption an institutional approach', *George Washington L.R.*, vol. 76, p. 449 ff. S. Issacharoff and C. Sharkey, 'Backdoor federalization', *UCLA L.R.*, vol. 53, p. 1353 ff.. For earlier significant contributions to the regulatory compliance debate see R. Rabin, 'Reassessing regulatory compliance', 88 *Geo. L. J.* 2049 (2000); R. Stewart, 'Regulatory compliance preclusion of tort liability: Limiting the dual track system', 88 *Geo. L. J.* 2167.

⁴⁵ See on state liability for defective products mainly in relation to health related injuries such as blood infection S. Whittaker, *Liability for products*, cit. p. 305 ff. In Italy see Cass. n. 11609, 31.05.2005, on which N. Coggiola, *The Italian Ministry of Health held liable for the damages arising out of contaminated blood and blood products*, ERPL, 2007, p. 451 ff.

⁴⁶ For a detailed examination of England and France see S. Whittaker, *Liability for products*, cit. p. 305 ff.

⁴⁷ See for example in UK, *Alan Balding v. Law Ways Ltd* [1996] ECC 417 where the Judge held that compliance with technical standards does not amount to due diligence under CPA. See C. Scott and J. Black, *Cranston's Consumers and the law*, 3rd ed., Butterworths, 2000, p. 331.

compliance with standards, imposed by legislation or by regulators constitutes a violation, often of dual, civil and criminal, character⁴⁸.

A different rule concerns technical standards when privately produced without the approval of a public authority or within a co-regulatory process⁴⁹. The function of private bodies in technical standard setting is not only to ensure that the best available scientific and technical knowledge is used to define the most updated standard, but also to foster innovation. The incentives to promote innovation in safety standards come from different sources but the liability of these bodies for negligent standard setting is potential engine for innovation scarcely used by consumers in litigation⁵⁰.

Compliance with technical standards is voluntary. Producers have to meet the essential requirements of safety. If they comply with technical standards they will be freed from the burden of proving that their products is safe. If they deviate the burden of proof will be on them⁵¹.

When is a private standard violated? In particular alternative product designs that do not follow the technical standards defined by private bodies should be deemed violations? The answer is negative. An examination of the deviation is needed. A rule which would consider violation every deviation would be questionable under art. 28 of the EC Treaty but would also hinder product innovation by forcing manufacturers to comply only with one technical standard⁵². Violations of standards privately defined, for example through self-regulation, do not always constitute negligence or at least *negligence per se*⁵³. Often

⁴⁸ See the national implementation of the GPSD. As to the UK, “Non-compliance with standards imposed by legislation is a different matter. It will typically constitute a criminal offence, and there may also be a civil remedy for breach of the statutory duty or, as it is termed in some jurisdictions, in respect of negligence per se. In some statutes the position with respect to civil remedies is stated clearly (as in CPA). Where it is not, one is called on to discover legislative intent both as to the existence of the remedy and as to the types of damage or loss covered.”, see C. L. Miller and R.S. Goldberg, *Product liability*, 2nd ed., cit., p. 612.

⁴⁹ As to the UK, see C. L. Miller and R.S. Goldberg, *Product liability*, cit p. 612: “Non-compliance with standards produced by a body such as the British Standards Institute is broadly comparable to non-compliance with general industrial standards. The main difference is that, being written and formulated by experts, such standards are more precise and authoritative. Consequently, it is that much less likely that non-compliance will be seen as consistent with reasonable safety”

For a critique of the approach that does not distinguish between technical and industry produced standards see below text p...

⁵⁰ See F. Cafaggi, ‘Rethinking self-regulation in European private law’, cit.

⁵¹ See art. 3.2 GPSD. On the interpretation see G. Spindler, ‘Interaction between product liability and regulation at European level’, in this volume p. 00

⁵² See G. Spindler, ‘Interaction between product liability and regulation at European level’, in this volume p. 00

⁵³ The legal status of private standard-setting varies even within one legal system. In some case is equated to custom, in other cases is qualified as non statutory standards, in other cases is qualified as private regulation and equated to administrative regulation. Divergences also depend on the reference to general clauses or to specific rules. Legal systems that apply general clauses like France or Italy confer to judges the power to define the relevant elements to identify due care, among which privately set standards are considered. Common law systems have a different approach. For US *Spearman v. Georgia Building Authority* 482 SE 2d 465 (GA App. 1997); for UK, *Ward v. Ritz Hotel* [1992] PIQR 315.

there is a presumption of negligence that can be rebutted if the tortfeasor can prove the obsolescence of the technical standard⁵⁴.

Compliance with self-regulation does not exclude liability but it may constitute evidence of due care. In many legal systems, privately defined standards are conceived to be minimum standards to the extent they reflect the state of the art⁵⁵. Violation of private standards is often held to be relevant though not always conclusive evidence of product defectiveness⁵⁶. It should however be pointed out that legal systems, within the European Union, diverge quite significantly in relation to the factors constituting breach of a regulatory standard and the relationship it bears to the notion of defect.

Technical standards should be differentiated from custom and from standards privately defined by industries. They are presumptively produced by 'impartial' technical experts. However, looking at the composition of governance bodies of technical standards this conclusion could be seriously questioned⁵⁷. Consumer interests' representation in technical standardisation is an open issue both at European and international level⁵⁸. In self-regulation, standards are often unilaterally produced by manufacturers. In this case, clearly there can not be presumption of impartiality. When they are negotiated with other constituencies, sufficiently representative of conflicting interests, these standards can be differentiated from custom⁵⁹. But representativeness is not the only issue; procedural rules that characterize public standard setting such as public hearings and

⁵⁴ The ECJ has interpreted Art. 7(e) of the PL Directive stating that "the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed. However, it is implicit in the wording of Article 7(e) that the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation. It follows that, in order to have a defence under Article 7(e) of the Directive, the producer of a defective product must prove that the objective state of scientific and technical knowledge, including the most advanced level of such knowledge, at the time when the product in question was put into circulation was not such as to enable the existence of the defect to be discovered". See Case C-300/95, *Commission v UK* [1997] ECR I-2649. See also, for a critical evaluation of the relationship between the definition of defective product and development risk defence, J. Stapleton, 'Products Liability in the United Kingdom: The Myths of Reform', 34 *Tex Int'l L.J.*, 1999, p. 50 at 53.

⁵⁵ See for the Italian system, F. Cafaggi, *Profili di relazionalità della colpa*, Padova, Cedam, 1996. For the German system, B. Markesinis, *The German law of torts*, 3rd ed., p 562; G. Spindler, 'Market Processes, Standardisation and tort law', *European Law Journal*, vol. 4, 1998, p. 316 ff. p. 320 and Id., 'Interaction between product liability and regulation at European level', in this volume p. 00. See for a comparative analysis H. Schepel and J. Falke, *Legal aspects of standardisation in the Member States of the EC and EFTA*, Volume 1 Comparative report, Luxembourg, 2000, p. 233 ss.

⁵⁶ In Germany, C. Von Bar, *The Common European law of torts*, OUP, 2000, 421; B. Markesinis, *The German law of torts*, op. cit., p. 99, S. Lenze, 'German product liability law between European directives, American restatement s and common sense', in D. Fairgrieve (ed.), *Product liability in a comparative perspective*, cit., p. 106.

In Italy F. Cafaggi, 'La responsabilità dell'impresa per prodotti difettosi', in N. Lipari (ed.), *Trattato di diritto private europeo*, Cedam, 2003, p. 996,

⁵⁷ In the area of technical standards see the agreement between CEN and CENELEC and the Commission 2003, (General Guidelines for the cooperation between CEN, Cenelec and ETSI an the European Commission and the European Free Trade Association, 28 March 2003, (2003/C 91/04)).

⁵⁸ See H. Schepel, *Constitution of private governance*, cit.; I. Ramsay, *Consumer law and policy*, 2 ed. Hart. Oxford, 2007 p. 711 ff.

⁵⁹ See below text and footnotes pp.00

duty to give reasons should be applied to private standard setting as well to ensure that the rule-making process is sufficiently accountable⁶⁰.

Moreover, in different legal systems, courts do not often explicitly distinguish - for the purpose of establishing civil liability - between purely private standard-setting and standard-setting by private bodies within a framework of co-regulation or delegated self-regulation⁶¹. This distinction is certainly relevant for judicial review purposes, but, so far, it has not been considered fundamental to the definition of civil liability for non-compliance⁶².

An integrated approach to regulation and civil liability should allow differentiating modes of regulatory standard-setting and their influences on the definition of negligence and strict liability⁶³.

The possibility for judges to evaluate injurers' and victims' conduct, beyond compliance with regulatory standards, has been justified in different ways. The most common interpretation is that administrative rules define minimum standards while civil liability can increase the required level of due precaution⁶⁴. The principle that regulatory compliance does not exclude liability shows the adoption of an approach based on the complementarity between civil liability and regulation. Such complementarity reflects the idea that regulation only defines minimum standards while civil liability can set higher standards⁶⁵.

⁶⁰ The question of consumer representation in technical standard setting has been one of the main preoccupations of the European Commission. See the results of the Consultation on the review and extension of the new approach, available at http://ec.europa.eu/enterprise/newapproach/review_en.htm.

⁶¹ For this distinction see F. Cafaggi, 'Le rôle des acteurs privés dans le processus de régulation: participation, autorégulation et régulation privée', in *La Régulation, Nouveaux modes ? Nouveaux territoires ?*, 109 *Revue française d'administration publique* (2004), p. 23 et Id., 'Gouvernance et responsabilité des régulateurs privés', *Revue Internationale de Droit Economique*, 2005, 111.

⁶² It is important to differentiate between standards that are purely private and binding only to those who consented upon and standards that are enacted in the context of co-regulation, delegated private regulation and ex post recognised self-regulation. See F. Cafaggi, *Contractualizing standard-setting in civil liability*, on file with the author.

⁶³ See G. Howell, 'Product Liability A History of Harmonization', in A. Hartkamp, M. Hesselink, and E. Hondius *et al.*, *Towards a European Civil Code*, Kluwer Law International, 2004, at 645; S. Whittaker, *Liability for Products*, cit. See also Reimann, 'Product Liability in Global Context: the Hollow Victory of the European Model', *European Review Private Law*, 2003, p. 132, "[j]urisdictions joining the product liability bandwagon have uniformly cast their special regimes in statutory form rather than relying on judicial decisions, restatements, or the like. This is no wonder in countries belonging to the civil law orbit, e.g., in continental Europe, Latin America, most Asian nations, and Quebec. But it is also true in several common law jurisdictions, namely United Kingdom, Ireland, and Australia. As a result, the field now has a legislative centrepiece in the vast majority of legal systems recognising it has a special subject. In fact, the only country where product liability is clearly established as a field with its own rules and principles (such as strict liability), but still remains a matter of case law, is the United States".

⁶⁴ For an evaluation of regulatory compliance in the US setting see R. Rabin, 'Reassessing regulatory compliance', cit., 2049; J. Stapleton, 'Regulating Torts', in C. Parker *et al.*, *Regulating Law*, cit., at 122

⁶⁵ For the definition of private regulatory standards as minimum standards see G. Spindler, 'Interaction between product liability and regulation at the European level', in this volume

A slightly different approach is taken in the area of regulation. No specific recognition of the relevance of civil liability as a complementary strategy occurs in this area⁶⁶. Regulatory schemes do not seem explicitly to acknowledge the existence of an underlying civil liability system. However, in the area of product safety, as we shall see, compliance with safety standards may be sufficient to shield manufacturers from criminal liability, but does not exclude the imposition of duties if the dangerous nature of the product becomes known after sale⁶⁷.

3.2 Contractualizing Standard-setting

The second point is concerned with the role of private actors in standard-setting. By private actors I refer to two main modes of participation in standard-setting: 1) through trade associations, 2) through market contracting⁶⁸. In both cases often there is a plurality of regulators aimed at achieving some level of competition in standard-setting. The degree and effectiveness of competition among private standard setters is scrutinized by competition law. Most of the ‘advantages’ of private regulation, however, may be lost if the private regulator is a monopolist⁶⁹. Private regulation should thus be distinguished from technical regulation by private body of ‘independent’ experts⁷⁰. In practice this is a difficult distinction given the risks of capture of experts by the industry. This difficulty, however, should not lead to eliminate the differences between expertise and interest based regulation. On the contrary, they should reinforce the necessity to identify clear boundaries between independent and non independent private regulation. A second question is related to access to standards. Private regulation often implies sale of technical standards to a greater extent by independent regulatory bodies than by private regulators representing the industries. How does the market for standards affect the level of safety? Does it increase it or decrease it? Empirical studies

⁶⁶ While it is very important the role of civil liability and judicial review for the content of regulatory activity and standards supervision. See below text and footnotes ...

⁶⁷ For the debate on product liability and the role of scientific knowledge see *Restatement of the Law Third, Torts: Products Liability*, s. 402 A) and American Law Institute, *Restatement Third on the Law of Torts: Liability for Physical Harm*, Proposed final draft, N1 (2005), in particular in relation to burden of proof in causation, at 477 ff. Specifically on the risk development defence, see J.-S. Borghetti, *La responsabilité du fait des produits. Étude de droit compare*, LGDJ, 2004, at p. 59-62 and reference to the vast case law there contained. The role of scientific knowledge in relation to product liability regimes also concerns possible defects which may depend on the projectual phase of the product rather than on the very manufacturing activity: for the German system see again *ibid.*, at 125-127. If para.823 BGB provides a principle of negligence liability for project defects, different solutions may be reached when there are European, national, or international provisions establishing safety standards (at.127). The problem is at the very core of the risk development defence. See *A and Others v National Blood Authority*, *supra* n. 26.

⁶⁸ For a detailed analysis concerning contract law see F. Cafaggi, ‘Self-regulation in European contract law’, *European journal of legal studies*, 1, 2007 available at www.ejls.eu.

⁶⁹ See O. Hart, A. Shleifer and R. Vishny, ‘The proper scope of government: theory and application to prisons’, 112 *Quarterly Journal of Economics*, 1997, 1127; F. Cafaggi, ‘A coordinated approach to regulation and civil liability’, *cit.* p.

⁷⁰ Art. 3.3 of GPSD includes different types of private regulation to assess general safety requirements without distinguishing criteria. Under letter (a) it mentions ‘voluntary national standards transposing relevant European standards’, under letter (d) product safety codes of good practice in force in the sector concerned; under letter (e) the state of the art and technology.

are needed to answer this question and to clarify the effects of the participation of private actors in the process of standard setting concerning product safety.

To what extent do private actors participate in standard-setting in civil liability and regulation? Are there differences in the two domains? How do the new models of regulation, broadening the participation of relevant stakeholders, affect standard-setting in civil liability?

In this section, I focus on the influence of private standard-setting in product safety and defectiveness and the consequences for violations of these standards by producers and distributors. I do not address the related question of the liability of the standard-setters and how it changes when a transfer from public to private has occurred⁷¹. Of course especially in the case of private standard-setting by market players the two questions are strictly inter-related⁷².

Standards are, in this context, related to product safety (dangerousness) and defectiveness. Part of the definition of a safe or non-defective product is related to the level and adequacy of information provided by producers and distributors. I will deal mainly with product design standards in this section and focus on information standards in the next section. The definition of defect, introduced with PL directive does not specifically refer to regulatory standards but to exclude liability if the defect is due to compliance with legislative mandatory rules. The general rule, with different applications across MS, states that compliance with regulatory standards can have relevant but not conclusive evidentiary weight. This leaves the judges discretion to hold liable producers who have fully complied with regulatory standards. Regulatory compliance is not a full defence⁷³. Does the existence of a regulatory standard affect the definition of what is a defective product, given that compliance with standards according to the GPSD constitutes a rebuttable presumption of safety? Should the regulatory standard have some influence in the definition of consumer expectation according to art. 6?

The regulatory standard contributes to define the minimum level of consumer expectation but certainly does not coincide with the expectation itself which is based on several factors, some legal some factual. Objectively defined consumer expectation may be higher than the regulatory standard or simply different. Thus, a safe product can be defective and a dangerous product might not be defective. Product safety and product defectiveness are not mutually exclusive because regulation and liability have complementary functions⁷⁴.

⁷¹ I have addressed this issue in 'La responsabilité des régulateurs privés', cit., p 111; and 'La responsabilità dei regolatori privati', Mercato Concorrenza e Regole, 2006, p. 1 ff.

⁷² For a detailed analysis of these aspects see S. Whittaker, *Liability for Products*, cit., p. 305 ff.

⁷³ See S. Whittaker, *Liability for products*, cit. p. 483.

⁷⁴ See F. Cafaggi, Rethinking institutional complementarities, cit. p. 00 See in Italy Corte di cassazione, n. 6007, 15.03.2007, which states: "*Senonchè, l'art. 5 della legge definisce difettoso non ogni prodotto insicuro ma quel prodotto che non offra la sicurezza che ci si può legittimamente attendere in relazione al modo in cui il prodotto è stato messo in circolazione, alla sua presentazione, alle sue caratteristiche palesi alle istruzioni o alle avvertenze fornite, all'uso per il quale il prodotto può essere ragionevolmente destinato, ed ai comportamenti che, in relazione ad esso, si possono ragionevolmente prevedere, al tempo in cui il prodotto è stato messo in circolazione.*

Il difetto del prodotto non si identifica, dunque, con la mancanza di una assoluta certezza o di una oggettiva condizione di innocuità dello stesso, ma con la mancanza dei requisiti di sicurezza

Traditionally, in civil liability the role of private parties as standard-setters has been neglected or denied but for technical standardisation. Given that civil liability is a domain of mandatory rules, the role of private parties in the definition of due care standard has generally been rejected. Standards of due care and strict liability have been the exclusive domain of legislators and judges for a long time. The rise of the regulatory state has added public regulators, that is, government or administrative agencies to the traditional institutional landscape.

Contract law has been considered to limit the freedom to contract out of publicly defined standards. In the traditional perspective, individual parties can modify legislatively defined liability standards on a contractual basis but only in a limited way. This is certainly true for contractual liability, but sometimes it is extended to extra-contractual liability⁷⁵. Parties however, cannot exclude civil liability between themselves and towards third parties⁷⁶.

In national legal systems, the possibility to modify standards of contractual liability has always been recognised at the individual level: so that the potential injurer and victim could negotiate, within certain limits, on the liability regime and on the level of compensation⁷⁷.

Limitations of contractual and extra-contractual liability are however scrutinized under unfair contract terms legislation⁷⁸. In those legal systems where unfair contract terms are scrutinized in relation to BtoC relationships, the ability to exclude liability for product defectiveness is almost non-existent⁷⁹. So that only a valid clause can limit injurer's or victim's extra-contractual liability. In those countries where unfair terms are scrutinized in both BtoB and BtoC the right to exclude liability is very limited.

The Draft Common Frame of Reference (hereinafter DCFR) takes a relatively strict position, prohibiting exclusion or limitation for intentional and reckless misconduct and for personal injuries, even in negligence⁸⁰. It allows exclusions or limitations only in

generalmente richiesti dall'utenza in relazione alle circostanze specificamente indicate dall'art. 5 o ad altri elementi in concreto valutabili e concretamente valutati dal giudice di merito, nell'ambito dei quali, ovviamente, possono e debbono farsi rientrare gli standards di sicurezza eventualmente imposti dalle norme in materia."

⁷⁵ See *Study on property law and non contractual liability as they relate to contract law*. Submitted to the EC Health and Consumer Protection, directorate general, Sanco B5-1000/02/000574 by Proffs. C. Von Bar and U. Drobnig, (hereinafter *The Study on non contractual liability*), available at http://ec.europa.eu/consumers/cons_int/safe_shop/fair_bus_pract/cont_law/study.pdf

⁷⁶ See the *Study on non contractual liability*, cit., p. 164 ff. In relation to the English and French system S. Whittaker, *Liability for products*, cit., p. 93 ff. and p. 260 ff.

⁷⁷ MS legal regimes differ quite significantly, but they all allow some possibility. See *The Study on non contractual liability*, p. 164 ff. For the French system see M. Fabre Magnan, *Les obligations*, PUF, 2004, p. 586 ff. For the English system see E. McKendrick, *Contract*, Palgrave Law masters, Palgrave Macmillan, p. 230.

⁷⁸ See Research Group on the Existing EC Private Law (Acquis Group), *Principles of the Existing EC Contract Law (Acquis Principles) – Pre-contractual Obligations, Conclusion of Contract, Unfair Terms Contract I*, European Law publisher, 2007.

⁷⁹ See art. 12 Dir. 374/85

⁸⁰ See *Principles, Definitions and model Rules of European private law*, Draft Common Frame of Reference, available at <http://webh01.ua.ac.be/storme/DCFRInterim.pdf>. In particular, see book VI Art 5:401, "Contractual exclusion and restriction of liability":

"Liability for causing legally relevant damage intentionally cannot be excluded or restricted

relation to economic interests⁸¹. When lawful clauses are introduced, they will be scrutinized under the fairness test and will be declared valid if they do not create a disproportionate ratio of rights and duties. It is important to point out that exclusions or limitations are prohibited when are 'otherwise illegal or contrary to good faith and fair dealing'.

Product safety regulation reveals a slightly different picture. The role of private actors in regulation has been debated for the last 20 years but their increasing relevance cannot be questioned⁸². Changes have occurred both in relation to the definition of private regulation and private regulators affecting the boundaries of the private-public divide⁸³. Private regulation in this area takes different forms, but co-regulation and delegation largely prevail over pure self-regulation⁸⁴. The use of private regulation is often framed within a cooperative approach aimed at increasing accountability of the regulatory process.

Traditionally private parties are unable to change or deviate from the standard of product safety and product defectiveness. Thus, pure self-regulation unlike co-regulation and delegated regulation has little role in the field.

My claim is that the influence of private regulation in product and service safety, in particular contractualization of standard-setting - but to some extent even of monitoring - has entered the field of product liability through that of product safety. Changes in the regulatory regimes affect the operation of product liability and the tort system. The interplay between the two areas is bringing about a higher degree of contractualization, even if rules about compliance are still kept different in administrative regulation and product liability. An open question which requires empirical research is which changes this contractualization has brought in relation to the type of standards. On the one hand, one could expect that private actors would move from design to performance standards, leaving more discretion to producers. On the other hand, incentives to reduce competitiveness on safety may induce to use more design than performance standards. The Commission has provided detailed guidelines concerning technical standardisation to prevent anticompetitive standardisation but there are no specific references to the preferability of performance standards⁸⁵.

(1) Liability for causing legally relevant damage as a result of profound failure to take care as is manifestly required in the circumstances cannot be excluded or restricted:

- (a) in respect of personal injury (including fatal injury), or
- (b) if the exclusion or restriction is otherwise illegal or contrary to good faith and fair dealing.”.

⁸¹ This can be inferred from the last part of the article where it is stated that “Other liability under this Book can be excluded or restricted unless statute provides otherwise”, DCFR VI-5:401(4).

⁸² See J. Black, ‘Tensions in the Regulatory State’, Public Law, 2007, p. 58, R. Baldwin and J. Black, ‘Really Responsive Regulation’, Modern Law Review, 2008, Vol. 71, p. 59.

⁸³ See J. B. Auby and M. Freedland (eds.), *The public-private law divide: Une entente assez cordiale?*, Oxford, Hart, 2006.

⁸⁴ Delegation occurs when a public body transfers its law making power to private bodies or when it shares it. See C.M. Donnelly, *Delegation of governmental power to private parties - A comparative perspective*, OUP, 2007 and before F. Cafaggi, ‘Rethinking Private Regulation in the European Regulatory Space’, in F. Cafaggi (ed.), *Reframing self-regulation in European private law*, Kluwer, 2006, p. 3.

⁸⁵ See Guidelines on horizontal cooperation 2001, in particular art. 6 on standard agreements: “Standardisation agreements have as their primary objective the definition of technical or quality requirements with which current or future products, production processes or methods may comply (47).

The interaction between regulation and civil liability poses new challenges if we consider the role of private regulation⁸⁶. Here the reference is to private regulation as normative not technical standard-setting⁸⁷. When industries self-define the standards of product safety or environmental protection, can the binding contractual arrangements they apply affect the standard of defectiveness in product liability? Should the limits of this private regulatory power be defined by the rules concerning contractual exclusion of liability or should they be defined according to different criteria, given the regulatory nature of the contract?

Possible alternative answers to this question are:

- (1) to consider self-regulation and co-regulation as a form of regulation and apply the rules developed for administrative regulation to the interaction between self-regulation and civil liability, or;
- (2) to apply the rules of contractual limitation of contractual liability⁸⁸.

The two aspects just examined reveal different relationships between regulation and civil liability. While potential injurers cannot escape liability even if they comply with administrative regulation, in the case of private parties who have contracted limitations of liability, judges are bound to apply the contractual arrangement even if it lowers the standards of protection, unless the clause is unfair.

While the principles developed in contract law for the exclusion of liability might be considered a starting point, a different account is needed for standard-setting defined through contractual arrangements, i.e. codes of conduct enacted by private actors in the field of product safety and environmental protection. The possibility that self-regulatory normative standards can be considered minimal should be preserved; therefore the judge, when evaluating injurers' liability should be able to hold an injurer liable even if she complied with standards defined by the private regulatory body. The use of private autonomy as a shield from liability would undermine the acceptability of private regulation as a complementary regulatory device. If private regulators could set standards that exclude or reduce potential injurers' liability without limits, the credibility of private regulation would be severely affected. If it is accepted that regulatory compliance related to administrative regulation is not a defence then, *a fortiori*, regulatory compliance related to private regulation should not be considered decisive⁸⁹.

The influence of private regulation on the level of consumer protection may also be indirect. If private regulators set standards that would reduce competition and these standards are internalised by the civil liability system, then negligence or strict liability

Standardisation agreements can cover various issues, such as standardisation of different grades or sizes of a particular product or technical specifications in markets where compatibility and interoperability with other products or systems is essential. The terms of access to a particular quality mark or for approval by a regulatory body can also be regarded as a standard”.

⁸⁶ For an overview see F. Cafaggi, ‘Rethinking Private Regulation in the European Regulatory Space’, cit., p. 16.

⁸⁷ See on the distinction between private normative and technical standard-setting, above text and footnotes ...

⁸⁸ On the role of self-regulation in civil liability and in particular in standard-setting see F. Cafaggi, *Contractualizing standard-setting in civil liability?*, cit.

⁸⁹ See F. Cafaggi, *Contractualizing standard-setting in civil liability ?*, cit.

may become anti-competitive devices that reduce the level of protection⁹⁰. A pro-competitive system of civil liability should encourage the adoption of alternative safer standards, promoting innovation.

To conclude: standards concerning safety of products are generated both within the civil liability and the regulatory systems. Coordination between these two activities is poorly defined both at national and at European level in relation to the traditional framework that compares administrative regulation and civil liability. New challenges to this interaction are posed by changes occurring in the field of regulation with the consolidation of the role of private regulators and the introduction of new regulatory schemes. An integrated system of civil liability and regulation requires coordination mechanisms that go beyond regulatory compliance.

Legislative intervention to coordinate the liability for defective products and safety regulatory regime is needed. This intervention should not eliminate the specificities of the two approaches, but it should define better coordination devices between the two regimes in relation to both deterrence and compensation. The preliminary step is to have a clear distinction among different types of regulatory strategies. Private standard setting may be distinguished among (1) custom, (2) negotiated standardisation and (3) standardisation by independent bodies. These differences should affect the influence of self-regulation on standard-setting in civil liability and should be differentiated between their impact on fault and on strict liability. Custom and unilateral standardisation should be considered only for evidentiary purposes. Negotiated standardisation, in compliance with clear procedural rules concerning openness, transparency and accountability, and independent standardisation could give rise to a rebuttable presumption of safety when there is compliance with the technical standard. Negotiated standardisation without procedural guarantees should be treated as unilateral standardisation and produce only evidentiary effects.

⁹⁰ See F. Cafaggi, 'Self-regulation in European Contract law', cit.

Agreements among firms that perform standard-setting functions are generally scrutinized under antitrust rules. See Commission notice of 6 January 2001, *Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements*, O.J. C 3 of 06.01.2001, p. 167. "The existence of a restriction of competition in standardisation agreements depends upon the extent to which the parties remain free to develop alternative standards or products that do not comply with the agreed standard. Standardisation agreements may restrict competition where they prevent the parties from either developing alternative standards or commercialising products that do not comply with the standard. Agreements that entrust certain bodies with the exclusive right to test compliance with the standard go beyond the primary objective of defining the standard and may also restrict competition. Agreements that impose restrictions on marking conformity with standards unless imposed by regulatory standards may also restrict competition."

See also General Guidelines for the cooperation between CEN, CENELEC and ETSI and the European Commission and the European Trade Association, cit., "With regard to possible restrictions to competition caused by horizontal cooperation agreements between companies operating on the same market level(s) the Commission published a notice on the applicability of Article 81 of the EC Treaty. In this notice standardisation agreements are considered to be a type of horizontal cooperation agreement, either concluded between private undertakings or determined under the aegis of public bodies or **bodies entrusted with the operation of services of general economic interests, such as the standard organisations recognised under directive 98/34 EC**. The notice also states that in principle standardisation agreements do not restrict competition if the standards are adopted by recognised standard organisations, based on non discriminatory open and transparent procedures."

On the relationship between standard-setting by private organizations and competition rules see F. Cafaggi, *Contractualizing standard-setting*, cit.

4. The effects of regulation on the private law dimension: the creation of industry networks to promote and control product safety⁹¹

The information flow towards consumers is defined by three different bodies of law at EU level: contract (sale of goods directive 99/44/EC), civil liability (PL directive), and GPSD. The three systems, not well coordinated, impose duties to inform on the producer, the distributor, and the final seller. They define different liability regimes which affect the incentives to produce information, but most importantly impact upon the incentives to monitor product safety and defectiveness once the product has been marketed. Information duties play different functions depending on the level and nature of risk but also on the identity of the addressee, buyer, user, bystander to whom the information is conveyed⁹².

(1) They reduce the level of risk by conveying information about the risks of the product and the modes of assessment by the consumer, (2) they allow consumers, buyers and users, to make informed choices about purchase and use of the product once it has been bought. In this context, I focus on information concerning safety leaving aside quality. Information may contribute to risk assessment when consumers have to make a choice, which is not always the case as the example of bystanders shows. Information can also contribute to risk management, if the risk is known and only partially avoidable with the cooperation of consumers or third parties.

Information duties are owed before the product is sold, when it is marketed, but also after sale, when they interact with the duty to monitor product safety. Post market surveillance has become a central issue in the current debate. Duties to inform are thus related to sale and post-marketing. They cover the whole life of the product. Thus, their relationship with monitoring becomes extremely relevant.

The debate about the liability standard which gives optimal incentives to inform is still open⁹³.

The GPSD takes a different approach from the PL and the Sale directives, but also from sector specific regulatory regimes. It must be recalled that the GPSD is residual and it only applies to consumer products whose safety is not specifically regulated. The

⁹¹ This part summarises the results of a broader project which I am currently working on “Creating safety networks. Moving away from hierarchy in product safety and liability”. See F. Cafaggi, *The divergences between real industrial organisational forms and regulatory strategies concerning product safety. When theory departs from reality in institutional design*. Unpublished manuscript

⁹² The issue becomes even more difficult in relation to liability for defective drugs where information has to be conveyed to doctors who prescribe the drugs as well as to potential users. The matter is regulated at EU level by directive 2001/83/EC and subsequent amendments. Under the directive the holder of market authorisation has to conduct pharmacovigilance of the products and to report adverse reactions to the competent authority. See M. Mildred, ‘Pharmaceutical products: the relationship between regulatory approval and the existence of a defect’, cit. p. 1269.

⁹³ For a recent analysis related to the US system see K. Spier, ‘Product safety, buybacks and the post-sale duty to warn’, Harvard Law and Economics Discussion Paper No. 597, available at <http://ssrn.com/abstract=1023125>, and, in a different perspective, A.M. Polinsky and S. Shavell, ‘Mandatory versus Voluntary Disclosure of Product Risks’, Stanford Law and Economics Olin Working Paper No. 327, available at <http://ssrn.com/abstract=939546>. For earlier influential contribution on these matters see G. Hadfield, R. Howse, M. Trebilcock, ‘Information based principles for rethinking consumer protection policy’, 21 *Journal of consumer policy*, 1998, 131.

analysis will focus on this regime and only occasional references to food and drug safety regimes will be made, in particular a propos to Regulation 178/2002⁹⁴.

The GPSD defines the industrial chain by distinguishing suppliers and distributors. The former, according to the directive, are those who can affect the safety of the product, the latter are those who cannot⁹⁵. While placing the burden of safety obligations on the producer it allocates information duties along the chain with some emphasis on the distributors and retailers.

Before examining the structure of information obligations and their implication for the network it is necessary to focus on the definition of the distributor.

The distributor is defined in a quite peculiar way for at least two reasons:

- 1) it is negatively defined as being unable to affect the safety, thus adopting a very abstract and old fashioned idea of the decision-making power between producers and distributors. It is evident how relevant big distributors are for the definition of product safety, not only in the case of private labelling. For reasons concerning market reputation and costs associated to withdrawal and recall, distributors impose on producers safety and quality control systems that can affect the safety;
- 2) it leaves unclear whether the expression 'cannot affect safety' refers to technological or contractual constraints. In the latter case the parties would be able contractually to allocate the regulatory burdens in ways that may not be the most efficient because driven by asset instead of real ability to control safety (i.e. producer is the small firm that can only be liable for a limited amount while the big and powerful distributor does not have any safety obligation whilst being better equipped to be in charge of safety precautions).

This definition of distributor is in tension with other rules of the directives requiring distributors' participation in monitoring, and recognising their importance in producing, collecting and transmitting information to the consumer and the producer⁹⁶. Compliance with these duties can contribute to make the product safe. On the contrary, violation of these duties may make the product dangerous⁹⁷. National authorities can require enterprises to warn consumers when there are reasonable grounds that a product can pose risks to all or certain categories of consumers⁹⁸.

⁹⁴ The food regime imposes on the food business operator the responsibility to ensure that requirements of food law are met within the food business under their control (see Art 3(3) Regulation 178/2002).

⁹⁵ See Art 5.3 of GPSD.

⁹⁶ See Art 5.2 of GPSD.

⁹⁷ To solve this contradiction a review of the Directive is needed to rephrase the definition of distributor. Before then a functional approach should qualify producers those who are generally considered distributors from an economic perspective whenever they are in the position to monitor products' safety.

⁹⁸ See in UK Regulation 13 (1) General Product Safety 2005: "Where an enforcement authority has reasonable grounds for believing that a product is a dangerous product in that it could pose risks for certain persons, the authority may serve a notice ("a requirement to warn") requiring the person on whom the notice is served at his own expense to undertake one or more of the following as specified in the notice:

- (a) where and to the extent it is practicable to do so, to ensure that any person who could be subject to such risks and who has been supplied with the product be given warning of the risks in good time and in a form specified in the notice

I turn to an examination of the potential effects of ‘duties to inform’ on the supply and distribution chain and the potential implications for a more general institutional design aimed at making information discovery and flow more effective.

A product can be deemed dangerous or unsafe if information is not adequately provided to consumers⁹⁹. GPSD imposes duties to inform not only on producers but also on distributors to final consumers¹⁰⁰. It also imposes coordination mechanisms between parties operating in the chain and especially between producers and distributors¹⁰¹. Distributors are bound to gather information and transmit it to producers; producers are bound to inform distributors¹⁰². Both are obliged to inform the competent national authorities about risks concerning the safety of the product to be processed through the RAPEX system¹⁰³. Uncertainty about who takes main responsibility may bring about coordination problems which are in some legal systems addressed by national authorities through their guidelines¹⁰⁴. One of the most relevant question is when a duty to inform the competent authorities arise and whether there is coincidence between this duty and the post-sale duties to inform regulated by the civil liability system and by contract rules.

Regulators have tried to define guidelines as to when information is to be transferred to combine the need to have a manageable system and that of protecting consumers as soon as risks become known¹⁰⁵.

(b) to publish a warning of the risks in such a form and manner as is likely to bring those risks to the attention of any such person,

(c) to ensure that the product carries a warning of the risks in a form specified by the notice”

⁹⁹ See P. Cartwright, ‘The regulation of product safety’, in G. Howells, *The law of product liability*, Lexis-Nexis, 2007, p. 734 f; F. Cafaggi, ‘A coordinated approach to regulation and civil liability in European Law’, cit., p. 214; S. Weatherill, *EU Consumer law and policy*, EE, 2005, p. 216 ff.

¹⁰⁰ In relation to producers Art 5.1 of GPSD correlates information duties and consumers’ risk assessment and deterrence: “Within the limits of their respective activities producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings and to take precautions against those risks”

In relation to distributors Art. 5.2 of GPSD states “Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products place on the market, **especially by passing on information on product risks, keeping and providing documentation necessary for tracing the origin of products, and cooperating in the actions taken by producers and competent authorities to avoid the risks.**”

¹⁰¹ Art 5.2 of GPSD: “Within the limits of their respective activities thy shall take measures enabling them to cooperate efficiently”.

¹⁰² See again GPSD Art 5.1 for producers and 5.2 for distributors.

¹⁰³ See Art 8 of GPSD.

¹⁰⁴ See for example in the UK DTI Guidance for business, consumers and enforcement authorities, August 2005, available at <http://www.berr.gov.uk/consumers/Safety/products/index.html>, par. 7.4

¹⁰⁵ See “Producers and distributors should analyse the information collected and decide whether a particular hazardous situation should be notified to the authorities taking into account:

The gravity of the outcome of the hazard, depending on the severity and probability of the possible health and safety damage. Combining the severity and probability gives an assessment of the gravity of the risk. The accuracy of this assessment will depend upon the quality of the information available to the producer or the distributor.

The severity of health/safety damage for a given hazard should be that for which there is reasonable evidence that the health and safety damage attributable to the product could occur under foreseeable

There is not a necessary coincidence between the duty to inform consumers and the duty to report to the competent authority. Often the type of information and the ways to inform might have to be defined in a coordinated way and it might be advisable to report to the authority first and then decide which information are to be given to the public and how define the appropriate means.

Monitoring techniques may differ according to each product¹⁰⁶. They also depend on the qualification of ‘dangerousness’ provided by art. 8 of GPSD¹⁰⁷.

This web of duties to inform implies the design of an informational network that would process information in a rapid and effective way. In some legal system it has been

use. This could be the worst case from health and safety damages that have occurred with similar products.

The probability of health and safety damage for a normal user who has an exposure corresponded to the intended or reasonably expected use of the defective product has also to be considered as well as the probability of the product being or becoming defective.

The decision to notify should not influenced by the number of products on the market or by the number of people who could be affected by a dangerous product. These factors may be taken into account in deciding on the type of action to be taken to solve the problem”. See Commission Decision, 14.12.2004, laying down guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors, in accordance with Article 5(3) of Directive 2001/95/EC of the European Parliament and of the Council, OJ L 381, 28.12.2004, p.63.

Compare the elements listed in Europe by the Guidelines enacted by the European Commission in the framework of Rapex system established with the GPSD with those defined by the Consumer Product safety Commission in the US in the Recall Handbook (Recall Handbook, A Guide for manufacturers, Importers, Distributors and Retailers on Reporting under Sections 15 and 37 of the Consumer and product safety Act, section II Identifying defect). “In determining whether a risk of injury associated with a product could make the product defective, the Commission considers the following :

- 1) What is the utility of the product? What is supposed to do?
- 2) What is the nature of the injury that the product might cause?
- 3) What is the need for the product?
- 4) What is the population exposed to the product and the risk of injury?
- 5) What is the Commission’s experience with the product?
- 6) Finally what other information sheds light on the product and patterns of consumer use?”

Available at <http://www.cpsc.gov/businfo/corrective.html>.

¹⁰⁶See C. Hodges, *European regulation of consumer product safety*, cit., p. 129 ff.

¹⁰⁷Art. 6 GPSD identifies 6 different categories:

- b) any product
- c) any product that could pose risks in certain conditions
- d) any product that could pose risks for certain persons
- e) any product that could be dangerous
- f) any dangerous product
- g) any dangerous product already in the market.

See for example in the UK Regulation 2005 on general product safety, art. 9

“(1) Subject to paragraph (2) where a producer or a distributor knows that a product he has placed on the market or supplied poses risks to the consumer that are incompatible with the general safety requirement, he shall forthwith notify an enforcement authority in writing of that information and-

- (a) the action taken to prevent risk to the consumer; and [...]
- (2) In the event of a serious risk the notification under paragraph (1) shall include the following
 - (a) information enabling a precise identification of the product or batch of products in question
 - (b) a full description of the risks that the product presents
 - (c) all available information relevant for tracing the product, and
 - (d) a description of the action undertaken to prevent risks to the consumer”.

suggested the creation of an internal coordinator in relation to product recall¹⁰⁸. It is important to point out the scope of these duties to inform. Not only do they refer to *ex ante* known risks but, and perhaps more importantly, they provide further incentives to the discovery of new risks and fast information processing¹⁰⁹. It is mainly in relation to post-marketing ‘duties to inform’ that the creation of an efficient network becomes important.

GPSD focuses on the activity and does not address the means through which individual enterprises and the chain as whole should comply. When compliance with these duties is evaluated by judges it becomes clear that the inquiry moves to the mechanisms put in place to collect and transmit information¹¹⁰. It becomes necessary to explore the structure of the chain to evaluate how individual enterprises cooperate to ensure that duties to monitor and to inform are complied with.

A preliminary distinction, related to information production and transmission, concerns groups and networks¹¹¹. In pyramidal groups, ownership control requires the adoption of an organisational structure that encompasses information production and transfer among the different participants. Unlike groups, networks - especially contractual ones - may lack an organisational form with ownership control¹¹². This is more true for production chain (i.e. subcontracting), less true for distribution chain, where the contractual nature of the network implies a higher level of coordination, as in franchising and dealership¹¹³. I discuss the relationship between decision power allocation along the supply and distribution chain and product safety elsewhere¹¹⁴. In this context, I would only like to suggest that the organisational form of the chain affects (or should affect) the regulatory design concerning product safety, in particular duties to inform consumers and competent authorities, but symmetrically the regulatory design will influence the business model. The relevant question is whether the regulatory design should operate irrespective of the different business models or should be tailored to them, i.e. are business models a relevant variable to define effective information systems about product safety.

The current approach of GPSD seems to ignore the differences among business models and apply to industrial chains which operate very differently. I suggest that business

¹⁰⁸See in the US the Handbook on recall issued by the Consumer Product safety Commission, cit.

¹⁰⁹See Art 5.3 of GPSD.

¹¹⁰See C. Hodges, *European regulation of consumer product safety*, cit., p. 132 ff and 191 ff., describing the different criteria for evaluating post-marketing obligations of producers and distributors

¹¹¹See for an introduction E. Todeva, *Business networks*, Routledge, 2006, part. pp. 85 ff.; A. Grandori, (ed.) *Inter-firm networks*, Routledge, 1999. For a more general framework see J. Zeitlin, ‘Industrial districts and regional clusters’, in J. Zeitlin, *Handbook of business history*, OUP, 2007, in a different perspective M. Granovetter, ‘Coase revisited: business groups in modern economy’, in G. Dosi, D. Teece, J. Chytry, *Technology, organization and competitiveness*, Oxford, 1998, p. 67 ff.

¹¹²On the definition of contractual networks see F. Cafaggi, ‘Contractual networks and the Small Business Act: towards European principles?’, EUI w.p. 2008/15

¹¹³For a comparison between networks and groups see F. Cafaggi, *Reti di imprese tra regolazione e norme sociali*, Il Mulino, 2004. For a broad analysis of business networks E. Todeva, *Business networks*, cit., passim.

¹¹⁴See F. Cafaggi, ‘*The divergences between real industrial organisational forms and regulatory strategies concerning product safety. When theory departs from reality in institutional design*’, Unpublished manuscript.

networks should be designed to ensure effective monitoring in product safety, thus taking into account the different organisational structures, distinguishing between big, medium and small enterprises. A specific policy for product safety in SMES may require different organisational networks from those operating for big multinationals.

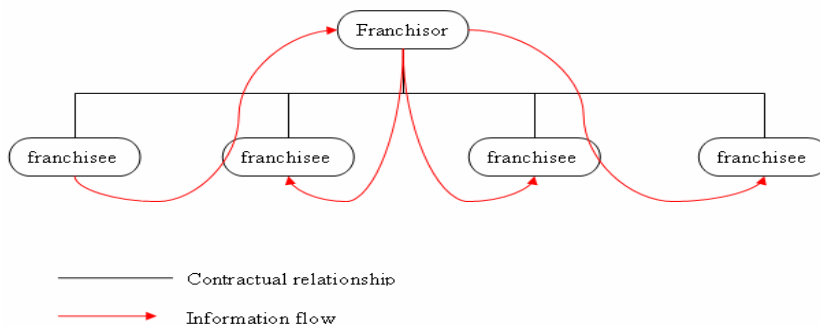
It is important to distinguish between production and information transfer within different links in the chain and information networks aimed at communicating with the public. Firms have created various informational networks to ensure that information about safety products is produced and transferred in effective ways. Individual enterprises have to take measures enabling them to monitor the safety of the product. While no specifications are made in the directive about size of enterprises and especially in relation to distribution between wholesale and retail, national legal systems have recognised that differences may affect the expected standard and the type of internal organisation set up to monitor product safety¹¹⁵.

In relation to the shape of networks aimed at producing and generating information within the chain, two main models can be identified¹¹⁶:

- a) hierarchical network
- b) horizontal network.

In the hierarchical network information gathered at different levels is all passed on to the producer who then conveys it to the relevant actors, both consumers and competent authorities. Hierarchy is relevant to decide which information should be transmitted, when the risk product-related is such that dissemination of information takes place within the group, in case of multinationals also independently from any administrative action. Competent authorities proceed through a parallel process to gather and disseminate information about product risks. The relevant decision-making power to define which information should be disclosed and at which speed is left to the producer.

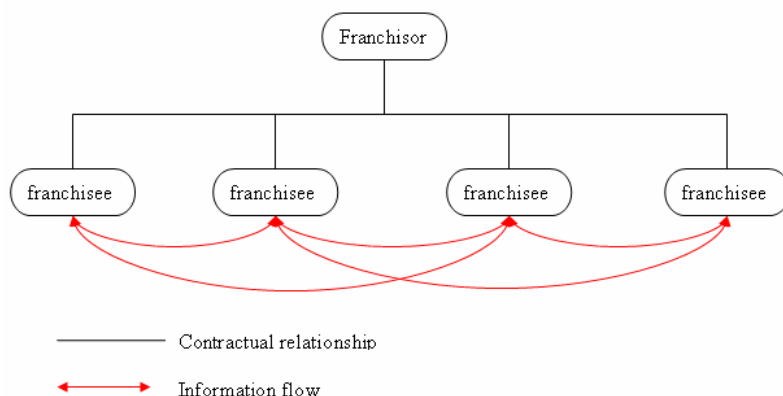
Hierarchical network : Let us take the example of franchise. The information flows from the franchisees to the franchisor and then back to the franchisees.



¹¹⁵In the UK these differences have been acknowledged by DTI Guidance suggesting agreements along the chain on who should make the notification. See DTI Guidance for Businesses, consumers and enforcement authorities, cit., p. 6.6. See also P. Cartwright, 'The regulation of product safety', cit., p. 738 ff.

¹¹⁶For a summary concerning different network configurations see E. Todeva, *Business networks*, cit. p. 130 ff.

Horizontal network: again the example of franchise. the information is exchanged directly among franchisees not necessarily after intermediation by the franchisor.



In the horizontal network data are shared by the different knots. For example in franchise, the franchisees communicate directly without the mediation of the franchisor. In dealership organised as horizontal network, the dealers communicate among themselves without the hierarchical intervention of the producer who may simply participate to the process.

These networks are aimed at generating information, providing each enterprise along the chain with incentives to collect information and to define tools to detect new risks and assess known ones. Search of the most effective information producer can place higher burdens on one particular knot, which, however, does not necessarily mean that it will bear the entire cost. Certainly, the structure of the GPSD suggests that producers may bear the higher costs of producing and distributing information.

The decision about the structure of the information network is driven by several interrelated factors. One is the liability regime if no information is collected and communicated, but others are related to the form of the chain and the decision-making power allocated along the chain. If market and contractual power is strongly asymmetric along the supply and distribution chain, it is likely that it would generate a hierarchical information network. Conversely, if power is distributed relatively evenly, chances for a horizontal network to arise are relatively higher.

The main policy question for product safety is the extent to which these networks, contractually organised, should only mirror the regulatory structure or can enjoy some level of discretion internally to allocate burdens and costs so as to improve the final results: i.e. effectiveness in producing and transmitting information about risks. In other words, should legislators and regulators define the shape of the network or should they only define their aims and leave parties the freedom to organise them?

The desirable policy is to define the goals and, accordingly, the liability system for non-compliance of information duties on producers and distributors, while leaving parties discretion to choose the most appropriate organisational form. To leave enterprises discretion does not mean that compliance evaluation should not take into account the

adopted organisational model, how the network performed and which improvements can be made. The producer or the distributor could never use compliance with the chosen organisational model as a defence if information was not produced or effectively transmitted. Scrutiny of the organisational model to gather information should thus be allowed.

The current regime should thus introduce default rules concerning the network forms to be adopted to comply with information duties related to product safety.

The example of information-networks in product safety shows how a specific regulatory strategy that imposes coordination to produce and transfer information about product risks may affect the industrial structure and promote vertical and horizontal cooperation concerning safety matters. GPSD places the most relevant safety burdens on producers but impose on distributors a fault based duty to act when they know or should know that the product can be dangerous or unsafe¹¹⁷.

This organisational form is very important for networks where the product is manufactured and sold in Europe but may have relevant implications for transcontinental safety networks where production is partly developed outside Europe (far East or South America) and thus safety control may be defined by different legal regimes and the importer would bear the costs of verifying compliance with European standards.

Following the toy recalls in summer 2007, the European Commission engaged in a wide-ranging stocktaking review on product safety and an audit of the business safety measures in the toy supply chain¹¹⁸.

The creation of these networks implies a relative high investment, albeit, not necessarily information-specific. Thus, the possibility of expanding the scope of the network for pure information collection and transfer to other safety aspects concerning risk-control should be explored.

The adoption of a network model for safety precaution would generate important benefits for the final consumer but also important positive externalities. To promote these networks may imply regulatory reforms. A change in both directives, PL and GPSD, should be made, reallocating the burden of safety control and risk detection among different actors through the definition of information networks¹¹⁹. This should occur by introducing default rules that design these safety-networks and leave parties free to reallocate the burden in a more hierarchical way, concentrating the burden on few specific actors with some constraints if they so wish.

¹¹⁷See art. 5.2 of GPSD: “Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements , in particular by not supplying products which they know or should have presumed, on the basis of information in their possession and as professionals, do not comply with those requirements”.

¹¹⁸See the speech of Commissioner for Consumer Protection Meglena Kuneva “Outcome of stocktaking review on consumer product safety”, of 22 November 2007 available at <http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/07/741&format=HTML&aged=0&language=EN&guiLanguage=en>

¹¹⁹On these questions beyond the specific issue of product safety see. C. Sabel, ‘A real time revolution in routines’, in C. Heckscher and P. Adler, *The firm as a collaborative community*, OUP, 2006.p.00

The freedom to use contracts in order to distribute burdens among parties should not lower the level of safety for the final consumers. Standards related to the network should thus be defined when the network form is adopted. These standards, which may include joint and several liabilities, should identify minimum rules that parties can specify through contracting.

To summarise the general principle should define the safety and information duties while default rules can design the means to organise network forms tailored to different business models. The current stress on producers can be left in the text of the directive, but the artificial hierarchical model, implicitly stemming from the current text, should be corrected by introducing a more generalised horizontal network model including distributors and reflecting the different business forms of industrial chains. A default rule should introduce the concept of safety network to allocate contractually the control and information, leaving the enterprises belonging to the network the power to allocate the costs of detecting and controlling the risks. Participation to the product safety network will be defined by the structure of the chain and the contractual links among enterprises related to the product circulated in the market. The boundaries will thus be designed according to the product and the process of production and distribution.

The advantages of the network model primarily concern the possibility to define incentives along the chain to produce and transfer information about product related risks instead of placing the entire burden on the producer regardless of the real allocation of decision making power. The current allocation, on the one hand, does not descriptively represent many current modes of allocating decision-making power; on the other hand, it may not efficiently allocate incentives to generate new information and to detect new risks to effectively protect consumers.

5. Concluding Remarks

This essay has dealt with product safety and liability, looking in particular at the interaction between regulation, contract and civil liability. The main aim has been to suggest that risk definition, assessment and management in product safety has changed in the last 20 years and that a well recognised role is played by private actors both in standard setting, in monitoring and risk management concerning post sale duties. Post-market surveillance has become a crucial part of the risk management strategies but the regulatory dimension has not been sufficiently linked with that of governance.

In the first part I have examined the current review of product safety at EU level with the proposed regulation on market surveillance and its relationship with the broader debate concerning better regulation.

In the second part, I have showed the increasing contractualisation of standard-setting concerning safety and product defectiveness, which influences both regulation and civil liability systems. In both cases, however, insufficient attention has been given to the implications of such a contractualisation for liability standards. Two sets of issues have been underlined:

- 1) the lack of accountability of private regulators when defining technical and non-technical standards and the difficulty to subject this activity to the scrutiny of judicial review.
- 2) The complementarity of regulation and liability is often not well designed. It is unclear when the standards are defined by private bodies how they should affect the definition of defect or when that of negligence and/or strict liability is not applicable.

Standard-setting may have different functions in the two fields due to institutional complementarity. However often this differentiation is not well designed and it only emerges in its quantitative dimension: regulation defines minimum standards, liability may increase the standard, mainly for the purpose of compensating the victims.

I then moved to information duties in product safety and product liability and claimed that business models of the supply and distribution chain may be affected by the regulatory design concerning product safety. I contented that a reform of GPSD and PLM directives should promote the creation of more structured information networks, aimed at making information production and transmission concerning product safety more effective. Enterprises should be constrained by the safety goals, but they should enjoy discretion in choosing organisational models that best fit with their business models. In particular the distinction between hierarchical and horizontal networks should be fruitfully employed to design default rules organising the information safety network. This would be particularly important for pan-European networks which have to coordinate enterprises operating in different legal systems with different institutional frameworks. I propose to introduce default rules concerning information networks that parties can adjust to their specific business models.

In this essay I have showed that private law and regulation interplay in the field of product safety. Not only it happens between administrative regulation and civil liability, as it has long been recognised, but also with contract law, given the increasing contractualization of standard-setting and the necessity to build contractual networks to implement monitoring of product safety in modern market economies. These examples suggest that the current approach to harmonisation of European Private Law is limited and does not reflect the necessity to coordinate different instruments to pursue unitary policy objectives: producing higher and more effective product safety in Europe at reasonable costs.