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**A Coordinated Approach to Regulation and Civil Liability  
in European Law: Rethinking Institutional Complementarities\***

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## 1. Civil liability, regulation and the transformations of the regulatory state

Civil liability is a much older regulatory device than administrative regulation. The emergence of a regulatory state is a relatively new phenomenon.<sup>2</sup> Within regulatory States different modes of regulation and administrative tools have developed, including the extensive use of private law.<sup>3</sup>

The relationship between civil liability and regulation as devices for risk assessment and risk management has been extensively explored.<sup>4</sup> But new developments in both strategies suggest the need to reconsider their interaction in the light of the European framework of legal integration. Historically there have been different modes of interaction between civil liability and administrative regulation.<sup>5</sup> In the last part of the nineteenth century and the first part of the twentieth, the

<sup>2</sup> See on the subject J. Jordana, D. Levi Faur, and E. Elgar (eds.), *The Politics of Regulation: Institution and Regulatory Reforms for the Age of Governance* (2004), at 145 ff.; P. Rosanvallon, *Le modèle politique français* (2004); the essays in 'La Regulation, Nouveaux modes? Nouveaux territoires?', 109 *Revue française d'administration publique* (2004); F. Roche (ed.), *Règles et pouvoirs dans les systèmes de régulation* (2004) and *Regulations économiques: légitimité et efficacité* (2004); Glaeser and Schleifer, 'The Rise of the Regulatory State' [2003] *J Economic Literature* 401; Taggart, 'The Nature and the Functions of the State', in P. Cane and M. Tushnet (eds.), *The Oxford Handbook of Legal Studies* (2003), at 101; Majone, 'The Regulatory State and its Legitimacy Problems', 22 *West European Politics* (1999) 1; A. Dixit, *The Making of Economic Policy – A Transaction-cost Politics Perspective* (1997); Majone, 'From the Positive to the Regulatory State. Cases and Consequences of Changes in the Mode of Governance', 17 *J Public Policy* (1997) 139.

<sup>3</sup> In relation to the US, see Stewart, 'The Reformation of American Administrative Law', 88 *Harvard LR* (1975) 1667 and 'Administrative Law in the Twenty-first Century', 78 *NYU LR* (2003) 437 ff. In the latter article Stewart points out the two concurring functions of administrative law: negative and affirmative. The negative function serves 'to prevent unlawful or arbitrary administrative exercise of coercive power against private persons'. As to the affirmative tasks Stewart states: 'through new procedural requirements and approaches to judicial review, it ensures that regulatory agencies exercise their policy making discretion in a manner that is reasoned and responsive to the wide range of social and economic interests affected by their decisions, including both the beneficiaries of regulatory programs and those subject to regulatory controls and decisions'. In relation to the Italian system see Cassese, 'Tendenze e problemi del diritto amministrativo' [2004] *Rivista Trimestrale Diritto Pubblico* 901. As far as the French system is concerned see P.-L. Frier, *Précis de droit administrative* (2001), in particular at 280-284. Frier, describing the ways in which administrative powers are exerted, highlights the specificities belonging to different types of administrative intervention by means of 'actes de droit privé'. Accordingly, public entities ('*les personnes publiques*') may operate outside their strict *puissance publique*, either in the framework of so defined '*gestion privée*' or in the framework of their *puissance privée*. Frier holds that '*depuis une vingtaine d'années, un nombre de plus en plus important des décisions prises en cette matière sont administratives, car elles expérimentent la puissance publique, qu'elles en réglementent l'usage général, ou qu'elles soient détachables de sa gestion même. Si les actes relatifs à l'organisation des services publics industriels et commerciaux, sont toujours de nature administratives, ceux, individuels, de gestion son de droit privé, même si leur auteur est une personne publique*'. The implied criteria used to draw such distinctions are those set out in extensive case law. The analysis of contractual phenomena in relation to public administration is carried out at 323-338. See also R. Chapus, *Droit Administratif Général*, (2000); L. Venezia and Y. Gaudemet, *Traité de droit administrative* (1994), i.. In relation to the English system see P. Craig, *Administrative Law* (5<sup>th</sup> edn., 2003).

<sup>4</sup> Among the vast and ever growing literature, see G. Calabresi, *The Costs of Accidents* (1970); J. Stapleton, *Disease and the Compensation Debate* (1986); D. Sugarman, *Doing Away with Personal Injury Law* (1989); P. Schuck (ed.), *Tort Law and the Public Interest: Competition, Innovation, and Consumer Welfare* (1991); Stapleton, 'Tort, Insurance and Ideology', 60 *MLR* (1995), 820; P. Atiyah, *The Damages Lottery* (1997); Cane, *The anatomy of tort law*, Oxford, Hart, 1997, Cane, *Atiyah's Accidents Compensation and the Law* (1999); M. Franklin and R. Rabin, *Torts and its Alternatives* (7<sup>th</sup> edn., 2001); C. Harlow, *State Liability, Tort and Beyond* (2004).

<sup>5</sup> The relationship varies quite significantly according to the function of administrative law and of civil liability in each legal system. For example the development of administrative law, and in particular of judicial review, in the US was a response to the weaknesses of tort law as a control mechanism of agencies created to regulate industrial accidents. See S. Stewart, *Administrative Law in the Twenty-first Century*, *supra* n. 2, at 439. In the US system Stewart enucleates five different approaches which characterized as many stages in the development of administrative action in the US; Stewart also notes that at present the last four paradigms are still used and that they can be seen as complementary: '[t]he tort and adjudicatory-hearing models will continue to be used to redress unlawful administrative impositions on specific persons. Analytic management of regulation and interest representation will continue to be used to structure and review agencies' exercise of discretionary lawmaking powers. The latter two systems operate in parallel and

emergence of regulation, and in particular that of welfare regulation, was primarily due to significant limits of compensation. These shortcomings were associated with the internal structure of civil liability and the weaknesses of other branches of private law, especially contract and labour law.<sup>6</sup> Worker compensation regimes for industrial accidents are only one example of an emerging body of legislation stimulated by the combined weaknesses of civil liability and labour law. While the causes of the development of administrative regulation are multiple, it is quite clear that in that context (the limits of) civil liability triggered welfare regulation.<sup>7</sup>

More recent cases in the area of mass torts have offered other examples of regulatory intervention caused by the inability of civil liability to provide for victims' adequate compensation.<sup>8</sup> In some contexts the main problem was related to the requirements of civil liability (in particular to the difficulty of proving causal link or to the limited range of available remedies) that undermined

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largely independently', at 444. A different development is that in continental Europe where administrative law developed as a device to express State authority over citizens. On this development see Cassese, *supra* n. 2, where he also notes that under the current circumstances of globalization we are facing a 'gradual convergence' of national administrative law systems: phenomena of convergence are mainly seen in a common set of institutions concerning independent agencies, regulation, privatizations, individual access, and participation in administrative proceedings and judicial review of administrative action.

<sup>6</sup> See for different accounts focusing on the US M. Horwitz, *The Transformation of American Law, 1870-1960. The Crisis of Legal Orthodoxy* (1992); C. Friedman, *Law in America, A Short History* (2004), at 125 ff.; Glaeser and Schleifer, *supra* n. 3; Jordana et al., *supra* n. 1. For the English model see Craig, *supra* n.2; C. Parker, C. Scott, N. Lacey, and J. Braithwaite, *Regulating Law* (2004); Cane, *supra* n. 3. For the French model see M. Fabre Magnan, *Les obligations* (2004), at 635 ff., G. Viney, *La responsabilité civile* (1995).

<sup>7</sup> On the complementarity of social security to tort law in general, see B.S. Markesinis, *The German Law of Obligations, vol. II, The Law of Torts: A Comparative Introduction* (1997), at 895, and Zweigert and Kötz, *Introduction to Comparative Law* (1998), at 463. See also on the topic Howarth, 'Three Forms of Responsibility: On the Relationship between Tort Law and the Welfare State', 60 *Cambridge LJ* (2001) 553. Welfare regulation, e.g. through the setting up of governmental insurance schemes, in Nordic countries was seen as a more efficient compensatory device than compensation through liability regimes, because it was seen as providing equal compensation for all injured parties and reallocating risk more evenly than in the case of civil liability. The welfare regulation approach was an acknowledged choice, however, now diminishing in importance. About Nordic welfare state and liability see T. Wilhelmsson and H. Samuli (eds.), *From Dissonance to Sense: Welfare State Expectations, Privatisation and Private Law* (1999). On the relationship between tort regulation and social security see also W. Van Gerven, J. Lever, and P. Larouche, *Tort Law* (2000), at 18-32. As regards the Italian system, see also C. Salvi, *La responsabilità civile* (1998); see also P.G. Monateri, *La responsabilità civile, Torino*, in Trattato di diritto civile diretto da R. Sacco, (1998), Alpa, G., *La responsabilità civile*, in Trattato di diritto civile, Milano, 1999. As regards the German system, see B.S. Markesinis and U. Unberath *The German Law of Torts. A Comparative Treatise* (4<sup>th</sup> edn., 2002), at 724-730.

<sup>8</sup> Asbestos and tobacco constitute interesting case studies. See Sugarman, 'Precise Justice and Rough Justice: Scientific Causation in Civil Litigation as Compared with Administrative Compensation Plans and Mass Tort Settlements', in G. Comandè and G. Ponzanelli, *Scienza e diritto nel prisma del diritto comparato* (2004). For the English system I refer to the well known case of *Fairchild v Glenhaven Funeral Services Ltd* [2002] UKHL 22, [2002] 3 WLR 89. See Weir, 'Making it More Likely v. Making it Happen', 61 *CLJ* (2002) 519. As far as the Italian system is concerned two different approaches have been put forward in literature. Civil liability has been perceived as a device performing mainly deterrent and regulatory functions by Ponzanelli, 'Mass Tort nel diritto italiano', [1994] *Responsabilità civile* 173. *Contra* the opinion that burdens of stricter liability could be imposed as pure regulatory devices: see Cafaggi, 'Immunità per i produttori di sigarette: barriere culturali e pregiudizi di una giurisprudenza debole', in [1997] *Danno e Responsabilità* 750, comment on a judgment of the Lower Court of Rome, 4 Apr. 1997, now reversed in 2005 by the Court of Appeal of Rome, which has recognized the right to recovery of the relatives of a smoker who died of lung cancer. Asbestos mass tort cases deeply influenced tobacco litigation. On the tobacco litigation in the US and its implications for the goals of the tort system see Rabin, 'The Third Wave of Tobacco Litigation', in R. Rabin and S. Sugarman (eds.), *Regulating Tobacco* (2001), at 176-206. As highlighted by Rabin, the first step of the new trend in tobacco litigation is marked by the well-known case *Castano v American Tobacco Co.*, 160 FRD 544, revised 84 F 3d 734 (5<sup>th</sup> Cir.1996). Concerning regulatory functions performed by tobacco litigation and arguing for the need for complementing torts devices with control strategies, Rabin observes that '[a]t no time, however, have litigation-associated costs operated as a rational scheme, from a regulatory perspective, in affecting the demand for the product'; at 200. For a detailed comparative assessment of the asbestos mass tort cases in the US and Europe from an economic standpoint, see White, 'Asbestos and the Future of Mass Torts', NBER Working paper n.10308 (2004), especially at 12. White illustrates continuous shifts in the balance between regulatory measures and civil liability rules facing asbestos litigation. See also J. Weinstein, *Individual Justice in Mass Tort Litigation: the Effect of Class Actions, Consolidations, and Other Multiparty Devices* (1995); and C. Scott and J. Black, *Cranston's Consumer and the Law* (2000), at 122.

the chance of receiving compensation.<sup>9</sup> In other cases the potentially unequal compensation within a relatively homogeneous group of victims, due to the particular features of adjudication, has suggested the adoption of regulatory schemes.<sup>10</sup> These areas extend from asbestos to tobacco, from vaccines to infected blood, from adulterated or poisoned food to drugs.

It should be noted that these ‘administrative’ alternatives have mainly emerged in relation to the compensatory functions. The boundaries of and the interaction between civil liability and regulation in relation to deterrence are much more subtle.

A somewhat different phenomenon has arisen more recently with de-regulation and the reduction of the resources and operations of the welfare state.<sup>11</sup> In many areas de-regulation, which occurred in the 1980s, has imposed greater burdens on civil liability from both a deterrence and a compensation perspective. The response in different legal systems has not been homogeneous, but the expansion of strict liability, that of available remedies, primarily economic losses, and the increased level of compensation for personal injury can be interpreted as a consequence of the new regulatory functions, perhaps unintentionally attributed to civil liability by states’ legal systems.<sup>12</sup>

It should be emphasized, however, that in many cases de-regulation has translated into a change of regulatory techniques more than the abandonment of regulation altogether.<sup>13</sup> The relevant question is related to the impact of these regulatory changes on the structure and the performance of civil liability. For example, how has the shift from command and control to responsive or market-based regulation affected standards of conduct or remedies in civil liability?

In relation to economic losses the role of civil liability has expanded to correct market failures (particularly asymmetric information in financial markets, professional malpractice).<sup>14</sup> In relation to personal injuries civil liability has provided responses both to market failures, particularly externalities, and to the reduction of welfare measures due to the fiscal crisis of the welfare state that began in early 1970s.

The current legal and institutional landscape is characterized by the coexistence of civil liability and administrative regulation in many fields in order to perform both deterrent and compensatory functions: from financial markets to privacy, from product safety to environmental protection, from professional malpractice to road traffic accidents. Modes of interaction within

<sup>9</sup> See in the American system Franklin and Rabin, *supra* n. 3, at 785 ff. In the English system see S. Deakin, A. Johnston, and B.S. Markesinis, *Markesinis and Deakin’s Tort Law* (6<sup>th</sup> edn., 2003). In the French system see Fabre Magnan, *supra* n. 5, at 637, and before J. Viney, *Vers la construction d’un droit européen de la responsabilité civile : les apports possibles du droit français* (1986). In the Italian system see G. Comandè, *Risarcimento del danno alla persona e alternative istituzionali: studio di diritto comparato* (1999).

<sup>10</sup> Typically this has occurred in motor accident compensation. In the French system an example is provided by the structure of the Loi Badinter, Van Gerven et al., *supra* n.6, at 587; J. Viney and M. Jourdain, *Traité de droit civil – Les conditions de la responsabilité*, (1995), at 1089 ff, Fabre Magnan, *supra* n. 5, at 800 ff. The application of a similar regulatory pattern was made in Italy in the case of personal injuries derived from compulsory vaccination: see G. Ponzanelli, *La responsabilità civile: profili di diritto comparato* (1992). Yet, for schizophrenic regulatory responses to related problems arising in the field of personal injuries and the National Health system, see a recent judgment released by the Italian Constitutional Court in the case of a person who contracted HIV by being exposed to the virus as a consequence of blood transfusion: Corte Costituzionale, 22 June 2000, n.226, annotated in [2001] I *Foro Italiano* 5. For a broader and more recent comparative view, see also Sugarman, ‘Precise Justice and Rough Justice: Scientific Causation in Civil Litigation as Compared with Administrative Compensation Plans and Mass Tort Settlements’, in Comandè and Ponzanelli, *supra* n.7.

<sup>11</sup> See Harlow, *supra* n. 3; C. Allcock et al., *Social Policy* (2000); D. Fraser, *The Evolution of the British Welfare State* (3<sup>rd</sup> edn., 2003).

<sup>12</sup> The expansion of regulatory functions of civil liability concern both deterrence and regulation.

<sup>13</sup> See, e.g., Picciotto, ‘Introduction: Reconceptualizing Regulation in the Era of Globalization’, 29 *J L and Society*, ‘New Directions in Regulatory Theory’, *Special Issue* (2002) 1.

<sup>14</sup> For a comparative analysis see M. Bussani and E. Palmer, *Pure Economic loss in Europe* (2003), and ‘The Frontier between Contractual and Tortious Liability in Europe: Insights from the Case of Compensation for Pure Economic Loss’, in Hartkamp, Hesselink, and Hondius et al., *Towards a European Civil Code* (2004), at 697 ff. On this issue, see earlier P. Cane, *Tort Law and Economic Interests* (1991). Cane distinguishes among four different types of economic losses that may occur in relation to interference with or invasion of economic interests: reduction of the value of existing assets; interruption of a stream of income; failure to realize or obtain some increase in one’s asset; and, finally, accretion of the defendant’s assets. See also Cane, ‘Contract, Tort and Economic Loss’, in M. Furmston (ed.), *The Law of Tort* (1986).

these fields illustrate the relative functional complementarity between administrative regulation and civil liability. In the first case the limits of civil liability did not ensure sufficient protection to workers and victims of road traffic accidents, thence stimulating the creation of regulatory schemes, primarily aimed at compensation. In the second case de-regulation has decreased the level of protection and forced civil liability to expand its boundaries to protect old and new victims. Civil liability and administrative regulations have often operated as complements, one covering the weaknesses of the other.

## **2. The relationship between regulation and civil liability in the framework of European integration.**

In this essay I will concentrate on European product safety and, to a lesser extent, on European environmental protection to examine their interaction and its consequences on the institutional design. My thesis is that civil liability and regulation are functional complements and not necessarily functional equivalents. In fact they often reflect different approaches to individual and collective responsibilities associated with the harmful consequences of unlawful conduct. I shall test this hypothesis in the light of recent regulatory changes which have occurred at European level.

The changes taking place in the area of regulation of product safety and environmental protection have been rather significant. They are related to both actors and techniques. The presence of private regulators setting technical standards has always been an important feature of product safety regulation.<sup>15</sup> The emergence of self-regulation and private regulators in the area of environmental law is, however, relatively newer.

Together with private bodies devoted to technical standardization, a plethora of other private actors today populate the regulatory space, giving rise to different forms of regulation: from self-regulation, to delegated regulation, to co-regulation.<sup>16</sup> These changes require the term 'regulation' to be given a broader meaning, to encompass private and public regulation and different forms of co-regulation.<sup>17</sup> The new role of private regulators in the fields of products and environmental liability, however, poses new challenges and questions in relation to different areas, but primarily for civil liability regimes and remedies.<sup>18</sup>

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<sup>15</sup> Developments concerning the role of private regulators are discussed by Ladeur who examines desirable forms of cooperation between private and public actors in the decision-making processes. See Ladeur, 'The Introduction of the Precautionary Principle into EU Law : a Pyrrhic Victory for Environmental and Public Health Law ? Decision making under Conditions of Complexity in Multi-level Political Systems', 40 *CML Rev* (2003) 1462. For a detailed recognition of normative background and implementation of private governance in relation to standard-setting focusing on product safety, see H. Schepel, *The Constitution of Private Governance. Product Standards in the Regulation of Integrating Markets*, PhD Thesis, EUI, Florence, 2003. A detailed analysis of standard-setting activities performed either by private actors, or by institutional actors is carried out in M. Egan, *Constructing a European Market* (2001) and E. Vos, *Institutional Frameworks of Community Health and Safety Regulation. Committees, Agencies and Private Bodies* (1999).

<sup>16</sup> Examples of legislative delegation of standard-setting powers are frequent. See Annex II ('The model Directive'), Council resolution on a new approach to technical harmonization and standards, OJ 1985 I/136/1. For a wider-ranging perspective on the issue see 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) 23. See G. Majone, Strategy and structure the political economy of agency independence and accountability, paper presented at OECD Meeting, London, January 10-11, 2005 available at [www.oecd.org](http://www.oecd.org).

<sup>17</sup> Black has re-defined regulation as a sustained and focused attempt to alter the behaviour of a subject according to identified purposes with the intention of producing a broadly identified outcome or outcomes. This process may involve functions of standard-setting, information-gathering, and behaviour modification: Black, 'Regulatory Conversations', 29 *J L and Society* (2002) 163, at 170. See also Scott, 'Regulation in the Age of Governance: The Rise of the Post Regulatory State', in J. Jordana et al., *supra* n. 1, at 145-174.

<sup>18</sup> Some of the challenges to contract law have been examined elsewhere. See Cafaggi, 'Gouvernance et responsabilité des régulateurs privés', *Revue Internationale de Droit Economique* (2005) 323; and *Self-regulation and European Contract Law* (forthcoming).

The relationship between civil liability and regulation cannot be analysed without reconsidering the profound internal changes that have taken place in each area.

Internal changes in regulatory techniques have been significant, moving from command and control to cooperative or incentive-based regulation.<sup>19</sup> Less visible but equally important modifications have also affected the evolution of civil liability.<sup>20</sup> The models of regulation have been modified at national and European level, although often not at the same pace. Parallel, though not necessarily symmetrical, changes have occurred on the other side of the Atlantic.<sup>21</sup>

Legislative style has also changed: EU institutions have moved from very detailed towards principle-based legislation. The new approach to standardization is only the epiphenomenon of a more diffuse change.<sup>22</sup> The use of responsive and market-based regulation in the field of environmental liability has increased significantly.<sup>23</sup> The promotion of environmental agreements has been an important example of 'regulated' self-regulation.<sup>24</sup>

These changes have been determined, among other factors, by: (1) the need to increase compliance while reducing the costs of monitoring, and (2) the need to foster innovation while regulating product safety and environmental protection.<sup>25</sup> Clearly, while these strategies can be

<sup>19</sup> See Stewart, 'The Importance of Law and Economics for European Environmental Law' [2002] *Yearbook of European Environmental Law* 1, at 9 ff. Stewart underlines changes in relation to both the USA and Europe. He points out that moves away from command and control have been quite relevant in the US, while European systems have evolved into 'negotiated command and control'. For a relatively different conclusion in relation to environmental law see Betlem, 'Environmental Liability and Private Enforcement of Community Law', in Hartkamp *et al.*, *supra* n. 13, at 677 ff: 'it is nevertheless true that environmental law is and is likely to remain clearly dominated by regulatory command and control regimes with tort or delict as most junior partner'.

<sup>20</sup> 'Internal' simply means that they have occurred in civil liability and regulation, but it does not imply that these changes have not been stimulated by the interaction of the two. Examples may be provided by the causation principle in civil liability.

<sup>21</sup> Stewart, *Administrative Law*, *supra* n. 2, at 448. According to Stewart, '[t]he answer lies in the adoption of new regulatory methods and instruments to ease the problems created by over-reliance on centralized command and control methods. Two such new methods are emerging in regulatory practice. They are government-stakeholder network structures and economic incentive systems'. Moreover he states that: '[r]ather than attempting to dictate unilaterally the conduct of the regulated, regulatory agencies have developed a number of strategies to enlist a variety of governmental and nongovernmental actors, including business firms and non-profit organizations, in the formulation and implementation of regulatory policy. Here are some examples: agency-supervised regulatory negotiation among representatives from industry, public interest, and state and local government to reach consensus on new agency regulations outside the formal administrative law rulemaking processes; cooperative arrangements involving governmental and non governmental entities in delivering families service or administering Medicare; and negotiation, in the draconian shadow of the Endangered Species Act, of regional habitat conservation plans by federal natural resource management agencies, private landowners, developers and state and local governments. In these examples, federal agencies are active, often dominant partners in the process and the result is a quasi contractual working relationship among the participants to solve regulatory problems on a coordinated basis. Rather than centralized mass-production, this methodology embraces a post-industrial strategy for producing regulation. Its watchwords are flexibility, innovation, benchmarking, transparency and performance measures, and mutual learning by doing. In the European Union this approach is being widely used under the title of the Common method of coordination'.

<sup>22</sup> See Council Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, OJ 1998 L 204/37.

<sup>23</sup> For the European experience see M. Faure (ed.), *Deterrence, Insurability, and Compensation in Environmental Liability* (2003), at 37 ff., 39 ff.; Betlem, 'Environmental Liability and Private Enforcement of Community Law', in Hartkamp *et al.*, *supra* n. 11, at 677 ff. For the US experience see R. Revesz, *Environmental Law and Policy* (2<sup>nd</sup> edn., 2000); Stewart, 'A New Generation of Environmental Regulation', 29 *Capital University LR* (2001) 21. In general see N. Cunningham and P. Grabonsky, *Smart Regulation: Designing Environmental Policy* (1998).

<sup>24</sup> See Communication from the Commission to the Council and European Parliament on Environmental Agreements, COM(96)561, 27 Nov. 1996. Voluntary and environmental agreements are widely used throughout Europe, especially in the Netherlands, Germany, Great Britain, and Denmark. There are also agreements at a Community level. The Netherlands, where in the majority of cases environmental targets are met through (legally binding) environmental agreements, appear to have the most mature system. In Europe voluntary and environmental agreements are used mainly in the area of waste management and for reduction of greenhouse gases.

<sup>25</sup> Standard-setting, both in product safety and environmental protection, should not be conceived as an obstacle to innovation but, if adequately designed, as a vehicle to promote innovation. This is the core criticism of command and control regulation that generally can at best ensure the adoption of existing technologies and does not provide incentives to innovate. See, in the American context, Stewart, *The Importance*, *supra* n. 18, at 11. See also Revesz,

contextually analysed as responses to failures of command and control, they are based on very different premises and they can combine with civil liability in radically different ways<sup>26</sup>.

Civil liability has also changed. We have witnessed different phenomena: (1) the increasing expansion of strict liability in areas where fault used to be the principle. Product liability and environmental protection provide good examples;<sup>27</sup> (2) the erosion by civil liability of areas covered primarily by disciplinary mechanisms, such as professional malpractice, illustrates phenomena of ‘publicization’ of functions and relationships that used to belong to private spheres; what previously had been an internal disciplinary matter for the profession has today become the object of judicial scrutiny; (3) finally the (potential) shift from tortious to contractual liability by reason of the use of self-regulation is an important change.<sup>28</sup>

The justifications for imposing liability have changed accordingly. The boundaries between individual and collective responsibilities do not overlap with those of civil liability and regulation. Civil liability can no longer be considered the domain of individual responsibility, while regulation remains more strongly correlated with collective responsibility.

An inquiry into the modes of interaction between regulation and civil liability therefore becomes very relevant to evaluating the effectiveness of the European strategy in the fields of product safety and environmental protection. To the extent that regulation has increasingly provided new standards for examining the conduct of potential injurers, the corresponding modifications in civil liability have proved significant for the definition of standards in negligence and strict liability. But the influence of regulation in the field of civil liability is and can be profound, judging from recent developments in the content and structure of remedies in relation to violations of environmental and product standards.

### 3. Liability and regulation in product safety and environmental protection: functional complements or alternatives?

Risk control associated with product safety and environmental protection is generally managed by considering the regulatory and liability approaches separately. Each strategy can be based on regulation, encompassing private and administrative types and different forms of co-

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*supra* n. 22. In the European context see Spindler, ‘Market Process, Standardisation, and Tort Law’, 4 *ELJ* (1998) 316; Monti, ‘Environmental risk: a comparative law and economics approach to liability and insurance’, [2001] *European Review of Private Law* (2001) 51; Faure, *supra* n. 22.

<sup>26</sup> For a short yet very effective comparison of network regulatory strategy and economic incentives strategies see Stewart, *supra* n. 2, at 451-452.

<sup>27</sup> A clear example of such a trend is provided by the well known English case, *A and others v National Blood Authority* [2001] 3 All ER 289, especially at paras. 50, 74-77. Reference is to be made also to the French system, where even if from a purely normative viewpoint plaintiffs are required to give evidence of the defendants’ fault, such a requirement has been progressively emptied of its content. Furthermore, this development of the French system took place long before the implementation of the Product Liability Directive, thus proving the ‘internal’ nature of the described change. See J.-S. Borghetti, *La responsabilité du fait des produits. Étude de droit comparé* (2004), at 208 ff. and 518 ff. and reference to relevant case law there contained. For a description in terms of policy of the alternative between strict liability and fault see respectively the White Paper on Environmental Liability (COM(2000)66 final), and the Green Paper on Product Liability (COM(1999)396 final). The White Paper states ‘[s]trict liability means that fault of the actor need not be established, only the fact that the act (or the omission) caused the damage. At first sight, fault-based liability may seem more economically efficient than strict liability, since incentives towards abatement costs do not exceed the benefits from reduced emissions. However, recent national and international environmental liability regimes tend to be based on the principle of strict liability, because of the assumption that environmental objectives are better reached that way’. See for the product context Reimann, ‘Product Liability in Global Context: the Hollow Victory of the European Model’ [2003] *ERPL* 132.

<sup>28</sup> See on this issue F. Cafaggi, *Contractualizing Standard Setting in Civil Liability?* (unpublished manuscript on file with the author).



regulation, and on liability, generally extra-contractual. Sometimes, however, contractual liability is employed as a result of the development of self-regulation.<sup>29</sup>

What is the relationship between regulation and civil liability at European and national level for controlling and managing these risks? To what extent is there complementarity between them? Or do civil liability and regulation operate as alternatives? In the area of product safety the differences are quite significant. The liability regime tends to be all-inclusive.<sup>30</sup> After 1999 agricultural products were integrated into the liability system. On the other hand the regulatory regime defined by the General Product Safety Directive (hereinafter GPS Directive)<sup>31</sup> is under-inclusive. The scope of the GPS Directive is residual.<sup>32</sup> It applies only to products not regulated by other directives, and in this case it provides only for matters not included in the specific directives.<sup>33</sup> Drugs, cars, and toys constitute other relevant areas of sector regulation. Food is perhaps the most prominent case. Within this area E.C. Regulation 178/2002 has established a different regulatory regime for food safety from that in the GPS Directive.<sup>34</sup> Until 2002 both directives could be

<sup>29</sup> Contractual liability operates when potential injurers have undertaken obligations to act or not to act within the framework of a code of conduct. These obligations are often directed towards third parties although they are not necessarily enforceable by them. An example of this trends may be seen in *Lloyds TSB General Insurance Holdings Ltd and others v Lloyds Bank Group Insurance Company Ltd; Abbey National plc v Lee and others* [2001] EWCA Civ 1643, [2002] 1 All ER (Comm) 42, [2002] Lloyd's Rep IR 11. In particular, as regards the last judgment, Longmore LJ at para. 56 states: 'I agree that the appeal should be dismissed. The liability of the claimants arises from the fact that their representatives failed to give 'Best Advice' pursuant to the Lautro code. As my Lord explains, that is a personal not a vicarious liability; it is also a liability that does not depend on negligence or any breach of duty of care. Once it is established that "Best Advice" has not been given, liability is automatic. The failure to give "Best Advice" was a breach of the provisions of the Financial Services Act 1986 or the Lautro rules and constitutes the relevant act or omission for the purposes of (a) the definition of that term contained in para 2 of the endorsement to section 3 of the policy and (b) the deductible clause in condition 2 of the same section.' The case in point also dealt with the problem of enforceability of such obligations by third parties, applying in point the aggregate clause doctrine.

<sup>30</sup> See 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 1985 L 210/29 (hereinafter PL Directive), Art. 1, and Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ 1999 L 141/20.

<sup>31</sup> Directive 2001/95/EC of The European Parliament and of the Council of December 2001 on general product safety (hereinafter the GPS Directive), OJ 2001 L 11/04.

<sup>32</sup> See recitals 11, 12, and 13 of the GPS Directive, *supra* n. 30: '(11) In the absence of more specific provisions within the framework of community legislation covering safety of the products concerned all the provisions of this directive should apply in order to ensure consumer health and safety.

(12) If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply only to the other risk

(13) The provisions of this directive relating to the other obligations of producers and distributors, the obligations and powers of members states, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations.'

<sup>33</sup> See Art. 1(2) of the GPS Directive, *supra* n. 30: 'This directive shall apply to all products defined in article 2(a). Each of its provisions shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned.

Where products are subject to specific safety requirements imposed by Community legislation, this Directive shall apply only to aspects and risks or categories of risks not covered by those requirements. This means that:

(a) Articles 2(b) and (c) 3,4, shall not apply to those products insofar as concerns risks or categories of risks not covered by the specific legislation;

(b) Articles 5 to 18 shall apply except where there are specific provisions governing the aspects covered by the said articles with the same objectives'.

On the relationship between the GPS Directive and sector directives see also Guidance Document on the Relationship between the GPSD and Certain Sector Directives, available at

[http://europa.eu.int/comm/consumers/cons\\_safe/prod\\_safe/DGSP/reviseDGSP-en.htm](http://europa.eu.int/comm/consumers/cons_safe/prod_safe/DGSP/reviseDGSP-en.htm).

<sup>34</sup> Art. 21 of Regulation 178/2002/CE of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety states: '[t]he provisions of this Chapter shall be without prejudice to

considered as setting minimum harmonization standards; however after the ECJ's much-criticized judgments of 2002 the liability directive 374/85<sup>35</sup> (hereinafter PL Directive) should be considered as a total harmonization, while the GPS Directive continues to provide a minimum standard<sup>36</sup>. Treaty provisions concerning consumer protection also play an important role. In particular article 153 EC defines the goal of high level of consumer protection (1) and impose that consumer protection shall be taken into account in defining and implementing other community policy and activities (153, 2).

In the area of environmental protection the principles are defined by treaty provisions, and in particular the precautionary principle, the principle of prevention, the principle that environmental damage should be rectified at source, and the polluter pays principle (Article 174 EC).<sup>37</sup> However, an important principle that plays a much greater role in environmental liability is its horizontal effect on other European policies, among which is product safety (Article 6 EC). The Environmental Liability Directive has represented a further shift from civil liability to regulation.<sup>38</sup>

In the area of product safety coordination between the two strategies is absent or, at best, implicit.<sup>39</sup> No explicit signs of complementarity can be seen in the directives. The only stated clear principle of coordination in the field of product safety is that the regulatory directives (in particular EC Directive 01/95) cannot be interpreted as decreasing the level of consumer protection ensured by the PL Directive.<sup>40</sup>

A functional analysis, aimed at identifying current and potential complementarities between the two strategies (i.e regulation and liability), implies that they can be read as functional complements. Such complementarity, however, does not imply functional coincidence. The rationales that justify civil liability, in particular the justifications for holding injurers responsible for product-related injuries, are often different from those employed to hold the regulated responsible. For example in the case of civil liability the importance of human agency is highly relevant, and this has a bearing on causation. Causation does not play such a significant role in economic regulation, while in welfare it may not play any role at all.<sup>41</sup>

Starting from the general assumption that two main goals of civil liability are deterrence and compensation, functional complementarity can be tested by asking whether regulation on product safety and environmental protection can also promote deterrence and compensation. While it is well established that the function of regulation in this field is primarily to achieve deterrence, in the last twenty years there has been a proliferation of administrative schemes for regulating compensation for product- and environment-related injury by means of the setting up of either *ad hoc* or general purpose funds.<sup>42</sup> The conventional view that associates administrative regulation with deterrence and civil liability with compensation is therefore at least debatable.

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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'.

<sup>35</sup> PL Directive, *supra* n. 29, at 51.

<sup>36</sup> An account of discontinuities in food regulation at European level is provided by Chalmers, 'Food for Thought: Reconciling European Risks and Traditional Ways of Life', 66 *MLR* (2003).532. For an interesting account of recent developments of the ECJ's case law on food safety see Dabrowska, 'GM Foods, Risk Precaution and the Internal Market: Did Both Sides Win the Day in the Recent Judgement of the European Court of Justice?', 5 *German LJ* (2004) 151.

<sup>37</sup> See Kramer, 'Thirty Years of EC Environmental Law: Perspectives and Prospectives' [2002] *Yearbook of European Environmental Law* 155, at 162 ff.; Faure (ed.), *supra* n. 22.

<sup>38</sup> See Betlem, *supra* n. 18, at 677 ff., but with reference to the common position.

<sup>39</sup> Not only does coordination seem to be very weak but choices concerning liability and the regulatory strategies seem to diverge quite significantly. This however does not seem to be the result of a specific institutional design but more the outcome of different institutional approaches within both the Commission and each Member State.

<sup>40</sup> See Art.17 of the GPS Directive, *supra* n. 30: '[t]his Directive shall be without prejudice to the application of Directive 85/374/EEC'. See also Art. 18(3) in relation to criminal liability: '[a]ny decision taken by virtue of this directive and involving restrictions on the placing of a product on the market requiring its withdrawal or its recall shall be without prejudice to assessment of the liability of the party concerned in the light of the national criminal law applying in the case in question'.

<sup>41</sup> For a general analysis of causation link see Van Gerven *et al.*, *supra* n. 9, at 427, and B.S. Markesinis, *supra* n.6, at 103; on the functional selection of the person to be charged of the damages, see Atiyah, *supra* n. 8, at 480; and W. V. H. Rogers, *Winfield and Jolowicz on Tort* (1998), at 34.

<sup>42</sup> See Harlow, *supra* n. 3, at 46.

Several combinations can occur in theory:

- 1) Both administrative regulation and civil liability use tools to deter and compensate, but in different ways. For example, regulation preserves minimum standards of both deterrence and compensation, while civil liability operates to increase the levels of deterrence and compensation when certain conditions occur.
- 2) The deterrence and compensation functions are allocated to administrative regulation and civil liability respectively or, vice versa, administrative regulation can primarily serve compensation while civil liability, perhaps in association with criminal liability, promotes deterrence. Thus, within this strategy we can further differentiate between two types of combination.
  - a) Deterrence is mainly the province of regulation, while civil liability intervenes to compensate once violations have occurred and harms materialized.
  - b) Compensation is ensured by administrative schemes, generally no-fault-based insurance schemes, leaving deterrence to civil liability or even to criminal law.

We can therefore conclude that deterrence and compensation can in theory be pursued either through an integrated strategy (by combining civil liability and regulation) or by separating the two (regulation – deterrence, civil liability - compensation or the opposite regulation - compensation, civil liability - deterrence) and allocating a specific function to each domain within a coordinated framework.

To consider regulation and civil liability as functional complements implies the recognition of a ‘regulatory’ function for civil liability.<sup>43</sup> But is it feasible and desirable? The answer to this question should not be purely normative, but grounded in the specific features of civil liability systems. There may be some civil liability systems that emphasize their regulatory functions and others that do not. An important role in identifying the nature and level of regulatory functions played by civil liability is related to the institutional framework, and in particular to the function of the judiciary and its effectiveness.<sup>44</sup> If the possibility that civil liability may play a regulatory function is accepted, the theoretical question should then move to the different ways in which regulation and civil liability can regulate. As a matter of positive law there are differences in the regulatory functions of civil liability systems, yet, at a certain level of generality, it is possible to contend that every liability system has some regulatory function. Unfortunately no final choices have been made at the European level concerning either the regulatory function of civil liability in the field of product safety and environmental protection or which strategy should be used for which goals and how they should be combined.<sup>45</sup>

<sup>43</sup> 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 Calabresi, *supra* n. 3; Shavell, ‘Liability for Harm versus Regulation of Safety’, 13 *J Legal Studies* (1984) 357, ‘A Model of the Optimal Use of Liability and Safety Regulation’ [1984] *Rand J Econ* 271 ff., and *Economic Analysis of Accident Law* (1987); W. M. Landes and R. Posner, *The Economic Structure of Tort Law* (1987); Ackerman, ‘Tort Law in the Regulatory State’, in Schuck, *supra* n. 3, at 80 ff.; Faure, *supra* n. 22; S. Shavell, *Foundations of Economic Analysis of Law* (2004). This approach has also been endorsed by the socio-legal studies movement: see Collins, *Contract Law* (2004). Critiques of this approach are made by some tort scholars. See, e.g. Stapleton, ‘Regulating Torts’, in C. Parker et al., *supra* n.5, at 122 ff. For contributions concerning the relationship between tort and environmental regulation see Abraham, ‘The Relation between Civil Liability and Environmental Regulation: An Analytical Overview’, 41 *Washburn LJ* (2002) 379; Cane, ‘Tort Law as Regulation’, 31 *Common Law World Review* (2002) 305 and ‘Using Tort Law to Enforce Environmental Regulation?’, 41 *Washburn LJ* (2002) 427; Hylton, ‘When Should We Prefer Tort Law to Environmental Regulation?’, 41 *Washburn LJ* (2002) 515, .

<sup>44</sup> The same rules of negligence or strict liability may or may not play a regulatory function due to the role of the judiciary in the specific legal system.

<sup>45</sup> See Green Paper of 14 May 1993 on Remedying Environmental Damage, COM(93)47, at 11, para. 2, and Commission Green Paper of 28 July 1999: Liability for defective products, COM(1999)396 final, at para. 3.2. The explanation of this bias is based on the different sources (the general directorates respectively in charge) that have produced the two directives, although this justification is certainly part of the story, but it cannot be conclusive. See on the institutional questions Howell, ‘Product Liability. A History of Harmonisation’, in Hartkamp *et al.*, *supra* n. 13, at 645. The analysis that followed the Communication of the Commission concerning Europeanization of contract law has shown that inconsistencies may occur even among directives that are prepared by the same directorates. The question of coordination certainly has an institutional dimension that can be solved by ensuring duties to coordinate the text with directives already in place concerning related subjects, but it relates to substantive questions that should be carefully scrutinized.

Important evolutions, however, have recently been occurring. Integration between health and consumer policies should soon become a reality and a corresponding institutional framework be accordingly defined.<sup>46</sup>

Furthermore there are important signs that an integrated approach between product and service safety and also between product safety and environmental protection is needed.<sup>47</sup> Less strong is the emphasis on coordination between regulation and liability in the field of product safety.<sup>48</sup> In more general terms, a coordinated functional approach is advocated for consumer protection.<sup>49</sup> Such an approach should be endorsed not only in law-making but also in adjudication.<sup>50</sup>

It is important to note that the choice is constrained not only by internal factors concerning competences and general principles relating to the internal market, but also by 'external' sources such as international Conventions.<sup>51</sup>

The task of this essay is twofold:

- a) to show how the evolution of the regulatory system poses new challenges both to the civil liability system and to its interaction with regulation;
- b) to emphasize the importance of a new coordinated approach of liability and regulation to deter and to compensate for product- and environment-related injuries.

Following the (stereo)typical description of the regulatory process I will analyse in turn standard-setting, monitoring, and enforcement to show the lack of a coordinated approach and the need to pursue one. The analysis will concern only specific aspects, emphasizing issues related to complementarity in the light of new rules introduced by European legislation. The essay is primarily positive. I sketch out an agenda for normative suggestions in the conclusions.

It is important to emphasize that the different combinations of civil liability and regulation may be affected by the multi-level regulatory system in which they operate. For example, as is clear from the ECJ's *Munoz* case, standard-setting may occur at the European level and follow a specific 'regulatory' approach, while enforcement of the rule may occur at national level through the use of civil liability systems.<sup>52</sup> In national legal systems breach of Community regulations would be

<sup>46</sup> See Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of Regions, 'Healthier, Safer, More Confident Citizens: a Health and Consumer Protection Strategy. Proposal for a Decision of the European Parliament and of the Council Establishing a Programme of Community Action in the Field of Health and Consumer Protection 2007-2013', Brussels, 6 Apr. 2005, COM(2005)115 final. The Commission states clearly: '[t]his Communication and the attached programme proposal bring together Public Health and Consumer Protection policies and programmes under one framework to make EU Policy work better for citizens'. Such a task implies a new implementation device: '[t]o implement the Joint Health and Consumer Programme, the Commission will be assisted by one single executive agency, which will consist of an extended version of the existing Public Health Programme's executive agency encompassing the "Consumer Institute"'.

<sup>47</sup> See Temmink, 'From Danish Bottles to Danish Bees: The Dynamics of Free Movement of Goods and Environmental Protection- A Case Law Analysis', 1 *Yearbook of European Environmental Law* (2000) 61.

<sup>48</sup> For the product/service safety question, see Communication on the safety of service, Doc 10506/03 CONSOM 66 MI 143 (2003) and Council Resolution of 1 Dec. 2003 on safety of services for consumers, OJ 2003 C 299/01. For integration between product safety and environmental protection see the Communication from the Commission to the Council and the European Parliament, Integrated Product Policy (IPP), COM(2003)302 final, 18 June 2003, in particular at para. 2: 'product expertise is increasingly concentrated in the hands of those who are responsible for their design. It is very difficult for regulators, let alone the general public, to have any realistic idea of what technical changes are achievable. For this reason any product policy needs to ensure that producers and designers become more responsible for ensuring that their products fulfil agreed criteria on health, safety and the environment'.

<sup>49</sup> See Green Paper on Consumer Protection, COM(2001)531 final, 2 Oct. 2001.

<sup>50</sup> See Van Gerven, 'The ECJ Case-law as a Means of Unification of Private Law?', in A. Hartkamp *et al.*, *supra* n. 7, at 117, who advocates a less textual and more teleological interpretation by the ECJ: 'ECJ case law would surely be more effective from a viewpoint of coherent and uniform application, if the Court were to take the habit of dealing with consumer law litigation from a more comprehensive viewpoint, that is viewing any specific directive within the broader context of consumer legislation as a whole'.

<sup>51</sup> E.g., in the environmental protection field the choice or the combination between tort and regulation is also affected by international conventions, e.g. the Aarhus Convention.

<sup>52</sup> Case C-253/00, *Antonio Munoz y Cia, Superior Fruiticola SA v Frumar Ltd, Redbridge Produce Marketing Ltd* [2002] ECR I-7289, note by Biondi, 40 *CML Rev* (2003) 1241.

sanctioned under general civil liability law. Some differences exist in the ability to recover, particularly in England where breach of statutory law is still interpreted relatively narrowly.<sup>53</sup>

#### 4. Framing the questions: complementarity of standard-setting in civil liability and regulation? Which institutional consequences?

Standard-setting is the institutional activity through which levels (quantitative aspect) and types (qualitative aspect) of conduct of injurers and victims are determined. It affects the degree of safety concerning the 'level of protection' of potential victims, and influences the potential level of competition on safety that firms may engage in. The modes of standard-setting and instruments employed may be relevant for determining effects on firms' competition. While the relationship between competition and regulation has been widely explored, the possibility that standard-setting in civil liability may have pro- or anti-competitive effects has not been adequately considered. Though they are not the focus of this essay, the effects on the competitive structure of the market caused by the choice between civil liability and regulation will be emphasized.

First I will focus on the relationship between technical and legal standard-setting, and then outline different methods of standard-setting in regulation and civil liability, discussing the current modes of interaction and suggesting improvements in some areas. In the areas of product safety and environmental protection, in particular, the distinction between technical and normative standards is very relevant to the following questions:

- a) who should produce the standards?<sup>54</sup>
- b) how should the standards be generated?<sup>55</sup>

This distinction has had relevant consequences on the processes of harmonization of European product safety.<sup>56</sup> While the processes of Europeanization and internationalization of

<sup>53</sup> On the impact of *Munoz* see Betlem, *supra* n. 18, at 692 ff. For a comparative analysis of breach of statutory duty see Deakin et al., *supra* n. 8, at 358-373. See also Von Bar, *The Common European Law of Torts* (2000). See also D. Fairgrieve, *State Liability in Tort. A Comparative Law Study* (2003), at 36-41

<sup>54</sup> See the GPS Directive's recitals (*supra* n. 30): '(14) In order to facilitate the effective and consistent application of the general safety requirement of this Directive, it is important to establish European voluntary standards covering certain products and risks in such a way that a product which conforms to a national standard transposing a European standard is to be presumed to be in compliance with the said requirement.

(15) With regard to the aims of this Directive, European standards should be established by European standardisation bodies, under mandates set by the Commission assisted by appropriate Committees. In order to ensure that products in compliance with the standards fulfil the general safety requirement, the Commission assisted by a committee composed of representatives of the Member States, should fix the requirements that the standards must meet. These requirements should be included in the mandates to the standardisation bodies.

(16) In the absence of specific regulations and when the European standards established under mandates set by the Commission are not available or recourse is not made to such standards, the safety of products should be assessed taking into account in particular national standards transposing any other relevant European or international standards, Commission recommendations or national standards, international standards, codes of good practice, the state of the art and the safety which consumers may reasonably expect. In this context, the Commission's recommendations may facilitate the consistent and effective application of this Directive pending the introduction of European standards or as regards the risks and/or products for which such standards are deemed not to be possible or appropriate' and Art. 3(4): '[c]onformity of a product with the criteria designed to ensure the general safety requirement, in particular the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous'.

<sup>55</sup> See *supra* n. 20.

<sup>56</sup> While, e.g., normative standards at national level can be considered barriers to trade and scrutinized under Art. 28 EU, technical standards, due to their voluntary nature, have been considered outside the domain of free movement and within that of competition. See H. Schepel and J. Falke, *Legal Aspects of Standardisation in the Member States of the EC and EFTA*, Comparative Report (2000), i, at 55. A case in point is the ECJ's judgment in Case C-23/99, *Commission of the European Communities v French Republic* [2000] ECR I-7653. In particular, in Mischo AG's Opinion, the compatibility of technical standards requirements for products to enter a Member State's territory is analysed according to the principle of proportionality which is part of the Court's case law on Arts. 30 (now Art. 28) and 36 (now Art. 30) EC. See Case C-23/99, also at 132. In Case C-166/03, *Commission of the European*

technical standards are consolidated, normative standards are still mainly defined by national institutions (regulators and judges) in accordance with European legislation.<sup>57</sup> A second important phenomenon is related to the pursuit of an integrated strategy to protect safety and environment through technical standards. This approach advocated for technical standards is less significant for normative standards.<sup>58</sup>

There is often an unfortunate overlap between the distinction between technical and normative standards and that between public and private bodies.<sup>59</sup> Such overlap may negatively affect an effective coordination strategy between regulation and civil liability. The former

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*Communities v French Republic* [2004] not published yet, for instance, France was reckoned to have infringed the duty to fulfil its obligations under Art.28 in establishing guaranteed standards for precious metals. The Court found that these standards were not justified either on grounds of consumer protection, or on those of fairness of trade, but, on the contrary, they were likely to produce the undesirable effect of quantitative restrictions on free movement of goods. See at paras. 17-21: '[i]t is common ground that the terms to be used to indicate the proportion of the precious metal content of articles and the method by which it should be indicated are, as Community law currently stands, not harmonised. It is also common ground that Article 522a of the CGI is applicable without distinction to French products and to products imported from other Member States. Furthermore, the provision of the CGI in question is admittedly intended to ensure fair trading and consumer protection. However, the contested legislation imposes, in respect of articles of the two lower levels of purity marketed at the retail stage to individuals, a redundant double designation, since it requires the use not only of the fineness of the article, which gives objective information on its level of purity, but also the term "gold alloy" which gives much less precise information on the same subject. It follows that the system requiring a double description laid down by Article 522a of the CGI is *not proportional to the aim of ensuring fair trade and consumer protection, and that that aim can be achieved by measures less restrictive to intra-Community trade*. Consequently, it must be held that, by reserving the term "gold" for articles of a fineness of 750 parts per thousand, whilst those of a fineness of 375 or 585 parts per thousand are termed "gold alloy", the French Republic has failed to fulfil its obligations under Article 28 EC' (emphasis added). A similar approach is taken by the Court in a homogenous group of cases: see, among others, Case C-358/01, *Commission v Kingdom of Spain*, 6 Nov. 2003, not yet reported. Codes of conduct may be regarded as potential obstacles to free movement of goods and freedom to provide services, although the assessment of the two should also take into account the possibility of praying in aid the exemption ex Art. 36 EC, especially if applied to the provision of services. See E. Vos, *Health and Safety Regulation. Committees and Private Bodies* (1999), at 251 ff.; M. Egan, *Constructing a European Market* (2001). See also C. Joerges, K.H. Ladeur, and E. Vos, *Integrating Scientific Expertise into Regulatory Decision-making. National Traditions and European Innovations* (1997); C. Joerges, H. Schepel, and E. Vos, 'The Law's Problems with the Involvement of Nongovernmental Actors in Europe's Legislative Process: The Case of Standardization under the "New Approach"', EUI Working Paper Law 99/9 (1999).

<sup>57</sup> See General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and the European Trade Association, OJ 2003 C 91/04: '[s]tandardisation activities in Europe have moved substantially from the national level to the European and international level. The role of the national standards organisations has, in consequence, taken a new dimension in the context of European and international standardisation. The national standards bodies will however, continue to play an important role in international and European standardisation. They contribute on a national level to consensus, in many cases provide support to the technical work as a permanent link between market players in particular SMEs, consumers and environmentalists, and provide access to, and advice on, both international and European standards. The official adoption through public enquiry and formal vote on European standards is carried out by national standards bodies', at 7.

<sup>58</sup> See Communication of the Commission on Integrated Product Policy, *supra*, n. 47, and Communication of the Commission on the Integration of Environmental Aspects into Standardisation, COM(2004)130 final, 25 Feb. 2004: '[i]n its communication on Integrated product policy, the Commission pointed out that standards have a high potential to support sustainable development, comprising economic, social and environmental aspects. It also listed standards as one of the tools whose improvements could help in establishing the framework for the continuous environmental improvement of products throughout their whole life cycle. Standardisers are now encouraged to give greater consideration to environment. Accordingly in its recent Communication on the integration of environmental aspects into standardisation, the Commission has, a key message, strongly encouraged all stakeholders in standardisation to take sustainable steps aiming to integrate environmental protection into standardisation'. See also Scott and Black, *supra* n. 7, at 392, in relation to the costs of using national standards: '[n]ational voluntary standards of the sort created by the BSI [British Standards Institution] create risks of fragmentation of international markets, either because regulators fail to recognise equivalent standards from other jurisdictions, or because business themselves believe that regulatory requirements downstream require them to ensure that components or process supplied by others should meet national standards'.

<sup>59</sup> On this point see G. Majone, *Regulating Europe* (1996), at 25. In the policy documents concerning the new approach to standardization a distinction is often drawn between technical and normative aspects in relation to the allocation of powers between public and private powers. See, e.g., Commission Report on Efficiency and Accountability in European Standardisation under the New Approach, COM(98)291 final.

distinction refers to the nature of the rules, and the latter to the body that generates the standards. Private bodies produce technical standards, but can also produce normative standards. They can generate normative standards by laying down codes of conduct that are binding 'regulatory contracts'. Public bodies, on the other hand, can use non-binding devices (soft law) together with binding rules to regulate behaviour.<sup>60</sup> Public bodies can also set technical and behavioural standards. Therefore, to maintain the difference between technical and normative standards, one should not associate the distinction between binding and non-binding standards with that between public and private bodies.<sup>61</sup> Consequently, for the purpose of the application of rules on free movement of goods (Article 28 EU) and competition law (Article 81 EU in particular), the driving criterion should be the binding nature of the rules, and not the public or private nature of the standard-setter.<sup>62</sup> The public or private nature of the regulatory body may have some impact on the breadth of the group of those people to whom the standards should apply.

Technical standards produced by private bodies strongly influence the effectiveness of regulation and of civil liability.<sup>63</sup> It is unclear whether recently European institutions have been favouring the substitution of legal standards by technical standards associated with a higher level of accountability of standardization bodies.<sup>64</sup> These changes may have important repercussions in the design of institutional complementarities between regulation and civil liability, as will be described later. Instead of conceiving the two as alternatives and shifting from normative to technical standardization, a more integrated approach to the production of technical and normative standards should be favoured.<sup>65</sup> The current institutional framework can be improved by promoting stakeholders' participation in technical standard-setting and revising the European co-regulatory model of technical standardization in the fields of both product safety and environmental protection.<sup>66</sup> But the idea of regulatory compliance also needs to be revised in the light of the new relationship between technical and legal standards.

<sup>60</sup> On the general question of the role of soft law in European law see L. Senden, *Soft Law in European Community Law* (2004).

<sup>61</sup> However even voluntary standards can become indirectly binding. For example, in the case of European technical standards, while they are held to be voluntary Member States have an obligation to comply with them. They have to recognize that products manufactured in compliance with standards defined by European standardization bodies are in conformity with essential requirements. See Case C-112/97, *Commission v Italy* [1999] ECR I-182, Case C-100/00, *Commission v Italy* [2001] ECR I-2785; Case C-103/01, *Commission v Germany*, judgment of 22 May 2003. See also Vos, *supra* n. 28, at 268 ff.

<sup>62</sup> In relation to Art. 81 and its application to self-regulatory agreements see the *Guidelines on the Applicability of Article 81 of the EC Treaty to the Horizontal Cooperation Agreements*, OJ 2001 C 3/02, that consider standardization and define the standardization agreements: '162 Agreements to set standards may be either concluded between private undertakings or set under the aegis of public bodies entrusted with the operation of services of economic interest, such as the standard bodies recognised under Directive 98/34/EC. The involvement of such bodies is subject to the obligations of Member states regarding the preservation of competition in the Community'.

<sup>63</sup> See Spindler, *supra* n. 24, at 316.

<sup>64</sup> See, e.g., Communication from the Commission to the European Parliament and the Council on the Role of European Standardisation in the Framework of European Policies and Legislation, COM(2004)674 final, 18 Oct. 2004, and Council Conclusions, 21 Dec. 2004.

<sup>65</sup> See Council Conclusions, 17 Dec. 2004, Annex to the Presidency Conclusions 13830/04 ENT 140 +ADD 1 on the Communication on Standardization, *supra* n. 57: '[r]ecommendations for further actions:

a) A more extensive use of European Standardisation in European policies and legislation

1 invites the Commission and the Member States to make a wider use of European (i.e CEN, Cenelec, ETSI) and international standards in their policies; particular attention should be paid to the role of standards in simplification of existing EU legislation, in order to meet the needs of stakeholders, including SMEs,

2 recognises that further progress can be made in new areas of legislation in making wider use of general references to voluntary standards, taking into account European policies on governance and better regulation;

3 invites the member states to apprise decision-maker of the advantages of European standardisation in support of Community legislation and policies'.

<sup>66</sup> See the Council Conclusions on the Communication on Standardization, *supra* n. 57:

'b) Improving the efficiency, coherence, visibility of European standardisation and its institutional framework

1 notes that adequate participation in standardisation of all parties concerned ( social partners, NGOs, environmental interest groups, consumers, SMEs authorities, etc.) is not sufficiently implemented at present within all member states, European standardisation should be recognised as a strategic tool for competitiveness and for the uniform

When we focus specifically on regulation of product safety, we see that significant differences still exist between the technical and normative approaches. The harmonizing role of technical standards in product safety has been much greater than that in product liability.<sup>67</sup> European and international technical product standardization has contributed to technical harmonization at supranational level which, in turn, has played a role in promoting and effectively achieving legal standardization.<sup>68</sup> In terms of actors contributing to the definition of standards the role of regulators, both public and private, often operating in a coordinated fashion, has been significant.

Technical and scientific knowledge affects normative standards even when it is not incorporated in technical standards. In the area of product liability and safety the definitions of defectiveness and safety are correlated to the state of the scientific knowledge and technology. When the development risk defence has been introduced the legal regime resembles more negligence than strict liability.<sup>69</sup> References to technical and scientific knowledge concerning standard-setting for defectiveness and safety imply that producers, and to some extent distributors, should make decisions taking into account available knowledge and technology. Of course when science and technology have not (yet) been translated into standards or consensus, compliance becomes more difficult to evaluate because knowledge is diffuse and sometimes conflicting.<sup>70</sup>

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application of technical legislation in the internal market. The commitment of everybody should be reactivated in this respect’.

<sup>67</sup> See *infra* text and nn. 54-57.

<sup>68</sup> See for instance Vos, *supra* n. 14, at 252-259, 268-281. Describing the institutional framework and the activity of standard-setting performed by regulatory bodies in the European panorama, Vos establishes a clear connection between them and market regulation in the light of the EU treaties’ goals. For a paradigmatic example of the foregoing, see the Communication on Standardization, *supra* n. 57..

‘4.3 European standardisation and the challenge of globalisation

- The Commission will continue to promote international standards drawn up by the international standardisation bodies (ISO,IEC,ITU) and to support their transposition in the EU.

When international standards are developed and transposed into European standards in support of European policies, The European standardisation organizations must ensure that these standards are consistent with the objectives of EU policies’.

<sup>69</sup> See PL Directive 374/85, *supra* n. 29, Art. 7(e) and the GPS Directive, *supra* n. 30, Art. 3(3)(e). 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. Further, in order for the relevant scientific and technical 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. On this last point, Article 7(e) of the Directive, contrary to what the Commission seems to consider, raises difficulties of interpretation which, in the event of litigation, the national courts will have to resolve, having recourse, if necessary, to Article 177 of the EC Treaty’. 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, Stapleton, ‘Products Liability in the United Kingdom: The Myths of Reform’, 34 *Tex Int’l LJ* (1999)50 at 53, where the author explains that ‘to the extent that a producer is sued for in-house design defects and in-house failure to warn defects (potentially the most explosive categories), the more reasonable interpretation of the ambiguous words of the Directive means that he will in practice virtually always escape liability if he has used all reasonable care. This result is a product of the interaction between the Directive’s concept of defect and the only reasonable interpretation of its development risk defence. In other words, in my view, in jurisdictions that have implemented the Directive with the development risk defence the only workable and reasonable interpretation of it is, in relation to in-house design and in-house warning defects, that the Directive in practice does not impose strict liability on producers.’

<sup>70</sup> 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 Borghetti, *supra* n. 26, at 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



Legal standards are differently arrived at in the areas of civil liability and regulation. These differences are not only institutional, concerning the different roles of legislators, regulators, and judges, but also functional.<sup>71</sup> Although civil liability and regulation can both promote, and do in fact promote, deterrence and compensation, there is a tendency to associate deterrence with regulation and compensation with civil liability. This tendency emerges, for example, quite strikingly in relation to the evaluation of human lives and environment for purposes of compensation and deterrence.<sup>72</sup> Such evaluation is very important, not only for compensation purposes but also for standard-setting. It should be noted that divergences in regulation and civil liability are not always justified by the supposedly different goals pursued by each strategy.

Differences in standard-setting emerge not only between civil liability and regulation but also within each field. In Continental legal systems the standard of fault in civil liability is generally legislatively defined (due care, diligence) and the role of judges is to verify whether or not a breach has occurred.<sup>73</sup> But the power of judges to specify the standard of due care is significant, given the width of the codified definition. Clearly in a common law jurisdiction where there are no relevant statutes judges define the standards while juries, when they operate, verify the existence of a breach.<sup>74</sup>

The level of expected harm is a relevant variable for determining the level of precautions to be taken in negligence.<sup>75</sup> Not only is human life valued differently when considered in the field of

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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.

<sup>71</sup> From a comparative perspective the institutional differences are also related to civil liability systems. The clearest example is the different function of judges in civil and common law countries and within each legal family. In civil law jurisdictions civil liability standards are generally defined by the legislator and specified by judges in the case law. In common law jurisdiction the general definitions used to be provided by judges; the development of statutory law has increased in particular in the field of product safety, bringing about the allocation of power between legislature and judiciary which is similar to that generally taking place in civil law jurisdictions. However, important differences still exist between common and civil law and within these legal families. See Zweigert and Kotz, *supra* n.6; Von Bar, *supra* n. 52, at 237; Van Gerven, *supra* n. 9, at 674; B. Koch and H. Koziol (eds.), *Unification of Civil Liability, Strict Liability* (2002), at 106; Rials, *Le juge administrative français et la technique du standard. Essai sur le traitement juridictionnel de l'idée de normalité* (1980), at n. 93. These distinctions are, however, relative, as the analysis concerning convergence of legal systems shows.

<sup>72</sup> On different regulatory techniques for determining the value of life for regulatory purposes see Revesz and Stavins, 'Environmental Law and Policy', NYU Public Law Research Paper 82, available at <<http://ssrn.com/abstract=552043>>.

<sup>73</sup> See Zweigert and Kotz, *supra* n. 6; Von Bar, *supra* n. 52, at 249, where the author states that 'the (few) specially codified standard of care, and the (abundant) "nominate torts" of judge-made common law are regularly complemented by a further autonomous *Normgenerator*: the general duty of care': Van Gerven *et al.*, *supra* n. 9, at 54 ff.

<sup>74</sup> For a comparative analysis of negligence standards in European legal systems see Von Bar, *supra* n. 52.; Deakin *et al.*, *supra* n. 8, at 167-184, Van Gerven *et al.*, *supra* n. 9, at 280 ff.

<sup>75</sup> This correlation is explicitly acknowledged in the US law and, perhaps less explicitly, in the UK. See for the US *Restatement Second of Torts* and *Restatement Third on the Law of Torts*, *supra* n. 69, section 3 Negligence: '[a] person acts negligently if the person does not exercise reasonable care under all the circumstances. Primary factors to consider in ascertaining whether the person's conduct lacks reasonable care are the foreseeable likelihood that the person's conduct will result in the harm, the foreseeable severity of harm that may ensue, and the burden of precaution to eliminate or reduce the risk of harm': at 34. In the UK see Stapleton, *supra* n. 68, at 53. In particular the author states that '[a]lthough liability in negligence includes carelessness by those who carry, store or resell the dangerous good, it is more commonly a route used to target the carelessness of manufacturers, especially with regard to manufacturing errors. In the case of manufacturing errors, carelessness is effectively presumed by U.K. judges. It follows that, since a manufacturer cannot in practice defend such a manufacturing defect claim by proof that he used reasonable care, this judicial attitude created and continues to maintain a covert area of strict liability masquerading as negligence liability'. See also Scott and Black, *supra* n. 7, at 189, where the authors recognize that '[w]ith the exception of the basic principle of the [Consumer Protection] Act 1987, ..., it is widely assumed that the key elements of liability – the concept of defectiveness, principle of causation, and scope of harm for which recovery is permitted – are virtually identical under the legislation as under common law negligence'. In civil law jurisdictions the express evaluation of expected harm is not generally acknowledged but it is implicitly considered. For the French system see Viney, *Traité de droit civil. Introduction à la responsabilité* (1998), at 65. For the Italian system see Cafaggi, *Profili di relazionalità della colpa* (1996). In comparative perspective see B.S. Markesinis (ed.), *The Gradual Convergence*.

civil liability and regulation but even within civil liability. For example the value of life defined to set the precautionary level owed by potential injurers often differs from the value attributed to life when an injury has occurred and has to be compensated.<sup>76</sup>

In strict liability regimes, based on defect, the procedure for standard-setting is relatively similar to due care in negligence. In the area of product safety and environmental law standards are often specified by the regulatory activity of different regulators. With the intervention of European law, product liability has become predominantly statutory in common law countries, too.<sup>77</sup> In this area, too, the differences between civil and common law countries are less relevant than they used to be<sup>78</sup>. Frequently, however, judges consider liability even if injurers have complied with regulation. If within negligence compliance with regulations does not rule out liability the same is (or should be) *a fortiori* the case in strict product liability.<sup>79</sup> In an absolute liability regime no standards are set, as the injurer is liable for the injuries if a causal link can be proved, but regardless of the level of precaution taken.

In the field of product liability a higher level of harmonization has been achieved.<sup>80</sup> While the differences between civil and common law jurisdictions are becoming less and less significant as far as the methodologies of standard-setting in civil liability are concerned, the distinctions, internal to each legal family, may however be considerable and increasing.<sup>81</sup> This is in part due to the Europeanization of Member States' private law systems. European harmonization may recombine national legal systems in different ways from those existing before the formation of a European legal system.<sup>82</sup>

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*Foreign Ideas, Foreign Influences and English Law on the Eve of the 21st Century* (1994), at 72; Von Bar, *supra* n. 52, at 20; Zweigert and Kotz, *supra* n. 6, at 599 and 615 ff.

<sup>76</sup> See Weir, *supra* n. 7, at 7. See also Ladeur, *supra* n. 14, at 15. See also Franklin and Rabin, *supra* n. 3, at 605, commenting on *General Motors Corporation v Sanchez*, SC Texas (1999), 997 SW 2d 584. In particular in the judgment the court states: 'We believe that a duty to discover defects, and to take precaution in constant anticipation that a product might have a defect, will defeat the purpose of strict liability. Thus, we hold that a consumer has no duty to discover or to guard against a product defect, but a consumer's conduct other than the mere failure to discover or guard against a product defect is subject to comparative responsibility [negligence]. Public policy favours reasonable conduct by consumers regardless of whether a product is defective. A consumer is not relieved of the responsibility to act reasonably nor may a consumer fail to take reasonable precautions regardless of a known or unknown product defect'.

<sup>77</sup> See Stapleton, *Products Liability* (1994), at 11; Howell, 'Product Liability A History of Harmonization', in Hartkamp *et al.*, *supra* n. 13, at 645; S. Whittaker, *Liability for Products – English Law, French Law and European Harmonisation* (2005). See also Reimann, *supra* n. 26: '[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'.

<sup>78</sup> Von Bar, 'Liability for Information and Opinions Causing Pure Economic Loss to Third Parties: a Comparison of English and German Case Law', in Markesinis, *supra* n. 74, at 98; see also \* Fleming, *The Law of Torts* (1998), chap. 23, on product liability in England; Markesinis, *supra* n. 40, at 91-102, on Germany; Zweigert and Kötz, *supra* n. 6, at 676 on France and Germany; Von Bar, *supra* n. 52, at 418-424, on Europe.

<sup>79</sup> See for a statement the French Civil Code implementing the PL Directive, *supra* n. 29, in art. 1386-1 to 1386-18. On this issue see Fabre Magnan, *supra* n. 3, at 830 ff. For the Italian system see Cafaggi, 'La responsabilità del produttore', in N. Lipari (ed.), *Trattato di diritto privato europeo* (2003).

<sup>80</sup> For a thorough analysis of comparative product liability see Reimann, *supra* n. 26; Howells, 'The Relationship between Product Liability and Product Safety. Understanding a Necessary Element in European Product Liability through a Comparison with the US Position', 39 *Washburn LJ* (2000) 305

<sup>81</sup> On the convergence of European systems of civil liability see Deakin *et al.*, *supra* n. 8, at 536. The relationship between European law and national legal systems in the area of tort law has been explored by Van Gerven, 'The Emergence of a Common European Law in the Area of Tort Law: the EU Contribution, in Tort Liability of Public Authorities in a Comparative Perspective', in D. Fairgrieve, M. Andenas, and J. Bell (eds.), *The British Institute of International and Comparative Law* (2002), at 125, and before *id.*, 'Bridging the Unbridgeable: Community and National Tort Laws after *Francovich and Brasserie*' [1996] *ICLQ* 520. On the impact of European law on civil liability national legal systems see also Von Bar, *supra* n. 52.

<sup>82</sup> For the relationship between European legislation and judicial intervention and the national systems of private law see Van Gerven, *supra* n. 13, at 101, n. 4, and *id.*, 'Comparative Law in a Texture of Communitarisation of National Laws

The institutional differences between strict liability and negligence, in particular the role of judges, increase when a law and economics approach is endorsed. This is probably due to the fact that such an approach has developed in the Anglo-American setting.<sup>83</sup> In negligence the standard is set by judges or by the legislator. In strict liability the injurer will define its own conduct and be held responsible for the injuries which have occurred, regardless of the level of care adopted by the injurer.<sup>84</sup>

## 5. Complementarity of standard-setting in European product civil liability and product safety

A taxonomy of factors contributing to the definition of standards in the field of product liability and safety at the European level is very complex. It is useful to start the analysis by underlining the differences between the definition of defect in the PL Directive, 85/374, and that of safe product in the amended GPS Directive. The PL Directive, when defining defect and the expectations of consumers, refers to regulation only briefly in relation to causes of exclusion of liability.<sup>85</sup> It is clear,

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and Europeanisation of Community Law', in D. O'Keefe (ed.), *European Union Law, Liber Amicorum in Honour of Lord Slynn of Hadley* (2000), at 43 ff. Van Gerven distinguishes between the bright and dark sides of harmonization and qualifies the latter as the disruptive effect of harmonization on national legal systems. See Schulze, 'European Private Law and Existing EC Law', 00 *ERPL* (2005) 3; Muller Graf, 'EC Directives as a Means of Private Law Unification', in Hartkamp *et al.*, *supra* n. 13, at 77. See further R. Schulze, H. Schulte-Nolke, and J. Jones (eds.), *A Casebook on European Consumer Law* (2002); Von Bar, *supra* n. 52.

<sup>83</sup> See Shavell, *supra* n. 42; *id.*, *Economic Analysis of Accident Law* (1987); R. Cooter and T. Ulen, *Introduction to Law and Economics* (3rd. edn., 2000); A. Ogus, *Regulation, Economics and the Law* (2001); Landes and Posner, *supra* n. 42.

<sup>84</sup> See Shavell, *supra* n. 42; see also *id.*, 'Uncertainty over Causation and the Determination of Civil Liability', [1985] *JLE* 587. Shavell argued that there is an economic justification for limiting the liability of the injurer to the damage that he has actually caused. Damages should, therefore, be allocated across potential tortfeasors in proportion to the probability that they caused the harmful event. Shavell argued that a proportional liability rule had particular appeal on grounds of efficiency 'where the chance of uncertainty over causation is significant', and pointed to health-related and environmental risks as examples of where this may be the case

<sup>85</sup> See Art. 7 of PL Directive, *supra* n. 29; '[t]he producer shall not be liable as a result of this Directive if he proves...d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities', and Art. 13: '[t]his Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified'. For a comparative analysis of product liability regimes in national systems see J.-S. Borghetti, *supra* n. 26. See also Howells, 'Product Liability – A History of Harmonisation', in Hartkamp, *et al.*, *supra* n. 13, at 645 ff. A wider set of comparative data is presented by Reimann, 'Liability for Defective Products at the Beginning of the Twenty First Century: Emergence of a Worldwide Standard?', 55 *AMJCL* (2003) 751: in particular on the causation principle at 772-774. In Reinman's perspective two paradigms of legal regimes emerged from the comparative analysis: an American approach and a European approach. As far as the former is concern, the plaintiff bears the burden of proof, which may be made even harder by courts according to specific requirements to be met in the individual case; the doctrine applied is that of *res ipsa loquitur*. Conversely the European approach is characterized by a twofold regime assigning the burden of proof. Pursuant to Art.4 of the Directive, the plaintiff needs to establish the causal link between the alleged defect and the harm. Art. 7 provides for legitimate causes of exemption from liability which might be used as defences by defendants. An example of the practical functioning of the European regime may be provided by a recent judgment released in Spain by the *Tribunal Supremo* (N.151/2003), 21 Feb. 2003, reported at [2005] 2 *ERPL*.171, in comparison with late developments of other Member States' systems. The issue at stake in the case is the inversion of the burden of proof due to the combination of the normative definition of product defect and safety standards requirements that the product itself has to meet according to the Spanish Products Liability Act 22/1994. The manufacturer must therefore bring evidence that the product meets safety requirements that allows it to avoid the application of s.3 of the Act, implementing Arts.2 and 6(1) of the Directive. As far as the Dutch system is concerned, even before the implementation of the Directive there had been a well known leading case establishing that the producer might be held liable for the damage caused by a defective product when the latter did not offer the consumer the degree of safety to be reasonably expected (Hoge Raad, 24 Dec. 1993 [1994] NJ 214, *Leebeek-Vrumona BV*). Italian case law presents similar features: see Jacometti, *Italian case note, ibid.*, at 178-194. The national literature is also unanimous in acknowledging scarcity of case law: see Tribunale di Monza, 20 July 1993 [1993] C (Contratti) 359, note by Carnevali [1994] I FI (Foro italiano) 252, note by Ponzanelli; Tribunale di Milano, 13 Apr. 1995 [1996] DR 381, note by Ponzanelli; Tribunale di Roma, 11 May 1998 [1998] DR 1147, note by Ponzanelli

however, that judges cannot decide whether a product is defective without taking into account regulation(s) concerning product safety.<sup>86</sup> In the GPS Directive the definition of product safety is the combination of several concurring legal sources.<sup>87</sup> The European Commission has issued two decisions on notification procedures, clarifying the criteria that national authorities should use to evaluate the dangerous nature of a product, according to the principles defined in the Directive.<sup>88</sup>

I shall consider in turn: (1) the definition of standards for producers and distributors, (2) the definition of standards for consumers, (3) the role of technical standards, (4) the *ex ante/ex post* distinction in relation to time evaluation of defectiveness and safety.

(1) While the level of risk is at the core of the definition of safety in the GPS Directive, it plays no explicit role in the definition of defect in the PL Directive.<sup>89</sup> In health and product safety

[1998] I FI 3661, note by Palmieri; Tribunale di Milano, 31 Jan. 2003 [2003] DR 634, note by Bitetto; [2003] RCP 1151, note by Della Bella; and, lastly, Tribunale di Vercelli, 7 Apr. 2003 [2003] DR 1001, note by Ponzanelli. It is to be added that Italy has recently implemented the GPS Directive, *supra* n.30, by means of Legislative Decree n.172/2004. Obviously at the moment there is no case law in which the producer-defendant has used the argument of regulation compliance as a defence or as a means to reverse the (reversed) burden of proof in product liability cases. Hence it is not yet possible to assess its effects on civil liability cases.

<sup>86</sup> It is important to use the plural (regulations) not only because a product can be a complex one but also because there can be concurring regulations.

<sup>87</sup> See Art. 3 of the GPS Directive, *supra* n. 30, and in particular para. (3): '[i]n circumstances other than those referred to in paragraph 2, the conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

- (a) voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;
- (b) the standards drawn up in the Member State in which the product is marketed;
- (c) Commission recommendations setting guidelines on product safety assessment;
- (d) product safety codes of good practice in force in the sector concerned;
- (e) the state of the art and technology;
- (f) reasonable consumer expectations concerning safety'.

<sup>88</sup> See Commission Decision 2004/418/CE, 29 Apr. 2004, OJ 2004 L 151/00, laying down guidelines for the management of the Community Rapid Information system (RAPEX) and for notifications presented in accordance with Art. 11 of GPS Directive, *supra* n.30, and Commission Decision 2004/905/EC, OJ 2004 L 381/63, 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 Art. 5(3) of Directive 2001/95/EC of the European Parliament and of the Council; *Guidance Document on the Relationship between the GPSD and Certain Sector Directives*, available at [http://europa.eu.int/comm/consumers/cons\\_safe/prod\\_safe/DGSP/reviseDGSP-en.htm](http://europa.eu.int/comm/consumers/cons_safe/prod_safe/DGSP/reviseDGSP-en.htm)

<sup>89</sup> Compare Art. 6 of the PL Directive, *supra* n. 29, and Art. 2(b) of the GPS Directive, *supra* n. 30. If the risk-utility test were adopted to define defect then risk would also play a strategic role in the liability system. Art. 6 states: '[a] product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account including:

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

Art. 2(b) states: "'safe product'" shall mean 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 risk 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, taking into account the following points in particular:

- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products
- (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- (iv) the categories of consumers at risk when using the product, in particular children and the elderly'.

See Commission Decision 2004/418, *supra* n. 87, para.3(2): '[t]he level of risk could depend on a number of factors such as for example the type and vulnerability of the user and the extent to which the producer had taken precautions to guard against the hazard and warn the user. It is considered that these factors should also be taken into account in determining the level of risk that is regarded as dangerous and requires producers to notify the competent authorities'.

See Reinmann, 'Liability for Defective Products at the Beginning of the Twenty-first Century: Emergence of a Worldwide Standard?', 51 *Am J Comp L* (2003) 767, where the author emphasizes that '[i]f the definition of a "product" is perhaps the easiest problem among the conditions of liability, the determination of what constitutes a "defect" is probably the most difficult. Three factors complicate the matter: the panoply of formulated definitions, the competition between two basic tests, and the existence of three defect types suggesting different treatment. First, there

regulation standards are broadly defined by a legislative act (Article 2 of the GPS Directive) and specified by regulators. In the two Commission Decisions are listed the relevant elements that producers and distributors should consider in notifying the dangerous nature of a product.<sup>90</sup> A definition of serious risk, recalling that of the GPS Directive, is further specified therein.<sup>91</sup> It is important to note that the probability and severity of the potential injury (or injuries) are factored into the evaluation of the dangerous nature of the product in accordance with the American model of liability. In the Decisions specific procedures for assessing the probability and severity of the risk are provided.<sup>92</sup> These methodologies could easily be employed by the judiciary to define defectiveness even within a strict liability regime.<sup>93</sup> The transplant of legal models concerning risk assessment could operate within liability, within regulation, and between the two.

(2) Standard-setting concerns consumers' conduct as well. Consideration of consumers' conduct in preventing or reducing hazards has had different relevance in the liability and regulatory systems. While the role of consumer expectation as an objective standard is crucial in the PL Directive, in the GPS Directive it only contributes to defining the conformity of the product to the general safety requirement.<sup>94</sup> Furthermore, while in the Liability Directive consumer conduct is relevant for the application of comparative negligence and assumption of risk criteria, consumers' conduct is not really considered in relation to the GPS Directive except for the definition of serious

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is a considerable diversity of definitions in the various product liability regimes. Some of these definitions are not very helpful to begin with because they are terribly imprecise or outright tautological. In addition, several systems eschew the notion of a 'defect' altogether but rather ask whether the product was 'dangerous', had a 'safety deficiency' or created an (undue) 'risk'. ... Second, most systems ultimately tend to rely on one of two tests. The first of these tests looks to justified consumer expectations: roughly speaking, a product is defective if it is more dangerous than the average consumer has reason to anticipate. This test prevails in the majority of jurisdictions. It rules supreme in Europe where it is codified in art. 6 (2) of the EC Directive and consequently applies in all EU member states as well as in most other European countries .... The other major approach is the risk-utility analysis. It renders a product defective if its risks outweigh its utility. To put it more colloquially: there is a defect if the product is more dangerous than absolutely necessary in light of its purpose. This test tends to dominate in the United States. There, it lies at the heart of the Third Restatement and looks like the trend of the future. ... Third, there are three basic types of defects which may call for different treatment: manufacturing defects, design defects, and insufficient warnings (sometimes called instruction defects). While these categories are almost generally recognized in theory by scholars and often even by courts, legal systems differ as to their recognition on the level of black letter law. The majority of specialized product liability regimes do not distinguish between them. Thus the EC-Directive applies the same rules to all defect types, as do the many statutes modeled after it in jurisdictions inside and outside of Europe. ... A minority of countries apply different approaches to the various categories. Such differentiation is pervasive in the United States where liability for manufacturing defects tends to be considerably stricter than in design and warning cases, but the distinction is apparently also persistent (in spite of the EC Directive) in Italian law and built into the Russian Consumer Protection Act.'

<sup>90</sup> In Annex I to Commission Decision 2004/418, *supra* n. 87, a risk-utility test is provided: '[i]n determining whether a product is dangerous under the terms of GPSD several issues should be analysed: the utility of the product, the nature of the risk, the population group exposed, previous experience with similar products, etc. A safe product must have no risk or only present the minimum risk compatible with the product's use and needed in order to ensure useful operation of the product... 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 an hazard depending on the severity and the probability of the possible health and safety damage. Combining the severity and probability gives an assessment of the gravity of the risk...
- The severity of health/safety damage for a given hazard should be that for which there is a reasonable evidence that the health and safety damage attributable to the product could occur under foreseeable use. This could be the worst case from health and safety damage that have occurred with similar products.
- The probability of health and safety damage for a normal user who has an exposure corresponding to the intended or the expected use of the defective product has also to be considered as well as the probability of the product being or becoming effective': at 68.

<sup>91</sup> See Commission Decision 2004/418, *supra* n. 87, at 92 ff.

<sup>92</sup> See Commission Decision 2004/905, *supra* n. 87, at 74-75.

<sup>93</sup> It should be emphasized that these decisions were issued in relation to notification procedures, and therefore the comparison with the PL Directive, *supra* n. 29, should be limited. Having specified that, one can conclude that the GPS Directive as interpreted by the European Commission defines a regulatory model whose standards are very similar to negligence as it is generally defined in common law jurisdictions. This constitutes an additional difference from the Liability Directive that on the contrary should be interpreted as introducing a strict liability regime.

<sup>94</sup> See Art. 6 of the PL Directive, *supra* n. 29, and Art. 3(3)(f) of the GPS Directive, *supra* n. 30.

risk.<sup>95</sup> While the structure of the liability system has been predominantly relational, that of the regulatory regime has been primarily unilateral.<sup>96</sup> The two Commission Decisions seem to shed new light on the possibility of considering consumers' conduct and not just consumer expectations in the regulatory regime in order to determine standards of conduct, moving from unilateral to relational in the regulatory field too. In this case regulation follows the logic underlying the evolution of the liability regime.<sup>97</sup>

(3) The role of technical standards is different in the PL and the GPS Directives. While in the GPS Directive the definition of safety is predominantly based on technical standards, in the PL Directive technical standards play a relatively small explicit role for the definition of defect.<sup>98</sup> In the PL Directive references to the state of scientific and technical knowledge are made in relation to the exclusion of liability, but they do constitute, at least explicitly, an element of the definition of defect.<sup>99</sup> On the contrary, in the GPS Directive the conformity of safety to technical standards is very important. Article 3(2) of the GPS Directive distinguishes between conformity to specific rules of national law, in which case the product *is deemed* safe, and conformity with voluntary national standards transposing European standards, in which case the product *shall be presumed* safe. Conformity to general safety requirement is evaluated according to different, concurring elements among which voluntary standards and codes of good practice are expressly mentioned.<sup>100</sup>

The adoption of European technical standards is clearly promoted by the GPS Directive in order to achieve a higher level of harmonization.<sup>101</sup> The definition of these standards is at least partially delegated to standardization bodies, but manufacturers can adopt their own standards regardless of those set by such bodies in accordance with the criteria defined by Article 3(3) of the GPS Directive.<sup>102</sup> Such adoption, however, would shift the burden of proof associated with the presumption of safety, grounded on conformity with voluntary national standards.

<sup>95</sup> See Art. 8 of the PL Directive, *supra* n. 29, which explicitly mentions fault of the injured person and the national legislation implementing this provision. In point, see also Reinmann, *supra* n. 88.

<sup>96</sup> In the PL Directive, *supra* n. 29, both standards for manufacturers' and consumers' conduct are defined. In the regulatory Directive, the standard-setting function predominantly concerns manufacturers' conduct, while consumers' conduct is considered only in relation to what manufacturers have to do.

<sup>97</sup> See Commission Decision 2004/418, *supra* n. 87, at 92 and 93, and Commission Decision 2004/905, *supra* n. 87, at 74: '[t]he potential of an hazard to materialise as an actual negative effect on health/safety will depend on the degree to which the consumer is exposed to it when using the product as intended or as it could reasonably be expected during its lifetime. In addition the exposure to certain hazards may in some case involve more than one person at a time. Finally when determining the level of risk presented by a product by combining the severity of the hazard with the exposure consideration should be given also to the ability of the exposed consumer to prevent or to react to the hazardous situation. This will depend on the hazard, the warnings given and the vulnerability of the consumer who may be exposed to it'. For a broader perspective on relational regulation see Cafaggi, *supra* n. 17, at 623.

<sup>98</sup> The procedure to define technical standard is defined by Art. 4 of the GPS Directive, *supra* n. 30: '[f]or the purposes of this Directive, the European standards referred to in the second subparagraph of Article 3(2) shall be drawn up as follows:

(a) the requirements intended to ensure that products which conform to these standards satisfy the general safety requirement shall be determined in accordance with the procedure laid down in Article 15(2);

(b) on the basis of those requirements, the Commission shall, in accordance with directive 98/34 of the European Parliament and of the Council of June 22 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of the rules on information society services call on the European standardisation bodies to draw up standards which satisfy these requirements

(c) on the basis of those mandates, the European standardisation bodies shall adopt the standards in accordance with the principles contained in the general guidelines for cooperation between the Commission and those bodies'..

<sup>99</sup> See Art. 7(e) of the PL Directive, *supra* n. 29

<sup>100</sup> See Art. 3(4) of the GPS Directive, *supra* n. 30.

<sup>101</sup> See *ibid.*, recital 26: '(26) It is necessary, for the purpose of ensuring a consistent, high level of consumer health and safety protection and preserving the unity of the internal market, that the Commission be informed of any measure restricting the placing on the market of a product or requiring its withdrawal or recall from the market. Such measures should be taken in compliance with the provisions of the Treaty, and in particular Articles 28, 29 and 30 thereof'.

<sup>102</sup> *Ibid.*, Art. 3(3) states: '[i]n circumstances other than those referred to in paragraph 2 the conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, when they exist:

(a) voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;

(4) In relation to the traditional distinction that refers to civil liability as an *ex post* and to regulation as an *ex ante* technique it should be pointed out that, while conformity implies the presumption of safety, subsequent controls can take place if the monitoring system, defined by the GPS Directive, reveals the existence of risks for consumer health and safety.<sup>103</sup> These controls can trigger remedial action by producers and distributors. But competent authorities can also require the adoption of specific measures before the product is circulated or can forbid circulation altogether.<sup>104</sup> The GPS Directive defines a system of monitoring and control of product safety that operates *ex post* when the product is on the market or is about to be circulated in the market. It is a regulatory device that reacts to unsafe products placed in the markets.

There are critical aspects in both Directives as to standard-setting concerning product defectiveness and safety.<sup>105</sup> Two problems in particular emerge: (a) given the existing legislative framework which mechanisms are in place between the GPS and PL Directives to coordinate the standard-setting process; and (b) is there an implicit functional differentiation of the two systems that justifies the current differences?

The coordination between techniques for defining standards in product liability and safety by the two Directives is unsatisfactory. While an approach based on institutional complementarity might justify different considerations of the role of technical standards in regulation and liability, it is certainly a mistake to neglect their role in the field of liability. There is no reason to justify such a disproportion concerning the importance of technical standards. While their importance in the regulatory field can be recognized, more relevance should be attributed to them in the liability system.<sup>106</sup> The role of technical standards, however, should be linked to innovation and promote the pro-competitive scope of civil liability, replacing the norm that prevents judges from evaluating liability in the light of existing safer products in the market.<sup>107</sup> While this evidence should not be conclusive, it could contribute to the assessment of defectiveness by considering what is available for consumers in the market place of goods or ideas.

But what is the implicit allocation of tasks concerning risk management and control of product safety at the European level? A significant difference between the two Directives concerns the relevance of time in evaluating defectiveness or safety. While the PL Directive fixes the point at which the product is put into circulation, as to the time at which defectiveness should be evaluated, the GPS Directive imposes an evaluation of safety encompassing the use of a product by consumers.<sup>108</sup> This distinction forces a critical rethinking of the *ex ante* versus *ex post* perspective as applied to the relationship between civil liability and regulation.

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- (b) the standards drawn up in the member state in which the product is marketed;
  - (c) Commission recommendations setting guidelines on product safety assessment;
  - (d) Product safety codes of good practice in force in the sector concerned;
  - (e) The state of the art and technology;

Reasonable consumer expectations concerning safety’.

<sup>103</sup> For the *ex ante/ex post* distinction see the analysis by Shavell, *supra* n. 42.

<sup>104</sup> Art. 8 of the GPS Directive, *supra* n. 30, allows competent authorities to impose conditions prior to the marketing of a product, to require that a product be marketed with warnings concerning any risks. See in particular Art. 8(b)(ii) and (c). Art. 8(e) concerns banning: ‘for any dangerous product [competent authorities can] ban its marketing and introduce the accompanying measures required to ensure the ban is complied with’. See also Commission Decision 2004/418, *supra* n. 87, at 90 ff.

<sup>105</sup> See on the subject Howells, *supra* n. 84, at 645 ff., 652 ff.

<sup>106</sup> One implicit reason for the relatively light weight of technical standards in the field of liability may be related to the fact that standardization bodies are mainly driven by industries. Technical standards end up playing an important function through expert evidence in trials. Instead of neglecting the importance of technical standards for liability purposes a more representative structure of private standardizing bodies should be favoured. If sufficient guarantees of participation were given in technical standard-setting functions they could play a more relevant role in the liability system. On the relationship between governance of private regulators and liability see Cafaggi, *supra* n. 15.

<sup>107</sup> See Art 7 of the PL Directive, *supra* n. 29.

<sup>108</sup> For the interpretation of *ibid.*, Art. 7(a) see Case C-203/99, *Henning Vedfeld v Aarhus Amtskommune* [2001] ECR I-03569. The ECJ held that ‘Article 7(a) of Council directive 85/375/EEC of 25 July on the approximation of the laws, regulations and administrative provisions of the member States concerning liability for defective products is to be interpreted as meaning that a defective product is put into circulation when it is used during the provision of a specific medical service, consisting in preparing a human organ for transplantation, and the damage caused to organ results from that preparatory treatment’.

In the product liability field the time at which the product is circulated defines quite clearly the domain of civil liability. The development risk defence contributes to the determination of a time limit for the evaluation of defectiveness.<sup>109</sup> Regulation of consumer safety for risks whose existence becomes known after the goods' circulation is (implicitly) attributed to the GPS Directive, in which an important set of duties, enforceable through criminal sanctions, is defined to monitor product safety, even when the products circulate in the market. Translated into costs, the manufacturer will bear civil liability-associated costs within a limited period, while he will bear regulatory-associated costs and criminal liability costs for the whole life of the product.<sup>110</sup>

In relation to the circulation of the product this distinction does not resemble the traditional *ex ante* versus *ex post* distinction. On the contrary the current approach at the European level suggests that, while the PL Directive uses an *ex ante* system of evaluation, the regulatory approach in the GPS Directive uses predominantly an *ex post* perspective.<sup>111</sup> While conformity to general safety requirements can be presumed at the time of circulation, controls on safety may occur when the product is used to verify the existence of product-related risks.<sup>112</sup>

The institutional design, defined by the two Directives, should be integrated by adding the component of national civil liability systems.<sup>113</sup> National general civil liability systems, in particular negligence, may 'back up' regulatory duties established by the GPS Directive. The ability to use national civil liability systems as a complement to the General Safety Directive depends on the different legal systems, in particular the relationship between civil liability and criminal liability.

As regards deterrence the GPS and PL Directives concur in defining the legal regime before the product is circulated, while after the product is circulated the main risk management device becomes regulation through the GPS devices. As regards compensatory function consumers can claim compensation for harms caused by defects existing before the product was circulated under the PL Directive, while they can use ordinary national civil liability, associated with the violation of

<sup>109</sup> See Case C-300/95, *Commission v United Kingdom* [1997] ECR I-2649, where the Court states that 'state of scientific and technical knowledge did not merely include: the practices and safety standards in use in the industrial sector in which the producer is operating, but [extends to] the 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'. For an analysis of the case see Stapleton, *supra* n. 74, at 58. See Case C-52/00, *Commission v France* [2002] ECR I-3827, at para. 47: '[i]n regard to the arguments based on Article 15 of the Directive it should be noted that whilst that provision enables the Member States to remove the exemption from the liability provided for in article 7 (e) thereof it does not authorise them to alter the conditions under which that exemption is applied. Nor does article 15 authorise them to cancel or amend the rules governing derogations provided for in article 7 (d). That interpretation is not negated by the Directive 92/59, which does not concern the producer's liability for products he puts into circulation'. See also for the French legislation J. Calais-Aulois and F. Steinmetz, *Droit de la consommation, Précis, droit privé* (6th edn., 2004), at 332, '*Nous regrettons que le législateur français de 1998 ait cru bon d'exonérer le producteur du risque de développement. Nous pensons que l'exonération est contestable dans son principe même. L'argument d'équité nous paraît plus fort que les arguments d'ordre économique. Ces derniers peuvent d'ailleurs se retourner si on envisage le long terme : les produits se vendent d'autant plus facilement qu'ils sont réputés plus sûrs ; et ils sont réputés plus sûrs s'ils sont fabriqués dans un pays qui n'hésite pas à mettre une lourde responsabilité sur la tête de producteurs. ... La jurisprudence française a d'ailleurs la possibilité de rendre le producteur responsable du risque de développement : nous savons que le système nouveau, issu de la directive, laisse subsister d'autres systèmes de responsabilité .... Nous souhaitons que cette jurisprudence soit maintenue*'.

<sup>110</sup> One can add liability costs that may be incurred under national systems in conjunction with criminal violations.

<sup>111</sup> It should be clear that here *ex ante* and *ex post* refer to the evaluation of defectiveness and not to the time of enforcement. From an enforcement perspective the PL Directive, *supra* n. 29, remains an *ex post* device.

<sup>112</sup> See Arts. 3 and 8 of GPS Directive, *supra* n. 30, and the analysis below. In particular Art. 8(1)(a) states '1. For the purposes of this directive, and in particular, of Article 6 thereof the competent authorities of the member states shall be entitled to take, inter alia, the measures in (a) and in (b) to (f) where appropriate:

(a) for any product:

(i) to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;

(ii) to require all necessary information from the parties concerned;

(iii) to take samples of products and subject them to checks'.

<sup>113</sup> The forms of integration will vary whether the directives are seen as establishing minimum or total harmonization. In both cases integration is possible but it operates in different ways.



one of the duties defined by the GPS Directive, where the danger becomes clear after the product has been circulated.<sup>114</sup>

The current differences between the two Directives in relation to standard-setting and the risk management strategies they aim to achieve are hardly justifiable under an institutional complementarity approach. There are no good reasons for ruling out the use of the European product liability regime after the product is circulated, especially if an important set of duties may arise in relation to new knowledge concerning the existence of product-related risks. This is not simply a question of harmonization.<sup>115</sup> In the framework of institutional complementarity it is a regulatory matter.<sup>116</sup> The reasons for limiting liability should be given within a regulatory framework and not (or at least not only) within a harmonization one.

The proper differentiation between regulation and liability should characterize the different nature of the duties imposed on manufacturers, distributors, and consumers, but most importantly the different instruments used for enforcing the duties of manufacturers and other parties along the production and distribution chain. So, as we shall see, while the regulatory domain should govern the procedures for recall and withdrawal, too complex to be defined by a judge, liability can be used to enforce duties concerning cases of unsafe and defective products related to specific classes of consumers or individual ones when the defectiveness emerged after the product was circulated.

The main purpose of this illustration has been to show the interdependence between standard-setting in civil liability and regulation, the insufficient coordination between the two at European level, and the desirability of a coordinated approach.

## 6. The complementarity in monitoring compliance and the use of civil liability as a tool for ensuring cooperation among public and private actors. The case of product safety

Monitoring compliance with legal standards differentiates the civil liability strategy from administrative regulation quite significantly. In the civil liability system monitoring is essentially achieved by the parties, and in particular by the potential victims, although potential injurers may have strong incentives to (self-)monitor as well.<sup>117</sup> Monitoring has to translate into action when there is evidence that unsafe products are in circulation. It may refer to products that were already defective and have been introduced into the market or to products that were correctly deemed safe when produced and have become defective as a result of new scientific or technological evidence. There are two main categories of action:

- a) duties to inform,
- b) duties to act.

<sup>114</sup> I have criticized the use of civil liability to complement regulatory techniques in the light of the complementarity approach, claiming that the use of regulatory strategies should be, at least in some cases, independent of the use of civil liability in cases of violation. This conclusion does not imply that civil liability cannot reinforce deterrence for certain 'regulatory duties' but the two strategies, if complementary, should be generally independently enforced. The burden of monitoring and enforcing regulatory duties should be placed on the regulator, not on the judicial system. See Cafaggi, *supra* n. 15 and 17, and before Cafaggi, 'La nozione di difetto ed il ruolo dell'informazione. Per l'adozione di un modello dinamico-relazionale di difetto in una prospettiva di riforma' [1995] *Rivista Critica del Diritto Privato* 447.

<sup>115</sup> One could in fact argue that compensation for product-related harms is taken care of by national legal systems of civil liability that ensure compensation when duties established by the GPS Directive, *supra* n. 30, are breached. From this perspective the problem could be framed as one of harmonization, since the conditions under which these duties can be enforced depend on national systems, while for harms related to defects existing before the product is circulated the conditions of liability are harmonized by the PL Directive, *supra* n. 29. Whether or not a different strategy that harmonizes liability systems by considering the whole life cycle is an open question. But the main problem is that there is no reason for having a liability system independent of regulation before the product is circulated and dependent on regulation afterwards. The complementarity between the two should be functional, not temporal.

<sup>116</sup> For the distinction between harmonization and regulatory questions see *infra* text and nn. 160 ff.

<sup>117</sup> These incentives are based on deterrence and reputational factors, i.e. the amount of damages they will have to pay and the loss they would suffer if one of their product were defective.

I shall consider here the duty to inform and later, within the section devoted to remedies, the duties to act. Duties to inform are mainly directed to competent authorities and to consumers. I shall first address the duties to inform competent authorities and then the duty to inform consumers, to the extent that can be considered part of the monitoring system. To leave only to potential injurers and victims the task of monitoring product safety compliance with standards would be highly inappropriate.<sup>118</sup> Many products require sophisticated techniques for effective monitoring and high costs that individual manufacturers may not be able to afford, let alone consumers. For this reason monitoring has always been the task of regulators that have performed directly or, more rarely, indirectly, delegating this function to other bodies.<sup>119</sup> In the regulatory domain monitoring used to be done by the regulator, at least in traditional models of command and control. With the evolution of new models of regulation peer monitoring has been associated with hierarchical monitoring and more cooperative relationships between regulators, the regulated, and third parties have taken place.<sup>120</sup> In the field of product safety, monitoring the safety of products during their lifetime has always been shared between public authorities and producers.<sup>121</sup> Producers and their distribution chain have always been key players, given the reputational incentives. But the roles of individual consumers and consumers' associations has increased. The GPS Directive endorses a collaborative model of monitoring, extending to distributors duties to monitor and to inform manufacturers and competent authorities about risks.<sup>122</sup> Even beyond these duties self-monitoring by producers and

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<sup>118</sup> On the relationship between product safety and market surveillance see the papers published at the conference on European Market Surveillance Programming, organized by DG SANCO, Brussels, 10 - 11 Mar. 2005.

<sup>119</sup> For the UK regime see Scott and Black, *supra* n. 7, at 401, '[r]esponsibilities for monitoring and enforcement of product safety and food safety rules are split between the ministere, local authority trading standards departments and (in respect to food safety) local authority environmental health departments. ... The European Commission has exercised a co-ordinating role in respect of product safety since the establishment of the system for rapid exchange of information (RAPEX) in 1984 [Council Decision 84/133 EEC]. Under this regime member States have a duty to inform the Commission of measures taken to address dangerous products, and the Commission then informs the other Member States'.

<sup>120</sup> See I. Ayres and J. Braithwaite, *Responsive Regulation* (1992); Ogus, *supra* n. 82; Cunningham and Grabonsky, *supra* n. 22; R. Baldwin and M. Cave, *Understanding Regulation. Theory, Strategy and Practice* (1999); R. Baldwin, C. Scott, and C. Hood (eds.), *A Reader in Regulation* (1998); C. Scott, *Regulation a Reader* (2003).

<sup>121</sup> See Art. 5(3) and (4) of Directive 01/95, *supra* n. 30: '[w]here producers and distributors know or ought to know, on the basis of information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirements, they shall immediately inform the competent authorities of the member states thereof and under the conditions laid down as in Annex I, giving details, in particular of action taken to prevent risk to the consumer' and '[p]roducers and distributors shall, within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The procedures for such cooperation, including procedures for dialogue with the producers and distributors concerned on issues related to product safety shall be established by competent authorities'. See Commission Decision 2004/905/EC, *supra* n. 87, at. point 2.2: '[t]he purpose of the notification is to enable the competent authorities to monitor whether the companies have taken appropriate measures to address the risks poses by a product already placed on the market and to order or take additional measures if necessary to prevent the risks. The notifications also allows the competent authorities to assess whether they should check other similar products on the market. Therefore competent authorities must receive adequate information to enable them to assess whether an economic operator has taken adequate measures to regard to a dangerous product. In this respect it should be noted that GSPD entitles the competent authorities to request additional information if they feel unable to assess whether a company has taken adequate measures with regard to a dangerous product'. For notification concerning safety of food products see Regulation 178/2002 of the European Parliament and the Council, OJ 2002 L 031/1, as amended by Regulation 1642/2003, OJ L 245/4.

<sup>122</sup> See Art. 5(2) of GPS Directive, *supra* n. 30: '[d]istributors 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 the information in their possession and as professionals, do not comply with those requirements. Moreover within the limits of their respective activities they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products and cooperating in the action taken by producers and competent authorities to avoid the risks. Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently'.

distributors constitutes a very important part of the regulatory chain that allocates the burdens and responsibilities between the public authorities, self-regulatory bodies, and individual operators.<sup>123</sup>

Distributors are generally closer to the products, since they have a relatively stable relationship with consumers. Distributors are able to obtain information from consumers more cheaply and have therefore been considered a key component in the monitoring chain for product safety.<sup>124</sup> The monitoring system envisaged by the GPS Directive is aimed at triggering controls and actions by national competent authorities. The monitoring system of the Liability Directive is aimed at achieving compensation for violations that have occurred and harms that have materialized.

Violations by producers and distributors of duties to monitor are punished by imposing administrative or criminal sanctions.<sup>125</sup> Legal systems vary in permitting corresponding action in civil liability to compensate consumers for violations of duties to monitor.

Systems that deny the possibility to sue in civil liability basically define a rigid complementarity; violations of regulatory duties are sanctioned only by administrative and criminal liability.

Systems that allow actions for civil liability for violations of duties concerning standard-setting, monitoring, and enforcement define a flexible complementarity in which civil liability may be used to reinforce the regulatory model and to protect the interests of third parties, generally not directly involved in the regulatory processes.

## 7. Complementarity in remedies. Coregulation, remedies, and the example of the environmental liability directive.

The Environmental Liability (hereinafter EL) Directive, 2004/35 is a good illustration of the new regulatory schemes and their potential influences on the relationship between regulation and civil liability.<sup>126</sup> Despite its title the Directive is basically aimed at defining the relationship between some regulatory authority (the competent authority), the polluters, and private parties, mainly, but

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<sup>123</sup> See the GPS Directive, *supra* n. 30, in particular, the duties of producers and distributors defined by Art. 5(1): ‘...Within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to: (a) be informed of risks which these products might pose; (b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.

The measures referred to in the third subparagraph shall include, for example: (a) an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified and (b) in all cases where appropriate, the carrying out of sample testing of marketed products, investigating and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring.

Action such as that referred to in (b) of the third subparagraph shall be undertaken on a voluntary basis or at the request of the competent authorities in accordance with Article 8(1)(f). Recall shall take place as a last resort, where other measures would not suffice to prevent the risks involved, in instances where the producers consider it necessary or where they are obliged to do so further to a measure taken by the competent authority. It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.’

<sup>124</sup> See Art. 5(2) of Directive 01/95, *supra* n. 00.

<sup>125</sup> See, e.g., Art. 11 of Italian decreto legislativo 172/2004 implementing the GPS Directive, *supra* n. 30.

<sup>126</sup> Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, OJ 2004 L.143/56.

not just, NGOs, that may be affected by environmental damage.<sup>127</sup> The EL Directive in the drafting process shifted from a liability to a regulatory perspective, attracting numerous criticisms.<sup>128</sup>

The competent authority or the set of competent authorities has to be defined by Member States.<sup>129</sup> It is quite clear, however, that they are administrative and not judicial authorities.<sup>130</sup>

These authorities have a duty to identify the polluter, to assess damages, and to determine what remedial measures should be taken.<sup>131</sup> They have monitoring and enforcement functions. Unlike in typical regulatory directives focusing on standard-setting, here the focus is on remedies and the procedures by which they have to be identified and implemented. It clearly emerges from the Directive that the type of environmental damage considered requires a set of remedies involving multiple parties and a complex procedure. This is certainly a specific feature that cannot be generalized to the entire field of civil liability, but it is (or can become) typical of mass torts.

The main scope of the EL Directive is the identification of types of remedies and associated procedures relating to the likelihood of the occurrence of environmental damage or to harms already materialized. Measures designed to combat environmental damage are distinguished by being preventive and remedial.<sup>132</sup> The polluter is required to take preventive action when there is an imminent threat of environmental damage even if it has not yet occurred. When damage has occurred s/he is obliged to take remedial action. In both cases the competent authority may require the operator to take the necessary preventive and remedial measures and/or give instructions to the operator to act to prevent or reduce the environmental harm. While a specific provision determines modalities of remedial measures, no specific provisions are identified for deciding on preventive action.

The procedure on remedial measures states that the polluter has to identify such measures in accordance with Annex II, and then submit them for approval to a competent authority (Article 7(1)).<sup>133</sup> The competent authority will decide in cooperation with the operator (Article 7(2)) and

<sup>127</sup> While polluters are considered injurers and mainly responsible for remedies NGOs and other private parties do not have a right to compensation (Art. 3(3)) but they 'shall be entitled to submit to the competent authority any observations relating to instances of environmental damage or an imminent threat of such damage which they are aware and shall be entitled to request the competent authority to take action' (Art. 12(1)).

<sup>128</sup> In relation to the draft proposal see the criticisms of Betlem, *supra* n. 18, at 679 concerning in particular conflict with the Aarhus Convention which requires a private action to be available to non-public bodies to ensure compliance with environmental law by other non-public bodies.

<sup>129</sup> The GPS Directive, *supra* n. 30, Art. 6(2) states: 'Member States shall establish or nominate authorities competent to monitor the compliance of products with the general safety requirements and arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive'.

<sup>130</sup> See *ibid.*, Art. 11, but especially Art. 13, in which the review procedures are regulated. From the wording of that Article it is quite evident that competent authorities cannot be national judges. Art. 13(1) states: 'the persons referred to in Article 12(1) shall have access to a court or other independent and impartial public body competent to review the procedural and substantive legality of the decisions, acts or failure to act of the competent authority under this directive' Other arguments in favour of the administrative nature of the authority are based on the procedure defined by Art. 7 concerning remedial measures.

<sup>131</sup> See Art. 11(2): '[t]he duty to establish which operator has caused the damage or the imminent threat of damage, to assess the significance of the damage and to determine which remedial measures should be taken with reference to Annex II shall rest on the competent authority. To that effect, the competent authority shall be entitled to require the relevant operator to carry out his own assessment and to supply any information and data necessary'..

<sup>132</sup> See Arts. 5 and 6 of the EL Directive, *supra* n. 125.

<sup>133</sup> Annex II is devoted to different remedies that can be undertaken: '[r]emediation of damage to water or protected species or natural habitats.

Remedying of environmental damage, in relation to water or protected species or natural habitats, is achieved through the restoration of the environment to its baseline condition by way of primary, complementary and compensation remediation, where

- (a) primary remediation is any remedial measure which returns the damaged natural resources and/or impaired services to, or towards, baseline condition
- (b) "Complementary" remediation is any remedial measure which return the damaged natural resources and/or services to compensate for the fact that primary remediation does not result in fully restoring the damaged natural resources and/or service
- (c) "Compensatory" remediation is any remedial measure taken to compensate for interim losses of natural resources and/or services that occur from the date of damage occurring until primary remediation has achieved its full effect'.

invite affected persons, natural or legal, to submit their observations and take them into account (Article 7(4)). Such procedure illustrates a cooperative method of defining the appropriate remedies for environmental harm that allows the party - who is likely to be best informed about the conditions of the polluted site and the methods of repair - to define a plan, but it gives the competent authority the final word and responsibility for avoiding self-interested solutions.

The changes with respect to command and control are relatively radical, since the definition of which remedies should be adopted is the outcome of a cooperative procedure. But the differences with judicial procedure are relevant as well. Under the Directive it is the injurer who makes the proposal, while in a typical judicial setting it is the plaintiff who identifies the remedies.

While there is no analogous procedure for preventive measures (Article 5), it is clear that for the definition of these measures, too, some type of cooperative procedure should take place. The wording of Article 5 of the EL Directive permits the choice of different approaches: from a more hierarchical one to a more cooperative one.

If this Directive is to be interpreted as a 'regulatory directive' what can its impact be on national environmental civil liability systems from the perspective analysed in this essay? What will happen to those cases brought before a court in which recovery is sought? It is unclear whether the Directive pre-empts judicial solutions. There are no explicit provisions and therefore it is unlikely that Member States, when implementing it, will opt for a single strategy based on administrative procedures, precluding the judicial one. By the same token, however, once preventive and remedial actions are approved by the competent authority and implemented, a judge should not be able to order different measures in a civil liability action. The role of the judiciary will be limited to judicial review procedures concerning those decisions defined in Article 13.

Here regulatory compliance should exclude liability. However damage not considered by the directive, such as personal injuries, property harms, and economic losses would still be recoverable.<sup>134</sup> In these cases judges can certainly operate in different ways to ensure reparation. Potential conflicts can arise, in relation to harm to property and personal injuries more than in relation to economic losses, between the remedies or preventive actions approved by competent authorities and potential remedies available in legal action.

Beyond the question of the priority to be given to regulatory institutions in relation to environmental damage the main lesson provided by the Directive in the perspective of this essay comes from the relationship between injurer and regulator (who is also the person entitled to seek recovery) *vis-à-vis* that typically established in judicial proceedings concerning environmental civil liability. The above-described procedures move towards a higher level of involvement of the parties, in particular the injurer, although the final word, substantiated by the conferral of the power to approve, is still given to the competent authority. The recognition of the superior knowledge of the injurer and its ability to operate promptly in its self-interest to protect the site from further damages has perhaps been a relevant consideration for establishing the cooperative procedure in the new environmental liability directive. While it is clear that the legal regime of environmental harm could not be mechanically transplanted into the general civil liability system, the institutional mechanism defined by the Directive can provide useful insights.

First, in relation to environmental harm, the level of complexity of the accident may suggest the use of different procedures, but also affect the choice between a regulatory and a liability strategy. Often this choice can only practically be made *ex post*, when the consequences of the unlawful conduct are clear. However in a coordinated framework a procedure for choosing between regulation and liability should be defined *ex ante*. When the level of complexity of the environmental harm allows a combination of liability and regulation reform of the civil procedure system would be useful to allow for the appointment of masters to monitor the reparation process in the civil liability context. Judges may not be the best parties to follow these procedures and the available resources suggest the use of special independent appointees. More generally, the considerable impact that environmental harms have on communities suggests that stakeholders' participation should be improved in the civil liability system. Functional complementarity does not

<sup>134</sup> See recital 14 of the EL Directive, *supra* n. 125.

imply equivalence, and therefore forms of participation and monitoring activities may and should still vary according to the different strategies.

## 8 The complementarity of remedies in civil liability and administrative regulation. The case of product safety and product liability

The field of European product safety gives another good illustration of a system of institutional complementarities between liability, administrative regulation, and self-regulation in relation to remedies. The PL Directive provides compensation for injuries suffered in relation to the marketing of defective products. Limitations on compensation were, however, strict, since harm to the product itself and economic losses are not recoverable under the Directive. Thus, the decision whether such damages are recoverable is left to the discretion of individual Member States. From the perspective of remedies, the main feature missing from the PL Directive is a provision concerning injunctive relief. Not only is compensation conditional upon the traditional requirement that harm has to materialize, but no complementary judicial measures such as product recall or withdrawal have been indicated in the PL Directive. In theory the silence on product recall can be interpreted as an implicit reference to national legal systems, at least for those that had already recognized recall. In fact in many systems judicial orders concerning product recalls were already available under the civil liability of negligence or equivalent fault principles.<sup>135</sup> But still the Directive is incomplete and has only partially harmonized the area of remedies.

An open question concerns the application of Directive 98/27 on injunctions for the protection of consumer interests.<sup>136</sup> Legal systems differ as to its applicability to product liability and safety.<sup>137</sup> Also important for defining available remedies is the coordination with Directive 2005/29 on unfair commercial practices, where injunctions against unfair practices are regulated.<sup>138</sup>

The initial General Safety Directive (Council directive 92/59/EEC of 29 June 1992) filled the gap to some extent by introducing a relatively clear measure of product recall. The new GPS Directive takes an important step forward: it clarifies the distinction between product recall and product withdrawal (Article 2) and it briefly regulates the procedures of product withdrawal and product recall (Article 8(f)(i) and (ii)).<sup>139</sup> Under the amended GPS Directive product 'recall' means

<sup>135</sup> Forms of product recall existed in specific areas (drugs, ...) and were administered by sector authorities. After the ECJ judgments of 2002 it is unclear whether judges could resort to remedies different from those available under the Directive. The suggested solution is that they can order a recall under national tort law only if there is fault, while they could not in the absence of fault be given complete harmonization. See Case 52/00, *Commission v France*, *supra* n. 00, at para 22: '[t]he reference in article 13 of the Directive to the rights which an injured person may rely on under the rules of then law of contractual and non contractual liability must be interpreted as meaning that the system of rules put in place by the Directive which in Article 4 enables the victim to seek compensation where he proves damages, the defect in the product and the causal link between the defect and the damage, does not preclude the application of other systems of contractual or non contractual liability based on other grounds such as fault or warranty in respect of latent defects'.

<sup>136</sup> Directive 98/27 EC of the European Parliament and of the Council of 19 May 1998 on injunctions for the protection of consumers' interests, OJ 1998 L 166/51.

<sup>137</sup> See for the French system Calais-Aulois and Steinmetz, *supra* n. 108, at 600 ff.

<sup>138</sup> See Art. 11 of Directive 2005/29 on unfair commercial practices, of 11 May 2005, OJ 2005 L 00/00: Art. 11(2).

Under the legal provisions referred to in para. (1), Member States shall confer upon the courts or administrative authorities powers enabling them, in cases where they deem such measures to be necessary taking into account all the interests involved and in particular the public interest:

(a) to order the cessation of or to institute appropriate legal proceedings for an order for the cessation of unfair commercial practices;

or

(b) if the unfair commercial practice has not yet been carried out but is imminent, to order the prohibition of the practice, or to institute appropriate legal proceedings for an order for the prohibition of the practice, even without proof of actual loss or damage or of intention or negligence on the part of the trader.'

<sup>139</sup> See Art. 8(1)(f) of the GPS Directive, *supra* n. 30: '[f]or the purpose of this Directive, and in particular of Article 6 thereof, the competent authorities of the Member States shall be entitled to take, inter alia, the measures in (a) and (b) to (f) below, where appropriate:

any measure aimed at achieving the return of a dangerous product that has already been marketed.<sup>140</sup> Product withdrawal is any measure aimed at preventing the distribution, display, or offer of a product.<sup>141</sup> Product recalls and withdrawals can take place in at least two different ways:

- a) as independent and voluntary actions of producers
- b) as implementation of orders coming from competent authorities.

Producers who are or become aware of the dangerous nature of a product should recall or withdraw it.<sup>142</sup> Lack of prompt action can trigger liability through not having taken appropriate measures.<sup>143</sup> Evidence shows that producers are generally rather effective at recalling products from the market when there is a serious risk to consumers.<sup>144</sup>

When action is not taken by producers it can be prompted or ordered by competent authorities.<sup>145</sup> The effective conditions under which the choice between product withdrawal and recall has to take place are not spelled out in the Directive.

In national legislations implementing the Directives, the conditions are spelled out in a little more detail, but significant discretion is still left to the decision-makers.<sup>146</sup> Both the decisions to recall and withdraw are taken by one or more coordinated, administrative authorities, but in a framework that promotes cooperation with manufacturers and distributors.<sup>147</sup> The relevance of consumers' cooperation also emerges both for the discovery of defects and for the effectiveness of the recall.<sup>148</sup> While it may appear at first sight an example of command and control, in practice it has often translated into cooperative regulation.

Two interesting features of the remedial structure associated with defective or dangerous products should be analysed. The first relates to the current structure of complementarity, implicitly defined by the two Directives (PL 85/374 and GPS 01/95). The second is associated with the relatively 'cooperative' nature of the process through which the relevant actors, and particularly the competent authorities, reach decisions concerning which control and which remedies should be used.

The remedial structure, defined by the two Directives together, seems clearly to distinguish between (1) compensation, based on the liability system articulated in the PL Directive, and (2) deterrence, implemented through 'regulatory' devices, and in particular the GPS Directive. The fact

- (f) for any dangerous product already on the market:
  - (i) to order or to organise its actual and immediate withdrawal and alert consumers to the risks it presents
  - (ii) to order or coordinate or, if appropriate to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions'.

<sup>140</sup> See *ibid.*, Art. 2(g): "recall" shall mean any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor'.

<sup>141</sup> See *ibid.*, Art. 2(h): "withdrawal" shall mean any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer'. The wording of the procedures in Art. 8 is not entirely consistent with this distinction because withdrawal and recall seem both to refer to products already on the market.

<sup>142</sup> See Art. 5(1)(b) of Directive 2001/95, *supra* n. 30: '[w]ithin the limits of their respective activities producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

- (a) ...
- (b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers'.

<sup>143</sup> Such liability is based on national civil liability system and not on the PL Directive, *supra* n. 29.

<sup>144</sup> For Italy For the UK see Department of Trade and Industry, Consumer Affairs Directorate, *Transposing the Revised General Product Safety Directive* (2001).

<sup>145</sup> See Art. 8 of the GPS Directive, *supra* n. 30.

<sup>146</sup> Formally the competent authorities; *de facto* it is often a consensual decision by administrative authorities and producers.

<sup>147</sup> See Commission Decision 2004/418, *supra* n. 87: '[o]ther measures and actions that authorities can adopt or take and should notify are:

- agreements with producers and distributors to take actions necessary to avoid risks poses by products;
- agreements with producers and distributors to organise jointly the withdrawal, the recall of products from consumers and their destruction or any other relevant action
- agreements with producers and distributors to coordinate the recall of a product from consumers and its destruction'.

<sup>148</sup> See Art. 8 of the GPS Directive, *supra* n. 30, and the chapter concerning monitoring compliance, above. See, e.g., Art. 6(7) of the Italian decreto legislativo 172, 21 May 2004, implementing the Directive.

that withdrawal and recall are administered not by the judiciary but by administrative authorities means that they have been considered institutionally better equipped to evaluate the desirability of these measures and the means of implementation.

The relevance of the principle of proportionality for the decision-making process undertaken by an authority is well spelled out.<sup>149</sup>

As mentioned, this conclusion does not imply that each Member State's legal system could not permit judges to order a manufacturer to recall a defective product or to withdraw it and subject its marketing to specific safety conditions. No specific limitations on exercising this option have been introduced by the Directives, and national civil liability systems often give this option.<sup>150</sup>

What are the possible reasons for giving administrative authorities the power to recall a product or to withdraw it from the market at the European level? Two sets of reasons can be identified: the first is institutional, the second is substantive but connected with the institutional framework. On the institutional side the traditional argument against a judicial product recall is time: it has to be at the same time a prompt and a very thoughtful decision. Often, at least in many legal systems, judges may lack sufficient time to decide promptly, especially when the features of the product are such that harm is at least potentially very high. On the other hand the nature of judicial intervention is such that it is the result of a dispute whose features are generally associated with a relatively small number of litigants if compared with those that can be negatively/positively affected by the decision.

In this context it may be difficult to admit evidence that takes into account the needs and positions of consumers other than those involved in the litigation. This analysis would be particularly useful in relation to a product whose preferred level of safety may differ for various classes of consumers.<sup>151</sup> Not to mention the situation in which other considerations, concerning for example environmental protection, may be taken into account. There is some evidence, although not yet conclusive, that these conditions are better associated with administrative authorities than with the judiciary. Such a complex and multi-layered analysis would be better taking place in a setting in which the regulator is or should be adequately equipped to evaluate the opportunity to adopt different remedies concerning the choice of introducing the product on to the market, but also recalling it.

A second set of reasons is substantive. While the solution of the final recall is certainly available, the possibility of a partial or temporary recall is higher, aimed at reintroducing the product to the market once the problem is solved. It is important that there is a monitoring system in place to administer these solutions. Judges could monitor only with great difficulty, assuming they had power and resources. Moreover, since often the products to be recalled are sold in the whole of the European market, a cooperative system among regulatory authorities is required. Such a system is developing among administrative authorities, while it is not yet available among the national judiciary.

For these reasons, while the choice on liability initially made by the Directive seemed inappropriate because it severely limited the available set of remedies, it is now more acceptable if it is framed in a context of institutional complementarity. Seen in the light of the GPS Directive the lack of injunctive relief appears less problematic.

The functional allocation between regulation and liability suggests that remedies concerning large numbers of dangerous defectively designed products should take place under the GPS Directive, while more specific and relatively diffused defects should be remedied under the PL Directive. The key feature is related to a design defect and the way in which the two systems interact. It can be inferred that while the regulatory Directive ought to apply as soon as the danger

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<sup>149</sup> See Art. 8(2) of GPS Directive, *supra* n. 30: '[w]hen the competent authorities of the member states take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f) they shall act in accordance with the treaty and in particular Articles 28 and 30 thereof in such a way as to implement measures in a manner proportional to seriousness of the risk and taking due account of the precautionary principle. In this context they shall encourage and promote voluntary action by producers and distributors in accordance with obligations incumbent on them under the Directive and in particular Chapter III thereof, including where applicable by the development of codes of good practice'.

<sup>150</sup> But see *supra* text and nn. 107-107, 134 on the potential implications of ECJ case law.

<sup>151</sup> See again the GPS Directive, *supra* n. 30.



becomes known, the Liability Directive can apply only when harms materialize. But if, for whatever reason, the administrative authority has not intervened and a judge finds a product to have been defectively designed, should the competent authority intervene, at least to verify whether the defectively designed product should be recalled? A coordination mechanism should require administrative authorities to examine the matter.

Analogous problems may occur in the field of failure to warn especially if judges not only order pecuniary sanctions but impose informational requirements on producers and distributors.

Coordination mechanisms between judicially defined duties to warn and regulatory information requirements are strategically very relevant, both at the standard-setting and the remedial level to ensure that a consistent overall regulatory strategy is applied.

## 9 Civil liability to ensure effective regulation? The liability of regulators in the field of product safety and environmental protection.

The shift towards regulation or the increasing importance of product safety regulation poses problems associated with its effectiveness in all domains: standard-setting, monitoring, and enforcement. The effectiveness of regulation as a risk management system for product safety is partly dependent upon regulators' liability. Civil liability of regulators may contribute to realizing a diffuse control mechanism for dealing with omission or defective regulation. The civil liability system here is not a complement of regulation but it constitutes an integral part of the regulatory system affecting its efficacy and accountability. Changes in actors and techniques influence the articulation of the regulators' liability system. But who are the regulators in the field of product safety?

The identity of product safety and environmental regulators and the modes of regulation have changed in the past twenty years, especially since the adoption of the new approach.<sup>152</sup> The importance of private standardization bodies has increased. Their role has changed in particular with the Normalization Directive of 1998.<sup>153</sup> Their relevance has been recognized even more by the GPS Directive. Within this pattern a growing importance is attributed to European standardizing bodies.<sup>154</sup> Other private actors populate the regulatory scene in the areas of product safety and environmental protection.<sup>155</sup> Consumers' associations play an increasing regulatory role in relation to both safety and environmental protection. Trade associations have also increased their influence. Furthermore, it is important to underline that private regulators are called to play a strategic role, not only in standard-setting but also in relation to monitoring and enforcement.<sup>156</sup> The role of private

<sup>152</sup> See Scott and Black, *supra* n. 7, at 390: '[the] highly detailed vertical measures of regulation from the EC have, since the 1980s, been gradually displaced by so-called "new approach" or "framework" directives. These legislative instruments set out minimum requirements while leaving the filling in of much of the detailed to voluntary standards and "soft law"'. See also Calais-Auloy and Steinmetz, *supra* n. 108, at 301, '[l]es premières directives verticales contenaient des règles techniques extrêmement précises. Devant l'ampleur de la tâche, une "nouvelle approche" fut entreprise en 1984: les directives se bornent à poser pour chaque produit, les exigences fondamentales; elle n'ont pas à entrer dans le détail de spécification techniques: celle-ci relèvent des normes élaborées par les organismes de normalisation. Il existe une vingtaine des directives "nouvelle approche", concernant des produits très variés'.

<sup>153</sup> See Vos, *supra* n. 14 ; Schepel and Falke, *supra* n. 55.

<sup>154</sup> See Communication on Standardization, *supra* n. 57.

<sup>155</sup> See Scott and Black, *supra* n. 7, at 383, where the authors state that '[c]ontemporary product safety regimes (both within the UK and in other jurisdictions) often generate a hierarchy of norms, within which the presence of detailed statutory standards take precedence but if there are no such statutory standards then private or industry standards govern the products. Only when there are no detailed standards of any kind can enforcement officers and courts fall back on general product safety standards which, because they are necessarily open-textured, give wide discretion in their interpretation. In practice the detailed content of general safety standards is often filled in by private standards set by standardisation institutions or industry groups. It is argued that the presence of the capacity of government to set statutory standards encourages industry to develop effective self-regulation, obviating the need for statutory approach'.

<sup>156</sup> Consider in the UK, e.g., where, on the basis of the Enterprise Act, Part 8 (Stop Now Orders), the Consumers' Association is given the right to use Stop Now Orders to clamp down on traders who harm the collective interests of consumers. The French legal system has similar enforcement devices for designated consumer associations.

actors in the regulatory chain has also been recognized. It has already been mentioned that, both in monitoring and enforcement, producers and distributors in the field of product safety and polluters in that of environmental liability can play a key role in gathering information about risks and managing safety-related risks.<sup>157</sup> The new regulatory roles played by private actors combine well with the new responsibilities of public regulators in relation, for example, to product recall and withdrawal.<sup>158</sup> How has this growing importance of private regulators translated into a change in the liability regime of regulators?

We should distinguish between liability of public and private regulators. While the liability of public authorities is relatively well defined, even though not homogeneous, across all the Member States, the liability of private regulators that combine with public regulators in setting standards, monitoring compliance, or enforcing the rules is relatively less clear.<sup>159</sup> It is unclear whether the liability regime applicable to these bodies is analogous to that of public regulators or whether it remains that of private organizations with some adjustments due to the nature of the activity in question (regulation in the public interest). Current private law instruments do not offer satisfactory responses and a new framework is needed.<sup>160</sup>

## 10 A coordinated approach to civil liability and regulation for safe products at the European level? Which implications for harmonization strategies?

The interaction of civil liability and regulation in a European perspective should be related to the strategies of European harmonization. The issue should be framed in the context of the broader question of the relationship between consumer protection, health and safety protection, and market integration.<sup>161</sup>

Before addressing the theme of future strategies of harmonization in the area of product safety and environmental protection in the light of the institutional complementarity approach it is useful to address the preliminary question of the relationship between harmonization, market integration, and regulation.<sup>162</sup> This relationship can take different forms:

- a) harmonization without regulation;
- b) regulation without harmonization;
- c) combined yet not necessarily symmetric levels of harmonization and regulation.

Harmonization without regulation can take place when there is de-regulation through pure negative integration. Regulation without (hierarchical) harmonization can take place in the regulatory competition context.<sup>163</sup> Such competition can, for example, use international private law as a regulatory device.<sup>164</sup> In this contribution the focus will be on the combination between

<sup>157</sup> See *supra* text to nn. 14 ff..

<sup>158</sup> See *supra* text to nn. 14 ff..

<sup>159</sup> On this topic see Cafaggi, *supra* n. 17.

<sup>160</sup> For this conclusion see *ibid.*

<sup>161</sup> See Weatherill, 'Consumer Policy', in P. Craig and G. de Búrca, *The Evolution of EU Law* (1999), at 702 ff., Weatherill, 'Why Object to the Harmonization of Private Law by the EC?' [2004] *ERPL* 633, at 635: 'harmonization at EC level was requires. So the strict constitutional purpose of harmonization was originally rule-making designed to make an integrated market, but its effect was to allocate to the Community level (albeit typically not exclusively) the competence to decide on the substance of the rules in question'. The ECJ has defined the relationship between consumer protection and market integration in recent cases. See Case C-52/00, *Commission v France*, *supra* n. 00, at para. 15.

<sup>162</sup> For a more detailed analysis see Cafaggi, *supra* n. 17.

<sup>163</sup> See *ex multis*, D. Esty and D. Geradin (eds.), *Regulatory Competition and Economic Integration* (2001); Bratton *et al.*, *International Regulatory Competition and Coordination* (1996).

<sup>164</sup> See, e.g., Muir Watt, 'Experiences from Europe: Legal Diversity and the Internal Market', 39 *Texas Int'l LJ* (0000) 429; *ead.*, 'The Challenges of Market Integration for European Conflicts Theory', in Hartkamp *et al.*, *supra* n. 13, at 191 ff.; Way, 'Transnational Liftoff and Judicial Touchdown: The Regulatory Function of Private International Law in an Era of Globalisation', 40 *Columbia J Transnat'l L* (2002) 209.

harmonization and regulation, since the field has been both partially harmonized and partially regulated.

The harmonization strategies in the field of product safety have proceeded separately and, as was analysed earlier, coordination has often been purely negative, i.e. the more recent directives provide that rights protected by previous directives should not be affected. Both directives in the field of product safety were enacted to define minimum standards that Member States could increase in their national standards.<sup>165</sup> As mentioned, recent interventions of the ECJ in the field of product liability pose more serious questions concerning the level of harmonization, shifting from a minimum harmonization perspective to total harmonization.<sup>166</sup> The landscape has therefore changed: while product liability is ‘fully’ harmonized in so far as the questions touched by the PL Directive are the object of harmonization, product safety continues to be harmonized only as far as minimum standards are concerned.<sup>167</sup>

An additional difference between liability and regulation should be considered. While administrative regulation concerning product safety and environmental standards is subject to mutual recognition, the liability system is generally not but for few exceptions.<sup>168</sup> It should be clarified that mutual recognition has not worked homogeneously across different modes of regulation. Much more problematic has been mutual recognition for privately defined technical standards. The new forms of regulation, incorporating privately set technical standards, therefore pose a serious challenge to the strategy of mutual recognition. Thus in the regulatory domain a serious problem concerning negative integration is related to the different regimes of administrative and private regulation in relation to freedom of goods. While the first are scrutinized under Article 28 EC, the second are only considered under the umbrella of competition law (Article 81 EC).<sup>169</sup>

<sup>165</sup> See Art. 3(4) of the GPS Directive, *supra* n. 30, and Art. 13 of the PL Directive, *supra* n. 29. Art. 3(4) states: ‘[c]onformity of a product with the criteria designed to ensure general safety requirement, in particular the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member states from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous’. Art.13 states: ‘[t]his Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or special liability system existing at the moment when this directive is notified’. In general for the competence system on consumer protection see Weatherill, *supra* n. 160, at 641: ‘[t]he consumer protection title limits the EC to measures that supplement State action, pursuant to article 153(3)(b). Articles 176,137 and 153 EC Treaty, governing competences to legislate in the fields of environmental protection, social policy and consumer protection respectively, stipulate that national measures that are stricter than the agreed Community standards are permitted. So common EC Rules are of a minimum nature’. See also *id.*, ‘Competence Creep and Competence Control’, 23 *YEL* (2004) 000..

<sup>166</sup> See Case C-52/00, *Commission v France*, *supra* n. 00, at paras. 20, 21, 22, 23, and 24; Case C-183/00, *Maria Victoria Gonzales Sanchez v Medicina Asturiana SA* [2002] ECR I-03901; Case C-154/00, *Commission v Hellenic Republic* [2002] ECR I-03879. These judgments have been strongly criticized because they do not correctly interpret Art. 13 of Directive 374/85, *supra* n. 00. On the role of these cases see Van Gerven, *supra* n. 9, at 112. For a critique see Howells, *supra* n. 84, at 645; Cafaggi, *supra* n. 27; Joerges, ‘On the Legitimacy of Europeanisation of Private Law: Considerations on Justi(ce)-fication (*justum facere*) for the EU Multi-level System’, in Hartkamp *et al.* *supra* n. 13, at 178.

<sup>167</sup> See Case C-52/00, *Commission v France*, *supra* n. 000, at paras. 20, 21, 22, 23, and 24. See also Calais-Auloy and Steinmetz, *supra* n. 108, at 329.

<sup>168</sup> For the use of mutual recognition as the harmonizing technique in the field of product safety standards see recitals 29 and 30 of the GPS Directive, *supra* n. 30: ‘(29) It is primarily for the member states in compliance with articles 28,29 and 30 thereof to take appropriate measures with regard to dangerous products located within their territory (30) However, if the member States differ as regards the approach to dealing with the risk posed by certain products, such differences could entail unacceptable disparities in consumer protection and constitute a barrier to intra-community trade’.

Note, however, that Art. 3(3)(b) of the Directive mentions among the elements upon which conformity to the general safety requirement should be assessed the standards drawn up in the Member State in which the product is marketed. This criterion suggests that when the place of manufacturing and place of marketing are different both should be taken into account.

<sup>169</sup> See Calais-Auloy and Steinmetz, *supra* n. 108, at 300, ‘*Nous savons que l’article 28 du Traité CE (ancien article 30) interdit, entre Etats Membres de l’Union Européenne, les restrictions quantitatives à l’importation “ainsi que toutes mesures d’effet équivalent”. Si elle était appliqué telle quelle, l’interdiction serai dangereuse pour la santé et la sécurité des consommateurs, puisqu’elle empêcherait chaque Etat membre des prendre des règles de sécurité plus rigoureuses que celles des autres Etats membres et qu’elle conduirait ainsi à une alignement des législation par les*

This distinction implies, for example, that technical standards produced by public regulators are evaluated under Article 28, while those produced by private bodies are evaluated under Article 81. This conclusion poses even greater problems once it is applied to self-regulation and private regulation in the fields of product safety and environmental protection.<sup>170</sup> A grey area is related to privately defined standards whose production has been delegated to private bodies or has been recognized *ex post* by public authorities.<sup>171</sup>

The main problems for a fully integrated approach to liability and regulation are related to civil liability. In this field mutual recognition is not yet applied except in a few exceptions. Standards defined by courts are therefore purely domestic, unless a directive harmonizes them. To the extent that the PL Directive operates, standard harmonization occurs at European level, while, for those aspects left to Member States, the degree of heterogeneity is higher. Perhaps lack of debate is due to lack of recognition of the regulatory function of civil liability. In this context judicially defined standards are not mutually recognized.<sup>172</sup> They circulate more as ‘case law’ through comparative law references employed by the judiciary both at national and European level.<sup>173</sup>

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*bas. Ils ont admis, dans l'article 30 (ancien article 36), des dérogations à l'article 28, notamment pour des raisons des "protection de la santé et de la vie des personnes et des animaux". La protection de la santé est considéré comme plus importante que la libre circulation des marchandises. Il en résulte que les règles nationales concernant la sécurité des produits peuvent valablement entraver le commerce intra-communautaire".*

<sup>170</sup> See Temmink, *supra* n. 46, at 61 ff.

<sup>171</sup> When there is state or public intervention the ECJ has been willing to allow scrutiny under Art. 28. See Schepel, *supra* n. 15.

<sup>172</sup> See however Directive 98/27. *supra* n. 135, on injunctions for the protection of consumer interests in relation to standing. Recital (11) and Art. 4. Recital (11) states that: ‘[w]hereas for the purpose of intra-community infringements the principle of mutual recognition should apply to these bodies and/or organisations whereas the member states should, at the request of their national entities, communicate to the Commission the name and the purpose of their national entities which are qualified to bring an action in their own country according to the provisions of this directive’ .Art. 4(1) states that: ‘[i]ntra-community infringements Each member-state shall take the measures necessary to ensure that, in the event of an infringement originating in that Member State, any qualified entity from another member state where the interests protected by that qualified entity are affected by the infringements, may seize the court or administrative authority referred to in Article 2 on the presentation of the list provided for in paragraph 3. The Courts or administrative authorities shall accept this list as proof of the legal capacity of the qualified entity without prejudice to their right to examine whether the purpose of the qualified entity justifies its taking action in a specific case.’ See also Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on cooperation between national authorities responsible for the enforcement of the consumer protection law (Regulation on consumer protection cooperation), OJ 2004 L 364/01. At Art. 9(2) on coordination of market surveillance and enforcement activities, it states: ‘[w]hen competent authorities become aware that an intra-Community infringement harms the interests of consumers in more than two Member States, the competent authorities concerned shall coordinate their enforcement actions and requests for mutual assistance via the single liaison office. In particular they shall seek to conduct simultaneous investigations and enforcement measures’; while at Art. 16(1) on enforcement coordination, it states: ‘1. To the extent necessary to achieve the objectives of this Regulation, Member States shall inform each other and the Commission of their activities of Community interest in areas such as:

- (a) the training of their consumer protection enforcement officials, including language training and the organisation of training seminars;
- (b) the collection and classification of consumer complaints;
- (c) the development of sector-specific networks of competent officials;
- (d) the development of information and communication tools;
- (e) the development of standards, methodologies and guidelines for consumer protection enforcement officials;
- (f) the exchange of their officials.

Member States may, in cooperation with the Commission, carry out common activities in the areas referred to in (a) to (f). The Member States shall, in cooperation with the Commission, develop a common framework for the classification of consumer complaints’.

<sup>173</sup> It should be mentioned that a strategic role can be played by the common principles of tort law elaborated by the ECJ in relation to liability for breach of Community law while applying art. 288 (2). The rule-finding exercise of the ECJ develops a peculiar multi level rule-finding system. See for example Joined cases *Brasserie du Pecheur and Factortame* [1996] ECR I-1029 and *A.G. Tesouro* Opinion ECR I-1066 where compensation and the duty to mitigate damage by the victim were clearly identified; in particular see paras 80-87. On these matters Van Gerven, Taking Art. 215 (2) EC Treaty seriously, in J. Beatson and T. Tridimas (eds) *New directions in European public law*, (Oxford Hart publishing), 1998, p. 36 ff., Lenaerts, ‘Interlocking Legal Orders in the European Union and Comparative Law’, *52 ICLQ* (2003) at 873. For a critical view of the role of the ECJ see Weatherill, *supra* n. 160, at 637: ‘[t]he Court’s

How should mutual recognition or some type of functional equivalent operate, if at all possible, in the context of a coordinated strategy between regulation and liability? If one recognizes the regulatory function of civil liability, the standards set by judges in relation to defectiveness could be considered as a source of interpretation by the courts of other legal systems in which the product is circulated.<sup>174</sup> Lack of mutual recognition or alternative solutions coordinating regulatory and liability standards pose a serious risk of diverging judicial opinions concerning product standards even if they operate within the framework of the PL Directive.<sup>175</sup> Certainly the ECJ can reduce these problems but only to a limited extent.

The more general question concerning governance of normative differences stemming from minimal harmonization of product safety and environmental protection cannot be avoided. In particular a crucial issue is that of different modes and degrees of enforcement.<sup>176</sup>

If the optimal approach is multi-level regulation, in particular to define minimum standards at European level and to allow Member States to increase the level of protection, the crucial question is how to govern excessive divergences that can undermine harmonization without resorting to complete harmonization. The sole reference to the ECJ to ensure coherent interpretation of the Directive may not be the most effective instrument. A governance mechanism that monitors standards implementation to which both regulators and judges contribute would be highly desirable. The legal basis can be found in article 153 (3.b) EC Treaty. Coordination mechanisms in both the fields of product safety and environmental protection are already in place for administrative authorities.<sup>177</sup> In the short term the most plausible institutional strategy is to empower them with a

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view is commonly that once a legal concept is embedded within a harmonization directive it cannot be allowed to depend for its meaning on local preference or tradition. In order to make real the harmonized nature of the regime it must be endowed with an autonomous European meaning'. See *Fairchild (suing on her own behalf) etc. v Glenhaven Funeral Services Ltd and others etc.* [2002] UKHL 22.

<sup>174</sup> Currently such a system could be implemented by referring to the duty of sincere cooperation in Art. 10 EC as applied to courts. I am indebted to Bruno de Witte for this suggestion. Several practical problems should however be tackled if this option were to be used: Which judgments should be considered? Only Supreme Courts? What if precedents are not entirely consistent?

<sup>175</sup> According to Calais-Aulois and Steinmetz, *supra* n. 108, at 602, a system of mutual recognition has been introduced by Directive 98/27.

<sup>176</sup> See Husu-Kallio, *Welcome Address Conference on European Market Surveillance Programming*, Brussels, 10 Mar. 2005, available at <http://europa.eu.int/comm/consumer> : '[w]hile a comprehensive and largely harmonised framework of consumer product rules and standards exists, the approaches, means, instruments and practices for market surveillance and enforcement are in general very diverse. The differences are at least partly rooted in the different internal institutional and administrative systems of the member states and are an unavoidable part of our diversity. Traditionally enforcement has been considered a matter covered by subsidiarity considerations. This has led to a variety of methods and internal organisations of national authorities. We have to take this fact into account in looking for ways to achieve the optimal enforcement of product legislation that we are aiming for'. See Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions Consumer policy strategy 2002-2006, COM(2002)208 final. The European Commission has welcomed private initiatives on monitoring and enforcement. For example, it has published private initiatives on its official website: *Mouvement des Entreprises de France MEDEF, Initiating a Code Of Conduct for European Governance*, 2001. Specific proposals concerning mutual recognition of judgments relating to consumer law in relation to injunctions have been made. See Calais-Aulois and Steinmetz, *supra* n. 108, at 602 : '[d]ans l'état actuel du droit, il faut appliquer le règlement communautaire du 22 décembre 2000, qui prévoit une procédure d'exequatur peu compatible avec la nécessaire rapidité de la cessation. Pourquoi ne pas admettre, en cas d'infraction à une directive, que le jugement de cessation rendu dans un Etat membre soit de plein droit exécutoire dans les autres Etats membres ? ... La réforme, certes, est ambitieuse; elle supposerait une réforme du règlement du décembre 2000'.

The risks of mutual recognition have also been highlighted and compared with alternative solutions based on uniform rules of conflict of laws. See in this volume H. Muir Watt, 'Integration and Diversity: The Conflict of Laws as a Regulatory Tool', at 000.

<sup>177</sup> See Art. 10 of the GPS Directive, *supra* n. 30: '1. The Commission shall promote and take part in the operation of a European network of authorities of the Member States competent for product safety, in particular in the form of administrative cooperation. 2. This network operation shall develop in a coordinated manner with the other existing community procedures, particularly RAPEX. Its objective shall be in particular to facilitate:

- (a) the exchange of information on risk assessment, dangerous products, test methods and result, scientific developments as well as other aspects for relevant control activities;
- (b) the establishment and execution of joint surveillance and testing projects;
- (c) the exchange and expertise and best practices and cooperation in training activities;

stronger coordination function.<sup>178</sup> In the long run a more sophisticated mechanism should be devised to monitor standard-setting and compliance, to ensure that divergences are compatible with the harmonization strategy and will not become barriers to trade, impermissible under Article 28 EC.

## 11. Concluding remarks

The influence of regulation, both administrative and private, on European civil liability has been a relatively neglected topic. Similarly the influence of civil liability on regulation is generally not deeply analysed. Often the regulatory space is defined without considering the actual and potential role of civil liability.

Changes in the regulatory environment do not allow the juxtaposition of regulation as a centralized rigid system of risk management and civil liability as a highly decentralized, bottom-up regulatory system. New regulatory techniques, especially incentive-based, have introduced a high level of decentralization which has dramatically reduced monitoring and compliance costs while, to a lesser extent, increasing coordination costs.<sup>179</sup>

This essay has asked two questions on the positive dimension:

- a) whether there is any explicit or implicit coordination between regulation and civil liability in the field of European environmental protection and product safety;
- b) what each 'strategy' could learn from the other.

On the normative dimension the essay has focused on whether higher coordination is desirable and which 'institutional' consequences such coordination may bring about in terms of liability of regulators and harmonization strategies.

The analysis has shown that (1) on a positive level there is reciprocal influence of the two techniques, (2) on a normative level a higher degree of coordination is desirable at European and national level in the field of environmental protection and product safety. Such coordination presupposes an effective system of liability for regulators and more coherent harmonization strategies. Such strategies should not be focusing solely on legislative harmonisation but they should consider multi-level rule finding techniques such as those developed by the ECJ in area of extracontractual liability of European and national institutions. The importance of rule-finding is strategic and that methodology should be expanded also to regulatory law.

As to the mutual learning aspect, recent developments of regulatory techniques, incorporated into the European legislative framework, can provide powerful insights for the civil liability system. While the complexity of regulatory analysis, favoured by the frequent use of regulatory impact assessment, cannot be entirely mimicked in the civil liability area, the adoption of impact evaluation for the most important judicial decisions should be promoted both at European and national level. Awareness and transparency of the efficiency and distribution effects of civil liability judgments through impact evaluation assessment could also improve the proposed coordinated strategy.

While economic reasons, mainly associated with the costs of administrative regulation and some of the transformation of the regulatory state, have recently overburdened civil liability with functions related to risk assessment and risk management, the more useful perspective is to conceive of civil liability and regulation as functional complements rather than functional equivalents in relation to both deterrence and compensation.

What are the main differences between regulation and civil liability within a coordinated strategy?

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(d) improved cooperation at Community level with regard to the tracing, withdrawal or recall of dangerous products'..

Coordination of administrative authorities takes place both within the Rapex system and the European Safety Network in the field of product safety and according to sectoral legislation with the Recreational Craft Administrative Cooperation Group, Market Surveillance in the Machinery sector, among other examples.

<sup>179</sup> See in relation to the environment for the US, Stewart, *supra* n. 5, at 9.

While regulation, especially the type based on cost-benefit analysis, is grounded on risk assessment that permits the differentiation of risks and the weighing of them in relation to the decision on whether and how to regulate, civil liability tends to be more over-inclusive once it is in place. In civil liability internal partitioning concerning risk management has occurred over the centuries in relation to different risks (for example, liability for wild animals versus liability for dangerous activities), between negligence and strict liability and within each regime. Within civil liability, however, environment and product-related risks are still considered relatively homogeneous in comparison to the level of specification and differentiation recently employed in the regulatory field. Such more highly tailored regulation has been made possible for the introduction of different forms of incentive-based regulations but also for the consolidation of ‘negotiated’ command and control.<sup>180</sup>

When the level of risk differentiation is very high civil liability may perform better. The strong decentralized decision-making system of civil liability permits highly specific and relatively idiosyncratic factors to be taken into account.

Regulation still performs better for highly homogenous risks and when they are coupled with relatively homogeneous harms. On the contrary, when homogeneity of risks and harms is relatively low, civil liability can be a better device.

Regulation is preferable to civil liability when the cost-benefit analysis encompasses several risk-risk and benefit-benefit analyses, i.e when, within the same regulation or in different regulations, trade-offs among risks and among benefits have to be made. Civil liability is relatively ill-suited to such trade-offs, and the selection of litigants may affect the inability of the judge to evaluate external risks and benefits of the decision concerning product defectiveness and consequent remedies.

In the area of monitoring compliance clearly civil liability may be insufficient. Furthermore, to leave the parties to bear the costs, especially when they are potential victims, may have unwelcome distributional consequences. The directives on product safety have introduced a coordinated system of monitoring using regulation, and criminal and civil liability.

Regulatory monitoring systems that impose specific duties on parties to organize network monitoring may satisfactorily complement the existing incentives of potential injurers and victims both to detect unknown risks and to monitor known hazards.

In the domain of enforcement a strategy that distinguishes *ex ante* from *ex post* remedies has become obsolete. The preventive nature of civil liability suggests the coupling of compensatory remedies with injunctions. The difference should not be based primarily on the nature of the remedy but (1) on the conditions they are subject to, (2) on the institutions that administer them, and (3) on the effects, general or specific, they produce.

The level of coordination between regulation and civil liability is insufficient, both at European and national levels. Changes in the regulatory environment have caused and will bring about important modifications of the liability system. Two main questions have to be addressed for a coherent European institutional design:

(a) the choice between different approaches to regulation and liability: i.e the alternative between sector-specificity and general;

(b) the different harmonizing strategies: i.e the alternative minimum versus complete harmonization.

Regulation of product safety is mainly based on specific products; and the GPS Directive is residual. The PI Directive includes all products. It remains to be demonstrated that there are good reasons for having different approaches, one specific and the other general. But even if there were good reasons for having fragmented regulatory directives and a unified liability system the problem of coordination mechanisms remains, and is perhaps even more relevant. The same liability system has to be complemented by different regulatory strategies for drugs, food, toys, cars, etc.

Currently the degree of harmonization is different. From the multi-level regulation perspective such differences impose different balances between the European and the national levels

<sup>180</sup> See for a comparative analysis Stewart, *supra* n. 5, at 9 ff.

for regulation and for liability. The current state is criticizable for this asymmetry. Such asymmetry again poses serious problems for vertical coordination even beyond functional complementarity.

European legislative intervention to integrate the different strategies is needed both in the field of product safety and in that of environmental protection. The means and the goals of the coordination should be on the agenda of future scholarship and policy-making.