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PRODUCT SAFETY REGULATION

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Abstract

Market failures paired with private law failures call for safety regulation. The main dilemma for policymakers is to find 'the optimal level' of product safety regulation. Hence, in this chapter science and cost-benefit analysis are presented as important technocratic tools for risk assessment and risk management. As product safety regulation covers a wide range of industrial activities, a variety of empirical studies have been reviewed. The lively controversies on the effectiveness of some regulations, often arisen among specialists, show how difficult the appraisal of cost and benefit of regulation is, especially in the presence of 'risk-compensation' behavior.

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1. Introduction

The need for product safety regulation should no longer be a source of controversy. Welfare economics provides a theoretical justification for such regulation. If it were realistic to assume individuals to behave 'rationally', possessing perfect information coupled with the absence of externalities, there would be no need for regulation. It has been generally recognized that the aforementioned assumptions should be, at least partially, disregarded when analyzing the real world. When these assumptions are fulfilled the interaction of market forces will generate allocative efficiency. The reason for governmental intervention is given by the 'market failures' that arise when the aforementioned assumptions are relaxed. Even the most liberal and market-oriented economist would agree on this point.

At the present moment, the conjugation of private and public regulation seems to be the only available answer to the question whether it is better to have a system based on tort or on product safety regulation. While investigating which is the better type of regulation, information regulation seems the most attractive option, because it preserves the consumer's choice. It improves competition among firms and does not induce technological rigidity which, for instance, may be caused by specification standards.

However, the shortcomings of this type of regulation, such as the problem consumers have in absorbing the disclosed information, or the harmful consequences suffered by bystanders, call for command-and-control regulation as a necessary complement of information regulation.

Once the need for product safety regulation, both in the form of information and command-and-control regulation, has been recognized and justified as a valid formula to correct market failures, the next step is to identify which are the most effective tools to find the optimal amount and formulation of regulation. If we accept that science is the best tool available for public risk assessment, then an indirect way to articulate efficiently regulation is to finance and protect scientific research. Up till now, much emphasis has been placed on the importance of using cost-benefit analysis in regulatory process. However, the flaws of cost-benefit analysis have induced some authors to entirely reject its use. What is suggested in this paper is that the proper question to pose is not whether it is opportune to use cost-benefit analysis, but how and when the application of cost-benefit analysis is suitable. The analysis of the downfalls of cost-benefit analysis already gives useful insights to answer these crucial questions.

The task of policymakers should not be a pure elaboration of safety regulations. Rather, it should be the elaboration of effective safety regulations. A brief survey of case studies highlights the question that safety regulations have not always resulted in being effective. However, there is frequently a lack of consensus on results. Therefore, it might be desirable to take into account how the author's beliefs might have affected the results of the empirical study. Moreover, from this review it appears that what Thomas Huxley said in 1860 is still valid: '[s]cience ... warns me to be careful how I adopt a view which jumps with my preconceptions, and to require stronger evidence for such belief than for one to which I was previously hostile. My business is to teach my aspirations to conform themselves to fact, not to try and make facts harmonize with my aspirations'. Hence, the result of an empirical study might be considered more reliable when it is supported by other empirical studies, which, even if utilizing different methods, lead to similar results.

Even if *prima facie* the analysis of the rationales for having product safety regulation may appear fragmentary, a more accurate look at it will disclose the deep interdependencies between the several issues treated in this paper. On the one hand, the benefits that different analytical approaches provide should not be underestimated. On the other hand, a global view of the points in question is valuable for a systematic and consistent formulation of product safety regulation and call for a crucial co-ordination with other regulatory policies.

2. The Spectrum of Legal Regimes from Tort Law to Safety Regulation

From an economic perspective, tort law and public safety regulation are two branches of law with the same goal: the minimization of accident costs (Calabresi, 1970). The issue of the relative desirability of having a system based on tort or on regulation has been frequently discussed. A review of the main literature on this topic shows that, in some circumstances, tort law will bring about an optimal allocation of resources whereas, in other cases, the contrary will be true.

Shavell (1984) points out four theoretical determinants of the relative desirability of liability and safety regulation and argues for a joint use of liability and regulation as the best solution to the problem of the control of risk, 'with the balance between them reflecting the importance of the determinants'. Rose-Ackerman (1991), who identifies three forms of complementarities, has addressed the issue of complementarity between tort and regulation. An overall conclusion is that, in order to control activities creating risks of harm, it is not conceivable to employ only liability or safety regulation (see also Shavell, 1987; Burrows, 1992; Rose-Ackerman, 1992).

As Skogh (1989) points out '[t]he reason is that cost-liability, regulation, private insurance and public insurance have specific benefits and shortcomings that make a mixture favorable'. However, in order to choose the best policy option to control the risk of harm, it seems crucial to take into account all the theoretical analyses, which are useful to distinguish the case when it is better to have a system based mainly on safety regulation, even if integrated by liability rules as opposed to a system based mainly on liability rules.

Therefore, when tort liability turns out to be an inefficient tool to correct market failures there is a call for regulation. However, among the different types of regulation there are some that still preserve the consumer's freedom of choice, that is information regulation. The demand for information regulation originates from the presence of information asymmetry, which is an exceptional source of market failures. The literature on this point is copious, but the topic is covered in another chapter (5110, Information Regulation), and therefore this survey is concise. The seminal article by Akerlof (1970) illustrates the consequences of information asymmetry relative to the quality of the product. Also cited is the article by Nelson (1970), who distinguishes 'search' and 'experience' goods and that of Darby and Karny (1973) who describe those types of goods which are said to bear 'credence' qualities.

If the lack of information about the quality has the evident consequence of an inefficient market outcome, the same is true for the uncertainty related to the safety of the item. Imperfect information about safety can be defined as the consumer ignorance about risks, or in other words, as a high degree of

uncertainty about the probabilities that a certain outcome will occur. It should be clear that facing a risk means facing an uncertain outcome that has certain probabilities; whereas uncertainty refers to unknown probabilities. If the consumer underestimates risk (that is, the risk of stroke), the quantity demanded will be more than optimal, whereas if the consumer overestimates the risk (that is, the risk of dying in an airline crash) the quantity demanded will be suboptimal (Asch, 1988).

However, it is noteworthy that in some circumstances a mandatory disclosure of information may turn out to have the opposite of the desired effect. This can happen, for instance, when the object of regulation is technically complex, as a succinct description of the product is almost impossible. In addition, it is predictable that an overload of information will not be read or digested by consumers (Bardach and Kagan, 1982). For empirical evidence of this theoretical statement see the study by Forrest (1992).

Notably, the theoretical perspective adopted, significantly affects the assessment of the information regulation's effectiveness. On the one hand, information regulation might be considered as an adequate political measure when a 'rationalist' approach is adopted, as the main assumption is that well-informed people make optimal decisions (Bernoulli, 1738/1954). On the other hand, 'behavioralists' believe that individuals do not act 'optimally', in the rationalist sense, especially when faced with risky choices. Actually, heuristics used to make complex decisions often lead to systematic errors. Such an approach is based on a wide range of literature and on empirical studies carried out by cognitive psychologists that show how people, when faced with risky decisions, make inconsistent choices (that is Allaix, 1953; Lichtenstein and Slovic, 1971, 1973; Tversky and Kahneman, 1974, 1981; Grether and Plott, 1979; Akerlof and Dickens, 1982; Karni and Safra, 1987).

Consequently, an important task for policymakers is to communicate information in an effective manner. Thus, the knowledge of how consumers respond to a certain communication effort is crucial. Notably, Magat and Viscusi (1992) provide 'specific guidelines for when different types of information provision instruments are effective and when they are not, as well as which kind of instruments will have the greatest impact'.

Even if a complete analysis of information regulation is beyond the scope of this chapter, it is worthwhile to spend some words on its distributional consequences. Pildes and Sunstein (1995) have argued that '[i]nformation remedies tend to favor the relatively well off'. This consideration leads to the normative conclusion that if politicians want to take into account the regulation's distributional effects as well, they should supplement informational remedies by other means such as education.

3. Safety Regulation

From the previous analysis it results that, even if information regulation is the least interventionist measure and has the advantage to preserve the consumer's choice, it has some limits. Therefore, product standards are necessary in order to correct market failures arising from information deficits and externalities. Ogus (1994) subdivides standards into three categories: (1) target standards, which impose criminal liability for accidents caused by the product; (2) performance standards which require the product to satisfy certain conditions without specifying which production process should be employed; (3) specification standards which impose (or prohibit) specific production methods. When standards are not sufficient to correct market failures, prior approval might be used. To choose one of these techniques, it is important to assess their efficacy. Thus, the relevant question is: 'how much regulation is efficient?'

Some advocates of consumer protection could probably argue that it is worthwhile to regulate until the point product risks are reduced to zero. The Delaney 'anticancer' amendment to the Food, Drug and Cosmetic Act of 1938 is a striking example of 'zero-risk' legislation. For a comment see Asch (1990). Each regulation, however, has its opportunity costs. The point where the curve of marginal benefits intersects the one of marginal costs indicates what the optimal amount of product safety regulation is. A first hint from an economic analysis is that regulation should not be adopted if its benefits do not exceed its costs (Asch, 1988).

This finding should not induce the regulator to adopt a measure whenever its benefits exceed its costs. In other words, the condition of higher benefits than costs is necessary, but not sufficient. A regulation to be adopted should also be the cheapest. If it does exist, the alternative regulation that can achieve the same results at lower cost, or better results at the same cost, should be adopted. Thus, we have found two criteria to refer to: (1) benefits should offset the costs and (2) between alternative regulations (effectiveness to be equal) the cheapest one should be chosen, or in case of diverse forms of regulations, having the same costs, the one that has the best outcome should be adopted.

To make use of cost-benefit analysis and to compare the effectiveness of different regulations, it is necessary to be able to assess costs and benefits. In the case of product safety regulation, the figures relative to costs and benefits are mainly based upon the probability that a product will harm the consumers or bystanders. The assessment of risk is, therefore, preliminary in a regulatory process. Nichols and Zeckhauser (1986) give the following definition of risk assessment and risk management. 'Measuring risks and deciding what to do about them are distinct activities. "Risk assessment"

refers to the primarily scientific enterprise of estimating risks. "Risk management" refers to formulations of policies to control those risks; relying on political, ethical, and economic judgements, it is informed but not determined by science.'

In order to assess the probabilities that a substance will turn out to be harmful for consumers or bystanders, *science* is used. It can be easily said that questions posed in the domain of risk assessment of hazardous products are hardly answerable with certainty. As scientific knowledge always grows, it can be inferred that risk assessment is never complete. For a case of integration of scientific expertise into regulatory decision making see Hankin (1996). In spite of its limits, science is still the only tool that should be used in risk assessment. Science is the only method for ranking risk. In addition, it should be remembered that science is knowledge so systematized that prediction and verification are still possible, which implies that the public can monitor the work of regulators. This makes science even more valuable in a democratic society.

Given the information provided by scientific research, the competent authority should judge whether the risk is acceptable or not. Therefore, here we move from the determination of risk to the decisions concerning risk. In doing so, it is highly recommended to take into account not only the risk but also the product efficacy, which measures the probability and the intensity of beneficial effects. Even if the general strength of cost-benefit analysis has been recognized, cost-benefit analysis as a technique of risk management has its pitfalls as well. As the issue is definitely broad, the flaws of cost-benefit analysis will be only rapidly and partially reviewed (Trebilcock and Fraiberg, 1997). For a critique against benefit-cost analysis see Lave (1996).

In the absence of firm data or scientific consensus, it might be that public agencies make use of 'conservative' assumptions (upper bound estimates). The point to be stressed is that 'differences in the degree of conservatism distort priorities and may well result in lower overall safety' (Nichols and Zeckhauser, 1986; Hende, 1996). Furthermore, in some cases, it is difficult in itself to attribute monetary values to the cost and benefit of regulation. For example it is very difficult to put a financial value on life (see Viscusi, 1996). Another non-trivial difficulty stems from the necessity of discounting the value of future benefits and costs. This is very complicated calculus fraught with several uncertainties. Furthermore, a common criticism of cost-benefit analysis is that it is not capable of coping with questions of distributive justice. The analysis might become even more tangled when the 'countervailing risks' created by the safety regulations themselves are taken into account, as it might turn out very difficult to assess their performance. On this point see Graham and Weiner (1995).

Moreover, it is noteworthy to remember that people, in fact, have different attitudes toward the nature of risk. A possible policy implication might be that in calculating the value of life, the nature of risk should be taken into account as well. Slovic (1990) argues that public 'conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessment. ... Each side, expert and public, has something valid to contribute.' A quite different solution has been reached by Breyer (1993), who highlights the public's misperception of risk and advocates the creation of a group of expert to build a coherent risk-regulation system. A suggestion can be that, for catastrophic events, the risk-conversion factor should be exponential, limited by the rule about effectively discounting zero probabilities. A very balanced approach is the one of Noll and Krier (1990), who point out the relevance of cognitive psychology for risk regulation.

In the light of the downfalls of the cost-benefit analysis, some general criteria to refer to should be found. Trebilcock and Fraiberg (1997) suggest the following rules: (1) maximize expected values, (2) avoid catastrophes, (3) dismiss extremely remote possibilities and (4) adopt equitable regulations. In addition, an easier alternative method to cost-benefit analysis is the so-called cost-effectiveness analysis, which compares the costs of diverse regulations.

Arrow et al. (1996) discuss the importance of cost-benefit analysis for regulatory decisionmaking. They suggest eight principles for an appropriate use of cost-benefit analysis, among which are the following: all major regulatory decisions should be based on cost-benefit analysis. The regulatory agencies should not be bound by strict benefit-cost tests. Economic variables such as the social discount rate, the value of reducing risks of premature death and accidents and the value associated with other improvements in health should be used in cost-benefit analysis. Distributional consequences should be taken into account as well. For a multi-disciplinary approach to cost-benefit analysis see Hahn (1996).

4. Review of Relevant Empirical Studies on Automobile Safety Regulation

In the previous section, the issue of cost-benefit analysis as a valuable technocratic tool for policymakers has been analyzed. In this and in the next two sections, a survey of the empirical literature devoted to an appraisal of safety regulation in different areas is presented. A relevant number of studies has focused attention on automobile safety regulation, as in the USA during the 1970s several regulations related to automobile safety were issued. The lively controversy on this topic deserves some attention.

Peltzman (1975) shows that auto safety regulation has had no effect on the highway death rate. One explanation given to this finding is that 'drivers have offset' the benefit of the regulation (that is, the reduced risk of death from accident) 'by taking greater accident risk'. In addition, a lower level of driving care may increase the number of pedestrians harmed. The Peltzman contribution has given rise to an animated debate among specialists. As the amount of empirical literature on the topic is enormous, only some of it will be reviewed. To be noted is the critical analysis carried out by Robertson (1977). The latter reached different results applying a revised model. However, Peltzman (1977) rejected the criticism arguing about the inconsistency of the revisions with a model of rational driver choice. For a critique of the Peltzman model, see Joksch (1976).

Some years later, the alternative analytical approach adopted by Graham and Garber (1984) has seriously challenged Peltzman's results. The central point emphasized by these authors is that Peltzman's results are very sensitive to his specifications. They have shown how the recalculation of Peltzman's regression estimates, changing the functional form (variables were expressed in the classical form and not in the logarithmic form), leads to different conclusions (that is, 'estimates suggest that regulation averted roughly 5000 fatalities between 1966 and 1972, rather than causing about 10000 deaths as Peltzman's estimates suggest'). At a more general level, the article gains relevance, as it tends to illustrate how general shortcomings in using statistical results in policy analysis can be avoided. Accordingly, it is contended 'that a political process can be greatly enhanced by taking into account how beliefs of the analyst might have affected the analysis'.

In defense of the auto safety regulation is the article of Claybrook and Bollier (1985), but they do not present convincing evidence to support their thesis. More convincing evidence is presented by Crandall and Graham (1984), Graham (1984) and by Crandall et al. (1986) who have found overall positive lifesaving effects of automobile safety regulation, as 'the intrinsic engineering effects of safety devices appear to swamp the behavioral responses'. Analogous conclusions have been drawn by Lindgren and Stuart (1980) who have found no offsetting behavioral response to Swedish vehicle safety and speed law. More general is the piece by Asch (1986). Even if aware of the risk of paternalism, he outlines that 'the benefits of regulation, though uncertain, are potentially enormous'. For further discussion, see also Arnould and Grabowsky (1983), Mashaw and Harfst (1987, 1990).

All the studies reviewed tell us something about the effects of auto safety regulation. Therefore, they might be used to draw normative conclusions. Also few studies devoted to investigate the issue of consumer demand for vehicle safety might turn out to be useful for drawing valuable normative conclusions for policymakers. An example is the writing of McCarthy

(1990), who uses extensive data set to focus the attention on the individual's demand for safety. He argues for the desirability of a policy, which mandates car dealers to make public crash test results. This normative conclusion stems from the positive conclusion of his analysis, which illustrates that individuals do exhibit a demand for safety. Also see Winston and Mannering (1984) who have carried out a cost-benefit analysis of safety regulation estimating the benefits on the consumer demand for automobile safety.

5. Evaluating Risk-Compensation Behavior

Particularly intriguing are the studies carried out by Viscusi (1984a, 1992, 1996) who has tried to determine the net risk effects of a certain regulation by comparing the risks reduced with the risks generated by such regulation. Viscusi (1984a, 1992) illustrates how consumers have responded to some of the CPSC (Consumer Product Safety Commission) regulations. The principal case he analyses is the effect of the regulation which imposes protective bottle caps on poisonings. He finds that there is no evidence of favorable impact on aspirin poisonings. Viscusi interprets this data as evidence of the so-called 'lulling effect'.

The enactment of a safety regulation may have three effects. It might give incentives to people to lower their level of care (similar to moral hazard problems in the insurance context). Additionally, if people misperceive the new risk, overestimating the new level of safety, the outcome of the regulation may turn out to be such that the overall level of safety is reduced. Hence, it may happen that a safety regulation reduces the risk so much that people completely ignore the risk. Finally, there can be spillover effects on the safety of unregulated products, in the case of indivisible actions. In the case of 'child resistant' caps for aspirins, if medicines are kept altogether, it is predictable that after the regulation all the drugs will no longer be locked in a cupboard. As a result, the risk of poisonings by other medicines will be increased by this behavior. Again, this outcome might offset the benefit of the regulation.

The case of child resistant caps fits perfectly the theoretical model, which implicates that regulation may be counterproductive. In this perspective the knowledge of how consumers react to regulation assumes a fundamental role. The more is known about their behavior, the more is possible to issue an effective regulation. Therefore, these adverse effects should be taken into account in the phase of risk management.

Nevertheless, Kelman (1988) casts some doubts on the reliability of Viscusi's analysis. He objects to Viscusi not taking into account the sharp drop in the absolute number of deaths from open bottles and he is also

highly critical of Viscusi's methodology, particularly of the econometric model. Therefore, Kelman seriously challenges the conclusions drawn by Viscusi that the regulation was counterproductive.

The hypothesis that the effectiveness of safety regulation can be offset by behavioral response of the consumer is also investigated by Adams (1983). He has analyzed the case of motorcycle helmet legislation and has found that helmet laws are not effective in decreasing motorcycle fatalities because of the 'risk-compensation' behavior by motorcycle riders. Similarly, Graham and Lee (1986) have observed an offsetting behavior by riders, but they conclude that helmet laws are effective public health policies. Moreover, they strongly advise to take more seriously the hypothesis of long-run behavioral feedback to safety regulation.

6. Some More Empirical Studies on Product Safety Regulation

The regulation of pharmaceutical products deserves special attention because, as it has been said by Kaufer (1989), 'the supply of drugs is an exceptional blend of actual and suspected sources of market failures'. Among the multitude sources of market failures present in this market, one can mention at least the dramatic problem of asymmetric information and the fact that pharmaceuticals 'may generate enormous externality' (Ogus, 1994). Ogus argues that 'this is a consequence both of the large numbers of individuals who may consume them, and of the size of harm which may ensue' (that is, the case of Thalidomide). Moreover, it is very likely that there will be also 'private law failures', as it is highly probable that a drug seller would not face the threat of suit for harm done given the insolvency risk, the difficulty for the average consumer in recognizing the etiological relation between harm and its cause (in our case, the medicine), the presence of causal uncertainty, especially for poli-pharmaceutical treatments, and given that a long length of time often elapses before the harm manifests itself.

Therefore, the presence of market failures and 'private law failures' is the public interest justification for the co-existence of several type of regulations, which go from information regulation (in Europe see Directive 92/27/EEC) to a system of prior approval (in Europe see Directive 93/39/EEC and Regulation 2309/93/EEC) and prescription-only regulation (in Europe see Directive 92/26/EEC).

As in the pharmaceutical industry firms' innovative capacity is a crucial factor, the sharp decline in new product introduction, which was predominant in the US, has induced several authors to investigate whether this was due to the regulation's rigidity. Peltzman (1973a, 1973b) has studied the effects of the 1962 Amendments to the 1938 Food, Drug and

Cosmetic Act, which added a 'proof of efficacy' requirement to the proof of safety requirement of 1938. He has concluded that the 1962 Amendments have reduced the flow of new drugs marketed and increased the gestation period for any new drug reaching the market. As a consequence, he has estimated that the amendments, intended to benefit consumers, have had the opposite effect. The consumer's losses stemmed from the forgone benefits (the consumer's surplus) due to the reduced flow of new drugs and from higher prices for existing drugs.

However, Pettinga (1975) has pointed out that the principal cause of the decline of new drug introduction was to be identified in the advances in pharmacological science. Similarly, the analysis of Grabowski, Vernon and Thomas (1978), reformulating a model previously developed by Baily (1972), suggests that other non-regulatory factors have an important aggregative effect on innovation. Thus, the decline in US productivity was not only caused by the tighter regulation introduced with the 1962 Amendments, but also by other factors such as the rise in costs, as a result of advances in the technology of safety testing, a general depletion of research opportunities and the Thalidomide incident which has made firms and physician more cautious (see also Ashford and Heaton, 1983; Backhaus, 1983; Wardell and Sheck, 1984; Wiggins, 1984).

Notably, in Europe 'most of the drugs are available only on prescription and the OTC (over-the-counter) sector is no more than 10-20 per cent of the whole' (Burstall, 1985). The underlying *rationale* of a mandatory prescription of some medicine is, of course, to protect consumers, which are supposed to know nothing about the therapeutic efficacy and the side-effects of drugs. Almost twenty years ago Temin (1980), discussing the prescription only regulation in the American system stated: '[i]t is tempting to imagine the mandatory use of prescriptions as the consequence of medical pressure on the regulatory process, and the result of the doctors ability to "capture" the FDA. But there is no indication that the process worked this way.' The same conclusion is well grounded for the European system. An interesting point emphasized by Temin is that if judges tend to consider consumers unable to understand information at all, consumers will not take into account the costs of their behavior offsetting the benefits of prescription-only regulation (case reported *Incollingo v. Ewing et al.*, 1971; see also Temin, 1979). Critical to prescription-only regulation is Peltzman (1987), who argues that individual behavior may completely offset the safety effects of regulation. At last, the fact can be stressed that it is quite impossible to reach precise conclusions about the need and effectiveness of different types of regulation within the pharmaceutical sector, as the calculation of costs and benefits of such regulations involves large imponderables. Even if very difficult for the aforementioned reasons, it would be stimulating to

investigate whether this mixed system (information regulation, prior approval and prescription-only regulation) does not lead to over-regulation.

Aggregate impact analyses, which provide a broader perspective than case studies, have been reviewed by Dewees, Duff and Trebilcock (1996, p. 227). They mention a report completed by the Consumer Federation of America (CFA) (unpublished), from which resulted that the creation of CPSC has had overall positive effects. From this report there followed a study by Viscusi (1985) who, applying regression analysis, concluded that any beneficial effect of CPSC regulation was too small to estimate reliably. Even if the study of Viscusi is much more technically refined from the one of the CFA, it did not escape criticism. Contrary to what Viscusi contended, Zick et al. (1986) found that the state's accidental home death rate dropped by 0.017 each year as a result of the CPSC's existence.

A rather different possible way of looking at the issue of product safety regulation is to analyze its effects on income redistribution. An overall comment might be that, in most cases, it is very likely that standards benefit large firms at the expense of smaller firms. As an example, Linneman (1980) has not only showed that consumer safety has not been significantly improved by the 1973 flammability standards, but he has also estimated that the 1973 flammability standards 'induced large and anticipatable income redistribution from small to large producers'.

Inherent to the issue of product safety regulation is also the analysis of the legal regimes governing the professions. Many studies have found that licences can be used as instruments to create barriers to entry and might generate rents for the practitioners themselves. For a review of the literature concerning this topic see Chapter 9400, *Self-Regulation*). Very intriguing contributions have been given by Beales (1980), Maurizi (1974), Moore (1961), Van den Bergh and Faure (1991).

7. An Overview of the EC Legal Context

In the USA, the Consumer Product Safety Act of 1972 has established the Consumer Product Safety Commission (CPSC), which is charged 'to protect the public against unreasonable risks associated with consumer products' and therefore 'has the power to establish mandatory product safety requirements'. The main difference between the American and the European system is that, in Europe, products safety is regulated mainly by directives and regulations (notably in the Member States by national laws implementing directives or directly by EC regulations).

In Europe, in order to control mass production risks, three important directives have been issued: EC Directive 85/374 on Product Liability, EC

Directive 92/59 on General Product Safety and EC Directive 93/68 on the Certification of Products. Even a brief economic analysis of the EC Product Liability Directive is beyond the scope of this paper. A significant contribution to this issue has been provided by Fisinger and Simon (1989). Nevertheless, when investigating whether the legal context reflects the economic goal of optimal safety, it is worthwhile to focus on the desirability of studying the convergence, divergence and the interaction of the three directives.

Cafaggi (1997) argues that the system based on certification of products should not necessarily be considered as an alternative technocratic tool to administrative controls on product safety. Actually, such a system, given its important signaling function, renders the administrative controls on product safety into a more valuable tool.

It is noteworthy to recall that when the Product Liability Directive was issued, safety regulation was to be considered as a special and residual discipline. The emphasis then shifted to safety regulation and with Directive 92/59, safety regulation became a general discipline parallel to tort law system. Such development of EC law might have been the outcome of a general consciousness that tort law was far from being a satisfactory answer to problems originating from mass production. Although a development of the legislation was needed, the co-existence of the two directives have given rise to some concerns such as the question of duplication of controls and, consequently, of costs, and of the useless waste of scarce resources.

Furthermore, one of the shortcomings of Directive 92/59 is that social benefits of products are not even mentioned. Therefore, it is quite difficult to introduce cost-benefit analysis in the European process of risk management. However, the Product Safety Directive contains some valuable rules such as, for instance, the general possibility of withdrawing defective products from the market. This rule seems valuable mainly because it renders the system more flexible and might balance the fact that, in the Directive, there is no mention of the definition of product defect in accordance with the state of science and technology.

The words spent on EC legal context do not give a complete idea of the European juridical scenario, not only because these general directives have not been entirely analyzed, but also because, parallel to such a general system, there are several specific directives regulating the safety of particular categories of products (that is, food, pharmaceuticals, toys, and so on). It might be attractive in the future to investigate whether the combination of such specific regulatory regimes with the general Directives would pass a cost-benefit test.

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