

# COMPARATIVE ANALYSIS OF THE NATIONAL COUNTRY REPORTS ON POST MARKET CONTROL AND PERSPECTIVES FOR A EUROPEAN SETTING OF POST MARKET CONTROL

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## Chapter I

### I. Introductory Remarks to the Comparative Analysis

The national reports on post market control represent an overwhelming magnitude of regulatory mechanisms to withdraw unsafe products from the market. There is not yet a common understanding to be found on the best potential management of post market control. There seems an overall tendency to establish some kind of administrative control of unsafe goods, but the exact shaping of the administrative control and especially the extent to which these administrative bodies are empowered to take action against unsafe products differs considerably. The comparison will focus on these administrative control mechanisms, but it cannot set aside that some countries consider product liability legislation as an equivalent to administrative control. Monitoring duties imposed on manufacturers should guarantee that unsafe products are taken away from the market. Last but not least, activities of consumer testing organisations and certification bodies have to be taken into account in their exercising impact on the manufacturers and administrative bodies, getting to get unsafe products withdrawn from the market. Most countries pursue different approaches to product safety regulation, but to a different degree of intensity. The comparison should reflect these differences and try to elaborate common trendlines of development in post market control regulation.

But the purpose of the different national reports has not been limited to a presentation of post market control regulation. Here reference could even be made to previous research emphasizing the role and importance of the concrete shaping of regulatory mechanisms<sup>1</sup>. The very same research, however, has more or less set aside aspects of how product safety regulation in general and post market control regulation in particular has been implemented. The national reports are aimed at bridging that gap. That is why the the second major objective of the research project on post market control consisted in evaluating the practice of post market control regulation. This is not done by way of a representative analysis. The evaluation of the practice on the basis of reports and interviews with national officials allows nevertheless for generalized conclusions which might be useful for the ongoing debate on the establishment of an emergency procedure under the auspices of the Commission<sup>2</sup>. The comparison intends to work out common

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1 Ch. Joerges/J. Falke/G. Brüggemeier/H.-W. Micklitz, *Die Sicherheit von Konsumgütern und die Entwicklung der Europäischen Gemeinschaft*, ZERP-Schriftenreihe Band 2, 1988.

2 OJ No. C 193, 31.7.1989, 1 et seq.

trends in the implementation of still heterogeneous post market control regulation.

## II. Systematic Comparison of Post Market Control Regulation

The intention of the systematic comparison is not so much to give a comprehensive overview on differences and similarities in post market control regulation in the classical sense. The analysis is much more limited. It intends to work out lines of development and trends which should help to understand the prospects of post market control regulation. The overview concentrates on administrative regulation. This is so for two reasons: here, individual state action has taken place in the last decades, and is thus the place where further action might be expected in the near future. The perspectives and restraints of product liability regulation which should be reflected in their impact on post market control have been the subject of a conference whose results are separately available now<sup>3</sup>. The *practice* of product liability regulation as a means of post market control will be considered however just as the activities of testing groups and certification bodies<sup>4</sup>.

### 1. The genesis of post market control regulation

The development of post market control regulation is enshrined in the overall context of the history of product safety regulation. The latter sets the frame in which administrative mechanisms of post market control have developed and are further developing.

#### a. *Historic sources of product safety policy concepts*

There were theoretically four possibilities at hand to regulate product safety when the necessity emerged in the sixties for understanding product safety as a *statutory responsibility*<sup>5</sup> which needs to be regulated:

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3 Ch. Joerges (ed.), *Product liability and product safety in the European Community*, EUI Working Paper No. 89/404.

4 Cf. IV.

5 Cf. G. Hermes, *Das Grundrecht auf Schutz von Leben und Gesundheit, Schutzpflicht und Schutzanspruch*, 1987; H.-W. Micklitz, *Consumer Rights*, Typoscript 1989, as part of the research project of the European University Institute, Florence, under the direction of Prof. Antonio Cassese. "Human Rights and the European Community: Towards 1992 and Beyond", to be published in 1990.

- (1) To integrate product safety regulations in the quite older occupational health and safety regulation, an approach which has been chosen by the FRG<sup>6</sup> and partly by the U.K.<sup>7</sup>;
- (2) to introduce product safety law in food regulation, what has occurred in the Netherlands and partially in the FRG<sup>8</sup>;
- (3) to understand the marketing of unsafe products as unfair marketing practice and submit the regulation of product safety to the legislation on unfair marketing practices. That is exactly what Sweden<sup>9</sup> and Australia have done, and here the French<sup>10</sup> approach is also grounded;
- (4) to define product safety as a separate policy which needs its independent regulatory frame. Such an understanding complies best with the US approach<sup>11</sup>, somewhat copied in France<sup>12</sup> and recently introduced also in Sweden.

Proceeding cautiously, it might be possible to discover tendencies which facilitate a preliminary orientation. Product safety law seems to enjoy the best perspective in a country where the management of unsafe products is understood as part of the regulatory mechanisms governing marketing practice regulation. The dynamics of the market process enable a flexible integration of the new policy field in old regulatory rules and permit within this wide umbrella independency to a considerable extent, even where implementation remains in the hands of institutions which are primarily charged with quite different tasks. Product safety law seems to meet difficulties in shaking off the historical chains of occupational health and safety regulation. Here, product safety appears as mere secondary law which is subordinate to the overall protective objectives of occupational health and safety. This is true mainly for the FRG, but also for the United Kingdom, because implementation lies in the hands of agencies which are primarily concerned with occupational health and safety. Product safety takes an in-between position where it forms an integral part of food law and is imple-

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6 J. Falke, *Die Produktsicherheitspolitik in der Bundesrepublik Deutschland*, in: Ch. Joerges et al., loc. cit. 132 et seq.

7 G. Brüggemeier, *Konsumgütersicherheitsrecht in Großbritannien*, in: Ch. Joerges et al., loc. cit. 106 et seq.

8 N. Reich/H.-W. Micklitz, *Consumer Legislation in Nine EEC Countries — A Comparative Analysis* 1980.

9 U. Bernitz/J. Draper, *Consumer Protection in Sweden Legislation, Institutions and Practice*, 2nd Ed. 1986, 121 et seq.

10 H.-W. Micklitz, *Produktsicherheitsrecht in Frankreich*, in: Ch. Joerges et al., loc. cit. 62 et seq.

11 Ch. Joerges, *Der amerikanische Consumer Product Safety Act und seine Implementation durch die Consumer Product Safety Commission*, in: Ch. Joerges et al., loc. cit. 210 et seq.

12 J. Calais-Auloy, *Droit de la Consommation*, 1980, 110 et seq.

mented by the competent agencies. The recently adopted amendment to the Dutch Warenwet<sup>13</sup> has made clear that it is possible to anchor an independent policy field of "product safety" under the umbrella of food law. Food law, however, then alters its character. It becomes a protective legislation against health hazards and safety risks. The best perspective for the further development of product safety seems to exist in those countries who have decided to establish product safety as an independent policy area even if the necessary administrative structure is still missing. It is not without reason that product safety law and especially post market control in the United States has achieved a level of consumer protection, amounting to a nightmare for some and wishful thinking for others.

*b. The two approaches for regulating product safety*<sup>14</sup>

The analysis of the different approaches of regulation enhances the hypothesis on the possible future development of product safety law. Historically, there were strongly defined traditions and clearly shaped regulatory approaches. The seemingly clear demarcation lines between different regulatory approaches, however, become more and more indiscernible. Regulatory traditions were set aside in the debate on the "best" regulatory approach, and also the most efficient distribution of competence between statutory agencies and private standard-setting bodies. Notwithstanding all differences in the legal traditions two regulatory models can be clearly defined:

- (1) Framework regulation which needs to be implemented by specific regulations in order to attain binding effect. Technical standards are important as far as they have been integrated in specific regulations. Contravention of binding regulations is regarded as a criminal offence;
- (2) General safety duties imposing on manufacturers an obligation to market safe products. The yardstick of safety is laid down in technical standards to which the general safety duty either explicitly or implicitly refers. Non-compliance with technical standards does not necessarily entail criminal sanctions.

The conclusion is, that framework regulation loses importance whereas general safety duties in whatever form gain importance<sup>15</sup>. The shift from the framework approach to the general safety duty approach enhances

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13 G. Snijders, Patterns of Dutch Product Safety Legislation: The Commodity Act 1988 and its Relation to the New Approach, in: Ch. Joerges (ed.), loc. cit. 102 et seq.

14 The issue is developed in more detail in: H.-W. Micklitz, Perspectives on a European Directive on the Safety of Technical Consumer Goods, CMLR 23 (1986), 617 et seq.

15 This tendency though valid for most of the investigated countries does not hold true for Australia. Here the framework character is maintained. The particularities of the Australian legislation on product safety will be considered in more detail cf. II.3.b.

the existence of an overall statutory responsibility. But the very same expansion of responsibilities shows the limited capacities of a state. It can realize the statutory responsibility only if it enhances cooperation with private standard setting bodies. That is why the introduction of a general safety duty goes together with a reform of the cooperation between the states and the private standard setting bodies. The inherent tendency to return to private resources in shaping product safety law entails consequences for the perspectives of further developing product safety as an independent area of law.

Frame work regulation, i.e. food regulation<sup>16</sup> and also marketing practice regulation<sup>17</sup> traditionally rely on product-specific regulations which determine the behaviour of manufacturers and traders. Infringements of product-specific regulations are sanctioned with a penalty or with a fine. The main administrative task then is to find out whether the addressees of the law comply with the requirements laid down in the product specific regulation. The distribution of competence between parliament, administrative bureaucracy on the one hand, (defining the mandatory requirements for the marketing of the dangerous products) and specific regulatory agencies on the other, (examining their compliance) is clearly shaped.

This traditional interrelationship is challenged with the shift from framework regulation to the general safety duty approach. The form in which the general safety duty as a "general safety requirement" or as "reference to standard" legislation does not play any role so far. The 1987 amendment of the Consumer Safety Act has introduced a general safety duty in the UK. Contraventions to the general safety duty are regarded as a criminal offence. A solution which has been supported by the french "Commission de la Refonte", but not yet become law<sup>18</sup>. The FRG relies on reference to standard legislation. Manufacturers are presumed to respect the general safety duty if their products comply with the officially registered technical standards<sup>19</sup>. Neither general safety duty legislation nor reference to standard legislation can be implemented in the same way as framework legislation. General safety duty legislation in whatever form does not contain concrete yardsticks against which action to be taken measured. Technical standards can be used as an auxiliary but they do not release the competent authorities from concretising the general safety duty and defining a

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16 Cf. for Netherlands, G. Snijders, in: Ch. Joerges, loc. cit.

17 Cf. for Australia, D. Harland, 4; and for Sweden, N. Ringstedt, 4.

18 Cf. H.-W. Micklitz, in: Ch. Joerges et al., loc. cit. 77.

19 § 5 para 2 of the Gerätesicherheitsgesetz.

safety standard for the product in question<sup>20</sup>. Control agencies which might have been established once to exercise compliance of products with mandatory safety standards (product specific regulations) have to enter into a learning process. Deducing a concrete level of protection from a general safety duty requires complex value-judgments<sup>21</sup>. The distinction between "compliance" and "setting safety standards" is crucial for the understanding of post market control.

Food law which is usually based on the interplay between framework regulation and specific regulations seems to hinder such a development. But even here a shift in the regulatory approach can no longer be excluded. The Community is considering the pros and cons of reconstructing Community food law according to the model of product safety law. A general safety duty should impose on manufacturers and traders an obligation to market only safe foodstuffs, supplemented with reference to food standards elaborated by private entities<sup>22</sup>. Only two legal traditions would finally survive, both originating from a coherent regulatory model: occupational health and safety *and* marketing practice regulation.

### *c. The concept of safety*

The concept of safety is the starting point of product safety legislation. Theoretically it should be possible to derogate a definition of safety from the existing rules. In practice a cascade of rules is to be found, independent of the differences in the regulatory approaches and all providing assistance in the definition of that which should be understood as a safe product.

Heading the list are the legislative rules, and the differing concepts of product safety as laid down in the legislation itself. Below the legislative targets come the regulatory activities of private standard-setting organisations. The English, French and German standard setting institutions have developed technical standards defining a general safety philosophy applicable to all product related standards<sup>23</sup>. The principles laid down there are then concretized in specific product related safety standards. These rules altogether define the concept of safety. Although the cascade of rules can be found in all industrialized countries they are integrated to a different degree into the regulatory concepts. These differences come into play when responsibility for the definition of safety is to be determined. The vital issue is the identity of those holding the power of definition for the meaning of

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20 Cf. III.1.

21 Cf. for further details cf. under II.3.a.

22 The Commission, however, seems to reconsider its position OJ C 271, 1989, 3 et seq.

23 Cf. H.-W. Micklitz, CMLR, loc. cit.



safety, namely, statutory entities and/or private standard setting bodies. Reference to standards legislation, though upholding in principle the statutory responsibility for the protection of consumers against unsafe products, provides for cooperation between the standard setting institutions and the responsible control entities (Gewerbeaufsichtsämter) in defining the notion of safety. The same cannot be said for the other regulatory concepts. The definition power remains per se in the hands of the competent entities, although the differences in the regulatory concepts seem to vanish in present practice<sup>24</sup>.

The set of rules is determined, the bearers of the definition power are identified, but how is safety defined legally and/or in technical standards? Despite the surviving inconsistency in terms and terminology in legal rules and technical standards, there is a common tendency to integrate the expectations of consumers into the notion of safety<sup>25</sup>. One might attribute this compromise with the term of "foreseeable use". Foreseeable misuse of products by consumers, a highly debated issue in product safety regulation, is incorporated into the regulatory concept.

But the categories described so far are quite rough and cannot provide much help in actual practice<sup>26</sup>. Cost benefit analysis has been promoted as a new category to be considered in the concept of safety. But its function within the regulatory concept is far from clear. The US legislator has repealed cost-benefit rules for the performance of post market control measures. German product safety legislation remains silent on the role and importance of cost benefit analysis. The German Institute for Standardization, however, formulates a seemingly clear supremacy rule. Safety ranks before economic efficiency.

## **2. The trend towards institutional independency**

All industrial countries show an inclination to put the implementation of product safety law in the hands of specific control institutions. Post market control of consumer goods seems to be manageable only in specifically equipped central entities. According to the degree of independence three types might be distinguished:

- (1) Federal agencies empowered with specific regulatory competence mainly in the field of post market control, like the US Consumer Product Safety Commission (CPSC);

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24 Cf. III.3.

25 Cf. Ch. Joerges et al., loc. cit. 42 et seq.

26 Cf. III.1.

- (2) Mixed forms whose integration into the ministerial bureaucracy differs considerably, the French Commission de la Sécurité des Consommateurs (CSC), the English Consumer Safety Unit (CSU), the National Swedish Board for Consumer Policies (NSBCP), the Australian Trade Practices Commission (TPC) and the Federal Bureau of Consumer Affairs (FBCA); the Dutch Consumer Safety Institute (CSI) die Stichting Konsument en Veiligheid as well as the Nordrhein-Westfälische Zentralstelle für die Sicherheitstechnik (ZSF).

(3) Where there are no independent central/federal administrative entities, like in the FRG<sup>27</sup> and the Netherlands<sup>28</sup>, ad hoc working groups are set up under the auspices of the competent ministries in case of need<sup>29</sup>.

*a. Consequences of the institutional independence for the nature of administrative control activities*

Institutional independence seems to be a precondition for administrative entities to shift from "compliance" to "defining safety standards". "Old" traditional control authorities remain restricted in their control tasks. Their field of activities comprises only the mandate of examining "compliance" with predefined product safety standards. They are still seen as the long arm of the ministerial bureaucracy to implement what has been decided at a higher level — often within the very same ministerial bureaucracy, sometimes confirmed by Parliament. This distribution of competence "compliance" versus "defining safety standards", is mostly provided for expressly by the legislator in the process of extending product safety legislation, sometimes it results implicitly from the states' responsibility of protecting their citizen against health hazards.

*b. Resources<sup>30</sup>*

Institutional independency can only lead to practical results if the entities are endowed with the necessary personnel and financial resources.

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27 Cf. J. Falke, "Die Nachrüstung gasgefederter Bürostühle", 5.3. of the german version of the national report which will be published at a later stage in the ZERP-Schriftenreihe as a separate volume.

28 Cf. B.M. Hummels/G.M.F. Snijders, 5.2.

29 Cf. Strictly speaking, there are no rulings providing for the establishment of an independent administrative entity. It would be misleading however, to set aside actual practice in the FRG and in the Netherlands, although the exact handling of risk situations must be dealt with when it comes down to describe the present practice of post market control.

30 Some "unsystematic" figures are given already here and not in the part on the practice of post market control.

The considerable organisational differences render a comparison rather difficult. Administratively independent control entities do not automatically have a separate budget at their own disposal. They are normally incorporated in traditional administrative structures. There are only a few countries in which the control of existing standards and the elaboration of new safety standards is organized in a separate body. Even where institutional independency has been achieved, specific control entities are charged, as in Sweden<sup>31</sup> and Australia<sup>32</sup> with quite a different set of regulatory tasks. That is why it is so difficult to identify the percentage of the budget which concerns the regulation of product safety. Three different types might be distinguished:

- (1) Post market control is taken over by occupational health and safety or food control agencies, this is true for the FRG (Gewerbeaufsichtsämter) for the U.K. (trading standard officers); the Netherlands (Keuringsdienst van waren; in Sweden, local consumer counsellors); in France (Direction de la Consommation et de la Repression des Fraudes (DCRF). Here, product safety represents only one activity in between a couple of others. Nothing but a "quantité négligeable" of all the hundreds and thousands of agents dedicate their activity to the control of product safety<sup>33</sup>.
- (2) Post market control is taken on by institutions which have to implement a whole set of consumer protection laws. This is true for the National Swedish Board for Consumer Policies as well as for the Australian Trade Practices Commission. The Swedish NSBCP engages 215 persons and has a budget of SEK 45 Mio<sup>34</sup>. For Australia there are no concrete figures available. The National Consumer Affairs Advisory Council believes that all over the country 24 persons are engaged with the control of product safety alone<sup>35</sup>.
- (3) Post market control lies in the hands of institutions endowed with the unique competence to implementing product safety legislation. The American Consumer Product Safety Commission has a budget of round about \$ 30 Mio and engages 500 full time employees<sup>36</sup>; the French Commission de la Sécurité des Consommateurs had a budget of FF 2.4 Million in 1985<sup>37</sup>, the Dutch Consumer Safety Institute has a budget of US\$ 3.5 Mio. and engages 50 full time employees<sup>38</sup>.

31 N. Ringstedt, 3. and 4., especially Figure 1.

32 D. Harland, 3. Outline of responsibility for product safety.

33 For the FRG, 2,2% of all control activities of the the German Gewerbeaufsichtsämter are devoted to product safety, J. Falke, in: Ch. Joerges et al., op. cit. 161.

34 N. Ringstedt, 3.

35 D. Harland, 5.6.

36 Ch. Joerges, in: Ch. Joerges et al., loc. cit. 204 et seq.

37 H.-W. Micklitz, in: Ch. Joerges et al., loc. cit. 70.

38 B.M. Hummels/G.M.F. Snijders, loc. cit.

The United States has taken and is still taking a lead position. The different figures available from the European countries as well as from Australia, do not give a clear idea on the perspective of exercising effective post market control. It is not the budget alone which decides on the effectiveness of a post market control system<sup>39</sup>. France, Sweden, Australia, Great Britain, to some extent the Netherlands have set up statutory entities which work at the national level as central addressees for consumer complaints. The FRG relies on a decentralised approach. The German Gewerbeaufsichtsämter are operating within the German Länder, they are autonomous. The FRG strongly resists any incentive by the Commission to centralize the product safety administration<sup>40</sup>. The majority of the investigated countries start from the idea that product safety can best be realized by centralized and highly professionalized control entities.

### 3. Development trends in post market regulation

Although the tendency to coherent extension and differentiation of post market control regulation seems inherent to product safety law, national differences sustain reflecting the differing inertia of the regulatory and administrative genesis. Despite these restrictions European countries are gradually matching the American product safety law since the late seventies. It might serve as a yardstick against which the post market control mechanisms and post market control instruments can be measured.

#### *a. Extension of post market control instruments*

There is no agreement on the terminology of instruments. A comparison is difficult to manage as each country is living with its own administrative notions. The US Consumer Product Safety Act distinguishes between "standards", "ban", "seizure" and "recall"<sup>41</sup>. Standards means the elaboration of mandatory rulings which the manufacturers have to respect when they intend to bring a product onto the market. Standard setting is first and foremost a means of preventive action but it can also come to bear as a means to guarantee the marketing of safe products from the emergence of the danger onwards<sup>42</sup>. Standard setting is then future orientated, it can not reduce the risks resulting from those products which have already been put into circulation. Standard setting exists as a regulatory means in all investi-

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39 Cf. II.4. Efficiency of post market control.

40 Within the debate on the product safety directive, cf. chapter II.

41 Cf. Ch. Joerges 2.2.1.1.

42 Cf. III.3.d.

gated countries. Its shaping is closely bound to the approach chosen to regulate product safety<sup>43</sup>.

A "ban" stops and/or restricts the further marketing of a dangerous product. The function of a ban is limited. It blocks the further marketing of an unsafe product and sets aside the problem of what should be done with the unsafe products circulating around. The instrument has been introduced in all investigated countries whatever its concrete notion might be — prohibition (UK, NL), banning order (Australia), FRG (*Untersagungsverfügung*), circulation de produit (France). There is agreement on the necessity to prohibit the further marketing of unsafe products but there is no agreement on how such a ban should be implemented. Two options must be distinguished: (1) A ban may concern a specific product or a category of products, it would then be called a "product ban" or a "prohibition notice"<sup>44</sup>, (2) A ban may also be realized in such a way that manufacturers and/or suppliers are approached in order to directly prohibit further marketing. The UK legislation provides for both paths, the FRG allows only for a ban addressed to manufacturers/importers and under restricted conditions to dealers. The overall tendency is to incorporate step by step all those addressees involved in the process of manufacturing and marketing, the manufacturer, the importer and most of all the dealer.

"Seizure" goes one step further, here the dangerous products are confiscated by the competent authorities<sup>45</sup>. The further marketing is not only forbidden, products are deemed to be so dangerous that they must be taken away from the market under the responsibility of administrative entities. Seizure as an instrument of post market control is not as widely spread as a product ban. It has been introduced in the US legislation, in the French Product Safety Act, the Dutch Commodity Act and the 1987 amendment of the UK Consumer Safety Act. One might even recognize a certain trend pointing in direction of extending the post market control instruments to "seizure", but i.e. the *Gewerbeaufsichtsämter* in the FRG are not entitled to seize a dangerous product. They may only issue a prohibition order under the *Gerätesicherheitsgesetz*.

"Recall" is certainly the most ideologically laden instrument of post market control. It is the only instrument which allows for the withdrawal of unsafe products from the market. Recall only guarantees that the danger resulting from unsafe products is eliminated. The United States has been

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43 Cf. II.1.b.

44 Cf. like in the UK, G. Brüggemeier, in: Ch. Joerges et al., loc. cit. 113.

45 In the US, seizure concerns a specific procedure not only a specific kind of action, Ch. Joerges, 2.2.1.2.1.

the forerunner in introducing recall already in 1972 in the Consumer Product Safety Act, France followed in 1983, Australia in 1986 and Sweden in 1989. Recall has no consistent meaning. That is why the regulatory concepts differ considerably<sup>46</sup>. For the moment it suffices to point out the efforts of countries which have not (yet) introduced product recall to find regulatory mechanisms, which represent a less stringent intervention in the market than recall, but come near to product recall in their effects. Reference may be made to the UK and the Dutch legislation. The 1978 UK Act provides for a "notice to warn" requiring the distributor of the dangerous product to notify his purchasers of its dangerous quality. The Netherlands have discussed the introduction of product recall in the recent revision of the Commodity Act in 1988, but finally decided to copy the UK model. But unlike the UK Act, the Minister can decide to publish the warning himself<sup>47</sup>, if the distributor fails to do so. Warning the public is seen as an equivalent to product recall.

*b. Differentiation of post market control mechanisms, ranking of risks, normal and emergency procedures*

It is a common characteristic of developed regulatory concepts of product safety legislation that they differentiate the procedures which are set into motion once a danger to the consumer arises. The technique applied is the ranking of risks:

- the US Consumer Safety Act makes a distinction between "unreasonable risk of injury", "imminent hazard" and "substantial product hazard"<sup>48</sup>,
- the Australian Trade Practices Act between "goods that may cause injury to any person" and "requirements of a standard that must be reasonably necessary to prevent or reduce a risk"<sup>49</sup>,
- the French Loi sur la Sécurité des Consommateurs between "les produits ne satisfaisant pas à l'obligation générale de sécurité" and the measures to be taken "en cas de danger grave et immédiat".

The other investigated countries have not explicitly laid down different concepts of risks, though some form of differentiation exists. The UK Consumer Product Safety Act distinguishes between the normal safety requirements, from those emergency situations, without defining what might be

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46 Cf. for more details under d.

47 G.F.M. Snijders, in: Ch. Joerges (ed), loc.cit., 103.

48 Cf. Ch. Joerges, 2.2.1.1.

49 Cf. D. Harland, 4.5.

understood as "emergency"<sup>50</sup>. The new Swedish Product Safety Act endows the Consumer Ombudsman both power to issue a prohibition order or an order to disclose information "in minor cases". The German Gerätesicherheitsgesetz leaves it "normally" to the discretion of the Gewerbeaufsichtämter whether they decide to take action or not, but oblige the authorities to examine intervention in cases of acute danger<sup>51</sup>.

The regulatory concept, despite the differences in terminology seems to be identical: ranking of risks should make clear that there are different degrees of intensity of dangers requiring different kind of action. "Normal" risks are separated from "emergency" risks, normal risks require a procedure of post market control which differs from the emergency procedure. The two procedures are spelt out to a different degree<sup>52</sup>. The characteristics of the two procedures are often not clearly shaped but must be deduced from the regulatory concept as such. Having said this, normal and emergency procedures might be distinguished under two aspects: (1) Questions of competence and (2) Questions of instruments.

(1) The competent authority endowed to take action in normal situations is not necessarily the same in emergency situations<sup>53</sup>. This is particularly true for countries like the US where the application of the law is put in the hands of an independant regulatory agency, the Consumer Product Safety Commission. This very same agency is bound to a specific procedure "seizure" — in cases where there is an "imminent hazard". The agency has to approach the competent District Court if it intends to take action against unsafe products. The spectrum of remedies at the Court's disposition ranges from the seizure of the product, the ordering of cautionary information directed to consumers, the ordering of a public notice or of even the recall of the product<sup>54</sup>. French law has not gone as far as US law, and has stayed away from establishing a Commission pour la Sécurité des Consommateurs with broad regulatory competence. The responsibility for taking action has always therefore remained in the hands of the ministerial bu-

50 G. Brüggemeier, in: Ch. Joerges et al., loc. cit. 112, with reference to the adoption of an prohibition order in case of an emergency. One might also raise the question whether the suspension notice must be regarded as an instrument which applies in emergency situations only.

51 Cf. § 5, para 2 of the Gerätesicherheitsgesetz, thereto J. Falke, loc. cit. under 5.2.

52 They are well developed in France i.e. cf. H.-W. Micklitz, in: Ch. Joerges et al., loc. cit. 75 et seq.

53 Australia and the UK do not make any difference in the distribution of competences in normal and emergency procedures. In the UK the Secretary of States remains responsible for both procedures, in Australia it is the Minister. There is a difference however between the drafting of regulations by the parliamentary counsel and the Minister's competence to publish in the Commonwealth Gazette a declaration that a standard os a consumer standard for the purpose of s. 65 C, D. Harland, 4.4.

54 Ch. Joerges et al., 2.1.2.1.

reaucracy. But even here the differences are striking. Actions to be taken within the normal procedure follow the legislative machinery applicable to the rules on the adoption of a regulation (*décret*). In emergency situations, the action is taken by the ministry responsible for the protection of consumers directly (*arrêté*). The Swedish Product Safety Act entrusts the Ombudsman with the management of minor cases. Emergency cases, however, have to be settled at the Market Court.

(2) Differentiation in the procedures to be followed goes together with differentiation of regulatory instruments. Such an approach is particularly developed in France<sup>55</sup>, where the set of instruments available to the competent authorities differs considerably according to the procedure concerned. The other investigated countries reserve specific far-reaching instruments to emergency situations. Australia empowers the Minister to declare, by a notice published in the Commonwealth Gazette, the goods to be unsafe in order to fight an emerging danger. The UK has recently introduced an amendment to the Safety Act entitling trading officers to issue a suspension notice. The background for the extension of powers has been the lack of flexible and quick regulatory instruments<sup>56</sup>. The US "seizure" procedure applies only where there is an imminent hazard. The Netherlands allow for the confiscation of the product if the public prosecutor has been involved by the Keuringdienst van Waren. One characteristic of emergency-related instruments of post market control is their preliminary character. Measures may be upheld beyond the legally defined expiry date but must then undergo the procedure normally provided for post market control action. This entails two consequences: the instruments change their character, the notice is transposed into a banning order i.e. those who are concerned by the regulatory action have to be heard before the permanent action is taken<sup>57</sup>.

Competences and instruments differ in normal and emergency procedures. However, there seems to be an underlying common principle. Institutionally independent entities are endowed with a limited set of legal instruments only. The stronger the intervention into the market, the higher the procedural requirements. Competences are delegated away from the independent institutions either to Courts — in the US and in Sweden — or are concentrated in the hands of the ministries. The most striking and most consistent mechanism can be found in Australia. Here post market control management lies principally in the hands of the manufacturers themselves.

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55 Cf. M.-Ch. Héloire, p. 15 alt.

56 G. Brüggemeier, in: Ch. Joerges et al., loc. cit. 112 et seq.

57 Cf. for more details on the right to be heard of the parties concerned, II.3.c.



Statutory control entities come into play only if the manufacturer fails to take sufficient action. Similar thinking may be reported from the Netherlands where the Keuringdienst van Waren may state in its official report that the producer was unwilling to cooperate, a statement which seems to be more or less preconditioning for taking further action<sup>58</sup>.

*c. The recall procedure*

The intention here is to summarize the different regulatory concepts of post market control and to concentrate them in the way through which product recall is regulated. The overview should serve at the same time as a pattern for the presentation of administrative practice. It has to be recalled:

- that there are central instances in the US (Consumer Product Safety Commission), France (Commission pour la Sécurité des Consommateurs), Australia (Federal Bureau of Consumer Affairs) and Sweden (National Board for Consumer Policies) and decentralised units in the UK (Trading officers), the Netherlands (Keuringdienst van Waren) and the FRG (Gewerbeaufsichtsämter). Here central entities might exist but they have no competence beyond informing the public in emergency situations.
- Where there is specific recall legislation like in the US, Australia and Sweden, recall is bound to a certain degree of danger — "substantial product hazard", "prevent or reduce risk or injury", "risk of personal injury". Otherwise the recall procedure cannot be set in motion. Countries without recall legislation have not laid down entry rules to use their influence to bring voluntary recall about. The last resort instrument, the "public notice" is contingent upon emergency situations.

What remains to be described is the management of product recall as provided for by the different legislations:

(1) Notification provides the competent administrative entities with information on risk and risk situations. But only the United States and Australia have imposed information duties on manufacturers. The American manufacturer has to notify any irregularity he has heard of. Clearly stated: he has to notify even incidents in which it is not yet clear whether a danger for consumers exists. Australian manufacturers have to approach the Federal Bureau of Consumer Affairs only if they are initiating voluntary product withdrawal. This is all the more surprising as notifications are a precondition for the workability of the Australian post market control sys-

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58 B.M. Hummels/G.M.F. Snijders, 5.2.

tem. The Federal Bureau of Consumer Affairs main task is to monitor the effectiveness of voluntary recall in consultation with the supplier<sup>59</sup>.

Notification duties of traditional control authorities and courts to institutionally independant product safety control entities exist in France only. Here control authorities endowed with the examination of complicity (Direction des Fraudes et Falsifications) have to notify "irregularities" to the Commission de la Sécurité des Consommateurs. The same holds true for the French Courts involved in product liability litigation or penal proceedings.

(2) Before the competent administrative entities decide to take a final action to fight the danger which has arisen from an unsafe product, they are obliged to initiate an "administrative hearing". This is more or less true for all investigated countries. But there are differences to be reported in the exact shaping of the hearing, mainly as to the question of who should be admitted to participate. If action is under consideration which is directed against individual suppliers or manufacturers, it goes without saying that these have to be heard before the administrative bodies. It seems to be widely accepted that representatives of supplier or manufacturer associations who might be or feel concerned are likewise admitted. But there is no agreement on the participation of consumers or consumer organisations<sup>60</sup>. Consumers remain locked out by two exceptions: the US administrative hearing led by the Consumer Product Safety Commission is open to non-concerned consumers and consumer organisations. The same is true for France where the Commission pour la Sécurité des Consommateurs is pluralistically composed. Access for Consumer organisations to the activities of the Commission is guaranteed.

(3) Based on the information received and after having heard the arguments of the parties concerned, the competent administrative entities must consider the spectrum of reactions. A very first reaction is notifying the danger. The instrument can be found in all countries, though the terminology is — once more — not consistent. It is exercised in a double step procedure. First, the competent entities order the manufacturer and the supplier to inform the consumer on the existence of a risk. Then, if the danger so requires, the competent entities issue a "public notice". There are countries who have finely tuned the necessary instruments, like the United States, Australia, the Netherlands, France or Sweden. There are other countries like the FRG and the UK where "notification" as a regulatory in-

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59 D.Harland, 6.11.

60 To be clear, we are talking of participation in administrative decision not of participation in the elaboration of a standard within private standard setting institutions or in the legislative machinery provided for the elaboration of regulations.

strument is not spelt out, the existence of such an instrument must be deduced from other regulatory mechanisms<sup>61</sup>. And once more it must be recalled that there are few countries which only allow explicitly for a "public notice" — the United States, the UK, the Netherlands, Australia, France and Sweden. The shift from the notification of the manufacturers or suppliers to the public notice is often bound with a re-delegation of competence from the newly established control entities back to the Ministries<sup>62</sup>.

(4) There are further means of reaction, mainly the recall of the product in the US, Australia, France and Sweden. Recall comprises a whole set of regulatory mechanisms, repair, refund, replacement. In the US, performance of the recall procedure remains in the hands of the Consumer Product Safety Commission, in Australia it is the Federal Bureau of Consumer Affairs who supervises the voluntary recalls of the manufacturers but it is the Minister who takes action. Such a shift of competence must be reported from France and from Sweden. All steps preparing a recall procedure remain in the hands of the Commission pour la Sécurité des Consommateurs, the National Board for Consumer Policies respectively. But mandatory recall action requires in France the engagement either of the Minister or of the legislative machinery, and in Sweden the involvement of the Market Court.

The UK, the Netherlands and the FRG might refer to a "ban" in order to exercise impact on the manufacturer or supplier, but to repeat it bluntly, there is no regulatory means to oblige the manufacturers or any other party to recall unsafe products.

(5) If the competent administrative entities have taken legally binding action, be it in form of a notification or be it in form of a recall order or a ban, contravention is a criminal offence. Courts might be approached to implement binding orders and to condemn the wrongdoers to fines or even imprisonment.

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61 Cf. for the FRG, J. Falke, loc. cit. 5.2. "andere Maßnahmen" i.S. des § 5 Abs. 2 are notification orders addressed to the manufacturers or the importers; for the UK reference should be made to the suspension notice whose issuance presupposes the attempt to regulate the risk by way of less stringent measures than the prohibition order.

62 Cf. as an example the new mechanism under the Dutch 1988 Warenwet, G.M.F. Snijders, in: Ch. Joerges (ed.), loc. cit. 102 et seq.

### III. Practice of Post Market Control

The perspective taken in the presentation is one of the competent regulatory body. It has first to make the concept of safety operable for the implementation process, it has then to investigate arising dangers, before it enters into the decision-making process. Consideration on the effectiveness of actual practice of post market control concludes the chapter.

#### 1. The definition of risk

The regulatory concepts remain vague even if they try to spell out differing degrees of danger. The competent authorities are therefore challenged with the task to use the given regulatory process as a means of risk assessment. Test cases might be an appropriate means to receive assistance from the courts in the understanding of the legislative risk concept. Initiating test cases presupposes the legal capacity of the control authorities to bring litigation before the courts, and the political intention to fight a conflict through. There are only a few examples to be reported. The National Highway Traffic Administration (NHTSA) had a dispute with General Motors on whether or not the normally foreseeable misuse might be considered in the determination of risks<sup>63</sup>. The competent Australian ministry and a manufacturer of tobacco products are quarrelling on the meaning of "injury" on the one hand and "disease" on the other<sup>64</sup>.

It cannot be surprising that the competent authorities are looking for further criteria of orientation. The most ambitious effort made so far, has been undertaken by the US Consumer Product Safety Commission. The "Substantial Product Hazard Reports" of 7.08.1978 seeks to present an authoritative clarification of the term "substantial product hazard"<sup>65</sup>. There is no equivalent in all other investigated countries. If any, reference might be made to the German "DIN 31000" which formulates an overall regulatory philosophy for the elaboration of technical standards. But the standard DIN 31000 is not destined to solve the practical problems of an authority in handling the safety concept of the German Gerätesicherheitsgesetz<sup>66</sup>.

The difference between the authorities involved in the process of defining the safety concept is indicative. The US Consumer Product Safety Commission tries to keep the definition power in its own hands, in order to

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63 Ch. Joerges, 2.1.2.1.

64 D. Harland, 8.23.

65 The implications are investigated in detail in Ch. Joerges, 2.3.1.

66 At least not as a general means, but in exceptional cases DIN 31000 may serve as a yardstick, J. Falke, German Version, 5.1.

have a self determined basis for exercising post market control. The shift from the "seizure" procedure to the recall mechanism underlines the intention of the US Commission to safeguard institutional independency<sup>67</sup>. For the German Gewerbeaufsichtsämter independence is not and cannot be an objective. The linkage between the definition of safety and the kind of implementation is even part of the regulatory concept. German Gewerbeaufsichtsämter proceed from compliance of the products with technical standards if this is documented by a specific certification mark. They are not bound to the level determined within the standards, but these standards provide substantial assistance in defining what should be understood by a safe product. The same stringent relationship can be found in the Netherlands where the Keuringdienste are "bound" to the certification of KEMA<sup>68</sup>. Nowhere else, however, have standards such an overwhelming role to play. They might be used as an orientation mark, but present practice may be characterized by a certain reluctance towards this.

The situation in France is exemplary for such a distant attitude. Here, the Commission de la Sécurité des Consommateurs holds the power of defining risk at least as far as it has got regulatory competence. It is true, the Commission is not the only competent organization to implement French product safety law, it can do so only in accordance with the ordinary control authorities competence for the implementation of the frame law of 1905. The Commission, however, remains autonomous. Technical standards elaborated by the French standardization organization AFNOR, provide assistance for risk assessment. But the Commission often determines the level of safety beyond the technical standards<sup>69</sup>.

Cost benefit analysis has been promoted as a means to put the risk assessment on a rational basis. Although the regulatory concepts are not consistent, one might proceed from the assumption that some kind of cost benefit analysis is made within all competent authorities. But the National Swedish Board for Consumer Policies's tremendous effort to apply cost/benefit analysis on the safety of ski bindings has remained an exception<sup>70</sup>. Cost benefit analysis is usually exercised at a lower level, in the form of weighing differing aspects rather than in engaging professional advice.

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67 Ch. Joerges, 2.

68 G.M.F. Snijders, *Productveiligheid en aansprakelijkheid*, 1987, 97 et seq.

69 H.-W. Micklitz, in: Ch. Joerges et al., loc. cit. 70.

70 N. Ringstedt, 5.4.3.

## 2. Investigation of danger

On precisely this issue, scientific tendencies clash with "provincialism". The positions taken are clearly defined and ideologically overloaded. Practice is determined to a large extent by the regulatory concept on how the investigation of dangers should best be managed. Quite generally one might conclude that the broader the sources of information on which the control authorities can base investigation of the danger, the better they are armed with a professional risk management. Such a perspective entails the necessity to continue the presentation of actual practice with conceptual considerations on the function of data collection for post market control.

### *a. Accident surveillance systems*

Accident surveillance systems form the core of product safety information policies all over the industrialized countries with one exception, namely the FRG<sup>71</sup>. It has adopted the representative interview from the European Community at some six-fold expense. The German position is hard to understand and defies logical explanation. Its objection, however, is still worth maintaining, because the FRG prevents the Community from setting up a Community wide accident surveillance system<sup>72</sup>. This system has a key role to play in the furtherance of product safety policy. Accident surveillance systems, this should be recalled, initiate a process of scientification of risk assessment<sup>73</sup>. Measuring risk is no longer based on anecdotal evidence or experience knowledge but on data which is systematically collected and evaluated. The process of "scientification" is accompanied by a process of politicization. The management of accident surveillance systems is put in the hands of persons other than technicians. The resistance of the FRG seems to be directed against the intended shift of competence from technicians to experts in other fields, it might likewise challenge the well established cooperation between the German standard setting organisations and the Gewerbeaufsichtsämter.

Accident surveillance systems represent an instrument of social policy. They indicate areas of risks, they do not necessarily supply product-related data. The American example of the ATV cars might serve as an example for underlining the importance of accident surveillance systems in practice<sup>74</sup>. But, accident surveillance systems can only serve as a starting point

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71 J. Falke, 3.

72 J. Falke, in: Ch. Joerges et al., loc. cit. 289 et seq.

73 Ch. Joerges et al., loc. cit. 42 et seq.

74 Ch. Joerges, 2.4.2.

for further in-depth investigation and evaluation of possible product risks. Without the necessary resources and the institutional frame required to make use of the accident surveillance systems in practice, the data collected might remain dormant. And that seems to be all too often the case. The British CSU who is in charge of the HASS system, is only a policy body, it is not a central administrative authority and it lacks the resources to undertake in-depth investigation. The situation is somewhat more encouraging in the Netherlands, where the accident surveillance system legitimates the activities of the Dutch Consumer Safety Institute. The erection of an accident surveillance system in Sweden might increase the importance of the National Swedish Board for Consumer Policies in the long run. Accident surveillance systems are all too often administratively separated from the competent regulatory authorities. The opposite solution would be required in order to increase their importance: integration instead of separation.

*b. Notification duties of manufacturers, traditional control authorities and courts*

The differing starting point of the US and the Australian notification duties of manufacturers does not play a substantial role. Australian manufacturers tend to notify all kinds of incidents even if they do not come under the formal notification duty. They behave just like their American counterparts. Although legally binding notification duties have led to a considerable increase of notifications in both countries, critiques of the American system claim that 10% of all relevant incidents are notified at best<sup>75</sup>. The reluctance of American manufacturers might be explained by the legal consequences resulting from a possible infringement of the notification duty. Consumers might feel invited to sue manufacturers for not having notified incidents early enough and claim compensation for damages under product liability rules. Australian consumer organisations have pointed out the key role of the notification for the workability of the whole Australian recall procedure. They fear that the delay resulting from the notification of recall only instead of risk situations hinders the implementation of the product safety legislation. The persistent engagement of the Consumer Product Safety Commission to implement the notification duties of manufacturers seems to confirm such an understanding<sup>76</sup>.

The notification duties of French traditional control authorities and courts meet some difficulties in practice. Both are quite reluctant to pursue their notification duty. The Commission de la Sécurité des Consommateurs

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<sup>75</sup> Ch. Joerges, 2.3.2.3.

<sup>76</sup> Ch. Joerges, 2.3.2.3.

has taken measures to increase confidence in its regulatory activities in order to effectuate the notification duty<sup>77</sup>. Other countries have set up more or less well established forms of cooperation between the traditional authorities competent for examining compliance and the special control entities endowed with risk assessment. Cooperation, however, has a different function to fulfill here, namely to guarantee the exchange of information between different regulatory levels<sup>78</sup>. Certification bodies might as well become the addressees of notification duties as in the FRG where certification bodies have to inform the Gewerbeaufsichtsämter of all kinds of incidents and irregularities<sup>79</sup>.

*c. Other sources of information*

Individual consumer complaints seem to play a key role in nearly all countries. This is even true for the American Consumer Product Safety Commission which aggregates its data on an accident surveillance system and which can base its activities on the notification of manufacturers. The overwhelming importance of individual consumer complaints is very well documented in France<sup>80</sup>. A specific hot line, indicating to consumers that the competent authority is available at any time seems to be extremely efficient. Only a limited number of control activities may be allocated to notifications by manufacturers or to data collection accident surveillance systems. Only five of the 25 most aggravating recalls have been triggered by the American Consumer Product Safety Commission<sup>81</sup>. Moreover, there are quite heterogeneous sources of information to be kept in mind, such as testing groups, certification bodies or insurance companies. The role and importance of these information bearers is difficult to evaluate. The accumulated knowledge seems to get lost or is intentionally (or again, unintentionally?) not transmitted to the competent control entities. The prospective role of consumer organizations and certification bodies needs to be further explored<sup>82</sup>.

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77 Personal information from R. Loosli, Commission pour la Sécurité des Consommateurs.

78 Cf. under V.1., 2.

79 Cf. for further details under IV.2.

80 Cf. the annual reports of the Commission pour la Sécurité des Consommateurs.

81 Ch. Joerges, 2.3.2.

82 Chapter II, cf. III.



### 3. The process of decision-making

The analysis is restricted to administrative decision making, because state induced recall activities seem to represent the overwhelming percentage of all post market control activities. Agreements between consumers and manufacturers might be concluded, like in the Netherlands where the *Konumentenbond* is involved in private arrangements<sup>83</sup>. The engagement of the Dutch Consumer Safety Institute should be regarded as a statutory activity. The process of administrative decision-making shall be presented in a twofold perspective: The elaboration of the criteria for decision-making and for defining priorities seeks to illuminate common denominators of administrative practice, against which the different regulatory mechanisms of control are then analysed.

#### *a. Criteria of decision-making — constraints to cooperation*

Our analysis focusses on factors which explicitly or implicitly determine the process of decision-making as well as the prejudice (*Selbstverständnis* = Self-image?) of the control agencies in the performance of their duties. The loss of certainty resulting from vague legal safety concepts puts pressure on the authorities to cooperate with the potential addressees of the negotiations. Since the control authorities are involved in a constant process of making value judgments, possible decisions are always debatable. But it is not the loss of certainty alone which urges the control authorities to look for mutual agreements with the parties concerned. Apart from the United States, statutory control authorities may be sued with compensation claims if they have made improper decisions. Nobody knows whether the risk exists in reality, as precedents are missing. It might not be excluded, however, that the potentiality suffices to influence the behaviour of the control authorities. Manufacturers, for obvious reasons, prefer to enter into negotiations with the control authorities. Two express grounds may be identified:

1. Manufacturers feel jeopardized by a formal administrative procedure which is open to the public at large and might violate their image;
2. Manufacturers try to avoid possible product liability claims by taking appropriate measures in good time. This might be a central motive in the United States, but it is also true to a lesser extent in France, the UK and the FRG.

Such a mutual approach complies best with the way the employees of the control agencies see themselves. They are prepared to engage their ex-

83 B.M. Hummels/G.M.F. Snijders, 4.2.

pertise in order to achieve the most effective solution, almost in a consultative role to the manufacturer. The employees change their position however, if the manufacturers refuse to take the necessary measures. They then slip into the role of regulators<sup>84</sup>.

*b. Defining priorities of post market control action*

Statutory control agencies can restrict their activities to examine whether the product complies with mandatory or quasi mandatory safety rules. They might be entitled as well to evaluate risks, to determine the level of safety, and then to take measures against manufacturers. Control agencies however are not completely free to decide what to do. Local authorities are mainly in charge of examining compliance. The newly established special control entities are concerned alternatively with the determination of the level of safety<sup>85</sup>.

Control authorities, no matter how different their financial and personal input might be, have always scanty resources to administer. They have to set priorities in their work. Countries disposing of an accident surveillance system will use the data collected as a starting point for initiating priority activities. Country-specific sensitivity towards particular product groups or groups of persons is another incentive for setting priorities. The National Swedish Board for Consumer Policies is engaged with ski and skating equipment<sup>86</sup>. Australia and Sweden deploy an overwhelming engagement in the risks children encounter in daily life<sup>87</sup>. Dutch and British control activities center on risks resulting from all kinds of electrical heating equipment. German control authorities start from the principle of "selective supervision"<sup>88</sup>. The Gewerbeaufsichtsämter employ their scanty resources to control fairs examining whether (imported) products to be brought onto the German market meet German safety standards. Systematic market investigations, triggered by "notifications" (from whatever source) or by experience knowledge of the employees, lead to the best result.

Defining priorities does not only mean marking the field of activity (compliance or determination of safety) and to engage in in-depth investigations. Defining priorities involves most of all, the necessity to differentiate between already known risks and to concentrate on cases which are especially severe and far-reaching. Such a differentiation allows for setting prior-

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84 Cf. G. Woodroffe/St. Weatherill, 6 (III) (iii).

85 Cf. II 1 a.

86 N. Ringstedt, 5.4.3.

87 N. Ringstedt, 5.7.; D. Harland, 8.6.

88 J. Falke, German Version, 5.1.

ities where action must be taken first and it must be appropriate in response to the danger in question. Scientific and professionalized parameters of decision-making are transparent and can be challenged by the public at large. The Consumer Product Safety Commission alone has translated the different parameters of decision-making into a classification scheme. It ranges the risks into groups from A to C<sup>89</sup>. The classification then entails priority setting. According to the group different post market control measures are to be taken. The already developed Australian<sup>90</sup> and the envisaged Dutch classification scheme<sup>91</sup> point to the same direction.

### *c. Informal dispute settlement and formal regulatory action*

Informal dispute settlement represents the most important mechanism of post market control activities. There are no statistics available, indicating the relationship between informal dispute settlement and formal administrative action. It seems not overestimated, however to consider informal mechanisms as representing more than 90% of all administratively induced control activities.

Conclusions on the kind of arrangements negotiated between the authorities and the manufacturers can be based on anecdotal evidence only. One might proceed from the assumption that below the formal administrative procedure, all those regulatory measures are to be found which belong to the traditional inventory of post market control measures. The availability of regulatory instruments determines the negotiation. Differentiated solutions are difficult to imagine in countries where legal recall mechanisms are not available. But informal dispute settlement seems to be much more flexible than legal solution patterns. Product recalls can be found in all countries notwithstanding the fact that only the United States, Australia and Sweden have explicitly anchored the recall of products in their product safety laws.

It is difficult to ascertain the factors determining the *style* of negotiation. Experience seems to indicate that the course of negotiations complies best with everyday theory. Economic power and the size of an undertaking seem to be the most important denominators for the course of negotiations. Much more concrete results might be reported from the *form* of the dispute settlement patterns, especially in countries where the kind of action to be taken is bound to the classification of dangers, like in the US and Australia.

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89 Cf. Ch. Joerges, 2.3.3.1.

90 D. Harland, 6.4.

91 B.M. Hummels/G.M.F. Snijders, 2.2.1.

The Consumer Product Safety Commission is operating with so-called corrective action plans or, if necessary, with consent orders<sup>92</sup>. The Australian FBCA has developed guidelines on the implementation of recall activities, which are made available to the manufacturers<sup>93</sup>. In the UK, the FRG and the Netherlands a formalized and professional management of recall activities is still lacking. This might explain the failure of a recall action on electrical blankets in the Netherlands<sup>94</sup>, and the rather delayed execution of the recall of unsafe office chairs in the FRG<sup>95</sup>.

The all-embracing character of informal dispute settlement should not lead to the conclusion that contentious procedures and formal decision-taking has no function any longer in the administrative practice. All control authorities share the common conviction to use *formal* administrative procedures as a last resort only. This might explain why there are so few formal regulatory actions to be reported from the different countries. The hurdles erected by the legislators should not be overestimated in that respect. On the other hand it should be recalled that only Sweden and the United States provide for a regulatory mechanism which allows a flexible shift from the measures the Consumer Product Safety Commission or the National Board for Consumer Policies (the Consumer Ombudsman) are endowed to take, which presuppose the involvement of the District Court (in the US) or the Market Court (in Sweden). So, the function of formal regulatory action here is to secure the implementation of informal agreements by way of formal action.

But, in practice legal instruments are mostly exercised in order to urge the addressees to take voluntary corrective actions — as a mere *coercive power*. The availability of differentiated rules as well as the capacity to make use of them, is preconditioning for the workability of regulatory means as a coercive power. Availability concerns the set of instruments given to the competent authorities, availability is a plea for further extension of post market control instruments. Making use of the instruments to demonstrate their existence safeguards the respect control entities must benefit of in day to day practice.

Highly professionalized product safety control entities know that they are obliged to make use of their legal armament in order to be taken seriously. That is why the Australian Trade Practices Commission initiates litigations as part of its policy, the same is true for the US Consumer Product

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92 Ch. Joerges, 2.3.3.2.

93 D. Harland, 6.17.

94 B.M. Hummels/G.M.F. Snijders, 6.1.

95 J. Falke, German Version, 5.3.

Safety Commission and the Swedish Board for Consumer Policies<sup>96</sup>. If the control entities refrain from using the legal mechanisms which are at their disposal against manufacturers, dealers or importers, their function as an administrative body endowed to take mandatory action is jeopardized. The German Gewerbeaufsichtsämter seem to have reached the threshold<sup>97</sup>.

*d. Promoting new standards*

One proven means for the control authorities to fight the existence of unsafe products might be a request to the competent entities/ministerial bureaucracies to elaborate new technical standards or adopt safety regulations, which define minimum requirements on the manufacturing of specific products. It is emphatically stated that standard setting does not belong to post market control regulation. It seems nevertheless to work quite successfully in Australia and Sweden. The difference between pre market and post market control activities is thereby losing importance<sup>98</sup>. New standards are used at the same time to respond to risk situations (preparing appropriate post market control measures) and to formulate prospective requirements for the manufacturing and marketing of products. This option exists everywhere. How it is managed depend to a large extent on the regulatory approach chosen. Standard setting is part of the statutory responsibility in countries where agencies/administrative entities within the ministerial bureaucracies are entitled to adopt mandatory safety standards and regulations. The overall tendency points to the opposite direction. Private standard-setting bodies become more and more involved in the elaboration of new safety standards. The shift of competences casts some doubt on the perspectives of promoting new standard setting as a means of post market control<sup>99</sup>.

96 Litigation then concern basic questions of the notion of risk, cf. III.1. The Australian Trade Practices Commission clearly states: "best use of resources, both public and private, requires that most compliance work be done at an administrative level, provided that the credibility of the Act is demonstrated by court proceedings, when necessary", D. Harland, 9.7.

97 J. Falke, German Version, 5.2.

98 This conclusion is underlined by D. Harland, 7.

99 Elaboration of standards is often delayed, it's complicated procedure does not allow for quick action. The Australian Minister's competence to declare a voluntary standard by the Standards Association of Australia to be consumer standard presupposes that there is an appropriate standard available, cf. D. Harland, 4.4.

*e. Compliance*

Compliance presupposes that there are mandatory standards to be pursued by the manufacturers and agencies which ensure its execution. The importance of compliance activities is difficult to assess. Differing regulatory approaches play a considerable role. Countries relying on penal sanction models often restrict their implementation activities to the execution of compliance. Countries having submitted safety regulation to market practices legislation, like Sweden, the US and Australia, use compliance activities to clean up the market of unsafe non-compliant products<sup>100</sup>. Australia, and this seems to be quite particular, employs Federal compliance activities to "harmonize" differing control activities at the state level. Compliance here gains an integrative function<sup>101</sup>.

Penal prosecution of mandatory standards/post market control measures is handled very cautiously. Not each and every violation is pursued<sup>102</sup>. Only unyielding manufacturers are sanctioned. Negligence is required even where it is not formally necessary (the UK)<sup>103</sup>. The parallel drawn to the prosecution of possible infringements of market practices legislation shows that infringements against product safety law are sanctioned much more strictly than infringements of the market practices law. This being so in the UK, but quite the opposite is true for Australia<sup>104</sup>.

The most important means to ensure compliance in practice seems not to be penal prosecution but rather injunction orders. British and Swedish control authorities are endowed with the capacity to pursue obvious infringements against safety standards or post market control actions by way of injunction orders<sup>105</sup>. Injunction orders threaten the addressee with penal sanctions, they do not already contain penal sanctions or even fines. Injunction orders postpone penal prosecution.

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100 D. Harland, 5.5.-5.6., N. Ringstedt, 5.6.3.

101 D. Harland, 5.5.-5.6.

102 D. Harland, 9.6.

103 G. Wooddroffe/St. Weatherill, 6. (III) (iii) (a).

104 G. Wooddroffe/St. Weatherill, 6. (III) (iii); D. Harland, 9.9.

105 D. Harland, 9.9.

#### 4. Efficiency of post market control

There are yardsticks available to measure the efficiency of post market control activities:

- (1) The repercussion of possible control measures on the quality policy of the manufacturer;
- (2) The innovative function of post market control;
- (3) The reaction quota on the part of consumers.

Statements can be made on points 2 and 3 only and under a further considerable restriction. Verifiable investigations are available from the United States only and the data is already ten years old.

Australia and the United States are operating with differentiated statistics on post market control activities. Australia had registered 319 notifications on voluntary recall activities between July 1986 and April 1988<sup>106</sup>. It does not cover state-induced measures done. The Consumer Product Safety Commission reports of round about a hundred self-organized activities<sup>107</sup>. Sweden seems to lead the European countries in initiating recall procedures<sup>108</sup>.

The US Consumer Product Safety Commission's study on the efficiency of recall activities concentrates on the number of the repaired and rendered products<sup>109</sup>:

The study evaluated 245 cases until 1976. 39% of all cases had a success rate over 90%, whereas the quotas range normally between 9 and 26%. In order to trace back the denominators of these quotas, the study scaled the different product categories. Durable goods (television sets, refrigerators, washing machines, etc.) had a higher success rate, over 70%, whereas the smaller electrical appliances achieved only a quota of 12%. The next step has been to identify six variables, showing a strong relation to the quota of recall: price, durability, number of marketed products, date of marketing (age of product), percentage of delivery to the consumer, nature of the measures taken (form of notification, locus of repair). The result of the evaluation is ranged on a scale demonstrating the success perspectives of recall activities:

- cases, concerning more than 100.000 units of low value (under 2\$) and low durability (less than 2 years) where

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106 D. Harland, 5.9.

107 Ch. Joerges, 2.3.4.

108 N. Ringstedt, 5.7.

109 Cf. Ch. Joerges, 2.3.4.

the marketing period covered already five years, had the worst success perspectives;

- a success rate under 50% may be calculated in cases where the products cost 25\$, had a durability of less than 6 months, a marketing period of 18 months and a delivery rate to the consumer of more than 66%, if only 10.000 units were concerned;
- a high success quota of more than 90% could be achieved if the users were directly informed and if the repair was done at home.

However, even these results cannot be taken for granted, as the study does not take into consideration the classification of dangers later introduced<sup>110</sup>. Moreover, the study sets aside that a recall might be successful if the user simply throws the product away or handles it more cautiously. Anecdotal evidence and knowledge obtained by experience available in Europe underlines the result evident in the empirical study by the US Consumer Product Safety Commission. An important initiative has been begun in Australia and the UK where the manufacturers are using their guarantee systems to carry out recall activities<sup>111</sup>. The systems allow direct contact with the consumer, thereby increasing the potential success rate.

It seems to be much more difficult to evaluate the innovative function of recall activities than to consider their potential efficiency. New standards might be developed due to recall activities, but there is no scientific evidence on the interrelationship<sup>112</sup>.

#### **IV. Additional Measures of Post Market Control**

Post market control is primarily subject to statutory responsibility in the form of administrative actions. The interrelationship between administrative control action and product liability should not be forgotten however. The FRG underlines the interrelationship between both spheres of responsibility and considers an efficient product liability system to be an equivalent for administrative recall measures. Certification bodies and consumer organizations are finally engaged in the implementation of post market control.

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110 Cf. Ch. Joerges, 2.3.4.

111 D. Harland, loc. cit.; G. Woodroffe/St. Weatherill, loc. cit.

112 Cf. for further details under IV.2 b.



## 1. Product liability — importance for post market control

Product liability in its repercussions on post market control is discussed under two aspects:

- product monitoring duties as an instrument for removing possible dangers, and an independent measure of post market control;
- the possible interdependency between administrative control and private liability.

### *a. Product monitoring duties*

Liability for product monitoring duties seems to be widely accepted now. Monitoring duties are circumscribed as an "extension of the general duty of care beyond the spatial radius of the undertaking from the present to the future"<sup>113</sup>. Product monitoring duties exist to a relatively developed extent in the United States, the FRG and the UK<sup>114</sup>. Their further development by the EC Member States seems to be safeguarded as the Product Liability Directive has left a lacuna here<sup>115</sup>. Product monitoring duties aim at the reduction of health hazards to consumers, resulting from the exclusion of development risks in the Directive. Manufacturers should not be liable if the defect could not be discovered at the time of manufacturing. If however, there is some evidence that the product is nevertheless risky, the manufacturer must take appropriate post market control measures. Bridging the regulatory gap left by the Product Liability Directive does not suffice to consider such product monitoring duties as being an independent instrument of post market control. Access to the instrument is limited to those who suffer loss or damage attributable to the unsafe product. Transforming product monitoring duties to a generally applicable instrument would entail the necessity to give non-concerned individuals and consumer organizations the legally unenforceable right to claim performance of appropriate post market control activities from the manufacturer. One might interpret German case law as being on the way to elaborating the product monitoring duties as an instrument of post market control<sup>116</sup>.

113 Translation of G. Brüggemeier, *Produzentenhaftung nach § 823 Abs. 1 BGB. Bestandsaufnahme und Perspektiven weiterer judizieller Rechtsentwicklung*, WM 1982, 1294 et seq., 1301.

114 J. Falke, *German Version*, 2; G. Woodroffe/St. Weatherill, 2, (1).

115 OJ No. L 210, 7.8.1985, 29 et seq.

116 There is some discussion in legal doctrine on opening up the procedure for non-concerned individuals or even group actions, but the courts have not taken on the academic considerations.

*b. Interdependency*

Whereas Europe is only beginning to discuss the interdependency between statutory post market control measures and private liability, the very same subject has already become a special discipline in the United States<sup>117</sup>. Here, questions of evidence and possibilities of manufacture are discussed to reject product liability complaints with reference to recall activities. One point at stake is the suitability of so-called recall letters as evidence in product liability litigation. What about a consumer who receives a recall letter, but continues to use the unsafe product? Is an assumption of risk justified or not? Another point at stake are the touchy consequence resulting from notifications made by manufacturers. They are obliged to notify all kind of risks, even those which might not be necessarily relevant for product liability matters because the notified risk cannot be regarded as a "defect". This has always been the position of the US Consumer Product Safety Commission. Administrative decisions of the Consumer Product Safety Commission, however, may not set a precedence for the manufacturer's liability under private law.

A factual interrelationship in the form of possible pressure on manufacturers to enter in negotiations, in order to refute potential product liability complaints, is supposed to exist but difficult to measure. The control authorities are advancing the argument that the manufacturers' willingness to negotiate is the greater if product liability law is shaped more explicitly. American experience cannot, however, simply be transposed to Europe. This factual interdependency should be dealt with very cautiously. The density of the interdependency is finally contingent upon the efficiency of product liability law especially in the consumer field<sup>118</sup>.

**2. Certification bodies and testing organizations — auxiliaries in post market control**

Both institutions, although serving different functions within the organization and administration of product safety law, might play an important role within the post market control of consumer goods:

- in their regulatory function to perform post market control measures;
- in their technical capacity to examine technical standards set by the manufacturers.

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117 Ch. Joerges, 3.

118 The issue cannot be dealt with here. The impact of product liability on consumer protection has never been evaluated.

### *a. Regulatory functions*

Both institutions are free to inform the public of possible risks and insufficient product safety standards. They then become involved in the restrictions of civil and constitutional law. The right to information has to be weighted against the manufacturer's right to privacy<sup>119</sup>. So far, only the testing institutions are using their capacity to inform the consumer. This is done either by publishing alerts in the test journals or by discrediting unsafe products in the testing itself. The majority of the certification bodies seem obliged to inform the competent administrative bodies of incidents found. They are aggregating their knowledge either in the type examination (Bauartprüfbescheinigung) or within their ordinary compliance activities. Sometimes they obtain an insight into the record-keeping of manufacturers in order to examine whether the manufacturers have taken adequate measures in reaction to "peculiarities" within the manufacturing process. These control activities correspond to the notification duties imposed on American manufacturers<sup>120</sup>.

Both institutions are engaged in the compliance control of statutory-induced safety standards. Consumer organizations might take consumer alerts as an incentive to discover whether the products which are subject to market restrictions are available on the domestic market<sup>121</sup>. Certification bodies check whether the holders of certification marks respect the documented requirements. Non-compliance with certification marks is to be reported to the prosecution authorities. Theoretically, non-compliance could be fought with the adoption of injunction orders. In practice, such a path exists in countries only where product safety law is incorporated in market practices legislation. Penal prosecution, provided for in most countries, is not, or only to a limited extent, exercised.

### *b. Technical capacities of post market control*

Theoretically, technical standards of private standard-setting organizations should not only define the necessary requirements for deeming a product safe, but also supplying the criteria for examining whether the products concerned comply with the defined technical standards. The so-called test criteria, are definitely throwing light on the safety level being de-

119 Cf. N. Reich/H.-W. Micklitz, loc. cit.

120 Cf. II.3 c.

121 Cf. for further details, under IV.2.

financed within the design requirements. This overall objective being taken for granted, considerable deficiencies have to be reported<sup>122</sup>. German "Prüfstellen" had to realize within their control activities that 20% of the technical standards in question do not provide for test criteria. A further 10% provide for test criteria which are completely outdated. The lack of necessary test criteria however, should not lead to the conclusion that the safety level between technical standards and test criteria differs. Even more alarming are the statistics on type examinations. In 60 — 95% of the cases investigated manufacturers had to change the product design. Self-certification, though favoured by the European Community within the different directives based on the New Approach<sup>123</sup>, is certainly not the right way to effectively protect European consumers against health hazards. The overall positive role test bodies are playing must be qualified in a double sense: 8% of all products notified to the German "Gewerbeaufsichtsämter" bore a certification mark and the German testing institution is constantly discovering products bearing the label "GS geprüft" (GS tested), though they are in fact unsafe.

There is a considerable difference between the official test institutions and the consumer organizations in the way they make use of technical standards in their daily activities. Consumer organizations are referring to technical standards elaborated by private standard-setting bodies as one possible source of information among others. Consumer testing institutions are developing their own test criteria and quite often they lay down standards which go beyond the level defined in the technical standards of private standard-setting institutions. This practice has been judicially recognized in the FRG<sup>124</sup>.

The activities of the consumer testing organizations seem to be quite efficient<sup>125</sup>. 90% of the manufacturers being the addressee of the test, eliminate the incriminated products from the product tender. The innovative function of post market control is likewise striking. 50% of the manufacturers are said to use the test results in order to improve the safety of their products; 66% are said to take into account test criteria of the consumer organizations in their product design. Though the input of these organizations in the standard-setting process seems to be guaranteed throughout the industrialized countries, their innovative functions should

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122 The following information is based on J. Falke's intensive research on the activities of German "Prüfstellen" and testing institutions.

123 J. Falke, Elements of a Horizontal Product Safety Policy for the European Community, JCP 12 (1989), 207 et seq.

124 BGH v. 10.3. 1987, VI ZR 144/87, mit Anmerkung N. Reich, VuR 1987, 221 et seq.

125 J. Falke, German Version, 6.

not be overestimated. The remaining competent standard-setting organizations are adopting better standards only, once the level inherent in the new standards has already found its way onto the market.

### **3. The specific status of post market control measures on cars**

The car sector is quite different from the sector of technical consumer goods dealt with here. Cars are much more expensive than most technical consumer goods. Car owners are relatively easy to identify, either by the record-keeping of the manufacturers themselves or by the records of the competent national registration authorities. Motor vehicles may be subject to a periodic safety check exercised by specific test institutions, and are subject to routine maintenance to a large extent. Consumers are not alone in defending their rights. Influential automobile clubs assist them with specifically trained personnel in all matters arising from use. Recalls of cars therefore have a considerable practical importance.

#### *a. Legal and institutional framework*

Once more the United States has taken the lead<sup>126</sup>. Recalls of cars are subject to a specific Act whose enforcement is entrusted to a particular Federal agency. The UK has not regulated the recall of cars in a single legislative act. It has, however, laid down performance conditions in the "Code of Practice on Vehicle Recall", elaborated with the participation of the Department of Transport, who is likewise involved in the implementation of recall actions. Self-regulation dominates the situation in the FRG. The specific Federal authority has no legal power to carry out motor vehicle recalls<sup>127</sup>. All efforts of consumer organizations and automobile clubs to introduce legal rules on recall of cars, failed so far.

#### *b. Practice of recall activities*

The decision-making procedure in the administrative practice as well as in voluntary control schemes appears to be similar to the post market control measures for consumer goods. Legal or quasi legal prerequisites defining the risk may be found in the United States and in the UK Code of Practice. Where legal assistance is not available, manufacturers have to define the danger themselves. Record-keeping is a common practice of all manufacturers for quite a number of decades. American and English man-

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126 Ch. Joerges, 2.1.

127 J. Falke, 7.

ufacturers have to notify possible risks to the competent authorities<sup>128</sup>. These are centrally registered. In practice, informal negotiations and procedures are dominating. The efficiency rate of recall activities is relatively high due to the social status of cars and their economic value. Concrete figures on the decision-making procedure are available from the United States only<sup>129</sup>. Here, post market control of cars seems to have served as a forerunner for the development of specific product safety legislation in other fields of product regulation. This is true for the development of appropriate instruments to exercise administratively induced recall actions. It is likewise true for judicial litigations between the authority and the most important car manufacturers in the post market control policy of the Federal agency<sup>130</sup>. The situation in Europe is different. Recall activities with cars cannot be brought into correlation with post market control of consumer goods.

## **V. Post Market Control, Centralism and Federalism**

Post market control activities are confronted with different administrative and constitutional structures. Centrally administered countries should be distinguished from federally administered ones. Both state concepts meet different necessities for adapting post market control measures to the level of regulation.

### **1. Distribution of power**

Compliance is usually managed at the local level, whatever the state concept might be. The 300 Swedish local consumer counsellors have an auxiliary function only, they have to inform the National Swedish Board for Consumer Policies on possible incidents, but they are not endowed with independent regulatory competence. The local authorities differ however in the extent to which they are independent in taking appropriate control measures. German and Dutch authorities are even obliged to refrain from any kind of control if compliance is documented by a specific certification-mark<sup>131</sup>.

The differences between federal and central states are much more obvious in the second major field of post market control: i.e. defining new

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128 G. Woodroffe/St. Weatherill, 7 (II), Ch. Joerges, 2.1.3.1.

129 Ch. Joerges, 2.1.3.4.

130 Ch. Joerges, 2.1.3.2.

131 Cf. III 1.

product safety standards. Federally organized states need a cooperation mechanism at the level of legislative competence, as well as in matters of implementation. Autonomy and dependency can take different forms. The German "Gerätesicherheitsgesetz" is a Federal law. Implementation however lies in the hand of the Gewerbeaufsichtsämter of the German Länder, who are taking measures in their own competence. The situation in Australia is different. Territories and the Federal State are concurrent at the level of legislation as well as at the level of implementation. The United States has chosen the central solution. The Consumer Product Safety Act is a Federal law, the Consumer Product Safety Commission a Federal agency with its own administrative structure. Centrally organized states have a clear perspective on the distribution of power. But even here independent administrative entities are set up, endowed with a certain autonomy to intervene in the market. This is true for the French Commission de la Sécurité des Consommateurs, for the UK Consumer Safety Unit and for the Dutch Consumer Safety Institute.

## 2. Binding effect of administrative action

Federal states have to solve competence conflicts between the Federal state and the Länder or Territories at the constitutional level. For the ongoing process of Europeanization of post market control the different solutions found seem to be of much interest.

The motive behind the adoption of the Consumer Product Safety Act in the United States was the idea of harmonizing market access rules. The Consumer Product Safety Commission was explicitly endowed to set out mandatory Federal safety standards as a common orientation for American manufacturers. A clearly formulated preemption rule should safeguard the priority of the Federal law over state competences<sup>132</sup>. The Consumer Product Safety Commission however was not in a position to fulfill the legislative mandate and refrained from this policy, not least due to political intervention in the regulatory scheme<sup>133</sup>. Nowadays technical standards developed by private standard-setting organizations should guarantee harmonization of American market access rules. *De facto*, the same differences reemerge which should have been removed with the adoption of the Consumer Product Safety Act. The centrally managed post market control leads however, to a far-reaching harmonization of market restrictions all over the United

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132 Ch. Joerges, 4.

133 Ch. Joerges, in: Ch. Joerges et al., loc. cit. 215 et seq.

States. The activities of the Consumer Product Safety Commission are binding federal-wide.

The FRG has chosen the opposite road. In order to guarantee a unified level of protection all over the FRG, the Gewerbeaufsichtsämter are bound among themselves to their decisions<sup>134</sup>. In Australia, divergent legal rules and divergent post market control actions are possible<sup>135</sup>. Theoretically, a preemption rule applies if particular territories infringe Federal law. *De facto*, possible conflicts between the territories and the Federal state are solved cooperatively. The CSCPAC provides for the institutional frame in which possible conflicts are managed.

The problem of the binding effect of regulatory decisions is simply unknown to centrally organized states. Conflicts might arise if local authorities exceed their competence in defining new safety standards instead of restricting themselves to mere compliance activities. Overlapping competence between local authorities is another issue at stake, which is solved at least in the UK by the "home authority principle"<sup>136</sup>.

### 3. Cooperation and coordination

The need for mechanisms of cooperation and coordination within both statutory concepts is striking. Compliance control, even if locally exercised, must be coordinated, in order to ensure that deviations within the same country might remain at a low level. Developed mechanisms of cooperation exist in Australia and the FRG. The Federal State is in charge of the coordination between the different levels, in Australia — the CSCPAC<sup>137</sup>, in the FRG — the Bundesanstalt für Arbeitsschutz<sup>138</sup>. The German RAL is organising an exchange of experience between the different testing bodies. Centrally administered States meet the same need. In the UK local authorities as well as the officers themselves have organized their own fora of coordination which rapidly gain importance even as a basis for bilateral cooperation with Netherlands<sup>139</sup>. *De facto*, these fora constitute a type of a safety agency where all information concerning product safety is managed. In France, cooperation and coordination between the different competent

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134 BVerfGE 11, 1 (6), thereto J. Falke, in: Ch. Joerges et al., loc. cit. 164.

135 D. Harland, 4 b).

136 G. Woodroffe/St. Weatherill, 6. (I) (ii).

137 D. Harland, 4 b).

138 J. Falke, in: Ch. Joerges et al., loc. cit. 161 et seq.

139 G. Woodroffe/St. Weatherill, 6 (II) (ii).



authorities, including the courts, lies in the hands of the Commission de la Sécurité des Consommateurs.

#### 4. Exchange of information

The most important means of cooperation at all levels and within both statutory concepts, is the exchange of information. It is technically managed either by a specific publication, though this may be restricted to the authorities concerned as in the FRG<sup>140</sup>, or in the form of a data bank where all relevant and sensitive information is collected. The UK has recently set up the HASPROD<sup>141</sup>. Australia calls its data bank "Alleged Register of Hazardous Products"<sup>142</sup>. Mechanisms of information exchange cover not only regulatory actions but all kind of "peculiarities", incidents and indications, which correspond to the notification reports American manufacturers are asked to supply<sup>143</sup>.

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140 J. Falke, German Version, 3.

141 G. Woodroffe/St. Weatherill, 6 (II) (ii).

142 D. Harland, 5.7.

143 Ch. Joerges, 2.3.2.3.

## Chapter II

### Perspectives for a European Setting of Post Market Control

The comparative analysis of post market control practice in selected Member States of the European Community, Australia, Sweden and the United States has set a number of focal points which should be taken into consideration for the establishment of a European post market control system. A short overview of the already existing Rapid Exchange System<sup>144</sup> and the planned procedure under the Draft Directive on Product Safety<sup>145</sup> shall introduce the European perspective. European practice and European plans will then be contrasted with the results of the comparative analysis.

#### I. European Approaches to Post Market Control of Consumer Goods — The Regulatory Framework

The idea of setting up a European<sup>146</sup> post market control system is relatively old. The 1975 Programme on Consumer Protection already formulates as a general principle<sup>147</sup>:

"goods and services offered to consumers must be such that under normal or foreseeable conditions of use, they present no risk to the health or safety of consumers. There should be quick and simple procedures for withdrawing them from the market in the event of their presenting such risks."

But it took another couple of years before the Spanish oil scandal shocked the Community into action<sup>148</sup>. The then established Rapid Exchange System<sup>149</sup> provides for information exchange only and can be regarded as an intermediary step to the further development of a European

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144 OJ No. L 70, 13.3.1984.

145 OJ No. C 193, 31.7.1989, 1 et seq.

146 "European" should be understood as harmonization of national product safety legislation.

147 OJ No. 92, 25.4.1975, 92 et seq., 94 under 15 (a) (i).

148 I. Uriarte, *The Toxic Syndrom Proceedings in Spain*, JCP 12, 1989, Special Issue: Consumer Autonomy and Health Services (ed. N. Reich), 433 et seq.

149 OJ No. L 70, 13.3.1984, 16 et seq., cf. the analysis of J. Falke, *What should be the Content of an E.E.C. General Directive on the Safety of Technical Consumer Goods*, BEUC Suppl. Juridique, Numéro 16, Nov./Déc. 1986; R. Milas, *La Signification Juridique de l'Institution d'un Système Communautaire d'Echange Rapide d'Informations sur les Dangers découlant de l'Utilisation de Produits de Consommation*, *Revue du Marché Commun*, 1984, 71 et seq.

post market control system. This objective might be realized within the ongoing debate on the adoption of a Product Safety Directive<sup>150</sup>.

### **1. Community System for the Rapid Exchange of Information on Dangers arising from the Use of Consumer Products**

"In cases where it is established that consumer products marketed in the European Economic Community may endanger the health and safety of users in such a way that the rapid implementation of appropriate measures is called for, means should exist for the rapid exchange at Community level, of information concerning such products and to this end an organized system should be established". This has been the official justification for the establishment of the Rapid Exchange System. Article 1 obliges any Member State who decides to take urgent steps to prevent, restrict or attach particular conditions to the marketing or use or the possible marketing or use, on its territory of a product, or a product batch, because of the serious and immediate risk which that product or product batch presents for the health or safety of consumers when used in normal and foreseeable conditions, to immediately inform the Commission thereof. Whenever possible, the producer, distributor or importer of the product or product batch shall first be consulted. The system applies to all products intended for use by consumers except products intended exclusively for professional use; and products which under other Community instruments are the subject of equivalent notification procedures (Article 2).

The Interim Report on the System for the Rapid Exchange<sup>151</sup> has made clear that medicines, coming under Directive 75/319/EEC and 81/851/EEC, and notifications on illnesses of animals and residues in food and fresh meat in accordance with Directive 74/432/EEC and Directive 82/894/EEC are considered as equivalent notification procedures<sup>152</sup>. The differing safeguard procedures provided for in quite a number of product-related directives cannot be put on an equal footing with the Rapid Exchange System<sup>153</sup>. They are not aiming at a speedy exchange of information. Safeguard procedures are covering only those kind of product categories, for which harmonized standards have already been developed. Safeguard procedures might enable quick intervention if necessary, they are mainly set up, however, to exercise compliance with Community standards. The Rapid

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150 OJ No. C 193, 31.7.1989, 1 et seq.

151 COM (88) 562 final, 24.10.1986, cf. Ch. Joerges et al., op. cit. 293 et seq.

152 Cf. op. cit. Interim Report, No. VI.

153 Ch. Joerges et al., loc. cit. 268 et seq., 358 et seq.

Exchange System on the contrary concerns serious and immediate risks requiring immediate action. It has not been set up to review long term risks which might entail the necessity to adapt product-specific requirements to altered circumstances. Foodstuffs, though formally under the scope of application of the Community Decision, are further governed by an informally introduced and reportedly well-functioning information system. This informal procedure has not been amalgamated with the non-food sector into one rapid exchange mechanism.

The Commission is located at the center of the information exchange. It is assisted by an advisory Committee, consisting of two representatives per Member State. The representatives of the Member State may be accompanied by up to two experts. On receipt of the Member State's decisions, the Commission verifies their conformity with the terms of the Rapid Exchange Decision and forwards them to the competent authorities of the other Member States. The competent authorities of a Member State shall then inform the Commission without undue delay of any measures they have taken, following receipt of the information referred to in Article 1. On receipt of this information, the Commission shall in turn forward it to the competent authorities of the Member States. In justified cases and if the competent authority of the Member State supplying information under this Decision, so requested, the information shall be treated as confidential. The Decision, adopted in March 1984 has been set up for a period of four years<sup>154</sup>. The Commission, in the light of the experience obtained, has presented an Interim Report in 1986 and Final Report in 1988<sup>155</sup>. The 1988 Report proposed the continuation of the Rapid Exchange System for a further 6 years<sup>156</sup>. The debate in the Council was highly controversial. Spain refuted the continuation of the Rapid Exchange System without having critically reviewed the mechanisms. The Spanish authorities felt somewhat discomforted by the notification pursuant to the Spanish oil scandal. The Council finally decided in December 1988 to prolong the Rapid Exchange System until June 1990<sup>157</sup>. The Commission is asked to present a report on the system by June 1989 — an obligation the Community has failed to perform so far.

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154 Cf. loc. cit. Article 8.

155 COM (88) 121 final, 12.3.1988, OJ No. C 146, 3.6.1988, 8 et seq.

156 COM (88) 121 final, 18.3.1988, OJ No. C 124, 11.5.1988, 9 et seq.

157 OJ No. L 17, 21.1.1989, 51 et seq.

## 2. Overview on the proposed regulatory mechanism for "emergency situations" of grave and immediate risks under the Council Directive on General Product Safety

The Draft Directive<sup>158</sup> considerably extends the Rapid Exchange System. It proposes a procedure adopting, at Community level, measures applicable throughout the Community in emergency situations. The objective should be pursued in a two-fold sense: (1) extending and defining minimum requirements for the national shaping of post market control; (2) developing mechanisms for the performance of a European post market control procedure.

(1) According to the draft Article 7, Member States are obliged to provide their national authorities with powers commensurate to the requirements of enforcing the general safety duty. The Article refrains, however, from imposing specific regulatory means which Member States would be compelled to implement. It refers rather to an indicative list of powers lying at the Member States' disposal, in an Annex to the Draft Directive. Where a Member State intends to take measures pursuant to Article 7 which restrict the placing of a product onto, or require its withdrawal from the market, the Member State should, to the extent that such notification is not required under any specific Community legislation governing the particular product or product sector concerned, immediately inform the Commission of any such measure, indicating the reasons for adopting it. Briefly expressed: although the intended post market control procedure should cover emergency situations only, Article 8 establishes a notification duty on all kind of regulatory actions taken by the Member State, if the products present an "unacceptable risk". Such a comprehensive notification duty should be interpreted as a precautionary measure to prevent Member States from circumventing their notification duty in emergency situations, by simply playing down the risk and classifying it as not being worthy of notification.

(2) The procedure for adopting, at Community level, measures applicable throughout the Community in emergency situations is laid down in Article 9 to 14. Article 9 regulates the information channels at the Member State level. Member States should develop a centrally administered *national rapid exchange system* guaranteeing rapid transmission of the information to the Commission. Article 10 restricts the Member State's power to adopt regulatory action in emergency situation to merely transitional activities.

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158 OJ No. C 193, 31.7.1989, 1 et seq.; COM (89) 162 final SYN 192, 7.6.1989.

Such a restriction is seen as preconditioning for the adoption of post market control measures at the Community level.

Article 11 describes the trigger mechanism for Community procedure on post market control in emergency situations. The Commission's knowledge might result from notifications of Member States actions taken under Article 8 in the normal procedure or from Member State notification under Article 9 in emergency situations. The latter notification is not limited to formal regulatory action, it covers "information about the existence or the likely existence of a grave and immediate risk having not only local effects". The introduction of the post market control procedure at the Community level is bound to three conditions: (1) the possible existence of a grave and immediate risk might affect directly or indirectly the safety and health of an indeterminate number of persons in more than one Member State, (2) the grave and immediate risk cannot adequately be dealt with under other procedures for information, consultation, concertation and decision-making and related powers where so laid down under specific Community legislation, (3) a grave and immediate risk can only be coped with appropriately by adopting adequate measures applicable throughout the Community.

Article 12 defines the consultation and investigation procedure. The Commission should immediately communicate the decision to initiate a consultation and investigation procedure to the Member States together with a summary of the evidence available. The purpose of the procedure is to obtain full information to identify its sources and to examine the need for adopting appropriate measures. The Commission should have the competence to request Member states to adopt measures for obtaining comprehensive information from all those concerned, per Article 12 para 3.

Article 13 provides for the establishment of a Committee on Product Safety Emergencies which should assist the Commission. The Committee is composed of the Member States' representatives and shared by a representative from the Commission. Article 14 finally formulates the conditions for the decision-making procedure. It sets out the mechanism for adopting *interim measures* (not permanent!) applicable throughout the Community according to the Management Committee<sup>159</sup> variant of Council Decision 87/373 of 13 July 1987<sup>160</sup>. That is considered as being the most appropriate,

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159 Cf. to the classification of a management committee with the formulation of an overall European product safety policy Ch. Joerges/J. Falke, Die Normung von Konsumgütern in der Europäischen Gemeinschaft und der Richtlinien-Entwurf über die Allgemeine Produktsicherheit, Beitrag zur Tagung des Arbeitskreises Europäische Integration, 9.-11.11.1989 in Bonn. The results of the conference will be published in the Schriftenreihe des Rechtskreises Europäische Integration, NOMOS, Baden-Baden.

160 OJ No. L 197, 18.7.1987, 33 et seq.

taking into account the need for rapid action at Community level and the necessary involvement of Member States.

(3) At the time of writing, it seems to be impossible to predict the future of the Draft Directive. The discussion within the Council focusses *inter alia* on the proposed mechanism of post market control. There is strong resistance from a number of countries towards delegating regulatory power to the Community. But even if a revised proposal would considerably deviate from the 1989 Model, the post market control issue will subsist. The Rapid Exchange System, though insufficient and highly debated might well constitute an intermediary step towards the full implementation of European post market control. A solution must be found, in some form, to realize the Internal Market<sup>161</sup>.

## II. EEC Post Market Control Regulation, Member States Experience, Prospects for the Future — A Comparison

The comparison of the the European regulatory approach with the selected national regulations on product safety regulation in general and the post market control in particular will be supplemented by a comparison of the administrative practice of post market control in the selected countries and the experience gained by the Commission within the Rapid Exchange System with the Draft Directive. Setting out pitfalls which might be taken into consideration within the shaping of a European system for post market control, will round off the analysis.

### 1. Comparison of regulations

The comparison is not meant to be comprehensive<sup>162</sup>. It tries to settle the Draft Directive into the overall trends of safety regulation<sup>163</sup>. The twofold objective of the Draft Directive has to be clearly separated: harmonization of national product safety legislation and establishment of a European post market control mechanism<sup>164</sup>.

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161 For an in-depth investigation cf. Ch. Joerges et al., loc. cit. 451 et seq.

162 For more systematic analysis of the Draft Directive in the European perspective of developing a product safety policy, cf. Ch. Joerges/J. Falke, loc. cit.

163 Cf. framework of the analysis are the categories applied in chapter I, II.

164 Cf. I 2.

*a. The impact of the Draft Directive on the harmonization of Member States product safety and post market control legislation*

The Draft Directive defines product safety as a separate policy. It is very much in line with the US approach to regarding product safety as marketing practices regulation<sup>165</sup>. It opens up far-reaching perspectives for the achievement of an *independant* product safety policy. This is documented by the formulation of a general safety duty which is at the heart of the Draft Directive. The concept of safety chosen remains within the progress made from "intended use" to "foreseeable use". The terminology of "unacceptable risk" seems to be near to the US concept of "unreasonable risk"<sup>166</sup>. Reference to standards is not explicitly provided for, but technical standards are considered as presumption of equivalence to the general safety duty requirement in the absence of mandatory safety rules (Art 5 (2)).

The Draft Directive does not explicitly engage the Community in a programme for development of a specific type of control body<sup>167</sup>. Art 9 requires the Member States to designate one single authority which is competent for cooperating with the Community on the exchange of information<sup>168</sup>. Although this obligation must be seen in the context of the EEC's intention to build up an effective network of information exchange, the plea for a central body is indicative. Such a central body must not necessarily be endowed with regulatory competence. But Member States experience shows that central units are normally given the competence to inform the public, be it in the form of an explicit delegation of competence, or as an implicit power deduced from the overall statutory liability for the consumer's health and safety. Art 9, though quite modest in language might yield a far-reaching effect on the shaping of the institution designed to co-operate with the Commission, but in fact administering post market market control.

The provisions on the instruments of post market control regulation are inspired by the perspective that harmonization of regulatory competence would be preconditioning for achieving a European product safety policy. The Draft develops a twofold approach on the instruments necessary for effectively monitoring post market control.

Firstly, it aims at information on the Member States level. Data collection on accidents and risks should be integrated in the national legal system for regulating product safety. Art. 7 might be interpreted as an attempt to

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165 Cf. chapter I, II 1.

166 Ch. Joerges/J. Falke, loc. cit. IV 2.

167 Chapter I, II 2.

168 Cf. b)



push the acceptance of an accident surveillance system, as promoted by the Community. The obligation of the Member States under Art. 9 to build up a national Rapid Exchange System for emergency situations would entail a considerable extension of existing information networking in the Member States. Art 6 devotes attention to the role manufacturers and suppliers might play in the information raising. They are regarding the manufacturers and suppliers as the parties primary responsible, being very much in line with the Australian understanding on product recall<sup>169</sup>. The Draft Directive does not impose an obligation on them to report on risks to the national competent authorities. It remains behind the existing rules in the United States and Australia<sup>170</sup>. But the Draft requires the Member States to take action ensuring that the supplier of the product makes appropriate arrangements for permanent monitoring. It relies on cooperation and information-sharing between the supplier and the competent authorities. Statutory interventions to secure the notification of information shall apply as a last resort only<sup>171</sup>.

Secondly, the Draft pushes for the harmonization of post market control instruments. The instruments listed in the Annex demonstrate the whole set of means necessary for an effective post market control monitoring, "standards", "ban", "seizure" and "recall". It goes far beyond the means available in most of the Member States, with the exception of France and all those non-EEC countries having already introduced product recall legislation.

- "Standards": the request of appropriate changes in a product or the production line<sup>172</sup>;
- "ban": the imposition of the appropriate restrictions as to the conditions of the distribution and marketing, and where appropriate, of disposal, of product<sup>173</sup>;
- "seizure": the request to seize the product concerned at any stage of the manufacturing process and the distribution chain, and where necessary, at the premises or homes of end users or final consumers<sup>174</sup>;
- "recall": it suffices to refer to the introduction of product recall mechanisms and public warning notices<sup>175</sup>.

169 Cf. chapter I, II 3 c.

170 Cf. chapter I, II 3 a.

171 Cf. Art 7 in connection with the indicative list (2), second hyphen.

172 Annex 2, (2) (h).

173 Annex 2, (2) (g); attention deserves the possibility to regulate the disposal of unsafe products. There is no such power to be found in any of the investigated countries' product safety legislation.

174 Cf. for further details of the recall procedure, cf. under b) (6).

175 Cf. Chapter I, II 3 a.

The Draft Directive uses the term "indicative list": "It is meant to systemize such powers and clarify their possible use in principle in respect of all relevant sectors"<sup>176</sup>. But the indicative list might become attached with mandatory effects. Firstly, because Member States are under an obligation to report all kind of activities to the Community and not only emergency measures<sup>177</sup> and secondly, because the measures shall be at the disposal of the management committee i.e. they should be introduced at the Community level<sup>178</sup>.

*b. The European procedure on post market control*

The analysis of the Draft Directive takes the view of recall regulation in the investigated countries<sup>179</sup> in order to facilitate a comparison and in order to highlight the difficulties for a Europeanization of post market control mechanisms.

(1) The administrative entity as foreseen in the Draft Directive is certainly the most striking innovation of the Draft Directive. The 1984 Rapid Exchange System has not yet been set out with the intention of building up regulatory competences. The obligation of the Member States to report on the activities they have taken pursuant to the notification to the Commission could not be yet understood as an intervention into the competences of the Member States themselves. Community measures, taken by the Commission in emergency situations, it was originally thought, should be directly applicable. The now published Draft Directive stays away from this even more ambitious concept. Member States should remain in charge of enforcing the European measures agreed upon within the decision-making procedure under Article 14. Homogeneous implementation of the Community measures could be guaranteed only, if all Member States would have the same legal instruments at their disposal — another reason for the quasi-mandatory character of the indicative list.

(2) The Draft Directive picks up the now well established differentiation between the *normal* and the *emergency* procedure in the investigated countries and adapts it to the needs of a European post market control management. Terminology used in differentiating risks is taken from the French law on product safety: "whenever the Commission has knowledge .. of the possible existence of a *grave and immediate risk*". But a European

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176 COM (89), 162 final — SYN 192, 7.6.1989, Proposal for a Council Directive concerning general product safety, 10 under Art 7.

177 Cf. Art 8. para 2, cf. Ch. Joerges/J. Falke, loc. cit.

178 Cf. Art 11 c.

179 Cf. chapter I, II 3 c.

management of emergency situations can be justified only if community-wide action is necessary to fight the unsafe product. Such a European concern should be assumed if more than one Member State is concerned by the grave and immediate risk, per Art. 11. Local and regional emergent immediate and grave risks are excluded from the European management of post market control<sup>180</sup>. They have to be notified only if the emergent danger unfolds transboundary effects. The present Rapid Exchange System does not formally restrict the notifications to *national* regulatory activities.

(3) Investigating the danger means for the proposed European management of post market control first and foremost that the Member States perform their notification obligations. Notifications from the Member States constitute the platform of operation for the European management of emergency situations within the Commission. The Commission is not endowed to undertake self-initiated research on the existence of emergency situations. "Knowledge" of the existence of a grave and immediate risk, which is preconditioning for initiating the consultation and investigation procedure under Art. 12 may be the product of one or more different sources of information: (a) from notifications on emergency situations pursuant to Art. 9, (b) from notification of Member States' action taken against unacceptable risks, Art. 8 (2), (c) from "knowledge" deriving from external sources like consumer complaints or press release. The Commission has a relatively broad set of information devices and it is free to decide whether it wants to initiate a consultation and information procedure or not.

But it goes without saying that the management will depend on the feasibility and the workability of the notification system. The Draft Directive does not make clear how the flow of information from the Member States to the Commission shall be secured. Art. 9 (3) refers to "detailed procedures for the transmission of information" which shall be adopted by the Commission in agreement with the competent authorities of the Member States". The position of the Commission is somewhat better if it has already got been notified of the existence of a risk from whatever source of information. It can then request the Member States concerned to supply all information about the matter which such Member State is seized of or which it can obtain<sup>181</sup>. If the Commission has already initiated a consultation and investigation procedure Member States are even obliged upon request of the Commission, to take appropriate measures against the party charged with obtaining appropriate information<sup>182</sup>.

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180 Art 8.

181 Art 8 (4).

182 More specifically, the measures under (2) (a)-(c) of Annex 2, Art 12. (3).

Access to notifications is limited to the Member States and the Commission. The 1986 Interim Report on the Rapid Exchange System<sup>183</sup> has mentioned the possibility of integrating consumers into the distribution of competences. It has taken into consideration the transmission of notifications without mentioning the name of the product and the name of the manufacturer. Art 6 of the Draft Directive addresses the Member States authority to keep the information confidential. But it permits the publication of information, if it is necessary to ensure adequate protection for health and safety. No mechanism is provided for to decide on the concrete conditions under which information should be made public<sup>184</sup>.

(4) The consultation and investigation procedure can be considered the equivalent of an "administrative hearing" as foreseen in Australian and American product safety legislation. But access at the Community level is — once more — limited to the Member States. No third parties are admitted to participate in the procedure. This does not mean that third parties are completely excluded from the European management of post market control. The enforcement authorities of the Member States, which carry out the measures adopted within the management committee, are obliged to give any party concerned an opportunity to submit its views<sup>185</sup>. What might be understood by "parties concerned" is nowhere defined, it could according to the UK terminology, encompass consumers<sup>186</sup>. But such an interpretation is not binding.

(5) The regulatory means made available to the management committee are simply enumerated in the indicative list of Annex 2. They cover *inter alia* the request addressed to manufacturers, importers and where necessary other professionals to disseminate adequate warnings to all persons likely to be exposed to the risk involved<sup>187</sup> as well as the warning of the public either by the manufacturers, importers and other professionals or by the competent authority<sup>188</sup>. But there is no ranking between the two ways of alerting the consumer<sup>189</sup>. The provisions on recall are worth being quoted in full:

"the request of a product recall already placed on the market, — even where it is already in the possession of an end user or final consumer and, where necessary, its destruction under appropri-

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183 Cf. loc. cit. 5 et seq.

184 Cf. the study undertaken for the Commission by ZERP, G. Winter.

185 Cf. Art 14 4.

186 G. Brüggemeier, in: Ch. Joerges et al., loc. cit. 112.

187 Cf. Annex 2 (2) (e).

188 Cf. Annex 2 (2) (d) and (e).

189 Cf. chapter I, II 3 c.

ate conditions, according to the circumstances Member States may

- (aa) invite a manufacturer to voluntary recall, in the most effective way, the product concerned,
- (bb) order manufacturers to recall, in the most effective way the product concerned<sup>190</sup>.

There are no provisions on replacement, repair or refund to be found. Recall as a regulatory instrument is introduced but not clearly shaped. The decision making procedure within the management committee leaves the final responsibility with the Council of Ministers. Criticism has been raised against the five-days delay, in which the Council would have to take action, in case of deviations from the Commission's proposal, Art. 14 para 1. The extremely short delay would lead to a *de facto* autonomy of the Commission.

## 2. Comparison of administrative practice

Practical experience to illuminate the functioning of the proposed mechanisms for a European post market control management may be drawn from selected Member States and from the Rapid Exchange System. Member States experience may provide assistance in the risk assessment, the investigation of the danger, the shaping of the administrative hearing, more precisely the extent to which third parties might participate and last but not least in the management of the recall mechanism. Extremely helpful would be efforts to rank different degrees of dangers to different kind of actions<sup>191</sup> and to transpose the recall in a corrective action plan or code of recall<sup>192</sup>. But the presentation of the post market control management in the foregoing chapter has demonstrated the specific prerequisites for a European mechanism of post market control. Information networking has a key role to play. And here Member States experience and administrative practice of the Rapid Exchange System might be fruitfully combined to pinpoint some basic pitfalls for the further development of information networking.

### a. Coverage of notifications — formal and informal action

The administrative practice of post market control within the investigated Member States, Sweden, Australia and the United States is determined by informal negotiation patterns. The Rapid Exchange System does

190 Cf. Annex 2 (2) (i).

191 Cf. chapter I, II 3 c.

192 Cf. chapter I, III 3 c.

not explicitly cover informal regulatory actions, although the addressees of the Rapid Exchange Systems have voluntarily transmitted informal actions to the Commission. The latter does not seem to appreciate the notification of voluntary control activities. Notifications of voluntary actions are said to refrain manufacturers and importers from taking appropriate control measures because they feel that their image on the market might be jeopardized<sup>193</sup>. It is difficult, however, to imagine that notifications whose distribution is kept confidential throughout the Community, might reach the public and, secondly, if voluntary measures are excluded from the notifications, European post market control could cover only 5% of all control activities of the competent authorities. We wonder whether the different sources of information under the proposed mechanism on post market control can guarantee comprehensive information by the Commission of these voluntary actions<sup>194</sup>.

Local and regional controls play an important role within the investigated states. The opponents of a Europeanization of post market control often argue against the necessity of notifying local and regional activities. Those controls are said to concern only a limited number of products within a limited area in the country itself. Experience shows however, that highly engaged local and regional control entities might have far-reaching influence at the central or federal level. Setting those activities aside would mean the restriction of a central source of information for Community action and that is exactly what Art. 8 of the Draft Directive is doing.

*b. Informational and organizational deficiencies of information networking*

Notifications are useless if they do not contain the information which is necessary for the addressee to take appropriate action. Article 1 para 2 of the Council Decision establishing the Rapid Exchange System, defines the kind of information which should be notified to the Commission. In practice, however, quite a number of difficulties arose in the extent to which Member States were willing to comply with their notification duty. The 1986 Interim Report<sup>195</sup> as well as the 1988 Final Report<sup>196</sup> deplores the unwillingness of Member states to provide the Commission with *full* information of all relevant cases. If relevant cases are notified, the information given is often delayed and not comprehensive enough for taking action. Some Member States seem to pursue a quite strange but obviously effective strat-

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193 Cf. loc. cit. 13 et seq.

194 Cf. II 1 b.

195 Cf. loc. cit. 5 et seq.

196 Cf. loc. cit. 11 et seq.

egy. Cases are collected within the Member State for a certain period of time and then transmitted altogether *uno acto* to the Commission<sup>197</sup>. It remains to be seen whether the proposed powers given to the Commission under the Draft Directive will suffice to secure full information<sup>198</sup>.

Comparative analysis has underlined the overwhelming role of consumer complaints, expert experience of insurance companies, certification bodies and testing institutions for the investigation of the danger. The Draft Directive as well as the Rapid Exchange System is, on the contrary state/administration orientated. Non-statutory information may be introduced only indirectly as "knowledge" which is necessary to initiate the consultation and investigation procedure. A systematic integration of all these information sources, however, is not even guaranteed in all Member States, its' integration involves far-reaching consideration of the future structure in the Community<sup>199</sup>.

### 3. Pitfalls of the European approach to post market control

The intention here is namely to highlight some issues which should be taken into consideration in the ongoing debate on the future shaping of European post market control; issues which have been neglected not only at the European level.

#### *a. Standing committee on consumer safety*

There is no forum in the Community where safety issues can be discussed. The Draft Directive is providing for the establishment of a committee. But such committee would be engaged in emergency situations only. If it is true that informal dispute settlement determines the Member States practice of post market control, it would be all the more important to have a forum in which information could be systematically exchanged. A Standing Committee on Consumer Safety<sup>200</sup> should be established. Such a committee should have consultative tasks only and should be composed not only of Member States' representatives, but also of representatives from non-governmental organizations and perhaps even from representatives of non-EEC countries. It should be an overall consumer safety committee, open to

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197 Cf. COM (88) final, OJ No. C 124, 11.5.1988, 9 et seq.

198 Cf. II 1 b.

199 Just like the role of the individuals on the Community level. Some effort is made on the intergration of certification bodies into a European concept, Decision of the Council OJ C 10, 16.1.1990, 1 et seq., thereto Ch. Joerges/J. Falke, loc. cit.

200 Cf. Ch. Joerges et al., 457 et seq.

any subject which is related to product safety and not only the management of post market control<sup>201</sup>.

*b. Participation of consumers in post market control*

The comparative analysis has underlined the limited role consumers and consumer organisations are playing in the administrative management of post market control. For a further development of post market control mechanisms it would be indispensable to investigate the role of consumers and consumer organisations<sup>202</sup>. Such an approach should discuss problems of access to information by consumer organisations to administrative activities, whether this is informal or formal; it should reflect the participation of consumer organisations in all kind of decisions, whether formal or informal ones. One might even go so far as to challenge the confidential character of the decision-making process at the Community and at the Member States' level. Public hearings could be a responsible alternative to the present practice in most EEC countries. Last but not least, it would be feasible to debate the introduction of a group action for consumer organisations giving them the power to approach safety authorities, requiring action and to bring the affair to the Court if the competent authorities refuse to take appropriate measures.

*c. Export to non-EEC countries*

The discussion on the shaping of post market control mechanisms sets more or less aside those problems resulting from the export of "banned and severely restricted"<sup>203</sup> products, i.e. the export of products which are subject of marketing restrictions or even a ban domestically but which may nevertheless be exported to non-EEC countries. Only some of the investigated countries, the United States, Australia, France and Sweden are providing for the possibility of informing these import countries of potential market restrictions on their domestic markets or simply prohibiting the export<sup>204</sup>.

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201 The idea is to create a counterpart to the Standing Committee under the New Approach, Ch. Joerges et al., loc. cit. 446 et seq.

202 Cf. H.-W. Micklitz, Considerations Shaping Future Consumer Participation in European Product Safety Law, in: Ch. Joerges (ed.), loc. cit.

203 This is the term used on the international level with the different UN bodies for those products whose marketing is restricted or even forbidden; cf. D. Harland.

204 Cf. for the United States S.L. Cohen, Export of Hazardous Products from the United States: An Analysis of Consumer Product Safety Commission Policy; the George Washington Journal of International Law and Economic, 123-163; for Australia D. Harland, 10; for France Art 2 and 3 de la Loi; for Sweden, Nils Ringstedt, 7.



All other Member States of the Community are pursuing a *laissez faire* policy.

The 1984 Rapid Exchange System has not yet made an effort to get to grip with the very touchy export issue. One year later, however, the Commission announced in its "New Impulse" the intention to integrate third countries into the information exchange system<sup>205</sup>. The Draft Directive does not, however, provide for any kind of export regulation. This is all the more astonishing as the proposed system does not even consider cooperation with the OECD<sup>206</sup>. Consumer organizations are very critical in this respect. They are calling for a clear prohibition of the export of products which are restricted or banned domestically.

### III. Conclusions

Whatever the solution for an establishment of a European post market control mechanism might be, it should have to take into consideration that there are differences in product safety regulations and that these differences will subsist for quite a while within the Community. The comparative analysis has made clear that there are safety and risk countries. Such an attribution might be possible under two aspects: (1) the degree of judicialization, or the extent of institutional independency respectively, and (2) the activities of competent post market control authorities to withdraw unsafe products from the market. There seems to be a coherent interrelationship between the improvement of legal instruments, the degree of institutional independency and the efficiency of administrative practice. Without discriminating against particular Member States of the Community, it seems as if the United States, Australia and Sweden have the furthest developed product safety law and the best functioning product safety implementation system. There are always remarkable differences to be reported from the EEC Member States which could be finalized and specified if the spectrum of the investigated countries could be extended.

The overall message, however, independently of ranking of safety and risk countries is this: Europeanization of post market control should make use of the existing differences in the Member States when dealing with product safety. Legal rules within a European post market control procedure should be shaped so as to permit safety-orientated countries to take the lead in the promotion of European product safety. This could be done by clearly distinguishing between *minimum standards*, leaving space for

205 COM (85) 314 final, 23.7.1985, under 25.

206 N. Ringstedt, OECD, Safety and Consumer Policy, JCP 9 (1986), 57 et seq.

safety countries as a forerunner for a further development and *maximum standards* which are binding on all Member States<sup>207</sup>. It would be likewise useful and necessary to provide for an opportunity to consult non-European countries in the process of the decision-making. Non-EEC countries, this is true, could not participate in the Committee on Product Safety Emergencies. But the extent to which it might be possible to consult the leading safety countries from abroad and from Northern Europe, should be taken into consideration.

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207 K. Hailbronner, Der "nationale Alleingang" im Gemeinschaftsrecht am Beispiel der Abgasstandards für PKW, EuGRZ 1989, 101 et seq.; D.H. Scheuing, Umweltschutz auf der Grundlage der Einheitlichen Europäischen Akte, EuR 1989, 152 et seq.; H.-W. Micklitz, Typoscript 1989 loc. cit.

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