The Necessity of Centralizing All the Measures Securing Product Safety in European Law

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I. Monitoring product conformity

We will provide an overview of the controls performed by the national agencies (A). We will then present a monitoring agency operating at the European level in the field of food industry (B). Finally, we will expose the drawbacks of controls being performed by national agencies and the drawbacks of the limitation to a single sector of a "truly European" control (C).

A. The European monitoring regime relying on national agencies

Directive 2001/95/EC (known as the General Product Safety Directive[1]) aims at improving consumer health, safety, and the availability of quality products, through a reduction of the incidence of death and injury and a minimization of the economic losses affecting individuals, business and the Member States[2]. In other words, Directive 2001/95/EC asks the Member States to set up agencies which are responsible for monitoring product safety and which are endowed with the power of taking appropriate measures (including inflicting efficient dissuasive sanctions) and of coordinating the various agencies. It is an adaptation of Directive 92/59/EEC to the actual market conditions[3].

It lets Member States establish their own requirements with regard to the products that are either introduced in the European Union or already on the market. It also lets Member States take any necessary action to deal with products presenting a serious risk. The new Directive also contains a positive obligation on all parties in the supply chain to inform the national authorities, if they realize that one of their products is dangerous. They will then have to work with these authorities to trace unsafe products and take them off the market. If necessary, national monitoring agencies can require the products to be recalled.

The EU rapid alert system for circulating and following-up information on measures and actions related to dangerous products (RAPEX) requires the various national agencies to inform the Commission as soon as they are aware of a product presenting a serious risk, and the Commission immediately informs all Member States, which then have to take all appropriate measures to ensure that consummers' health and safety are not at risk.

In order to be able to assess the risks inherent in the products placed on the market, the state monitoring authorities must have the ability, the competence and the means to regularly

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[1] The new Directive, 2001/95/EC was adopted on 3 December 2001 and published in the Official Journal L 011 on 15 January 2002.

[2] See generally CHRISTOPHER HODGES, European Regulation of Consumer Product Safety, London 2005.

[3] When dangerous products are identified, the EU's powers to order a recall or an emergency ban have been simplified and reinforced. The Commission can now impose an emergency ban lasting up to one year - under the old Directive such bans were limited to three months. For the first time, the Commission can act on its own initiative to suspend a product – earlier it could only initiate Community action upon the request of a Member State.

visit the commercial, industrial and stocking premises; to set up random controls; to take samples of products; to subject them to tests and controls, as well as to ask for all the necessary information. If this process is to be efficient, a priority treatment must be given to the sectors in which the risk probability is very high or in which non-conformity cases are very frequent.

B. European Food Safety Authority as an exception

The only monitoring agency at the European level is the European Food Safety Authority (EFSA). It concerns a sector in which risk probability is rather high and problems are common which is the reason for its creation.
In Europe, several recent food crises (BSE[4], dioxin, MFD[5], the Coca Cola case, etc.) have made the general public aware of the risks posed by a series of factors: a food chain which is not (or not well) controlled, a lack of expertise, and a risk management system which is not adapted to the new stakes of product safety[6]. So, as to win back consumer trust and to remedy to the drawbacks of the actual system, in accordance with Art. 152 of the EC treaty (ex Art. 129), the European Commission proposes to reinforce its food legislation and to create its own independent assessing authority, the EFSA[7].
The establishment of the EFSA in order to harmonize and reinforce the food legislation which aims at securing food safety shows that the European Commission attaches a particular importance to the safety of foodstuffs. The EFSA plays almost the same role as the American Food and Drug Administration (FDA). Its tasks include:

(1) Risk assessment. The assessment is based on scientific advice taking into account all the issues in relation with food consumption and affecting, directly or indirectly, consumer health and safety[8]. Thus, the EFSA is active in the fields of food primary production (at the agricultural and veterinary levels), industrial processing, storage, and retail trade. It also takes care of the issues linked to animal health and wellness. It keeps up with risk assessment in other sectors, notably the environmental and chemical fields, when they interact with food-related risk assessment.
(2) Information collection and analysis. Through the drawing up and implementation of food safety surveillance programs, the Authority plays a preventive role. It has to establish a contact network with similar agencies, laboratories and consumer associations in the whole EU as well as in other countries. The EFSA's work is based on the EC White Book which lists the Commission's general principles of the European food safety policy[9]. These include implementing the internationally accepted

[4] BSE: Bovine Spongiform Encephalopathy.
[5] MFD: Mouth Foot Disease.
[6] See GIJS BERENDS/IGNACIO CARRENO, Safeguards in Food Law – Ensuring Food Scares Are Scarce, in European Law Review 2005, p. 396; BEATRICE MARRE, Rapport d'information sur la sécurité alimentaire européenne, 28 juin 2001, published in 2001 on www.assemblee-nat.fr/europe/rap-info/3212.pdf, p. 7.
[7] In January 2002, EC Regulation 178/2002 lay down the general principles and requirements of the European food law, thus establishing the EFSA on the basis of the principles of the highest degree of independence, scientific excellence and transparency. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in OJ of 01.02.2002.
[8] The European Commission favors the adoption of directives on food safety. These texts aim at approximating national laws for the sake of the internal market (free movement of products).
[9] COM(1999) 719, 29 decembre 2000, p. 142: European Parliament resolution on the Commission White Paper on food safety.

principles of risk analysis (risk assessment, risk management and risk communication) and applying the precautionary principle as a tool in risk management[10].

(3) Communication. The Authority must inform all concerned parties of its conclusions, not only with respect to scientific advice but also with respect to the results of its surveillance and control programs. The EFSA should become the first source for scientific information concerning food safety and nutritional issues. It should also become the agency which one automatically contacts in order to signal the problems one has encountered.

Thus, the main goal of the EFSA is to provide independent risk assessment and an efficient communication on existing and emerging risks. Risk management, however, including legislation and controls, remains the competence of the European institutions, which are accountable to the European public[11].

Having established the EFSA, the European Commission is currently revising the Community hygiene regulations with regard to food safety. According to the revised version, every person involved in the food production chain is responsible for the safety of their products[12]. The regulations are innovative in that they entail the applicability to all foodstuffs and to all the operators in the food production chain (a farm to table approach to food safety) of a single, transparent hygiene policy, together with instruments that can efficiently guarantee food safety and manage any future crisis in the sector.

With this end in view, the European Commission plans to implement the Hazard Analysis Critical Control Point (HACCP[13]) system, according to which food companies must identify themselves the risks and the critical points of their production method, devise and apply means of prevention (Art. 3 al. 2, Directive 93/43/EEC[14]). With a strict monitoring and a control of each step of the process, there is less chance for hazards to occur. The HACCP system is appropriate to manage the safety and the quality of all foodstuffs. It is thought to be one of the best tools to control the risks linked to various sectors (food and drink processing, distribution, retail as well as catering)[15].

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[10] COM (2000) 1, 2 February 2000, p. 19: Communication from the Commission on the Precautionary Principle. See also DUNCAN FAIRGRIEVE/GERAINT HOWELLS, General Product Safety – a Revolution Through Reform?, Modern Law Review 2006, p. 63 ss; THOMAS DAEMEN, The European Community's Evolving Precautionary Principle – Comparisons with the United States and Ramifications for Doha Round Trade Negotiations, in European Environmental Law Review 2003, p. 6 ss.

[11] On this subject, in June 2001, the Senate passed a resolution on food safety which insists that the EFSA cannot be given risk management responsibility and, especially not responsibility for the rapid alert system.

[12] The new regulations will harmonize the detailed and complex hygiene requirements mentioned in Council Directive 94/43/EEC on the hygiene of foodstuffs and in other directives. The reform of the European legislation with regard to food hygiene provides for the detailled requirements listed in the sectoral directives to be repealed. Henceforth, the producers must define themselves their own sanitary safety measures, as is already the case for vegetal foodstuffs. All these measures concern the purely sanitary aspects (guarantee of the innocuousness of the products), the quality of the agricultural production (good farming practice codes, animal welfare) as well as processing and distribution (control of the cold chain).

[13] HACCP was developed in the 1960's by the Pillsbury Company and the NASA to produce the safest and highest quality food for astronauts to eat in space.

[14] Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs, published in Official Journal L. 175 on 19 July 1993.

[15] HACCP is a preventive system to guarantee food safety. It involves seven principles: analyzing hazards; identifying critical control points; establishing preventive measures with critical limits for each of these points; establishing procedures to monitor these critical control points; establishing corrective actions to be taken when monitoring shows that a critical limit has not been met; establishing procedures to check that the system is working; keeping records to document the HACCP system.

C. The drawbacks of controls being performed by national agencies and the drawbacks of the limitation to a single sector of a "truly European" control

The national agencies verifying product conformity make up for some of the shortcomings of Directive 2001/95/EC, which does not institute a European authority having the power to inspect and confiscate goods, when the products placed on the market may endanger consumers' health. However, the national agencies' handling of new products is inefficient. Because of the non-existence of a Community mechanism in charge of verifying product conformity, the requirements necessary to the affixing of the CE conformity marking are heterogeneous. In other words, the various national agencies do not always impose the same requirements. Yet, to have access to the single European market, producers could submit their products to any monitoring body recognized in Europe.

Moreover, the multiplicity of national regulations and the diversity of practices changing from one country to another engender an unnecessary multiplication of safety analysis and generate additional costs, since, every time a product is placed on a new national market, a control assesses its safety.

Given the absence of Community rules and given the various requirements for product safety at the European level, the establishment of the EFSA and the implementation of the HACCP system are considerable progresses in the field of food-related risk prevention.

In our opinion, the fact that the application of the control systems planned by the EFSA and the HACCP is limited to foodstuffs poses nevertheless a major problem. The mass diffusion of other products which present a potential risk can create "serial risks". This type of risk covers a large range of phenomena. It may, for example, concern pharmaceutical or chemical products such as asbestos. Yet, at the European level, such products are subjected to a few controls only.

Thanks to the adoption of the European food legislation, the harmonization of sanitary rules with respect to foodstuffs meets the new requirements of approximating national policies. However, at the Community level, there lacks a structure allowing the centralization of the information and measures concerning the other products which may present a danger to health or goods[16].

In order to avoid a divided opinion among the Member States concerning the measures to be taken to face up to this normative deficit and to detect early on the risks presented by these products, we think it is indispensable to set up an efficient system allowing for an exchange between the various national market surveillance agencies. Only a harmonization of the regulations can render possible the necessary institutionalization of the Community policies. Statistics and risk evaluation procedures can help directing this priority treatment to such sectors[17]. Such a control is compulsory for a certain number of products, such as electrical appliances or medicines.

[16] For a similar idea, see WALTER FELLMANN, Produktsicherheit und Qualitätsmanagementsysteme, in Jahrbuch des Schweizerischen Konsumentenrechts 2000, Bern 2000, p. 44 and the quotes.

[17] See ERDEM BÜYÜKSAGIS, La notion de défaut dans la responsabilité du fait des produits, Analyse économique et comparative, Fribourg 2005, p. 41.

II. Prohibiting the placing on the market of dangerous products

Due to the absence of a Community market surveillance authority, the national monitoring agencies keep almost all the powers they had under Directive 92/59/EEC, including the power to prevent the putting on the market of unsafe products. Thus, Directive 2001/95/EC does not favor a real harmonization of the various national dispositions (A). We will explain why the approximation of these dispositions is desirable within the European Union (B).

A. The procedure followed by the national organizations

On the European scale, there is not yet a structure centralizing all the measures concerning the products that might be harmful to human health or to the integrity of goods. As stated in the "New Approach" directives and Directive 2001/95/EC, the measures aiming at getting rid off dangerous products depend, still today, on the Member States. In the same way, neither the Directive on the deliberate release into the environment of genetically modified organisms (90/220/EEC) nor the « Novel Food » Regulation (258/1997/EC) has a provision about a Community-wide withdrawal of products subjected to the special authorization regime. The national authorities alone are competent with regard to this subject.
According to the Directives based on the dispositions found in the ''new approach'', two things must be done in case of non-conformity:

1) the state monitoring authority requires from the producer or from its commercial agent to make sure that the products to be put onto the market or the products already on the market comply with the dispositions;
2) if the competent state authority does not get any result, it must limit or forbid the products to be put on the market and, if necessary, it must make sure the products are withdrawn from the market[18].

Directive 2001/95/EC follows the same line of thinking. Art. 8 § 2 encourages and favors the producers' and distributors' voluntary action, including the development of good behavior codes. Art. 5 § 3 states that "where producers and distributors[19] know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately warn the competent authorities of the [Member State] thereof (...)". If the action undertaken by the producers and the distributors is unsatisfactory or insufficient, the state authorities supervise the measures stated in Art. 8 § 1[20], which lists the measures that the competent

[18] See Guide relatif à la mise en application des directives élaborées sur la bases des dispositions de la "nouvelle approche" et de l'approche globale, Office des publications officielles des Communautés européennes, Luxemburg, 2000, p. 54.
[19] According to Art. 5 § 2 of the Directive, the producers' role with regard to safety is clearly specified and enhanced by comparison with the 1992 Directive: "Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements [...] Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market [...] Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently".
[20] The text is almost the same as that of the old Directive (Art. 6 § 1 Directive 92/59/EEC) but reworked into six product categories: "any product", "any product that could pose risks in certain conditions", "any product that could pose risks for certain persons", "any product that could be dangerous", any dangerous product", "any dangerous product already on the market". For each of these categories, one or several points define responsive

authorities in each country can take. The Member State then informs the Commission when it takes urgent measures aiming at preventing the placing on the market or the use of consumer goods presenting a serious danger (Art. 10).
In general, in the EU countries, consumer protection as regards product safety is high. However, in our opinion, this does not justify the absence of a European body able to prohibit products presenting an excessive danger to human health or goods being put onto the Common Market.

B. The drawbacks of having national agencies in charge

Even if it is the fruit of a lot of work, whose results are in many respects quite remarkable, Directive 2001/95/EC does not solve all the product safety issues. Rather than focusing on its positive aspects, we will direct our attention to five points which are open to criticism:

(1) Directive 2001/95/EC does not create an efficient system concerning the procedures designed to prevent the placing on the market of products that might be harmful to human health or to the integrity of goods, to withdraw products from the market and to recall already-bought products[21]. The reason is that it does not establish a European authority able to coordinate the measures taken in the various Member States in order to limit or forbid the placing on the market of products[22].

(2) The lack of coordination between the national market surveillance agencies may well confuse the consumer. When one of these agencies forbids the placing on the market of a defective product in a given country, the consumers of the other EU countries wonder why they do not benefit from the same protection.

(3) If Member States can take diverging decisions concerning the placing on the market of consumer goods, it is necessary to maintain customs controls. A Single European Market therefore necessitates pan-European measures aiming at suppressing the risks linked to the products circulating in this market. Let us look at an example[23]. In 1981, in Spain, thousands of people fell sick and hundreds died after consuming poisoned olive oil. France and Italy then forbade the import of conserves and oil from Spain. Yet, this ban could easily have been bypassed by having the products transit via another European country before entering France or Italy.

(4) Maintaining customs controls is not the most opportune solution to the problem of suppressing dangerous products. The customs system generates costs to be added to those of the usual controls performed by the national institutions monitoring product safety.

measures to be taken. For the "dangerous product already on the market" category, these measures are: "to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents" and "to order or coordinate or, if appropriate, to organise together with producers and distributors its recall (an innovation) from consumers and its destruction in suitable conditions".

[21] See THEODOR BÜHLER, Ist die Schadensprävention kein Thema für das Schweizerische Haftpflichtrecht?, in Festschrift für Heinz Rey zum 60. Geburtstag, Aktuelle Aspekte des Schuld- und Sachenrechts, Zurich 2003, p. 205.

[22] The EC dispositions on the free movement of products standardize product safety in all the Member States only for the EC-labeled products, such as electrical or electronic appliances, machines, medical devices, building materials, etc.

[23] See LUDWIG KRÄMER, La CEE et la protection du consommateur, Bruxels 1988, p. 187.

(5) Resales, parallel imports, giving various names to the same product, re-labeling and re-packaging, which the national monitoring agencies cannot prevent, complicate the task of these agencies[24].

The Council calls for "the approximation of the provisions laid down by law, regulation or administrative action" (Art. 95 § 1 EC Treaty), yet, paradoxically, it lets Member States take their own dispositions concerning product safety, which does not favor the harmonization of the various national dispositions. Yet, the provisions on product safety implemented at the national level only turn out to be insufficient. Given the quasi inexistence of a control of the movements of products within the Community, national withdrawals can at best have limited effects. As a result, a Community crisis management is almost impossible.

III. Final remarks

In order to avoid a divided opinion among the Member States concerning the measures aiming at preventing the placing on the market of unsafe products and at managing a possible crisis due to the absence of a Community structure, it is necessary to establish a Community structure allowing the centralization of:

(1) any piece of information concerning products that might be harmful to human health or goods;
(2) any measure aiming at making sure that only safe products are put into circulation.

We believe that the grouping together in a single European structure of all the functions having to do with product-related risks as well as product safety would be in accordance with the Community's wish to harmonize the policies of the various Member States. This would also obviously facilitate the implementation of several measures (preventing the putting into circulation of dangerous products, withdrawing them from the market, or recalling such products that have already been sold). Such a structure would also significantly diminish practices such as attributing various names to the same product, re-labeling, or re-packaging.

Moreover, the free movement of products within the Community and the suppression of strict customs controls can indeed be justified only by an equivalence of the safety measures[25]. It is necessary to design and implement rules allowing the withdrawal of products from the entire Common Market. If a company withdraws a washing machine in a country to add some extra safety devices, the consumers of the other Member States in which the same machine is sold should be given the same protection.

[24] See KRÄMER, *supra*, p. 187.

[25] See FRANÇOISE MANIET, La transposition de la Directive 92/59/CE relative à la sécurité générale des produits dans les Etats Membres de l'Union Européenne, in Revue européenne de droit de la consommation 1997, p. 176 ss; HANS MICKLITZ, Sicherheit und Umweltqualität von Produkten und Dienstleistungen, in NORBERT REICH/HANS MICKLITZ Europäisches Verbraucherrecht, 4th edn., Baden-Baden 2003, p. 924.