COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 29.3.2000 COM(2000) 140 final

COMMISSION REPORT TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

ON THE EXPERIENCE ACQUIRED IN THE APPLICATION OF DIRECTIVE 92/59/EEC ON GENERAL PRODUCT SAFETY

TABLE OF CONTENTS

I.	Background to the report		
II.	General aspects		
	1.	Scope of the Directive	4
	2.	Main contents of the Directive	4
III.	Practical application of the Directive		
	1.	National Transposition of the Directive	6
	2.	Institutional and administrative arrangements at national level	6
	3.	Relationship between the General Product Safety Directive and Sectoral Community Legislation (article 1)	7
	4.	Scope of the Directive (article 2)	8
	5.	General Safety Requirement (articles 3 and 4)	9
	6.	Obligations and Powers of the Member States (articles 5 and 6)	10
	7.	Notification and Exchanges of Information (article 7)	12
	8.	Emergency Situations and Action at Community level (articles 8, 9, 10, 12)	13
IV.	Cor	nclusions	18
	1.	National Transposition of the Directive	18
	2.	Institutional and administrative arrangements at national level	18
	3.	Relationship between the General Product Safety Directive and Sectoral Community Legislation (Article 1)	19
	4.	Scope (Article 2)	19
	5.	General Safety Requirement (Articles 3 and 4)	19
	6.	Market Surveillance (Articles 5 and 6)	20
	7.	Notification and Exchange of Information System (Article 7)	21
	8.	Rapid Exchange of Information System (Article 8)	21
	9.	Emergency Action at Community Level (Article 9)	21
	10.	Committee (Article 10)	21

11. Confidentiality Requirements (Article 12)	21
Annexes	22
Annex 1: Transposition laws in the Member States	22
Annex 2: The national administrations responsible for the Application of the Transposition Law	24

I. BACKGROUND TO THE REPORT

Council Directive 92/59/EEC on general product safety (GPSD) was adopted on 29 June 1992 and was to be applied by the Member States at the latest by 29 June 1994. The Directive was based on Article 100A (now Article 95) and was adopted, before the entry into force of the Maastricht Treaty, in co-operation with the European Parliament.

Article 16 of the Directive states that:

"Four years from the date referred to in Article 17 (1), on the basis of a Commission report on the experience acquired, together with appropriate proposals, the Council shall decide whether to adjust this Directive, in particular with a view to extending its scope as laid down in Article 1 (1) and Article 2 (a), and whether the provisions of Title V should be amended".

The Commission has conducted an in-depth review and assessment of the implementation and practical application of the Directive. An extensive survey of the Rapid exchange of information system with interviews in all Member States carried out by the Commission services (hereafter referred to as "the survey") has also contributed to the identification of problem areas.

In addition a study on the legal and practical application of the Directive, including the identification of problem areas and conclusions on needs for amendment, has been carried out on behalf of the Commission by the "Centre de Droit de la Consommation" of the Université Catholique of Louvain (hereafter referred to as "the study"). This study covered all EU Member States, as well as Norway and Iceland in the EEA.

The Commission services have involved interested parties in these activities with the aim of evaluating the application of the Directive and assessing problems and possible content for its revision. Member States, Consumer Organisations, European standardisation bodies and ANEC (European Association for the Co-ordination of Consumer Representation in Standardisation) have been consulted, several times, in the framework of the Consumer Safety Working Party. Consultations with the European industry and trade federations have taken place. The Economic and Social Committee issued an own-initiative opinion on General Product Safety during this period.

The conclusions of this report are based on the information gathered from the different sources and the experience of the Commission services. The main function of the Directive in relation to food is, in practice, the Article 8 procedure for the rapid exchange of information on emergency situations. Therefore this report only deals with food matters to a very limited extent and only when discussing this Article.

The report is intended to summarise briefly the findings of the assessment. The study carried out on behalf of the Commission by the Centre de Droit de la Consommation (is available on http://europa.eu.int/comm/dgs/health_consumer/index)

As far as the food aspects are concerned, the Commission has recently presented a White Paper on Food Safety which assesses the needs and presents the Commission's intentions in this area.

II. GENERAL ASPECTS

1. SCOPE OF THE DIRECTIVE

The Directive regulates the safety of consumer products and aims at ensuring that products placed on the market are safe. The products covered are those intended for consumers or likely to be used by consumers, supplied in the course of a commercial activity. This includes new, used and reconditioned products, with the exception of antiques and products sold with a view to them being reconditioned, provided that the supplier informs the consumer of this fact. A generic definition of "safe product" has been provided. The overall aim of this Directive is to harmonise the measures of the Member States aimed at imposing a general obligation to market only safe products, in order to ensure both a consistent and high level of protection of consumer health and safety through the EU and the proper functioning of the internal market.

According to the preamble of the Directive, a broadly based, legislative framework of a horizontal nature is needed in order to cover products not covered by specific, sectoral Community legislation as well as to "cover lacunae in existing or forthcoming specific legislation". Therefore, the Directive is intended as a complement to sectoral Community legislation in order to:

- cover products which are not subject to sectoral legislation;
- also cover products that are subject to sectoral legislation (existing and forthcoming), for the categories of risks, safety aspects, and administrative and control requirements, which are not addressed in such sectoral legislation.

However, the preamble of the Directive clarifies that, when there are rules involving total harmonisation which lay down obligations regarding product safety, further obligations on the placing on the market of the products covered by such rules should not be imposed on economic operators. This is in general the case of products covered by the "new approach" Directives. Moreover, Article 1 states that "where specific rules of Community law contain provisions governing only certain aspects of product safety or categories of risks for the products concerned, those are the provisions which shall apply to the products concerned with regard to the relevant safety aspects or risks".

2. MAIN CONTENTS OF THE DIRECTIVE

In summary, Directive 92/59/EEC includes the following main provisions:

Obligations for producers:

- to place only safe products on the market;
- to provide consumers with the relevant information to assess the risks associated with a product;

• to adopt measures to ensure that they will be informed of risks posed by the products which they supply, and to take action to prevent those risks, including withdrawal of products when necessary.

Obligations for distributors:

- not to supply products which they know or should have presumed to be dangerous;
- to collaborate in the monitoring of the safety of products they supply and in action to prevent any risks posed by such products.

<u>Definition of criteria for assessing product safety and deciding under which conditions a product should be deemed to be safe.</u>

- products conforming to specific rules of national law of the Member State in which they circulate are deemed to be in compliance with the general safety requirement of the GPSD;
- in the other cases, the safety of a product shall be assessed having regard to European or national voluntary standards, Community technical specifications, codes of good practice, the state of the art and expectations of consumers.

Obligations of the Member States:

- to take measures in order to make producers and distributors comply with their obligations. This includes in particular establishing or designating market surveillance authorities empowered to adopt a range of control and enforcement measures and to impose sanctions in the event of failure to comply with the obligations of the Directive;
- to notify the Commission of the measures they take restricting the marketing of products or imposing their withdrawal from the market. The Commission will then examine the reasons for the measures and inform all Member States when it concludes that a measure is justified;
- to ensure that their officials and agents do not disclose information covered by professional secrecy, obtained for the purposes of the Directive, except for information relating to the safety of a product which must be made public in order to protect the health and safety of persons. This also applies to Commission officials.

Establishment of a rapid exchange of information system (RAPEX) for products posing a serious and immediate risk.

Under this system, when a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the marketing or use of products posing a serious and immediate risk, it must notify the Commission, which, in turn, will inform the other Member States. Details of the functioning of the system are set out in an annex to the Directive.

Procedures for Community-wide measures

The Commission, assisted by a Committee, may adopt temporary, Community-wide measures concerning products posing a serious and immediate risk, subject to a number of substantive and procedural conditions.

Committee

A regulatory (ex "3b") Committee is in charge of assisting the Commission on adaptations to the Annex, related to RAPEX procedures, and in the adoption of Community measures in case of emergency situations.

III. PRACTICAL APPLICATION OF THE DIRECTIVE

1. NATIONAL TRANSPOSITION OF THE DIRECTIVE

Some countries had adopted general product safety laws before the adoption of the Directive (Austria 1983¹, Finland 1986, France 1983, the United Kingdom 1987, Norway 1976, Sweden 1989, and the Netherlands 1935). In some countries most of the Directive's objectives had been attained before its adoption. In the countries where a general act existed prior to the Directive, it was sometimes debated whether such amendments were necessary if the same objectives were attained but with different wording. Those obligations, which were not included in the legislation, which already existed, i.e. information, monitoring and withdrawal requirements binding on economic operators, were added in the case of the United Kingdom and the Netherlands.

In Belgium and Germany, with horizontal (or specific) legislation covering a large range, but not all consumer products coming under the scope of the Directive, a new act was adopted, which, although entitled the acts on "general" consumer product safety, have a residual application for products previously unregulated. Hence in these countries the new legislation mainly meant imposing additional requirements on economic operators, though restricted to a variety of products not regulated elsewhere, and extending to these products the existing emergency mechanisms.

In Iceland the Directive greatly improved the legislative framework with regard to product safety. The laws that applied before the Directive came into force were long outdated (1936) and only very vaguely touched upon product safety.

For the remaining countries Denmark, Greece, Ireland, , Italy, Luxembourg, Portugal , and Spain), where complete or horizontal general legislation in the field of product safety did not exist, the Directive was transposed almost word for word. However as the scope, e.g. in Denmark, was generally limited to products not covered by the sectoral rules, the impact of the law in practice was considerably reduced.

A list of the national legislation which have transposed the Directive in the different countries is annexed (Annex 1).

However, this law was not complete and has been completely modified by a new act adopted in 1995 transposing the Directive.

2. INSTITUTIONAL AND ADMINISTRATIVE ARRANGEMENTS AT NATIONAL LEVEL

The responsibilities for handling the legislation at national level were normally given to already existing bodies, according to the central or federal administrative structure, already in place in each country. A decentralised structure for product safety control activities has existed in some countries for a long time. In Germany and Spain and to a lesser extent Austria, Finland, and the United Kingdom considerable responsibility has been given to the regional and local structures.

In practice in Ireland, Spain, France, the Netherlands, Portugal and the United Kingdom, a single national, or several regional or local authorities are responsible for all (non-food) consumer products, whether or not they are covered by the act transposing the Directive or by sectoral rules. In Norway two ministries are responsible for the act.

In the other countries, the designated authority is responsible only for some consumer products, normally in principle those products falling under the Directive. Some of the sectors regulated by specific legislation may also come within their remit but not systematically.

A list of the administrations responsible for the application of the transposition law is annexed (Annex 2).

Existence of co-ordination bodies

Sweden has appointed a special body (SWEDAC) whose task is to co-ordinate market surveillance on the part of the different authorities responsible. Italy has recently created a body that is responsible for organising co-ordination, called "Conferenza di Servizi".

In the UK the Local authorities Coordinating Body on Food and Trading Standards (LACOTS), set up in 1978, provides enforcement guidance to the UK's local authorities, and consultation on legislative matters.

Existence of advisory bodies

Seven countries have put in place a "Consumer Safety Commission" or an equivalent body – Austria, Spain (Technical Safety Committee), Finland (Product Safety Advisory Body), France, Belgium, the Netherlands (Warenwet Advisory Commission) and Portugal. In most cases, the commissions already existed before the adoption of the Directive. In all countries except for Portugal, where it has a decision-making role, this body has an advisory function and is a forum for all those concerned (economic operators, consumer organisations and the authorities) to pool their experiences. According to the study, all the parties concerned have recognised the importance of its role.

Some national authorities organise training and information activities for economic operators on the transposition of the Directive (Austria, the Netherlands and Finland).

Role of consumer organisations

In four countries consumer organisations play a special role in the field of product safety: France (lobbying and suing), Denmark (market surveillance), Austria (market surveillance and information on the law) and the Netherlands (safety tests, awareness-raising and training of professionals, drafting of a code of conduct on the emergency procedures). In the other countries the consumer organisations' role is normally confined to performing comparative tests, whose results are published in the magazines, and to collecting consumer complaints. In Ireland, Greece, Sweden, Finland, Portugal and Luxembourg consumer associations play a relatively minor role in the field of product safety at least.

3. RELATIONSHIP BETWEEN THE GENERAL PRODUCT SAFETY DIRECTIVE AND SECTORAL COMMUNITY LEGISLATION (ARTICLE 1)

The present wording of the Directive on its relationship with other Community legislation is not completely clear in its interpretation and has been interpreted differently in national legislation. The study indicated that the interpretation of Article 1 can even vary within the same country. Consequently, the scope of the transposition acts is ambiguous.

The terms of the Article have sometimes been transposed without a clear understanding of what they mean and consequently confusion has ensued. This confusion has had repercussions as regards the powers vested in the sectoral authorities and the obligations to be respected by economic operators. This has resulted in the Directive in many cases not being well known amongst economic operators and is probably the reason why the law has not had the intended impact. According to the study most economic operators agree that the preventive effect of the product liability acts transposing the Directive on product liability, which has a clearly defined scope, is far greater than that of the acts transposing Directive 92/59/EEC.

The majority of countries have almost completely excluded the product sectors already regulated, partly or fully, by Community and national sectoral rules. Certain countries, e.g. Austria, Belgium and France, however, do not exclude such products in the case of emergency procedures. In Denmark, Greece, Spain, Iceland, Ireland, the United Kingdom, the Netherlands (except for the accessory obligations imposed upon economic operators), Norway and France the general act covers everything except the safety aspects already covered by specific Community Directives.

4. SCOPE OF THE DIRECTIVE (ARTICLE 2)

Belgium, Denmark, Finland, France, Iceland, Norway², Sweden, Portugal³ and Spain⁴ include both products and services intended for consumers within the scope of their act, which allows them to avoid grey areas resulting from interpretation of the terms of the Directive: "product ... likely to be used by consumers". The Nordic countries have a common position on this issue, although Denmark, Norway (in the transposition law) and Iceland include only services linked to products. However, in

_

In Norway since 1993 all services have been covered in a separate act.

In its consumer protection act.

In its consumer protection act.

the countries where services are covered in the transposition law very few cases of application of the law have occurred.

Whilst in most countries the transposition texts cover only consumer products and/or services, the French, Dutch (Warenwet) and Norwegian acts do not have any such restrictions and the rules apply to any product or service placed on the market, hence protecting both workers and consumers. In Sweden, products supplied by schools, hospitals, municipalities, etc. are also covered; while in Finland the act also regulates products supplied by professionals to these entities.

There are also additional uncertainties as to whether certain products are covered by the Directive. Firstly, a problem has arisen with products which, although originally intended only for the professional sector, are now used by consumers. Secondly, products are sometimes supplied to consumers by service providers or made available to consumers as part of a service activity. In some cases services associated with the product supplied could affect the safety of the products. Several Member States consider that the Directive should be extended to cover also services.

• Definitions (Article 2)

- Product

France does not define the product at all, while the other countries reproduce the definition of Article 2(b) of the Directive. Certain countries distinguish between immovable and movable products (property is excluded under the Austrian, Portuguese and Netherlands transposition acts), or the tangible or material nature of the products covered. The majority of countries exempt second-hand products supplied as antiques, like the Directive, as well as products that have to be repaired or reconditioned before use. Finland, France, the Netherlands (Warenwet) and Sweden do not however mention any such exemption, whilst Belgium excludes antiques but not second-hand products which need to be repaired or reconditioned before use.

- Economic operators

Definitions of the economic operators covered are to be found in most of the transposition acts. In the Swedish, Finnish, French, Dutch (Warenwet) and Norwegian acts, no definition of economic operators is given, because the obligations contained in these acts apply to all those involved in the marketing or distribution chain without exception. However, in practice most of these countries recognise that it is producers and importers who are mainly affected by the obligations imposed by their legislation.

5. GENERAL SAFETY REQUIREMENT (ARTICLES 3 AND 4)

All countries, except Sweden, have an explicit general safety requirement in their legislation, although the wording sometimes differs from the Directive. Several countries (Denmark, Finland, France, Greece, Spain and the Netherlands) apply the general safety requirement to all economic operators without exception, but limit their responsibilities to their respective activities and do not make a distinction between producers and distributors. The Nordic countries focus more on the potential impact of the product and the need to prevent problems arising. In Sweden the

general safety requirement is derived implicitly from the powers vested in the administration.

In fact only Sweden and France have extensive case law based on the general safety requirement. Moreover, the authorities sometimes have no information concerning the follow-up and outcome of actions that have been brought before the courts.

• obligations concerning information, monitoring and withdrawal

In addition to the general safety requirement, the obligations concerning information, monitoring and withdrawal laid down by the Directive exist in most Member States, where they have been transposed almost literally. Germany does not require withdrawal of the offending product and only stipulates an obligation to avoid risks. Besides the general safety requirement, France holds liable only whoever first puts the product on the market. Sweden confines itself to requiring economic operators to provide information.

According to the study the obligations have had very little impact as they are in general unknown to economic operators. This applies to all the countries apart from France, which has no specific requirements but where the obligations derive from compliance with the general safety requirement and the French system as a whole.

Producers and distributors may discover, or be informed, of risks related to a product. The experience has shown that this happens quite often. However, the authorities are rarely informed of their findings and measures.

Austria, Belgium and Finland and Norway require economic operators to inform the administration of any risks that come to their attention or of any voluntary measure taken to address the risk.

Even in those Member States where it is obligatory for this information to be communicated to the national authorities, this does not happen, except in Austria and Finland where large companies do notify.

• Obligations on distributors

Most countries that distinguish between producers and distributors have incorporated the obligations imposed on distributors in their transposition acts. Moreover, in Austria distributors are obliged to inform the authorities about dangerous products. The Irish law also strengthens the obligations imposed on distributors by obliging them to control the safety of products. On the other hand, Germany has not included the obligation to participate in monitoring the products or to collaborate in measures to avoid risks (the only obligation is to contribute to compliance with the general safety requirement).

In practice, distributors too are unaware of their obligations. It seems that compliance differs depending on the sectors and the size of the firm. Major distributors often have the resources to develop systems for evaluating consumer complaints, to perform sample checks before and after orders are placed and to foster close links with producers, but small distributors and retailers often do not.

• Conformity with general safety requirements

The presumption of conformity with the general safety requirement set out in Article 4 of the Directive is not to be found in the French, Finnish, Dutch, Icelandic, Norwegian and Swedish acts. The study notes that most of these countries consider that these principles apply without their having to be spelled out. In other countries the presumption of Article 4 is reproduced with certain nuances.

In practice reactions to Article 4 of the Directive vary greatly from one Member State to another and from one individual to another. Article 4 is, according to the study, mostly unknown in France and in Finland, where it has not even been transposed, even if the players concerned acknowledge that they apply it on the ground. According to the study, it is poorly understood in several countries and often not used in Sweden and Ireland (which however has transposed it).

The study notes the following different views on Article 4 in Member States: in Italy, it is considered as very useful for economic operators. The Belgian, Austrian and Danish administrations consider this article to be extremely useful in their daily work, because it gives them a basis for the adoption of measures and for going beyond mere <u>formal</u> compliance. The Portuguese and United Kingdom authorities argue that the ranking of the criteria taken into account should be modified. This has already been done in Denmark, where consumers' legitimate expectations outweigh compliance with codes of conduct. For Germany, only compliance with German and European standards is of relevance.

Some national administrations, such as the Netherlands and Sweden, have begun the preparation of criteria for defining safe products by product sector.

6. OBLIGATIONS AND POWERS OF THE MEMBER STATES (ARTICLES 5 AND 6)

• Market surveillance

Before adoption of the Directive, certain Member States did not have the means to address an emergency situation or even to take samples in the context of normal market surveillance. The powers set out in Article 6 of the Directive have been introduced almost across the board in all Member States, where they did not already exist before the transposition of the Directive. Hence, market surveillance powers, such as the power to carry out checks, to take samples, to elicit information from the parties concerned, and to submit placing on the market to prior conditions, are now recognised by all the competent authorities at different levels.

However, the study notes that the approach to market surveillance in the Member States differs considerably in the following respects: several Member States survey the market on the basis of annual programmes based on e.g. EHLASS⁵ results, consumer complaints, notifications under the RAPEX system, etc. This is the case for example for Belgium, Denmark, Spain, Finland, France and the Netherlands.

In addition to annual programmes, or in the absence of such programmes, most countries also carry out occasional or random checks, depending on the requirements

12

European Home and Leisure Surveillance System, now part of the Injury Prevention Programme in the framework for action in the field of public health (1999-2003)

of the moment, or on new products placed on the market. This applies in particular to Belgium, the Netherlands, France, Sweden, Austria and Italy. The Luxembourg and Irish authorities most frequently perform controls on the basis of information provided by the RAPEX system. In the Netherlands, Sweden, and Denmark, an annual report available to everyone is published on the basis of the surveys carried out. In Spain and Finland, programmes are also prepared at the level of the autonomous communities and regions respectively, which may deviate from the federal programme. The German states (Länder) are independent. Most of the checks performed by the Member States concern the retail trade. Certain countries such as France and the Netherlands also carry out checks at production level, which have been found to be a very effective way of preventing possible dangerous products in good time. In Norway the approach is to control the systems enterprises put in place for ensuring their products do not present a risk to health and safety.

Almost all national authorities in the interviews carried out for the study, complained of a lack of resources in terms of personnel and equipment. The study draws the following conclusions: the problem is particularly acute in Portugal, Ireland, Italy, and Greece. In Spain and Germany, because of the their federal structure, there are great disparities between regions. Finally, several countries (France, Finland, Spain, and Austria) have found specific problems with controlling cheap products which are sold over a very short period at a low price and whose importers swiftly disappear.

• Intervention by the authorities

As regards risk situations giving rise to an intervention by the authorities, powers to temporarily or definitively ban the placing on the market of the offending products and to order that persons liable to be exposed be alerted to the danger have also been introduced where they did not already exist in the national legal arsenal.

The power of "organizing the effective and immediate withdrawal of a dangerous product" has been incorporated in the transposition acts of all the countries that did not already provide for such a power.

Nevertheless, the power to order the withdrawal of a product has not been explicitly introduced in the Netherlands or in the United Kingdom, since it has been deemed that the resources already available to the authorities (notice, prohibition, suspension notices, press alert, prohibition decree, etc.) are in practice enough to force economic operators to withdraw their products from the market.

There are major divergences in the forms taken by the withdrawal decisions and as regards the players who may make these decisions. Belgium, Finland, France, Iceland, Norwayand Sweden also have the power to mandate economic operators to recall from the consumer (as distinct from withdrawing from the retailers and distribution chain) products and provide for the possibilities of reimbursing consumers and for replacement or repair of the product. Certain Member States allow their authorities to ban the export of products (France, Belgium, Netherlands, Austria, Norway and Sweden).

According to the study, certain countries have never or virtually never exercised the powers granted in the event of an emergency (Austria, Greece, Ireland and Luxembourg), arguing that in all cases economic operators have voluntarily taken the necessary measures. Germany, where the states (Länder) are responsible for

emergencies, also reports that the problem is generally resolved on a consensual basis. According to the study, this is confirmed by most countries, which consider that even if in practice products are generally withdrawn voluntarily, it is extremely important to be able to impose such measures if necessary. However, other countries (France, Netherlands, and Belgium) regularly exercise the powers they have, including the power to ban exports. The power to order the destruction of products is less frequently used.

The time taken to adopt emergency measures in some countries is a problem. In Sweden for example, in the case of disagreement by the economic operator, a lengthy, costly and ultimately uncertain procedure, can follow.

Several national administrations report that they would like to be able to order the *recall* of dangerous products from consumers. Certain administrations (Austria, Norway, the Netherlands and Denmark) do not make a distinction between recall from the consumer and withdrawal from the retailers and distribution chains and cannot, according to the study, imagine a product being withdrawn unless it is also recalled from the final consumer as well (even if this is not so easy to achieve). Most national administrations interviewed in the course of the study are in favour of banning exports.

In addition consumer organisations have been granted the right to bring actions for injunctions in the field of product safety in a few countries (such as France, Sweden, Greece, the Netherlands and Portugal. .

7. NOTIFICATION AND EXCHANGES OF INFORMATION

• Safeguard clause (Article 7)

Experience has shown that national administrations are uncertain about the function of this procedure, when to notify and feel it is difficult to distinguish it from Article 8 and the notification requirements of other Directives. Many Members States consider that the Commission is slow to react so they are discouraged from notifying. They may only learn of a measure taken by one Member State many months or even years after the measure has been taken. Moreover, the Commission is not obliged to notify all the Member States if it disagrees with a measure taken.

In addition, the administrative burden put on the Commission by this procedure is very heavy which explains the length of time it takes: the Commission has to consult the interested parties, even when the parties concerned have in fact agreed with the measure. A formal opinion has to be adopted in each case. Other problems encountered by national administrations, reported in the study, include understaffing or poor co-ordination at national level and overlapping with the procedure under Directive 98/34/EC.

8. EMERGENCY SITUATIONS AND ACTION AT COMMUNITY LEVEL

• The Rapid Exchange of Information System (Article 8)

According to the Commission's survey, Member States are in general satisfied with the Rapid Exchange of Information system and considered it to be effective. According to the study, the information notified under the system is circulated also to distributors in Belgium and Sweden via the trade federations, to alert them to the problems and to assist in tracing the product. In Finland, it appears that economic operators of the sector concerned (distributors or producers) are systematically contacted when a RAPEX notification is sent. Germany also reports that notifications are often the basis for one-off measures on the part of the supervisory authorities. However Member States have also highlighted various difficulties and the need to improve the system.

Operation of the System at Commission level

The system covers measures related to products placed on the market which present a serious and immediate risk to consumers. It consists of two networks, one for non-food industrial products and the other for food products.

Each notification received from the Member States or from EEA/EFTA countries is subjected to an analysis and validation process by the Commission before being transmitted to the official contact points in the other Member States. At present, non-EU countries do not have access to the system.

Structure and functioning of the system in the Member States

The network structure differs from one Member State to another. In certain Member States, the national contact points belong to the same Ministry or body as the local authorities charged with market surveillance, which is not the case in others, notably those with a federal structure (Germany, Spain, and Austria). In every Member State, the services involved in the rapid exchange of information system have other functions and the few members of staff who are directly responsible for its operation, normally also have additional tasks.

As a general rule, the national contact point plays a filtration role when a notification is sent from one of their authorities to the Commission. They can equally play this role when a notification is received from another Member State, via the Commission, before sending it on to their authorities. In the majority of countries, , neither economic operators or consumer associations are directly involved in the system. They are more often informed on a case-by-case basis.

Few national authorities have connections with other formalised information exchange systems on products representing a risk, except the Nordic countries which are involved in the Nordic information exchange system.

- Problems encountered in both the food and non-food systems

The overall assessment of Member States authorities is that the current number of notifications,, is difficult to handle because of the lack of staff available. Moreover not all national administrations agree that the level of risk in all notifications is sufficient to warrant an Article 8 notification.

The lack of a precise definition of "serious and immediate" (risk) is considered by the majority of national administrations as an explanation for the lack of harmonisation in their use of the system. The concept of confidentiality of the information contained in the notifications is somewhat disconcerting for the majority of the national administrations and should be clarified at EU level. The lack of clarity and detail in numerous notifications was highlighted by several administrations, notably with regard to information on the circulation of products, which have been

the subject of a prosecution notice. For certain Member States, the absence of a translation in their national language has slowed down the exchange of information.

Most administrations consider that the Commission should play a more active role in evaluating and filtering the notifications. The majority of these administrations consider that the technical follow-up of alert notifications needs to be improved.

Specific Problems Encountered in the Non Food Sector

For many Member States, the distinction between Article 7 and Article 8 of the Directive as well as the safeguard clauses in the vertical, 'New Approach' directives is difficult to identify which, equally, has overloaded the system.

Specific Problems Encountered in the Food Sector

Given that Article 7 of the Directive is very rarely used in the food sector, its alert system is overloaded with information which is not directly considered as alert notifications. During the period of time the SHIFT system has not been able to work⁶ an agreement has been approved for the use of the RAPEX/RASFF network to transmit SHIFT information: this fact further overloads the system for some countries.

• Emergency action at Community level (Article 9)

National administrations interviewed in the context of the study expressed different opinions about the role the European Commission should play in respect of Article 9. The Belgian, Danish, Spanish, Greek, Italian, Luxembourg and the Netherlands' authorities would welcome a greater role for the European Commission, and would like to see it become more active in the field of product safety. Hence these countries would like the Article 9 procedure to be simplified and to relax the restrictions placed on its use. Moreover, certain countries see it as a way of reinforcing their own market surveillance by enabling them to benefit from tests and checks performed by other Member States or by the Commission itself. Some administrations have suggested creating a European non-food product safety agency. Many of the economic operators interviewed in the course of the study would also welcome such a measure, in order to eliminate distortions to competitions in this area, mainly due to a perceived reverse discrimination.

• Committee (Article 10)

The Emergency Committee also acts, informally, as an advisory committee. Experience has shown that the Emergency Committee has, during its years of operation, also taken on the task of giving advice to the Commission on general product safety matters and has also functioned as a forum for the exchange of information between Member States. There is consensus that these functions are important and should be better framed.

SHIFT is a network between the border inspection posts for animal and animal products originating in non Member countries which do not fulfil the EU requirements

• Confidentiality requirements (Article 12)

Experience has demonstrated that there is uncertainty about the exact implications of the confidentiality requirements stipulated in Article 12. In some cases confidentiality requirements have limited the effectiveness of public authorities activities. Whilst for a few countries disclosure could cause problems because of the existing legal system in those countries, others, in particular the Nordic countries and Austria, are keen that the information should not be considered as confidential and should be circulated to consumer organisations.

IV. CONCLUSIONS

1. NATIONAL TRANSPOSITION OF THE DIRECTIVE

• Impact on legislation

The structure and content of the transposition laws in those Member States, which enacted totally new legislation, are in general closer to that of the European Directive.

Generally, few differences in the content of the transposition law have been noted. According to the study, the Directive has had limited impact in practice. However, this does not necessarily mean that unsafe products are being placed on the market. Cases in point include France and the Netherlands which have not transposed formally all the provisions of the Directive but seem, nevertheless, to have attained its goals. Finland, Austria, Sweden, the United Kingdom and Germany also, despite certain problems, seem to have achieved the objectives of the Directive. But in some countries due to a lack of resources and enforcement problems the transposition seems to have had a far more subdued impact.

• Scope of the transposition acts

More than half of the transposition acts exclude from their scope sectors that are already covered (partly or fully) by sectoral rules, whether they are of Community origin or not. The scope of these acts is therefore very restricted. Hence, their overall coverage includes for example childcare articles, lighters, furniture, bottles, imitation firearms, laser pointers, oil lamps, leather articles, sports equipment and DIY products (but not machinery).

• Effectiveness of the transposition

The application of the Directive has encountered certain problems. There are three possible explanations for this: firstly, the very limited scope of the transposition acts in general, which have become residual laws rather than general laws; secondly, certain countries had already enacted general laws prior to adoption of the Directive. Finally, the penalties provided for in the transposition acts have never or virtually never been enforced, except in a few countries (mainly France and the Netherlands). Most other countries consider that the penalties do not have a dissuasive effect, while in Spain and Portugal, according to the study, most economic operators believe that it is ultimately cheaper to pay fines than to respect the law. It appears that professionals are far more worried about being held answerable on the basis of the product liability act.

2. INSTITUTIONAL AND ADMINISTRATIVE ARRANGEMENTS AT NATIONAL LEVEL

The very narrow scope of the transposition acts and the limited powers of the designated authorities go hand in hand with a dilution of responsibilities in regard to consumer product safety in several countries. This can lead to duplication of effort or to gaps in market surveillance, impede the resolution of emergency situations (first of all it has to be decided which authority is responsible), and give rise to problems of co-ordination and mutual information and general disparities in the policies adopted, depending on the product sector in question.

The problems resulting from having a multitude of responsible authorities have not yet been solved by adequate co-ordination mechanisms. The problem of horizontal co-ordination does not really arise in countries that have designated a single authority for all consumer products for the whole territory. By contrast, in the other countries where several different authorities (sometimes more than ten) share responsibility for product safety, co-ordination between the authority responsible for enforcing the transposition act and the others is generally weak or non-existent.

3. RELATIONSHIP BETWEEN THE GENERAL PRODUCT SAFETY DIRECTIVE AND SECTORAL COMMUNITY LEGISLATION (ARTICLE 1)

The review of the practical application of the Directive has shown that there is confusion, disagreement or lack of awareness on the applicability of certain provisions of the Directive in the case of products covered by sectoral legislation. Areas where confusion arises are: the identification of the safety requirements, stipulated in the Directive, to be applied to the different risks and safety aspects of products and the applicability of the Directive concerning the obligations of producers and distributors, the rapid exchange of information system, emergency Community measures and market surveillance provisions to certain products covered by sectoral legislation.

4. SCOPE (ARTICLE 2)

There is uncertainty whether certain products are covered by the Directive. The definitions contained in the transposition acts generally do not pose problems in practice. The main problem appears to be with products, which were originally intended for professional use, which are now used by consumers.

5. GENERAL SAFETY REQUIREMENT (ARTICLES 3 AND 4)

The Directive sets out the obligations of producers and distributors. While the existing requirements appear to be appropriate, experience has shown that they are not complete and that some important aspects are missing in the present formulation of the Directive.

One such aspect is that the authorities are not always informed of when producers and distributors discover risks related to a product. They, therefore, do not have the possibility to make the necessary checks on similar products and exchange the relevant information with the other Member States and the Commission.

It is clear that various countries have different practices concerning the co-operation of producers and distributors with market surveillance authorities. This has led to additional difficulties in dealing with unsafe products already sold. In addition to withdrawing a dangerous product from the market, there is also a need for producers and distributors to inform consumers of the risk presented by a product already sold.

Even in those countries where there is an obligation for economic operators to inform the authorities, there is often a failure to comply. The absence of penalties for non-compliance with this obligation, ignorance of its existence and the lack of guidelines as to what has to be notified and the manner and time at which the notification has to be made may explain the failure to comply with an obligation which would however be very useful for the administration.

The obligation on economic operators to inform the authorities is, according to the study, considered to be desirable by several national authorities. The fact of having alerted the authorities as soon as possible does not necessary rule out the possibility of having to stand trial. On the other hand, it means the firm can prove its good will and above all prevent other consumers from being injured.

Economic operators often believe that the best way of ensuring that their product complies with this requirement is to ensure compliance with existing standards and, where these do not exist, are keen to establish them. They are uncertain about the nature of the general safety requirement in the absence of binding rules or standards and look to the national authorities for guidance.

This experience has shown that the potential of the Directive for ensuring a consistently high level of protection through the EU and the proper functioning of the internal market is limited by the way in which conformity assessment criteria are defined in Article 4 and the lack of a legal status for them. In particular, European standards do not confer "presumption of conformity" under this Directive, unlike the harmonised standards under the "new approach" directives.

The lack of "status" of European standards under the Directive has weakened its credibility as an effective instrument for ensuring harmonisation, when that is felt necessary. The nature, status and practical relevance of the other documents or references mentioned in Article 4 are very unclear. Consequently both industry and consumers feel there is often a need for additional legislation, as the Directive is not always considered sufficient for the objectives of consumer protection and the internal market.

6. MARKET SURVEILLANCE (ARTICLES 5 AND 6)

Market surveillance is crucial for the effectiveness of the Directive and, more in general, the Community legislation applicable to consumer products. Weaknesses in the functioning of market surveillance throughout the EEA and the need for improvements have often been identified. The Directive sets out the obligations and powers of the Member States relating to market surveillance and intervention. It requires the Member States to establish the relevant powers, but says nothing about the application of those powers or the practical operation of market surveillance. In some cases the necessary steps to appoint the competent authorities, to empower them to take the various kinds of measures foreseen, may have been taken but those powers are often implemented in a weak, insufficient or ineffective way. Experience has shown that at present sanctions are often not effective or not applied.

Consumer associations complain about unsafe products they find on the market, in spite of the requirements of Community legislation, including "new approach" Directives. In practice products circulate freely in the internal market but no formal requirements for arrangements for collaboration between market surveillance authorities are stipulated by Community legislation. The market is unified but the surveillance is fragmented.

7. NOTIFICATION AND EXCHANGE OF INFORMATION (ARTICLE 7)

The main problems encountered are that Member States are unclear when to notify under this procedure, its information value is limited and the administrative burden on the Commission is heavy.

8. RAPID EXCHANGE OF INFORMATION SYSTEM (ARTICLE 8)

Member States and the EEA/EFTA countries are generally satisfied with the Rapid exchange of information system. They consider it to be effective but nevertheless feel the system could be improved. Difficulties highlighted by the Member States include non-notification of voluntary measures, problems defining "serious and immediate risk", lack of detail and unclear notifications, too many notifications and reactions on the same type of product, absence of follow-up by Member States to the notifications, long delays in receiving information, no notifications from some countries and no notification of national products and linguistic problems. The national authorities have also highlighted the need to clarify whether the system applies to products covered by the New Approach Directives. Most of these national authorities agree that the system could be extended to third countries on the basis of reciprocal agreements.

9. EMERGENCY ACTION AT COMMUNITY LEVEL (ARTICLE 9)

The absence of a definition of a "serious and immediate risks" and the exclusion of long-term risks represent a shortcoming of the Directive and it have posed problems in the implementation of Articles 8 and 9 (emergency action at Community level). In four years since the entering into force of the Directive the Article 9 procedure has only been applied on one occasion. The multiple conditions applicable are difficult to reconcile with a rapid intervention.

10. COMMITTEE (ARTICLE 10)

The Emergency Committee also acts, informally, as an advisory committee. The need for the Committee to act in an advisory role with a wide scope has been demonstrated on several occasions. Moreover, an appropriate forum should permit consultation and collaboration with interested parties.

11. CONFIDENTIALITY REQUIREMENTS (ARTICLE 12)

The present provisions of the Directive have not ensured a consistent approach throughout the EU/EEA. Information, which is confidential in one Member State, may have to be disclosed in another, under the freedom of information requirements of that country. This creates difficulties regarding public access to the information circulated, in particular under the Rapid Exchange of Information system.

It is widely considered that, in the field of consumer health and safety, the general principle should be transparency, and secrecy should be limited to only information covered by duly justified exigencies of professional secrecy.

$\frac{\text{ANNEX 1}}{\text{TRANSPOSITION LAWS IN THE MEMBERS STATES}}$

MEMBER STATE	TRANSPOSITION LAW
Austria	Bundesgesetz vom 18.01.1995 zum Schutz vor gefährlichen Produkten Produktsicherheitsgesetz 1994-PSG 1994) (Protection against Dangerous Products Act of 18 January 1995 Product Safety Act 1994 – PSG 1994)
Belgium	Loi du 9 février 1994 relative à la sécurité des consommateurs (Consumer Safety Act of 9 February 1994)
Denmark	Lov nr. 364 af 18.5.1994 om produktsikkerhed (Product Safety Act, n°364 of 18 May 1994)
Finland	Tuoteturvallisuuslaki 914/1986 (Product Safety Act of 1986 (914/1986) as last amended 1993 (539/1993))
France	Articles L 212-1, L 221-1 à L 225-1 du Code de la consommation (ex Loi n° 83-660 du 21 juillet 1983 relative à la sécurité des consommateurs) (Articles L 212-1, L 221-1 à L 225-1 of the Consumer Code (previously Consumer Safety Act No 83-660 of 21 July 1983))
Germany	Gesetz zur Regelung der Sicherheitsanforderungen an Produkte und zum Schutz der CE-Kennzeichnung vom 22 April 1997 (Act on product safety requirements and on protection of CE marking of 22 April 1997)
Greece	Νόμος 2251 της 16ης Νοεμβρίου 1994 περί προστασίας των καταναλωτών, άρθρο 7 + Απόφαση 15/2/1995 Consumer Protection Act n° 2251 of 16 November 1994, article 7 + Decision 15/2/1995
Iceland	Lög um öryggi vöru og opinbera markaðsgæslu nr. 134/1995 Product Safety and Official Market Control no. 134/1995
Ireland	Statutory Instrument S.I. n° 197 of 1997 European Communities (General Product Safety) Regulations, 1997
Italy	Decreto legislativo 17 marzo 1995 – Attuazione della direttiva 92/59/CEE relativa alla sicurezza generale dei prodotti (Decree-Law of 17 March 1995 transposing Directive 92/59/EEC on general product safety)
Luxembourg	Loi du 27 août 1997 relative à la sécurité générale des produits (General Product Safety Act of 27 August 1997)
Norway	Lov om kontroll med produkter og forbrukertjenester (produktkontrolloven) av 11 juni 1976.
	Act relating to the control of products and consumer services (the Product Control Act of 11 June 1976)

Portugal	Decreto-lei 311/95 de 20 de Novembro 1995. Transpoe a Directiva 92/59/CEE – relativa à segurança geral dos productos (Loi générale 1981 + 24/96) (Decree-Law 311 of 20 November 1995 transposing Directive 92/59/EEC on general product safety) (General Act 1981 +24/96)
Spain	LGDCU 26/1984 + Real Decreto 44/1996 de 19 de enero, por el que se adoptan medidas para garantizar la seguridad general de los productos puestos a disposicion del consumidor (General Consumer and User Protection Act No 26/1984 + Royal Decree No 44 of 19 January 1996 adopting measures to ensure the general safety of products made available to consumers)
Sweden	Produktsäkerhetslag 22.12.1988, Svensk författningssamling (SFS) 1988: 1604 (Product Safety Act of 22 December 1988, Swedish Law Gazette (SFS) 1988: 1604) amended 1/7/1994)
The Netherlands	Warenwet 1935 Besluit van 28 September 1993 houdende regelent betreffende de algemene produktveiligheid "Warenwetbesluit algemene produktveiligheid" (Food and Drugs Act 1935, as last amended by the Act of 21 April 1988 + Decree of 28 September 1993 on general product safety under the Food and Drugs Act)
UK	Consumer Protection Act 1987 + Statutory Instruments 1994 n°2328 Consumer Protection, The General Product Safety Regulations 1994 of 5 September 1994

ANNEX 2

THE NATIONAL ADMINISTRATIONS RESPONSIBLE FOR THE APPLICATION OF THE TRANSPOSITION LAW

Austria:*

The Consumer Affairs Office, attached to the Federal Ministry for Women and Consumer Affairs (Bundesministerium für Frauenangelegenheiten und Verbraucherschutz, Büro für Konsumentenfragen). Market surveillance is a matter for the provincial authorities (Länder).

Belgium:*

The Ministry for Economic Affairs, administration for quality and safety (Le Ministère des Affaires Economiques, l'administration de la Qualité et Sécurité) is responsible for consumer products with several exceptions. This Ministry is the contact point for RAPEX notifications. Market surveillance is carried out by the Economic Inspectorate (Inspection Economique) of the same ministry.

Denmark:

The National Consumer Agency (Forbrugerstyrelsen) which operates under the supervision of the Ministry for Affairs and Industry (Erhvervsministeriet) with respect to products not covered by sectorial laws. The 14 sectoral authorities, can use the act for products under their responsibility and have to report to the Agency any measure taken against a dangerous product. The Agency coordinates the activities of the sectorial authorities and checks their application of the Act. Field work for the Agency is carried out by the Secretariat of the Electricity Council.

Finland:*

The Finnish Consumer Agency (Kuluttajavirasto), which is attached to the Ministry for Trade and Industry, the customs authorities, the provincial state governments and the local municipalities. Market surveillance is carried out by the local municipalities and co-ordinated by the provincial state governors.

France:*

The Ministry for Economic Affairs, Finance and Industry, Directorate-General for Competition, Consumer Affairs and the Prevention of Fraud (Ministère de l'Economie, des Finances et de l'Industrie, Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes). The DGCCRF, as well as a central administration in Paris, has directorates in each of the different departments which carry out market surveillance.

Germany:

Several agencies are responsible, at national level, according to the category of products. Each of the 16 Länder (states) has its own structure for implementing the Act. The German Länder mainly entrust enforcement to the Labour Inspectorates (Gewerbeaufsichtsämter). In practice, co-ordination of the notification procedures (Articles 7 and 8) is carried out as follows: for incoming notifications from the European Commission, the Contact Point (Lagezentrum) of the Ministry of Internal Affairs acts as a mail box for the notifications which it then sends to the Länder, with a copy for information to the Federal Institute for Safety and Health at Work (Bundesanstalt für Arbeitschutz). This Ministry is responsible in practice for outgoing notifications i.e. a notification is received from one Land, then circulated to the other Länder and to the European Commission.

Greece:

The Ministry for Development, Directorate of Consumers (Υπουργείο Ανάπτυξης, Διεύθυνση των Καταναλωτών). No department is specifically responsible for product safety monitoring.

Iceland:

The Icelandic Metrology and Accreditation Service (Löggildingarstofa), an agency under the Ministry of Trade and Industry (Iðnaðar- og viðskiptaráðuneytið). Responsibility for market surveillance lies with the Market Surveillance Department on that agency.

Ireland:

The Office of the Director of Consumer Affairs. The day-to-day enforcement is carried out by Inspectors working for the Office. The Consumer Protection Branch of the Department of Enterprise, Trade and Employment is responsible for handling the RAPEX system whilst general product safety policy is the responsibility of the Science and Technology section of that ministry.

Italy:

The authority responsible is the Ministry of Industry, Trade and Craft Trades, the Directorate-General for the protection and harmonisation of the market (il Ministero dell'Industria, del Commercio e dell'Artigianato). Several other ministries are involved in the application of the Directive. Market surveillance is carried out by each ministry using its own organisations and laboratories. A recently created body, Conferenza di Servizi, is responsible for organising co-ordination between the different authorites.

Luxembourg:

Ministry of the Economy – Price, Competition and Consumer Service (Ministère de l'Economie, Service Prix, Concurrence et Consommateurs). It is responsible for those products which are not covered by sectoral legislation. Market surveillance is carried out by the same administration.

The Netherlands:*

The Ministry of Health, Welfare and Sport, Inspectorate for health protection, commodities and veterinary public health (Minister van Volksgezondheid, Welzijn en Sport, Inspectie Gezondheidsbescherming Waren en Veterinaire Zaken). Besides the General Inspectorate in the Hague there are five regional inspectorates which carry out market surveillance.

Norway:

The Ministry for the Environment, through the State Pollution Authority and the Ministry of Children and Family Affairs, through the Directorate for Product and Electrical Safety. The authorities supervisory activities are normally carried out as systems-based audits or verifications or both in enterprises.

Portugal:*

Three institutions are responsible: the Product Safety Commission (Commissão para a Segurança de Serviços), the Consumer Institute (Instituto do Consumidor) and the Inspectorate-General for Economic Activities (Inspecção-Genal das actividades Economicas -IGAE). Market surveillance is carried out by the IGAE.

Spain:*

At national level it is the National Consumer Institute (Instituto nacional de Consumo) under the responsibility of the Health and Consumer Ministry. The autonomous authorities are responsible for market surveillance.

Sweden:

The Swedish Consumer Agency (Konsumentverket), headed by the Ombudsman, Department for household management and product quality. The 15 other sectoral authorities can also use the powers foreseen by the Act. Market surveillance for the Agency is carried out by local advisors in the municipalities. Only the Market court can impose a measure against a dangerous product. A special body (SWEDAC) co-ordinates the market surveillance activities of the different authorities.

UK:

The Department of Trade and Industry (DTI) is the central government body responsible for the implementation of the General Product Safety Act. Day-to-day enforcement of this legislation is the responsibility of the local trading standards departments. There are 202 such enforcement authorities in the United Kingdom. The Local authorities Co-ordinating Body on Food and Trading Standards (LACOTS) provides enforcement guidance to the UK's local authorities, and consultation on legislative matters.

* Seven countries have put in place a "Consumer Safety Commission" or an equivalent body – Austria, Spain (Technical Safety Committee), Finland (Product Safety Advisory Body), France, Belgium, the Netherlands (Warenwet Advisory Commission) and Portugal.