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# A Guide to the EU Directive on General Product Safety

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# A Guide to the EU Directive on General Product Safety

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### **ABSTRACT**

This guide (prepared under contract by Helen Delaney and Rene van de Zande, DVZ Joint Ventures) is an easy-to-use introductory reference for industry and government officials on the requirements of the European Union's (EU) Directive on General Product Safety [92/59/EEC]. It is designed to help business and government officials understand the purpose of the directive, its relationship to other directives, the essential requirements contained in the directive, pending revisions to the directive, product coverage, definitions, producers' and distributors' duties, conformity assessment criteria and standards, the safeguard clause, and the obligations and powers of the Member States. The guide also contains the text of the directive. In addition, the guide references appropriate sections of NIST Special Publication 951: A Guide to EU Standards and Conformity Assessment for further information on some of the generic conformity assessment concepts and requirements of the EU's New Approach.

Key Words: CEN; CENELEC; conformity assessment; defective products; directives; European Union; legal liability; liability; New Approach directives; product safety; safety

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# The Directive on General Product Safety 1

### Directive 92/59/EEC

Applicable since June 29, 1992

### To Be Considered:

## 1. Pending Revision of Directive 92/59/EEC

On November 30, 2000, the European Council reached political agreement on a Commission draft directive to improve the rules governing product safety in Europe, i.e., a revision of the Directive on General Product Safety (92/59/EEC).

Because the new (proposed) Directive on General Product Safety is expected to be adopted before the end of the year 2001, (the year of publication of this document), it is presented here along with the present Directive. The <u>text of the proposed Directive</u> is presented at the end of this document, along with the <u>text of the present Directive</u>. There is also a <u>table of present and revised texts</u> shown in correlation to one another.

It should be noted that, until final adoption, the provisions presented in the Commission's proposal might undergo additional revision. In general, however, the concepts in the Commission's proposed revision are not likely to change.

The proposed date on which the revised directive is to enter into force is January 1, 2003.

### Main Points of the Revision

- Scope: The revision clarifies which products are covered. The consumer health and safety protection rules of the directive will in future apply to all consumer products, including those products which are supplied to consumers, or used by consumers, in the course of a service, as well as products used to provide a service (tourist services and fitness centers, beauty centers, hotels or gas and electricity suppliers, etc). Also, products "migrating" from the professional sector to the consumer market, as has been the case for example with laser pens, will be included in the scope of the Directive.
- Obligations of Producers and Distributors: The revision places an added obligation on producers and distributors to inform the authorities when they have determined that a product they have placed on the market is dangerous. They are also obliged to disclose whatever action they have taken to prevent harm to consumers. They will be obliged to collaborate with authorities and provide

<sup>1</sup> Readers of this report may wish to refer to NIST SP 951: A Guide to EU Standards and Conformity Assessment, which is available on NIST's website at: http://ts.nist.gov/ca.

documentation that will aid in tracing the origin of such products. Producers will also be required to not only warn consumers of risks posed by such products, but to **recall** such products from consumers when other measures will not prevent the risks involved.

Conformity Assessment Criteria and Product Safety Standards: A significant change occurs in the revision as relates to standards. Under the present directive, European standards (See SP 951: A Guide to EU Standards and Conformity Assessment, Page 10) do not confer "presumption of conformity" (See SP 951, Page 11) as they do as Harmonized Standards (See SP 951, Page 11) under the "New Approach" Directives (See SP 951, Page 2). The revised Directive strengthens the role of European standards by stating that products in compliance with standards mandated by the European Commission and published in the Official Journal of the European Communities will be presumed in conformity with the safety requirements of the Directive. This provision effectively establishes Harmonized Standards for the general safety requirements. *In other words, standards mandated and developed for this Directive will have* the same legal status as standards mandated for New Approach Directives. Mandates have already been received under this proposed directive for standards for bunk beds, baby-walkers, flammability of nightwear, oil-lamps, childcare articles, lighters, and ladders.

There is not at present, nor will there be CE Marking (See <u>SP 951, Page 17)</u> requirements for consumer products under this Directive.

• Market Surveillance and Enforcement Powers: More active and effective market surveillance will be achieved by strengthening the obligations and powers of national surveillance authorities and by stronger sanctions at national level. There will be established a European Product Safety Network between the Member States and the European Commission which will operate to exchange information, establish joint surveillance and testing projects, and coordinate tracing, withdrawal and recall of dangerous products.

# 2. Relationship of Directive 92/59/EEC to Other Community Legislation

The Directive on General Product Safety (92/59/EEC) is intended to cover risks associated with products (such as childcare products and lighters) that are not covered by other sectoral legislation. If products are covered by other sectoral legislation, but all of their risks are not addressed by that legislation, the Directive on General Product Safety covers those (uncovered) risks. In other words, it is a broad-based, horizontal legislative framework for all consumer products to cover products not subject to specific Community legislation, but also to fill gaps where such legislation exists. It also recognizes that some products are still covered by national legislation.

The safety requirements of the GPSD do not apply to consumer products covered by New Approach Directives (See <u>SP 951, Page 2</u>)<sup>2</sup> However, the GPSD does afford additional protection (other than safety) to such products. For consumer products regulated by New Approach Directives, the GPSD provides additional safeguards, such as additional obligations of producers and distributors, market surveillance, a rapid alert system for unsafe products, and Community emergency measures.

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# **Purpose of the General Product Safety Directive (Article 1 of the Directive)**

The purpose of this Directive is to ensure that products placed on the market are safe. It also places obligations on producers, distributors, and Member State authorities to that end.

# Determining Whether or Not the Product Has to Comply with the General Product Safety Directive

Products covered by this Directive are those intended for consumers or likely to be used by consumers and which are supplied in the course of a commercial activity. This includes new, used and reconditioned products, with the exception of antiques and products sold but intended for reconditioning, provided that the supplier informs the consumer of this fact.

- It covers products which are not subject to sectoral legislation;
- It also covers 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.

Note: For products covered by New Approach Directives (See <u>SP 951, Page 2</u>), the safety requirements of the GPSD (Articles 2 to 4) do not apply (See <u>Relationship to other Community Legislation on Page 2 of this report</u>). They do have to comply, however, with the other provisions of this Directive.

Production equipment, capital goods, and other products used exclusively in the context of a trade or business are not covered.

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<sup>&</sup>lt;sup>2</sup> Some consumer products are regulated for "total safety" under this kind of sectoral European legislation, such as electrical products under the Low Voltage Directive.

### **Definitions (Article 2 of the Directive)**

For the purposes of this Directive, the following definitions will be used:

**Product**: Any product intended for consumers or likely to be used by consumers, supplied whether for consideration or not in the course of a commercial activity and whether new, used, or reconditioned. This Directive does not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect.

<u>Safe Product</u>: Any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly, and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labeling, any instructions for its use and disposal, and any other indication or information provided by the producer,
- the categories of consumers at serious risk when using the product, in particular children.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "unsafe" or "dangerous."

<u>Dangerous Product:</u> Any product that does not meet the above definition of "safe product."

### **Producer:**

- the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark, or other distinctive mark, or the person who reconditions the product;
- the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product; or
- other professionals in the supply chain insofar as their activities may affect the safety properties of a product placed on the market.

**<u>Distributor:</u>** Any professional in the supply chain whose activity does not affect the safety properties of a product.

## **General Safety Requirements (Article 3 of the Directive)**

<u>Producers' Duties:</u> Producers are obliged to place only safe products on the market. Within the limits of their respective activities, producers shall:

- provide consumers with information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Provision of such warnings does not, however, exempt any person from compliance with the other requirements in this Directive; and
- adopt measures commensurate with the characteristics of the products that they supply, to enable consumers to be informed of risks that these products might present and to take appropriate action, including, if necessary, withdrawing the product in question from the market.

The above measures include, for example, whenever appropriate:

- marking of the products or product batches in such a way that they can be identified;
- sample testing of marketed products; and
- investigating complaints made and keeping distributors informed of such monitoring.

Note: The prudent producer will conduct a risk assessment in the design phase of the product (See <u>SP 951, Page 25)</u>. Not recognizing or dealing effectively with a hazard will not help the producer's argument in a product liability lawsuit.

<u>Distributors' Duties</u>: Distributors are required to act with due care to help ensure compliance with the general safety requirement, in particular by not supplying products that they know or should have presumed to know, do not comply with this requirement. In particular, within the limits of their respective activities, they must participate in monitoring the safety of products placed on the market, especially by passing on information about product risks and cooperating in the action taken to avoid these risks.

# **General Safety Requirements (Article 4 of the Directive)**

<u>National Law:</u> Where there are no specific Community provisions (European laws) governing the safety of the products in question, a product is deemed safe when it

conforms to the specific rules of national law of the Member State in whose territory the product is in circulation.

In other words, when there is no European law that covers the product, but the product complies with specific national regulatory requirements (Member State law) in the Member State in which it is placed on the market, the product is deemed to be "safe" according to the GPSD.

Conformity Assessment Criteria and Standards: In the absence of specific rules, the conformity of a product to the general safety requirement must be assessed using standards. The Directive is specific. A product must be assessed using voluntary European standards or, where they exist, to Community technical specifications or, failing these, to standards drawn up in the Member State in which the product is in circulation, or to the codes of good practice in health and safety in the sector concerned, or to the state of the art and technology and to the safety that consumers may reasonably expect.

In other words, Article 4 states that, unless specific relevant regulatory requirements exist at Community or national level, conformity to the safety requirement must be assessed using

- European standards, (See <u>SP 951, Pages 10, 11, 12)</u> or
- Community technical specifications, or
- National standards, or
- Codes of good practices in respect of health and safety in the sector concerned, or
- The state of the art and technology and the safety that consumers may reasonably expect.

Note: The Directive suggests the use of standards in this order, seeming to establish a hierarchy. Unlike Harmonized Standards specifically developed for New Approach Directives (See <u>SP 951, Page 11)</u>, the types of standards listed in the GPSD have no clearly defined legal status. Unlike their counterparts the Harmonized Standards, they do not confer a "presumption of conformity" upon the product. This will change when the new Directive is adopted (See: <u>Pending Revision of Directive 92/59/EEC, Page 1 of this report)</u>

<u>Safeguard Clause</u>: Even if a product conforms with the standards and specifications mentioned above, competent authorities (Ministries of National Governments) of the Member States still may impose restrictions on the product's placement on the market or withdraw the product from the market where there is evidence that, despite such conformity, the product is dangerous to the health and safety of consumers.

# Obligations and Powers of the Member States (Article 5 of the

## Directive)

Member States have to adopt the necessary laws, regulations, and administrative provisions to make producers and distributors comply with their obligations under this Directive.

In particular, Member States have to establish or nominate authorities to monitor and ensure that only safe products are placed on the market. Further, states must ensure that such authorities have the requisite power to take the appropriate measures incumbent upon them under this Directive, including the imposing of suitable penalties. Then states have to notify the Commission of the said authorities. The Commission then passes on the information to the other Member States.

# Obligations and Powers of the Member States (Article 6 of the Directive)

Member States must have the necessary powers, acting in accordance with the degree or risk, to adopt appropriate measures that, among other things:

- organize appropriate checks on the safety properties of products, even after they are placed on the market as "safe;"
- require all necessary information from the parties concerned;
- take samples of a product or a product line and subject them to safety checks;
- subject product marketing to prior conditions designed to ensure product safety and require that suitable warnings be affixed regarding the risks which the product may present;
- make arrangements to ensure that persons who might be exposed to a risk from a
  product are informed in good time and in a suitable manner of the said risk by,
  among other things, publishing special warnings;
- temporarily prohibit, for the period required to carry out the various checks, anyone from supplying, offering to supply, or exhibiting a product or product batch, whenever there are precise and consistent indications that they are dangerous;
- prohibit the placing on the market of a product or product batch which has proved dangerous and establish the accompanying measures needed to ensure that the ban is complied with; and
- organize the effective and immediate withdrawal of a dangerous product or product batch already on the market and, if necessary, its destruction under appropriate conditions.

The measures to be taken by the competent authorities of the Member States under this Article shall be addressed, as appropriate, to:

• the producer;

- within the limits of their respective activities, distributors and, in particular, the party responsible for the first stage of distribution on the national market; and
- any other person, where necessary, with regard to cooperation in action taken to avoid risks arising from a product.

# Notification and Exchanges of Information (Safeguard Clause, Article 7 of the Directive)

When a Member State withdraws a product from the market or places restrictions on it, that State has to inform the Commission that it has done so. This obligation does not apply when the situation concerns a local event that is limited to the territory of the Member State concerned.

The Commission will begin consultations with the concerned parties as soon as possible to determine whether the Member State's action was justified and if further action is necessary.

## **Emergency Situations (Article 8 of the Directive)**

When a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of a product or product batch because of a serious and immediate risk presented by the said product or product batch, it will have to inform the Commission. It does not have to do so if the effects of the risk do not, or cannot, go beyond its territory. Even if it does not initiate an emergency measure, a Member State can still pass on to the Commission information regarding the existence of a serious and immediate risk.

Note: The Annex to the Directive points out that "it is impossible to lay down specific criteria as to what, precisely, constitutes an immediate and serious risk; in this regard, the national authorities will therefore judge each individual case on its merits."

When it receives this information, the Commission will check to see if it complies with the provisions of this Directive and shall forward it to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.

Detailed procedures for the Community information system described in this Article are set out in the <u>Annex</u>: Detailed Procedures for the Application of the Community System for the Rapid Exchange of Information Provided for in Article 8.

# **Emergency Situations (Article 9 of the Directive)**

If the Commission becomes aware, through notification given by the Member States,

(See Article 7 or Article 8) of the existence of a serious and immediate risk from a product to the health and safety of consumers in various Member States; and if:

- one or more Member States have restricted the marketing of the product or has withdrawn it from the market;
- Member States differ on the adoption of measures to deal with the risk in question;
- the risk cannot be dealt with in a manner compatible with the urgency of the case under the other procedures laid down by the specific Community legislation under which the product or category of products is governed; and
- the risk can be eliminated effectively only by adopting appropriate measures at Community level;

then the Commission, after consulting the Member States and at the request of at least one of them, may adopt a decision, (See Article 11 of the Directive) requiring Member States to take temporary measures from among those listed in Article 6 of the Directive.

Note: Article 8 of this Directive relates to immediate threats posed by a product. It does not provide for products involving possible long-term risks, which would call for a study of possible technical changes by means of directives or standards (See <u>Annex</u>).

The explicit exclusion of "long-term risks", in the view of the European Commission, represents a shortcoming of the Directive and this exclusion has posed problems in its implementation. In particular, there have been uncertainties on the applicability of Articles 8 and 9 to risks related to long-term effects (carcinogenic, mutagenic, endocrine disruption...), but requiring immediate intervention because of the need to rapidly remove the causes of such long-term effects.

This was brought to bear in the case of toys containing phthalates. The Commission felt compelled to address the applicability of the provisions of Article 9 on Community emergency measures in a case (like the toy case) where the risks for child health are related to release of substances whose potential adverse effects would be apparent only in the long term. Similar considerations would apply to all risks that, in spite of being related to exposure taking place in the short term, would bring serious adverse effects only at a much later stage.

Therefore, the Commission has addressed the need to cover all "serious risks requiring immediate intervention" in the proposed revision of the GPSD (See <u>Text of the Proposed Revised Directive on General Product Safety Page 21</u>) and <u>Correlation Table, Page 35</u>).

# The Committee (Articles 10 and 11 of the Directive)

See *Text of the Directive, Page 17.* 

## **Confidentiality (Article 12 of the Directive)**

The Member States and the Commission shall take whatever steps are necessary to ensure that their officials and agents do not disclose information obtained for the purposes of this Directive that, by its nature, is covered by professional secrecy, except for information relating to the safety properties of a given product which must be made public if circumstances so require.

## **Miscellaneous Provisions: (See Text, Article 13 of the Directive)**

### **Miscellaneous Provisions (Article 14 of the Directive)**

Any decision adopted under this Directive and involving restrictions on the placing of a product on the market, or requiring its withdrawal from the market, must include the appropriate reasons on which it is based. As soon as possible, the parties concerned shall be informed and apprised of the remedies available under the provisions in force in the Member State in question and the time limits applying to such remedies.

The parties concerned must, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. If this has not been done in advance because of the urgency of the measures to be taken, such opportunity must be given in due course after the measure has been implemented.

Measures requiring the withdrawal of a product from the market are required to take into consideration the need to encourage distributors, users, and consumers to contribute to the implementation of such measures.

Member States shall ensure that any measure taken by the competent authorities involving restrictions on the placing on the market or requiring its withdrawal from the market can be challenged before the competent courts.

Any decision involving restrictions on the placing of a product on the market or requiring its withdrawal from the market shall be considered quite apart from assessment of the liability of the party concerned (See <u>Directive on Product Liability</u>).

### **ANNEX** to the Directive

# Procedures for the Application of the Community System for the Rapid Exchange of Information

The system for the rapid exchange of information covers products, as they are defined in this Directive, which are placed on the market. Pharmaceuticals, which

come under Directive 75/319/EEC and 81/851/EEC; and animals, to which Directive 82/894/EEC applies; products of animal origin, as far as they are covered by Directive 89/662/EEC; and the system for radiological emergencies, which covers widespread contamination of products (Decision 87/600/Euratom), are excluded, since they are covered by equivalent notification procedures.

The system is essentially aimed at a rapid exchange of information in the event of a serious and immediate risk to the health and safety of consumers. Because it is impossible to lay down specific criteria as to what, precisely, constitutes an immediate and serious risk; national authorities have to judge each individual case on its merits. Products involving possible long-term risks, which call for a study of possible technical changes by means of directives or standards, are not concerned.

As soon as a serious and immediate risk is detected, the national authority must, if possible, consult the producer or distributor of the product concerned. Their point of view and the details, which they supply, may be useful both to the administrations of the Member States and to the Commission in determining what action should be taken to ensure that the consumer is protected with a minimum of commercial disruption. The Member State should try to obtain as much information as possible, as quickly as is possible.

As soon as a Member State has detected a serious and immediate risk, the effects of which extend or could extend beyond its territory, and measures have been taken or decided on, it shall immediately inform the Commission for further investigation and, if necessary, action. Every year the Commission will carry out a review of the effectiveness of the network to determine the need for any improvements to the communications system.

## Text of the Directive on General Product Safety 92/59/EEC

The following text of the Directive on General Product Safety (92/59/EED) has been taken from EUR-Lex, the digital version of the legislation issued in the Official Journal of the European Communities. Web Site: <a href="http://www.europa.eu.int/eur-lex/en/lif/dat/1992/en\_392L0059.htm">http://www.europa.eu.int/eur-lex/en/lif/dat/1992/en\_392L0059.htm</a>

Only European Community legislation printed in the Official Journal of the European Communities is deemed to be authentic.

COUNCIL DIRECTIVE 92/59/EEC of 29 June 1992 on general product safety
THE COUNCIL OF THE EUROPEAN

THE COUNCIL OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof.

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament(2), Having regard to the opinion of the Economic and Social Committee(3),

Whereas it is important to adopt measures with the aim of progressively establishing the internal market over a period expiring on 31 December 1992; whereas the internal market is to comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas some Member States have adopted horizontal legislation on product safety, imposing, in particular, a general obligation on economic operators to market only safe products; whereas those legislations differ in the level of protection afforded to persons; whereas such disparities and the absence of horizontal legislation in other Member States are liable to create barriers to trade and distortions of competition within the internal market;

Whereas it is very difficult to adopt Community legislation for every product which exists or may be developed; whereas there is a need for a broadly-based, legislative framework of a horizontal nature to deal with those products, and also to cover lacunae in existing or forthcoming specific legislation, in particular with a view to ensuring a high

level of protection of safety and health of persons, as required by Article 100 a (3) of the Treaty;

Whereas it is therefore necessary to establish on a Community level a general safety requirement for any product placed on the market that is intended for consumers or likely to be used by consumers; whereas certain second-hand goods should nevertheless be excluded by their nature;

Whereas production equipment, capital goods and other products used exclusively in the context of a trade or business are not covered by this Directive;

Whereas when there are specific rules of Community law, of the total harmonization type, and in particular rules adopted on the basis of the new approach, which lay down obligations regarding product safety, further obligations should not be imposed on economic operators as regards the placing on the market of products covered by such rules;

Whereas, when the provisions of specific Community regulations cover only certain aspects of safety or categories of risks in respect of the product concerned, the obligations of economic operators in respect of such aspects are determined solely by those provisions;

Whereas it is appropriate to supplement the duty to observe the general safety requirement by an obligation on economic operators to supply consumers with relevant information and adopt measures commensurate with the characteristics of the products, enabling them to be informed of the risks that these products might present;

Whereas in the absence of specific regulations, criteria should be defined whereby product safety can be assessed;

Whereas Member States must establish authorities responsible for monitoring product safety and with powers to take the appropriate measures;

Whereas it is necessary in particular for the appropriate measures to include the power for Member States to organize, immediately and efficiently, the withdrawal of dangerous products already placed on the market;

Whereas it is necessary for the preservation of the unity of the market to inform the Commission of any measure restricting the placing on the market of a

product or requiring its withdrawal from the market except for those relating to an event which is local in effect and in any case limited to the territory of the Member State concerned; whereas such measures can be taken only in compliance with the provisions of the Treaty, and in particular Articles 30 to 36; Whereas this Directive applies without prejudice to the notification procedures in Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations(4) and in Commission Decision 88/383/EEC of 24 February 1988 providing for the improvement of information on safety, hygiene and health at work(5);

Whereas effective supervision of product safety requires the setting-up at national and Community levels of a system of rapid exchange of information in emergency situations in respect of the safety of a product and whereas the procedure laid down by Council Decision 89/45/EEC of 21 December 1988 on a Community system for the rapid exchange of information on dangers arising from the use of consumer products (6) should therefore be incorporated into this Directive and the above Decision should be repealed; whereas it is also advisable for this Directive to take over the detailed procedures adopted under the above Decision and to give the Commission, assisted by a committee, power to adapt them:

Whereas, moreover, equivalent notification procedures already exist for pharmaceuticals, which come under Directives 75/319/EEC(7) and 81/851/EEC(8), concerning animal diseases referred to in Directive 82/894/EEC(9), for products of animal origin covered by Directive 89/662/EEC(10), and in the form of the system for the rapid exchange of information in radiological emergencies under Decision 87/600/Euratom(11);

Whereas it is primarily for Member States, in compliance with the Treaty and in particular with Articles 30 to 36 thereof, to take appropriate measures with regard to dangerous products located within their territory;

Whereas in such a situation the decision taken on a particular product could differ from one Member State to another; whereas such a difference may entail unacceptable disparities in consumer protection and constitute a barrier to intra-Community trade;

Whereas it may be necessary to cope with serious product-safety problems which affect or could affect, in the immediate future, all or a large part of the

Community and which, in view of the nature of the safety problem posed by the product cannot be dealt with effectively in a manner commensurate with the urgency of the problem under the procedures laid down in the specific rules of Community law applicable to the products or category of products in question;

Whereas it is therefore necessary to provide for an adequate mechanism allowing, in the last resort, for the adoption of measures applicable throughout the Community, in the form of a decision addressed to the Member States, in order to cope with emergency situations as mentioned above; whereas such a decision is not of direct application to economic operators and must be incorporated into a national instrument; whereas measures adopted under such a procedure can be no more than interim measures that have to be taken by the Commission assisted by a committee of representatives of the Member States: whereas, for reasons of cooperation with the Member States, it is appropriate to provide for a regulatory committee according to procedure III (b) of Decision 87/373/EEC(12);

Whereas this Directive does not affect victims' rights within the meaning of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products(13);

Whereas it is necessary that Member States provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal;

Whereas it is appropriate to consider, in the light of experience, possible adaptation of this Directive, particularly as regards extension of its scope and provisions on emergency situations and intervention at Community level;

Whereas, in addition, the adoption of measures concerning imported products with a view to preventing risks to the safety and health of persons must comply with the Community's international obligations,

HAS ADOPTED THIS DIRECTIVE:

TITLE I Objective - Scope - Definitions
Article 1

- 1. The purpose of the provisions of this Directive is to ensure that products placed on the market are safe.
- 2. The provisions of this Directive shall apply in so far

as there are no specific provisions in rules of Community law governing the safety of the products concerned.

In particular, where specific rules of Community law contain provisions imposing safety requirements on the products which they govern, the provisions of Articles 2 to 4 of this Directive shall not, in any event, apply to those products.

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.

#### Article 2

For the purposes of this Directive:

(a) product shall mean any product intended for consumers or likely to be used by consumers, supplied whether for consideration or not in the course of a commercial activity and whether new, used or reconditioned.

However, this Directive shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

- (b) safe product shall mean any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:
- the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance.
- the effect on other products, where it is reasonably foreseeable that it will be used with other products,
- the presentation of the product, the labeling, any instructions for its use and disposal and any other indication or information provided by the producer,
- the categories of consumers at serious risk when using the product, in particular children.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'unsafe' or 'dangerous'; (c) dangerous product shall mean any product which does not meet the definition of 'safe product' according to point (b) hereof;

- (d) producer shall mean:
- the manufacturer of the product, when he is established in the Community, and any other person

presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product,

- the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product,
  - the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product,
    - other professionals in the supply chain, insofar as their activities may affect the safety properties of a product placed on the market.
    - (e) distributor shall mean any professional in the supply chain whose activity does not affect the safety properties of a product.

# TITLE II General safety requirement Article 3

- 1. Producers shall be obliged to place only safe products on the market.
- 2. Within the limits of their respective activities, producers shall:
  - provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

Provision of such warnings does not, however, exempt any person from compliance with the other requirements laid down in this Directive,

- adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present and to take appropriate action including, if necessary, withdrawing the product in question from the market to avoid these risks.

The above measures shall for example include, whenever appropriate, marking of the products or product batches in such a way that they can be identified, sample testing of marketed products, investigating complaints made and keeping distributors informed of such monitoring.

3. Distributors shall be required to act with due care in order to help to ensure compliance with the general safety requirement, in particular by not supplying

products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with this requirement. In particular, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks and cooperating in the action taken to avoid these risks.

### Article 4

- 1. Where there are no specific Community provisions governing the safety of the products in question, a product shall be deemed safe when it conforms to the specific rules of national law of the Member State in whose territory the product is in circulation, such rules being drawn up in conformity with the Treaty, and in particular Articles 30 and 36 thereof, and laving down the health and safety requirements which the product must satisfy in order to be marketed.
- 2. In the absence of specific rules as referred to in paragraph 1, the conformity of a product to the general safety requirement shall be assessed having regard to voluntary national standards giving effect to a European standard or, where they exist, to Community technical specifications or, failing these, to standards drawn up in the Member State in which the product is in circulation, or to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.
- 3. Conformity of a product with the provisions mentioned in paragraphs 1 or 2 shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market where there is evidence that, despite such conformity, it is dangerous to the health and safety of consumers.

TITLE III Obligations and powers of the Member States

### Article 5

Member States shall adopt the necessary laws. regulations and administrative provisions to make producers and distributors comply with their obligations under this Directive in such a way that products placed on the market are safe. In particular, Member States shall establish or nominate authorities to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers to take the appropriate measures incumbent upon them under this Directive, including the possibility of imposing suitable penalties in the event of failure to comply with the obligations deriving from this Directive. They shall notify the Commission of the said authorities: the Commission shall pass on the information to the other Member States.

#### Article 6

- 1. For the purposes of Article 5, Member States shall have the necessary powers, acting in accordance with the degree or risk and in conformity with the Treaty, and in particular Articles 30 and 36 thereof, to adopt appropriate measures with a view, inter alia, to: (a) organizing appropriate checks on the safety properties of products, even after their being placed on the market as being safe, on an adequate scale, up
- to the final stage of use or consumption;
- (b) requiring all necessary information from the parties concerned:
- (c) taking samples of a product or a product line and subjecting them to safety checks:
- (d) subjecting product marketing to prior conditions designed to ensure product safety and requiring that suitable warnings be affixed regarding the risks which the product may present;
- (e) making arrangements to ensure that persons who might be exposed to a risk from a product are informed in good time and in a suitable manner of the said risk by, inter alia, the publication of special warnings:
- (f) temporarily prohibiting, for the period required to carry out the various checks, anyone from supplying, offering to supply or exhibiting a product or product batch, whenever there are precise and consistent indications that they are dangerous;
- (g) prohibiting the placing on the market of a product or product batch which has proved dangerous and establishing the accompanying measures needed to ensure that the ban is complied with:
- (h) organizing the effective and immediate withdrawal of a dangerous product or product batch already on the market and, if necessary, its destruction under appropriate conditions.
- 2. The measures to be taken by the competent authorities of the Member States under this Article shall be addressed, as appropriate, to:
- (a) the producer;
- (b) within the limits of their respective activities. distributors and in particular the party responsible for the first stage of distribution on the national market;
- (c) any other person, where necessary, with regard to cooperation in action taken to avoid risks arising from a product.

TITLE IV Notification and Exchanges of Information Article 7

1. Where a Member State takes measures which

restrict the placing of a product or a product batch on the market or require its withdrawal from the market, such as provided for in Article 6 (1) (d) to (h), the Member State shall, to the extent that such notification is not required under any specific Community legislation, inform the Commission of the said measures, specifying its reasons for adopting them. This obligation shall not apply where the measures relate to an event which is local in effect and in any case limited to the territory of the Member State concerned.

2. The Commission shall enter into consultations with the parties concerned as quickly as possible. Where the Commission concludes, after such consultations, that the measure is justified, it shall immediately inform the Member State which initiated the action and the other Member States. Where the Commission concludes, after such consultations, that the measures is not justified, it shall immediately inform the Member State which initiated the action.

# TITLE V Emergency situations and action at Community level Article 8

1. Where a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of a product or product batch by reason of a serious and immediate risk presented by the said product or product batch to the health and safety of consumers, it shall forthwith inform the Commission thereof, unless provision is made for this obligation in procedures of a similar nature in the context of other Community instruments.

This obligation shall not apply if the effects of the risk do not, or cannot, go beyond the territory of the Member State concerned.

Without prejudice to the provisions of the first subparagraph, Member States may pass on to the Commission any information in their possession regarding the existence of a serious and immediate risk before deciding to adopt the measures in question.

- On receiving this information, the Commission shall check to see whether it complies with the provisions of this Directive and shall forward it to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.
- 3. Detailed procedures for the Community information system described in this Article are set out in the Annex. They shall be adapted by the Commission in accordance with the procedure laid down in Article 11.

### Article 9

If the Commission becomes aware, through notification given by the Member States or through

information provided by them, in particular under Article 7 or Article 8, of the existence of a serious and immediate risk from a product to the health and safety of consumers in various Member States and if: (a) one or more Member States have adopted measures entailing restrictions on the marketing of the product or requiring its withdrawal from the market, such as those provided for in Article 6 (1) (d) to (h); (b) Member States differ on the adoption of measures to deal with the risk in question; (c) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product and in a manner compatible with the urgency of the case, under the other procedures laid down by the specific Community legislation applicable to the product or category of products concerned; and (d) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure the protection of the health and safety of consumers and the proper functioning of the common market, the Commission, after consulting the Member States and at the request of at least one of them, may adopt a decision, in accordance with the procedure laid down in Article 11, requiring Member States to take temporary measures from among those listed in

### Article 10

(1) (d) to (h).

Article 6

- 1. The Commission shall be assisted by a Committee on Product Safety Emergencies, hereinafter referred to as 'the Committee', composed of the representatives of the Member States and chaired by a representative of the Commission.
- 2. Without prejudice to Article 9 (c), there shall be close cooperation between the Committee referred to in paragraph 1 and the other Committees established by specific rules of Community law to assist the Commission as regards the health and safety aspects of the product concerned.

### Article 11

1. The Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee, having verified that the conditions listed in Article 9 are fulfilled, shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter but which may not exceed one month. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty for adoption of decisions by the Council on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

The Commission shall adopt the measures in question, if they are in accordance with the opinion of the Committee. If the measures proposed are not in accordance with the Committee's opinion, or in the absence of an opinion, the Commission shall forthwith submit to the Council a proposal regarding the measures to be taken. The Council shall act by a qualified majority.

If the Council has not acted within 15 days of the date on which the proposal was submitted to it, the measures proposed shall be adopted by the Commission unless the Council has decided against them by a simple majority.

- 2. Any measure adopted under this procedure shall be valid for no longer than tree months. That period may be prolonged under the dame procedure.
- 3. Member States shall take all necessary measures to implement the decisions adopted under this procedures within less than 10 days.
- 4. The competent authorities of the Member States responsible for carrying out measures adopted under this procedures shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.

### Article 12

The Member States and the Commission shall take the steps necessary to ensure that their officials and agents are required not to disclose information obtained for the purposes of this Directive which, by its nature, is covered by professional secrecy, except for information relating to the safety propertiies of a given product which must be made public if circumstances so require, in order to protect the health and safety of persons.

TITLE VI Miscellaneous and final provisions Article 13

This Directive shall be without prejudice to Directive 85/374/EEC.

### Article 14

1. Any decision adopted under this Directive and involving restrictions on the placing of a product on the market, or requiring its withdrawal from the market, must state the appropriate reasons on which it is based. It shall be notified as soon as possible to the party concerned and shall indicate the remedies available under the provisions in force in the Member State in question and the time limits applying to such remedies.

The parties concerned shall, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. If this has not been done in advance because of the urgency of the measures to be taken, such opportunity shall be given in due

course after the measure has been implemented. Measures requiring the withdrawal of a product from the market shall take into consideration the need to encourage distributors, users and consumers to contribute to the implementation of such measures.

- 2. Member States shall ensure that any measure taken by the competent authorities involving restrictions on the placing on the market or requiring its withdrawal from the market can be challenged before the competent courts.
- 3. Any decision taken by virtue of this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal from the market shall be entirely without prejudice to assessment of the liability of the party concerned, in the light of the national criminal law applying in the case in question.

#### Article 15

Every two years following the date of adoption, the Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council.

### Article 16

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.

### Article 17

- 1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive by 29 June 1994 at the latest. They shall forthwith inform the Commission thereof. The provisions adopted shall apply with effect from 29 June 1994.
- 2. When these measures are adopted by the Member States, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
- 3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the area covered by this Directive.

### Article 18

Decision 89/45/EEC is hereby repealed on the date referred to in Article 17 (1).

### Article 19

This Directive is addressed to the Member States. Done at Luxembourg, 29 June 1992.

### ANNEX

DETAILED PROCEDURES FOR THE APPLICATION OF THE COMMUNITY SYSTEM FOR THE RAPID EXCHANGE OF INFORMATION PROVIDED FOR IN ARTICLE 8 1. The system covers products placed on the market as defined in Article 2 (a) of this Directive. Pharmaceuticals, which come under Directive 75/319/EEC and 81/851/EEC, and animals, to which Directive 82/894/EEC applies and products of animal origin, as far as they are covered by Directive 89/662/EEC, and the system for radiological emergencies which covers widespread contamination of products (Decision 87/600/Euratom), are excluded, since they are covered by equivalent notification procedures.

- 2. The system is essentially aimed at a rapid exchange of information in the event of a serious and immediate risk to the health and safety of consumers. It is impossible to lay down specific criteria as to what, precisely, constitutes an immediate and serious risk; in this regard, the national authorities will therefore judge each individual case on its merits. It should be noted that, as Article 8 of this Directive relates to immediate threats posed by a product to consumers, products involving possible long-term risks, which call for a study of possible technical changes by means of directives or standards are not concerned.
- 3. As soon as a serious and immediate risk is detected, the national authority shall consult, insofar as possible and appropriate, the producer or distributor of the product concerned. Their point of view and the details which they supply may be useful both to the administrations of the Member States and to the Commission in determining what action should be taken to ensure that the consumer is protected with a minimum of commercial disruption. To these ends the Member States should endeavor to obtain the maximum of information on the products and the nature of the danger, without compromising the need for rapidity.
- 4. As soon as a Member State has detected a serious and immediate risk, the effects of which extend or could extend beyond its territory, and measures have been taken or decided on, it shall immediately inform the Commission. The Member State shall indicate that it is notifying the Commission under Article 8 of this Directive. All available details shall be given, in particular on:
- (a) information to identify the product;
- (b) the danger involved, including the results of any tests/analyses which are relevant to assessing the level of risk;
- (c) the nature of the measures taken or decided on;

- (d) information on supply chains where such information is possible.
- Such information must be transmitted in writing, preferably by telex or fax, but may be preceded by a telephone call to the Commission. It should be remembered that the speed with which the information is communicated is crucial.
- 5. Without prejudice to point 4, Member States may, where appropriate, pass information to the Commission at the stage preceding the decision on the measures to be taken. Immediate contact, as soon as a risk is discovered or suspected, can in fact facilitate preventive action.
- 6. If the Member State considers certain information to be confidential, it should specify this and justify its request for confidentiality, bearing in mind that the need to take effective measures to protect consumers normally outweighs considerations of confidentiality. It should also be remembered that precautions are taken in all cases, both by the Commission and by the members of the network responsible in the various Member States, to avoid any unnecessary disclosure of information likely to harm the reputation of a product or series of products.
- 7. The Commission shall verify the conformity of the information received with Article 8 of this Directive, contact the notifying country, if necessary, and forward the information immediately by telex or fax to the relevant authorities in the other Member States with a copy to each permanent representation; these authorities may, at the same time as the transmission of the telex, be contacted by telephone. The Commission may also contact the Member State presumed to be the country or origin of the product to carry out the necessary verifications.
- 8. At the same time the Commission, when it considers it to be necessary, and in order to supplement the information received, can in exceptional circumstances institute an investigation of its own motion and/or convene the Committee on Emergencies provided for in Article 10 (1) of this Directive.
- In the case of such an investigation Member States shall supply the Commission with the requested information to the best of their ability.
- 9. The other Member States are requested, wherever possible, to inform the Commission without delay of the following:
- (a) whether the product has been marketed in its territory;
- (b) supplementary information it has obtained on the danger involved, including the results of any tests/analyses carried out to assess the level of risk, and in any case they must inform the Commission as soon as possible of the following:
- (c) the measures taken or decided on, of the type

mentioned in Article 8 (1) of this Directive;

- (d) when the product mentioned in this information has been found within their territory but no measures have been taken or decided on and the reasons why no measures are to be taken.
- 10. The Commission may, in the light of the evolution of a case and the information received from Member States under point 9 above, convene the above Committee on Emergencies in order to exchange views on the results obtained and to evaluate the measures taken. The Committee on Emergencies may also be convened at the request of a representative of a Member State.
- 11. The Commission shall, by means of its internal coordination procedures, endeavor to:
- (a) avoid unnecessary duplication in dealing with notifications:
- (b) make full use of the expertise available within the Commission;
- (c) keep the other services concerned fully informed:
- (d) ensure that discussions in the various relevant committees are held in accordance with Article 10 of this Directive.
- 12. When a Member State intends, apart from any specific measures taken because of serious and immediate risks, to modify its legislation by adopting technical specifications, the latter must be notified to the Commission at the draft stage, in accordance with Directive 83/189/EEC, if necessary, quoting the urgent reasons set out in Article 9 (3) of that Directive.
- 13. To allow it to have an overview of the situation, the Committee on Emergencies shall be periodically informed of all the notifications received and of the follow-up. With regard to points 8 and 10 above, and in those cases which fall within the scope of procedures and/or committees provided for by Community legislation governing specific products or product sectors, those committees shall be involved. In cases where the Committee on Emergencies is not involved and no provisions are made under 11 (d), the contact points shall be informed of any exchange of views within other committees.
- 14. At present there are two networks of contact points: the food products network and the non-food products network. The list of contact points and officials responsible for the networks with telephone, telex and fax numbers and addresses is confidential and distributed to the members of the network only. This list enables contact to be established with the Commission and between Member States in order to facilitate clarification of points of detail. When such contacts between Member States give rise to new information of general interest, the Member States which initiated the bilateral contact shall inform the Commission. Only information received or confirmed through contact points in Member States may be

considered as received through the rapid exchange of information procedure.

Every year the Commission shall carry out a review of the effectiveness of the network, of any necessary improvements and of the progress made in the communications technology between the authorities responsible for its operation.

### Text of the Proposal for a Revised Directive on General Product Safety

The following text of the Proposal for a Directive on General Product Safety has been taken from EUR-Lex, the digital version of the legislation issued in the Official Journal of the European Commission Web Site: ://www.europa.eu.int/eur-lex/en/com/dat/2000/en 500PC0139.html

Only European Community's legislation printed in the Official Journal of the European Communities is deemed to be authentic.

### Amendments:

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on general product safety (Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof, Having regard to the proposal from the Commission [2],

[2] OJ C

Having regard to the opinion of the Economic and Social Committee [3].

[3] OJ C

Whereas:

- (1) Under Article 16 of Council Directive 92/59/EEC of 29 June 1992 on general product safety [4], the Council was to decide, four years after the date set for the implementation of the Directive, on the basis of a report of the Commission on the experience acquired, together with appropriate proposals, whether to adjust the Directive. Since it is necessary to introduce several amendments into the Directive, in order to complete, reinforce or clarify certain of its provisions in the light of experience as well as new and relevant developments on consumer product safety, Directive 92/59/EEC should be recast in the interest of clarity. [4] OJ L 228, 11.8.1992, p. 24.
- (2) It is important to adopt measures with the aim of improving the functioning of the internal market, comprising an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.
- (3) In the absence of Community provisions, horizontal legislation of the Member States on product safety, imposing in particular a general obligation on economic operators to market only safe products, might differ in the level of protection afforded to persons. Such disparities, and the absence of

horizontal legislation in certain Member States, would be liable to create barriers to trade and distortion competition within the internal market.

- (4) In order to ensure a high level of consumer protection, the Community must contribute to protecting the health and safety of consumers. Horizontal Community legislation introducing a general product safety requirement, provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and for rapid exchange of information and action at Community level in certain cases, should contribute to that aim.
- (5) It is very difficult to adopt Community legislation for every product which exists or which may be developed. There is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, and also to cover lacunae and to complement provisions in existing or forthcoming specific legislation, in particular with a view to ensuring a high level of protection of safety and health of persons, as required by Article 95 of the Treaty. (6) It is therefore necessary to establish at Community level a general safety requirement for any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them. In all these cases the products under consideration can pose risks for the health and safety of consumers which must be prevented. Certain second-hand goods
- should nevertheless be excluded by their very nature. (7) The provisions of this Directive should apply to products irrespective of the selling techniques including distance and electronic selling.
- (8) The safety of products should be assessed taking into account the categories of consumers which can be particularly vulnerable to the risks posed by the products under consideration, in particular children and the elderly.
- (9) Production equipment, capital goods and other products used in the context of a trade or business should be covered by this Directive, if they are intended to be used for supplying a service to

consumers, as far as consumer health and safety aspects are concerned. It is necessary, in order to achieve the objectives of this Directive, that manufacturers ensure that such products do not pose risks for the safety of consumers when used under normal or reasonably foreseeable conditions by service providers.

- (10) Products which are designed exclusively for professional use but have subsequently migrated to the consumer market must be subject to the requirements of this Directive because they can pose risks to consumer health and safety when used under reasonably foreseeable conditions.
- (11) In the absence of more specific safety provisions, within the framework of Community legislation covering the products concerned, all the provisions of this Directive are to apply in order to ensure consumer health and safety.
- (12) If specific Community legislation sets out safety requirements covering only certain safety aspects or categories of risks with regard to the products concerned, the obligations of economic operators in respect of the safety requirements, including data generation, hazard identification and risk assessment, should be determined by those provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other aspects.
- (13) Where there are specific rules of Community law of the total harmonisation type, in particular those adopted on the basis of the new approach, which lay down the safety requirements applicable to certain products, further obligations should not be imposed on economic operators as regards the safety requirements to which products must conform in order to be placed on the market. Accordingly, the general safety requirement of this Directive should not apply in such cases.
- (14) The provisions of this Directive relating to the other obligations of producers and distributors, the obligations and powers of the Member States, the exchanges of information and rapid intervention situations and confidentiality should apply in the case of products covered by specific rules of Community law, without prejudice to any specific requirements on the same aspects in such rules.
- (15) In order to facilitate the effective and consistent application of the general safety requirement of this Directive, it is important to establish European voluntary standards covering certain products and risks in such a way that a product which conforms to a national standard transposing a European standard is to be presumed to be in compliance with the said requirement.
- (16) With regard to the aims of this Directive, European standards should be established by

- European standardisation bodies, under mandates set by the Commission assisted by a Committee. The mandates should indicate the objectives that the standards must meet in order to ensure that products in compliance with the standards fulfil the general safety requirement.
- (17) In the absence of specific regulations and when the European standards established under mandates set by the Commission are not available or recourse is not made to them, the safety of products should be assessed taking into account national standards transposing any other relevant European standards, Commission recommendations or, failing those, national standards, codes of practice, the state of the art and the safety which consumers may reasonably expect.
- (18) It is appropriate to supplement the duty to observe the general safety requirement by other obligations on economic operators because action by economic operators is necessary to prevent risks to consumers under certain circumstances.
- (19) The additional obligations on producers should include the duty to adopt measures, commensurate with the characteristics of the products, enabling them to be informed of the risks that these products may present, to supply consumers with information enabling them to assess and prevent risks, to warn consumers of the risks posed by dangerous products already supplied to them, to withdraw those products from the market, and, as a last resort, to recall those products when necessary.
- (20) Distributors must help in ensuring compliance with the applicable safety requirements. Both producers and distributors must cooperate with the competent authorities in action aimed at preventing risks and informing them when they conclude that certain products supplied are dangerous. The conditions regarding such information should be set in the Directive to facilitate its effective application and prevent an excessive burden for the economic operators and the authorities.
- (21) In order to ensure the effective enforcement of the obligations incumbent on producers and distributors, the Member States must establish or designate authorities which are responsible for monitoring product safety and have powers to take appropriate measures, including the power to apply effective proportionate and dissuasive penalties, and ensure appropriate coordination between the various designated authorities.
- (22) It is necessary in particular for the appropriate measures to include the power for Member States to organise or order, immediately and efficiently, the withdrawal of dangerous products already placed on the market, to prohibit the export of dangerous products and as a last resort to recall from consumers

dangerous products already supplied to them. Those powers should be applied when producers and distributors fail to prevent risks to consumers in accordance with their obligations. Where necessary, the appropriate powers and procedures must be available to the authorities to decide authorities to decide and apply any necessary measures rapidly. (23) The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic approaches to ensure the effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and interested parties. (24) Collaboration between the enforcement authorities of the Member States is necessary in ensuring the protection objectives of this Directive. It is, therefore, appropriate to establish a European Product Safety Network between the enforcement authorities of the Member States to facilitate collaboration at operational level on market surveillance and other enforcement activities, in particular risk assessment, testing of products, exchange of expertise and scientific knowledge, execution of joint surveillance projects and tracing, withdrawing or recalling dangerous products. That Network should involve the authorities in charge of the specific products and risks concerned.

- (25) In conformity with the provisions concerning the applicability of this Directive, the provisions relating to collaboration between enforcement authorities should apply without prejudice to specific collaboration procedures established under sectoral Community legislation, in particular in the pharmaceutical sector. The European Product Safety Network should cooperate with relevant bodies in which Member States enforcement authorities collaborate in product sectors covered by specific Community legislation. Systems for Interchange of Data between Administrations may be used in support of that cooperation as appropriate.
- (26) It is necessary, for the purpose of ensuring a consistent, high level of consumer health and safety protection and preserving the unity of the internal market, that the Commission be informed of any measure restricting the placing on the market of a product or requiring its withdrawal or recall from the market. Such measures may be taken only in compliance with the provisions of the Treaty, and in particular Articles 28, 29 and 30.
- (27) Effective supervision of product safety requires the setting-up at national and Community levels of a system of rapid exchange of information in situations of serious risk requiring rapid intervention in respect of the safety of a product. It is also appropriate for this Directive to set out detailed procedures for the

- operation of the system and to give the Commission, assisted by an advisory committee, power to adapt them.
- (28) It is primarily for Member States, in compliance with the Treaty and in particular with Articles 28, 29 and 30 thereof, to take appropriate measures with regard to dangerous products located within their territory.
- (29) However, if the Member States differ as regards the approach to dealing with the risk posed by certain products, such differences could entail unacceptable disparities in consumer protection and constitute a barrier to intra-Community trade.
- (30) It may be necessary to deal with serious productsafety problems requiring rapid intervention which affect or could affect, in the immediate future, all or a significant part of the Community and which, in view of the nature of the safety problem posed by the product, cannot be dealt with effectively in a manner commensurate with the degree of urgency of the problem under the procedures laid down in the specific rules of Community law applicable to the products or category of products in question. (31) It is therefore necessary to provide for an adequate mechanism allowing, as a last resort, for the adoption of measures applicable throughout the Community, in the form of a decision addressed to the Member States, to cope with situations created by products presenting a serious risk and requiring rapid intervention in the abovementioned circumstances and accordingly to ban their export. Such a decision is not of direct application to economic operators and must be incorporated into a national instrument. Measures adopted under such a procedure are interim measures, save when they apply to individually identified products or batches of products. They should be taken by the Commission assisted by a committee composed of representatives of the Member States.
- (32) Since such rapid intervention measures necessary for the implementation of this Directive are measures of general scope within the meaning of Article 2 of Council be created without prejudice to the competence of the regulatory committee. Moreover, the various aspects of its application may need to be discussed between experts from the different national administrations in charge of enforcement and market surveillance activities.
- (34) Public access to the information available to the authorities on product safety should be ensured. However professional secrecy, as referred to in Article 287 of the Treaty, must be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.
- (35) This Directive should not affect victims' rights

within the meaning of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [6].

- [6] OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).
- (36) It is necessary for Member States to provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal or recall.
- (37) In addition, the adoption of measures concerning imported products with a view to preventing risks to the safety and health of persons must comply with the Community's international obligations.
- (38) The Commission should periodically examine how this Directive is applied and the results obtained, in particular in relation to the functioning of market surveillance systems, the rapid exchange of information and measures at Community level, together with other issues relevant for consumer product safety in the Community, and present reports to the European Parliament and the Council on the subject.
- (39) This Directive should not affect the obligations of Member States concerning the deadlines for transposition and application of Directive 92/59/EEC, HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

Objective - Scope - Definitions Article 1

- 1. The purpose of this Directive is to ensure that the products referred to in Article 2(a) placed on the market are safe.
- 2. This Directive shall apply only in so far as there are no specific provisions in rules of Community law governing the safety of the products concerned. In particular, where products are subject to safety requirements imposed by Community legislation specific to those products:
- Articles 2, 3 and 4 of this Directive shall not apply to those products in so far as concerns the risks or categories of risks regulated by the specific legislation; the other Articles of this Directive shall apply in so far as there are no specific provisions in that legislation governing the aspects covered by the said Articles of this Directive.

### Article 2

For the purposes of this Directive:

(a) "product" shall mean any product which is intended for consumers, or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity and whether new, used or reconditioned.

This definition includes products used to provide a service, in so far as consumer product safety aspects under reasonably foreseeable conditions of use of those products are concerned.

It does not include second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

- (b) "safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:
- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance.
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products, (iii) the presentation of the product, the labelling, any
- instructions for its use and disposal and any other indication or information provided by the producer and by distributors,
- (iv) the categories of consumers at risk when using the product, in particular children and the elderly,
- (v) the services directly associated with the product supplied, when these services are provided by the producer, in particular the installing and the maintenance of the product.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'unsafe' or 'dangerous';

- (c) "dangerous product" shall mean any product which does not meet the definition of 'safe product' in point (b):
- (d) "producer" shall mean:
- (i) the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product,
- (ii) the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product,
- (iii) other professionals in the supply chain, in so far as their activities may affect the safety properties of a product placed on the market;
- (e) "distributor" shall mean any professional in the supply chain whose activity does not affect the safety

properties of a product;

(f) "recall" shall mean any measures aimed at achieving the return of a dangerous product, for reimbursement or replacement or repair, that has already been supplied or made available to consumers by the producer or distributor.

CHAPTER II

General safety requirement, conformity assessment criteria and European standards
Article 3

- 1. Producers shall be obliged to place only safe products on the market.
- 2. Where there are no specific Community provisions governing the safety of the products in question, a product shall be deemed safe when it conforms to the specific rules of national law of the Member State in whose territory the product is lawfully produced or marketed, such rules being drawn up in conformity with the Treaty, and in particular Articles 28 and 30 thereof, and laying down the health and safety requirements which the product must satisfy in order to be marketed. The product shall be deemed safe in so far as the aspects covered by the rules of national law are concerned.

Products in conformity with voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the European Communities in accordance with Article 4 shall be presumed to be in conformity with the general safety requirement of this Directive, in so far as the aspects covered by those standards are concerned. The Member States shall publish the references of such national standards.

- 3. In the absence of specific rules or national standards transposing European standards as referred to in paragraph 2 or when recourse is not made to such standards, the conformity of a product to the general safety requirement shall be assessed having regard, where they exist, to voluntary national standards giving effect to other relevant European standards, to Commission recommendations setting guidelines on product safety assessment or, failing these, to standards drawn up in the Member State in which the product is lawfully produced or marketed, to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.
- 4. Conformity of a product with the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market where there is evidence that, despite such conformity, it is dangerous to the

health and safety of consumers.

Article 4

this Directive.

1. For the purposes of this Directive, the Commission shall establish the mandates to the European standardization bodies and publish in the Official Journal of the European Communities the references of European standards. Where there is evidence that a standard does not ensure compliance with the general safety requirement of this Directive, the Commission shall withdraw such publication in whole or in part, in accordance with paragraph 4. The mandates shall be established in accordance with Directive 98/34/EC of the European Parliament and of the Council [7]. The Commission shall ensure coordination with the Regulatory Committee on Consumer Product Safety referred to in Article 14(1) of

[7] OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18). The mandates shall define the objectives that the standards must meet to ensure that products conforming to such standards are in compliance with the general safety requirement of this Directive.

- 2. The standards referred to in paragraph 1 shall be adopted by European Standardization Bodies, in accordance with the principles contained in the general guidelines for cooperation between the Commission and those Bodies.
- 3. The Commission, after consulting the Committee established by Article 5 of Directive 98/34/EC, may decide to publish in the Official Journal of the European Communities the references of European standards relating to products covered by this Directive which were adopted by European Standardisation Bodies before the entry into force of this Directive.
- 4. Where a Member State or the Commission considers that a European standard referred to in Article 3(2) does not satisfy the general safety requirement of this Directive, the Commission or the Member State shall refer the matter to the Committee established by Directive 98/34/EC, setting out its reasons. After receiving the Committee's opinion, the Commission shall notify the Member States whether or not the standard concerned or a part thereof has to be withdrawn from publication as referred to in Article 3(2) of this Directive.

CHAPTER III

Other obligations of producers and obligations of distributors

Article 5

1. Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such

risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Provision of warnings does not, however, exempt any person from compliance with the other requirements laid down in this Directive.

Also within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present and to take appropriate action including, if necessary to avoid these risks, withdrawing the products in question from the market, adequately and effectively warning consumers of the risks posed by the products, or, in the last resort, recalling from consumers products already supplied to them when other measures would not suffice to prevent the risks involved.

The measures shall for example include, whenever appropriate, marking of the products or product batches in such a way that they can be identified, sample testing of marketed products, investigating complaints made and keeping distributors informed of such monitoring.

- 2. Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, safeguarding and providing documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks.
- 3. Producers and distributors shall immediately inform the competent authorities of the Member States if they conclude that a product that they have placed on the market is dangerous. They shall in particular inform the authorities of the action taken to prevent risks to consumers. Specific requirements for this information are set out in Annex I. They shall be adapted by the Commission Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [5], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision. [5] OJ L 184, 17.7.1999, p. 23.
- (33) In accordance with Article 2 of Decision 1999/468/EC, the other measures necessary for the implementation of this Directive should be adopted by use of the advisory procedure provided for in Article 3 of that Decision. An Advisory Committee on Consumer Product Safety should therefore be created without

prejudice to the competence of the regulatory committee. Moreover, the various aspects of its application may need to be discussed between experts from the different national administrations in charge of enforcement and market surveillance activities.

- (34) Public access to the information available to the authorities on product safety should be ensured. However professional secrecy, as referred to in Article 287 of the Treaty, must be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.
- (35) This Directive should not affect victims' rights within the meaning of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [6].
- [6] OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20). (36) It is necessary for Member States to provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal or recall.
- (37) In addition, the adoption of measures concerning imported products with a view to preventing risks to the safety and health of persons must comply with the Community's international obligations.
- (38) The Commission should periodically examine how this Directive is applied and the results obtained, in particular in relation to the functioning of market surveillance systems, the rapid exchange of information and measures at Community level, together with other issues relevant for consumer product safety in the Community, and present reports to the European Parliament and the Council on the subject.
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This definition includes products used to provide a service, in so far as consumer product safety aspects under reasonably foreseeable conditions of use of those products are concerned.

It does not include second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

- (b) "safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use, including duration, does not present any risk or only the minimum risks compatible with the product's use, considered as acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:
- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and maintenance.
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products,
- (iii) the presentation of the product, the labelling, any instructions for its use and disposal and any other indication or information provided by the producer and by distributors,
- (iv) the categories of consumers at risk when using the product, in particular children and the elderly,
- (v) the services directly associated with the product supplied, when these services are provided by the producer, in particular the installing and the maintenance of the product.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'unsafe' or 'dangerous'; (c) "dangerous product" shall mean any product which does not meet the definition of 'safe product' in point (b):

- (d) "producer" shall mean:
- (i) the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product,
- (ii) the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product,
- (iii) other professionals in the supply chain, in so far as their activities may affect the safety properties of a product placed on the market;
- (e) "distributor" shall mean any professional in the supply chain whose activity does not affect the safety properties of a product;
- (f) "recall" shall mean any measures aimed at achieving the return of a dangerous product, for reimbursement or replacement or repair, that has already been supplied or made available to consumers by the producer or distributor.

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Products in conformity with voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the European Communities in accordance with Article 4 shall be presumed to be in conformity with the general safety requirement of this Directive, in so far as the aspects covered by those standards are concerned. The Member States shall publish the references of such national standards.

3. In the absence of specific rules or national standards transposing European standards as referred to in paragraph 2 or when recourse is not made to such standards, the conformity of a product to the general safety requirement shall be assessed having regard, where they exist, to voluntary national

standards giving effect to other relevant European standards, to Commission recommendations setting guidelines on product safety assessment or, failing these, to standards drawn up in the Member State in which the product is lawfully produced or marketed, to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.

4. Conformity of a product with the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market where there is evidence that, despite such conformity, it is dangerous to the health and safety of consumers.

Article 4

1. For the purposes of this Directive, the Commission shall establish the mandates to the European standardization bodies and publish in the Official Journal of the European Communities the references of European standards. Where there is evidence that a standard does not ensure compliance with the general safety requirement of this Directive, the Commission shall withdraw such publication in whole or in part, in accordance with paragraph 4. The mandates shall be established in accordance with Directive 98/34/EC of the European Parliament and of the Council [7]. The Commission shall ensure coordination with the Regulatory Committee on Consumer Product Safety referred to in Article 14(1) of this Directive.

[7] OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18). The mandates shall define the objectives that the standards must meet to ensure that products conforming to such standards are in compliance with the general safety requirement of this Directive.

- 2. The standards referred to in paragraph 1 shall be adopted by European Standardization Bodies, in accordance with the principles contained in the general guidelines for cooperation between the Commission and those Bodies.
- 3. The Commission, after consulting the Committee established by Article 5 of Directive 98/34/EC, may decide to publish in the Official Journal of the European Communities the references of European standards relating to products covered by this Directive which were adopted by European Standardisation Bodies before the entry into force of this Directive.
- 4. Where a Member State or the Commission considers that a European standard referred to in Article 3(2) does not satisfy the general safety requirement of this Directive, the Commission or the

Member State shall refer the matter to the Committee established by Directive 98/34/EC, setting out its reasons. After receiving the Committee's opinion, the Commission shall notify the Member States whether or not the standard concerned or a part thereof has to be withdrawn from publication as referred to in Article 3(2) of this Directive.

### CHAPTER III

Other obligations of producers and obligations of distributors

#### Article 5

1. Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Provision of warnings does not, however, exempt any person from compliance with the other requirements laid down in this Directive.

Also within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present and to take appropriate action including, if necessary to avoid these risks, withdrawing the products in question from the market, adequately and effectively warning consumers of the risks posed by the products, or, in the last resort, recalling from consumers products already supplied to them when other measures would not suffice to prevent the risks involved.

The measures shall for example include, whenever appropriate, marking of the products or product batches in such a way that they can be identified, sample testing of marketed products, investigating complaints made and keeping distributors informed of such monitoring.

- 2. Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, safeguarding and providing documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks.
- 3. Producers and distributors shall immediately inform the competent authorities of the Member States if they conclude that a product that they have placed on the

market is dangerous. They shall in particular inform the authorities of the action taken to prevent risks to consumers. Specific requirements for this information are set out in Annex I. They shall be adapted by the Commission acting in accordance with the procedure referred to in Article 15(2).

4. Producers and distributors, within the limits of their respective activities, shall collaborate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The competent authorities shall define the procedures for such collaboration, including procedures for dialogue with the producers and distributors concerned on issues related to consumer product safety enforcement.

#### CHAPTER IV

Specific obligations and powers of the Member States Article 6

- 1. Member States shall ensure that producers and distributors comply with their obligations under this Directive in such a way that products placed on the market are safe.
- 2. In particular, Member States shall establish or nominate authorities competent to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers and responsibility to take the appropriate measures incumbent upon them under this Directive.
- 3. The Member States shall define the tasks, organisation and powers of the authorities competent for the various product categories, risk aspects and surveillance activities, as well as the appropriate arrangements for the exchange of information, coordination and collaboration between such authorities and shall notify the Commission thereof, as well as any subsequent modification thereto. The Commission shall pass on such information to the other Member States.

### Article 7

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 20(1) at the latest and shall also notify it, without delay, of any subsequent amendment affecting them.

### Article 8

1. In order to achieve the objectives of this Directive and in particular for the purposes of Article 6, the competent authorities of the Member States shall have the necessary powers, and take the necessary action

- in accordance with the degree of risk and in conformity with the Treaty, and in particular Articles 28 and 30 thereof, to adopt appropriate measures with a view to: (a) organising appropriate checks on the safety properties of products, even after their being placed on the market as being safe, on an adequate scale, up to the final stage of use or consumption;
- (b) requiring all necessary information from the parties concerned;
- (c) taking samples of products and subjecting them to safety checks:
- (d) subjecting product marketing to prior conditions designed to ensure product safety and requiring that suitable warnings be affixed regarding the risks which the product may present;
- (e) making arrangements to ensure that persons who might be exposed to a risk from certain products are informed in good time and in a suitable manner of the said risk by, inter alia, the publication of special warnings:
- (f) temporarily prohibiting, for the period required to carry out the various checks, verifications or safety assessments, anyone from supplying, offering to supply or exhibiting, certain products whenever there are precise and consistent indications that they could be dangerous:
- (g) prohibiting the placing on the market of dangerous products and establishing the accompanying measures needed to ensure that the ban is complied with:
- (h) organising or ordering, the effective and immediate withdrawal of dangerous products already on the market, the warning of consumers on the risks posed by dangerous products, the recalling from consumers of those products already supplied, and the destruction of the products in question under appropriate conditions, if necessary, in cases where action by producers and distributors to the same aims, in conformity to their obligation under this Directive, is not satisfactory or is insufficient.
- 2. In particular, the competent authorities shall have the necessary powers and take the necessary action, to apply with due rapidity appropriate measures among those mentioned in paragraph 1(d) to (h), in the case of products posing a serious risk which requires rapid intervention.
- 3. The measures to be taken by the competent authorities under paragraphs 1 and 2 shall be addressed, as appropriate, to:
- (a) the producer;

a product.

(b) within the limits of their respective activities, distributors and in particular the party responsible for the first stage of distribution on the national market;(c) any other person, where necessary, with regard to cooperation in action taken to avoid risks arising from

### Article 9

- 1. The approaches established by the Member States for operating effective market surveillance, including the working procedures and the procedures for exchanging information and coordination and collaboration between the various authorities concerned, shall aim at guaranteeing a high level of consumer health and safety protection.
- 2. In order to achieve the objective referred to in paragraph 1, the Member States shall ensure that appropriate and effective means and procedures are put in place, which may include in particular:
- (a) the establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks;
- (b) the follow-up and updating of scientific knowledge concerning the safety of products publicly available. periodical reports on surveillance activities, findings and results achieved;
- (c) periodical reviewing and assessments of the functioning of the control activities and their effectiveness, and, if necessary, revision of the surveillance approach and organisation put in place.
- 3. The Member States shall ensure that consumers and other interested parties may present complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are considered, followed up as appropriate and answered. The Member States shall actively inform consumers and the other interested parties of the procedures established to that end.

### Article 10

- 1. The Commission shall promote the establishment and operation of a European Product Safety Network between the authorities of the Member States competent for market surveillance of consumer products and involving also the Commission.
- 2. The Network shall cooperate with relevant bodies in product sectors covered by the legislation referred to in Article 1(2) and shall have as its objectives, in particular, to facilitate:
- (a) the exchange of information on risk assessment, dangerous products, test methods and results, the recent scientific developments as well as other aspects relevant for control activities;
- (b) the establishment and execution of joint surveillance and testing projects;
- (c) the exchange of expertise and best practices and collaboration in training activities;
- (d) coordination at Community level of tracing, withdrawal and recall of dangerous products. CHAPTER V

Exchanges of information and rapid intervention situations

### Article 11

1. Where a Member State takes measures which

restrict the placing on the market of products or require their withdrawal from the market, or the recall from consumers of those products already supplied. as provided for in Article 8(1)(d) to (h), the Member State shall, to the extent that such notification is not required under Article 12 or any specific Community legislation, inform the Commission of the measures, specifying its reasons for adopting them. Where the notifying Member State considers that the measures relate to an event which is local in effect and in any case limited to its territory, the notification will specify it. It shall also inform the Commission of any modification or withdrawal of such measures. The guidelines referred to in Annex II, point 8, shall define the contents and standard form for the notifications provided for in this Article. In particular the guidelines shall provide criteria for determining which measures related to purely local events must not be notified because they are not relevant for the aims of this Article.

- 2. The Commission shall forward the notification to the other Member States, unless it concludes, after examination, that the measure does not comply with Community law. In such a case, it shall immediately inform the Member State which initiated the action. Article 12
- 1. Where a Member State adopts or decides to adopt, recommend or agree with manufacturers, importers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk for the health and safety of consumers which requires rapid intervention, it shall immediately inform the Commission thereof through the Community Rapid Information System (RAPEX). The Member States shall also inform the Commission without delay of any modification or withdrawal of such measures or actions.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, the notification shall indicate it taking into account the relevant criteria established in the guidelines referred to in Annex II, point 8.

Without prejudice to the first subparagraph, Member States may pass on to the Commission any information in their possession regarding the existence of a serious risk requiring rapid intervention before deciding to adopt the measures or action in question.

- 2. On receiving this information, the Commission shall check whether it complies with the requirements applicable to the functioning of RAPEX, and shall forward it to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.
- 3. Detailed procedures for RAPEX are set out in

Annex II. They shall be adapted by the Commission in accordance with the procedure referred to in Article 15(2).

4. Access to RAPEX may be open to candidate countries, third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to modalities defined in these agreements. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Community.

#### Article 13

- 1. If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States requiring rapid action, it may, after consulting the Member States, adopt a decision, in accordance with the procedure laid down in Article 14(1), requiring Member States to take measures from among those listed in Article 8(1)(d) to (h) if:
- (a) Member States differ on the approach to deal with the risk:
- (b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product and in a manner compatible with the degree of urgency of the case, under other procedures laid down by the specific Community legislation applicable to the products concerned; and
- (c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.
- 2. Decisions referred to in paragraph 1 shall be valid for a period not exceeding one year and may be confirmed, under the same procedure, for additional periods of one year.

However, decisions concerning specific, individually identified products or batches of products, shall be valid without a time-limit.

- 3. Export from the Community of products for which Member States have been required to take measures among those listed in Article 8(1)(f), (g) and (h) shall be prohibited.
- 4. The Member States shall take all necessary measures to implement the decisions referred to in paragraph 1 within less than 10 days, unless a different period is specified in those decisions.
- 5. The competent authorities responsible for carrying out the measures referred to in paragraph 1 shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.

CHAPTER VI

## Committee procedures

#### Article 14

- 1. The Commission shall be assisted by a Regulatory Committee on Consumer Product Safety, composed of representatives of the Member States and chaired by a representative of the Commission.
- 2. In cases where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof. The period provided for in Article 5(6) of Decision 1999/468/EC shall be fifteen days.

## Article 15

- 1. The Commission shall be assisted by an Advisory Committee on Consumer Product Safety composed of representatives of the Member States and chaired by the representative of the Commission.
- 2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.
- 3. The Advisory Committee on Consumer Product Safety shall also assist the Commission in examining any question concerning the application of this Directive, in particular issues related to enforcement and market surveillance activities.

#### CHAPTER VII

Miscellaneous and final provisions
Article 16

1. Information available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public. In particular the public shall have access to information on product identification, the nature of the risk and the measures taken.

However, the Member States and the Commission shall take the steps necessary to ensure that their officials and agents are required not to disclose information obtained for the purposes of this Directive which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public if circumstances so require, in order to protect the health and safety of consumers.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant for ensuring the effectiveness of market surveillance and enforcement activities. The authorities receiving information covered by professional secrecy shall ensure its protection.

#### Article 17

This Directive shall be without prejudice to Directive 85/374/EEC.

#### Article 18

1. Any measure adopted under this Directive and

involving restrictions on the placing of a product on the market, or requiring its withdrawal from the market, or its recall from consumers must state the appropriate reasons on which it is based. It shall be notified as soon as possible to the party concerned and shall indicate the remedies available under the provisions in force in the Member State in question and the time limits applying to such remedies.

The parties concerned shall, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. If this has not been done in advance because of the urgency of the measures to be taken, such opportunity shall be given in due course after the measure has been implemented. Measures requiring the withdrawal of a product from the market or its recall from consumers shall take into consideration the need to encourage distributors, users and consumers to contribute to the implementation of such measures.

- 2. Member States shall ensure that any measure taken by the competent authorities involving restrictions on the placing of a product on the market or requiring its withdrawal from the market or recall from consumers can be challenged before the competent courts.
- 3. Any decision taken by virtue of this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal from the market or its recall from consumers shall be without prejudice to assessment of the liability of the party concerned, in the light of the national criminal law applying in the case in question.

## Article 19

- 1. Every three years following the date referred to in Article 20(1), the Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council.
- 2. The report shall in particular include information on the safety of consumer products, the functioning of market surveillance, standardisation work, the functioning of RAPEX and Community measures taken on the basis of Article 13. To this end the Commission shall conduct assessments of the relevant issues, in particular the approaches, systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Community legislation relating to product safety. The Member States shall provide the Commission with all the necessary assistance and information for performing the assessments and preparing the reports.

#### Article 20

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive with effect from 1 January 2003. They shall forthwith inform the Commission

#### thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive. Article 21

Directive 92/59/EEC is hereby repealed with effect from 1 January 2003 without prejudice to the obligations of Member States concerning the deadlines for transposition and for application of the repealed Directive as indicated in Annex III. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

#### Article 22

This Directive is addressed to the Member States. Done at Brussels,

For the European Parliament For the Council The President The President

# ANNEX I REQUIREMENTS CONCERNING INFORMATION ON DANGEROUS PRODUCTS TO BE PROVIDED TO COMPETENT AUTHORITIES BY PRODUCERS AND DISTRIBUTORS

- 1. The Information must be provided in cases where producers or distributors conclude, based on data, test results or other information which become available to them, that a product which they supply is not safe, within the meaning of Article 2(b) or, as appropriate, in the light of the specific safety requirements set in rules of Community law applicable to the product considered.
- 2. This requirement applies in the case of product lines or batches, not for individual dangerous products.
- 3. The information to be provided shall include at least:
- the details that permit a precise identification of the product or product batch in question;
- full description of the risk posed by the products concerned;
- all available information, useful to trace the product;
- description of action taken to prevent risks to consumers.
- 4. The information shall be provided to the authorities designated for that purpose in the Member States where the products in question are or have been placed on the market or otherwise supplied to consumers.

ANNEX II PROCEDURES FOR THE APPLICATION

OF THE COMMUNITY RAPID INFORMATION SYSTEM (RAPEX) PROVIDED FOR IN ARTICLE 13 AND GUIDELINES FOR NOTIFICATIONS REFERRED TO IN ARTICLES 12 AND 13

1. The system covers products as defined in Article 2(a) of this Directive that present a serious risk to the health and safety of consumers which requires rapid intervention.

Pharmaceuticals, which come under Directives 75/319/EEC and 81/851/EEC, are excluded from the application of the RAPEX system.

- 2. The system is essentially aimed at a rapid exchange of information in the event of a serious risk to the health and safety of consumers requiring rapid intervention. In this regard, the national authorities will judge each individual case on its merits taking into account the guidelines referred to in point 8 which will define specific criteria for identifying serious risks requiring rapid intervention.
- 3. Member States notifying under Article 12 of this Directive shall give all available details. In particular, the notification shall contain the information stipulated in the guidelines referred to in point 8 and at least:
- (a) information to identify the product;
- (b) a description of the danger involved, including a summary of the results of any tests/analyses and of their conclusions which are relevant to assessing the level of risk:
- (c) the nature and the duration of the measures or action taken or decided on, if applicable;
- (d) information on supply chains and distribution of the product.

Such information must be transmitted, using the special standard notification form and by the means stipulated in the guidelines referred to in point 8. When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States shall provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available. They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93 in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC in the case of a new substance. The guidelines referred to in point 8 shall define the details and procedures for the information requested in that respect.

4. When a Member State has informed the Commission, according to Article 12(1), third subparagraph, about a serious risk, before deciding to

adopt measures it must inform the Commission within a deadline of 45 days whether it confirms of modifies this information.5. The Commission shall verify, in the shortest time possible, the conformity with the provisions of this Directive of the information received under this rapid information system and, when it considers it to be necessary and in order to assess product safety, may carry out an investigation of its own motion. In the case of such an investigation Member States shall supply the Commission with the requested information to the best of their ability. 6. Upon receipt of a notification the Member States are requested, to inform the Commission, at the latest within the set period of time stipulated in the guidelines referred to at point 8, of the following: (a) whether the product has been marketed in their territory and if they have adopted or intend to adopt the same or different measure(s) or action(s) adapted to their own circumstances or they consider it is not necessary to adopt measure(s) or action(s) for the product concerned in view of their own circumstances and explain why:

- (b) supplementary information they have obtained on the danger involved, including the results of any tests/analyses carried out to assess the level of risk;
- (c) whether they disagree with the measure(s) or action(s) in question and explain why;
- (d) whether they consider that no follow-up is necessary and they explain why;
- (e) whether it is unnecessary to adopt measures or take action for the products concerned under their circumstances and why.

The guidelines referred to in point 8 shall specify how to deal with notifications concerning risks which are considered by the Member State notifying not to go beyond its territory.

- 7. Member States shall immediately inform the Commission of any modification, or withdrawal of the measure(s) or action(s) in question.
- 8. Guidelines concerning the operation of the exchange of information system by the Commission and the Member States, shall be prepared and regularly up-dated by the Commission assisted by the Advisory Committee set up under Article 15(1).
- 9. The Commission may inform the national contact points regarding products posing risks requiring rapid action, imported to or exported from the European Community and the European Economic Area.
- 10. The responsibility for the accuracy of the information provided and the liability for it lie with the notifying Member State.
- 11. The Commission shall ensure the proper functioning of the system.

ANNEX III REPEALED DIRECTIVE AND DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW AND

FOR APPLICATION
Repealed Directive (referred to in Article 21): Council

Directive 92/59/EEC; Deadlines for transposition and for application (referred to in Article 21): 29 June 1994.

## **Correlation Table**

## Directive 92/59/EEC

## Article 1

- 1. The purpose of the provisions of this Directive is to ensure that products placed on the market are safe.
- 2. The provisions of this Directive shall apply in so far as there are no specific provisions in rules of Community law governing the safety of the products concerned.

In particular, where specific rules of Community law contain provisions imposing safety requirements on the products which they govern, the provisions of Articles 2 to 4 of this Directive shall not, in any event, apply to those products. 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.

#### Article 4

- 1. Where there are no specific Community provisions governing the safety of the products in question, a product shall be deemed safe when it conforms to the specific rules of national law of the Member State in whose territory the product is in circulation, such rules being drawn up in conformity with the Treaty, and in particular Articles 30 and 36 thereof, and laying down the health and safety requirements which the product must satisfy in order to be marketed.
- 2. In the absence of specific rules as referred to in paragraph 1, the conformity of a product to the general safety requirement shall be assessed having regard to voluntary national standards giving effect to a European standard or,

## **Proposed Revision to the Directive**

#### Article

- 1. The purpose of this Directive is to ensure that the products referred to in Article 2(a) placed on the market are safe.
- 2. This Directive shall apply only in so far as there are no specific provisions in rules of Community law governing the safety of the products concerned.

In particular, where products are subject to safety requirements imposed by Community legislation specific to those products:

- Articles 2, 3 and 4 of this Directive shall not apply to those products in so far as concerns the risks or categories of risks regulated by the specific legislation;
- the other Articles of this Directive shall apply in so far as there are no specific provisions in that legislation governing the aspects covered by the said Articles of this Directive.

#### Article 3

- 1. Producers shall be obliged to place only safe products on the market.
- 2. Where there are no specific Community provisions governing the safety of the products in question, a product shall be deemed safe when it conforms to the specific rules of national law of the Member State in whose territory the product is lawfully produced or marketed, such rules being drawn up in conformity with the Treaty, and in particular Articles 28 and 30 thereof, and laying down the health and safety requirements which the product must satisfy in order to be marketed. The product shall be deemed safe in so far as the aspects covered by the rules of national law are concerned. Products in conformity with voluntary national standards transposing European standards, the references of which have

where they exist, to Community technical specifications or, failing these, to standards drawn up in the Member State in which the product is in circulation, or to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.

- 3. Conformity of a product with the provisions mentioned in paragraphs 1 or 2 shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market where there is evidence that, despite such conformity, it is dangerous to the health and safety of consumers.
- been published by the Commission in the Official Journal of the European Communities in accordance with Article 4 shall be presumed to be in conformity with the general safety requirement of this Directive, in so far as the aspects covered by those standards are concerned. The Member States shall publish the references of such national standards.
- 3. In the absence of specific rules or national standards transposing European standards as referred to in paragraph 2 or when recourse is not made to such standards, the conformity of a product to the general safety requirement shall be assessed having regard, where they exist, to voluntary national standards giving effect to other relevant European standards, to Commission recommendations setting guidelines on product safety assessment or, failing these, to standards drawn up in the Member State in which the product is lawfully produced or marketed, to the codes of good practice in respect of health and safety in the sector concerned or to the state of the art and technology and to the safety which consumers may reasonably expect.
- 4. Conformity of a product with the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market where there is evidence that, despite such conformity, it is dangerous to the health and safety of consumers.

## Article 4

1. For the purposes of this Directive, the Commission shall establish the mandates to the European standardization bodies and publish in the Official Journal of the European Communities the references of European standards. Where there is evidence that a standard does not ensure compliance with the general safety

requirement of this Directive, the Commission shall withdraw such publication in whole or in part, in accordance with paragraph 4. The mandates shall be established in accordance with Directive 98/34/EC of the European Parliament and of the Council [7]. The Commission shall ensure coordination with the Regulatory Committee on Consumer Product Safety referred to in Article 14(1) of this Directive.

7] OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

The mandates shall define the objectives that the standards must meet to ensure that products conforming to such standards are in compliance with the general safety requirement of this Directive.

- 2. The standards referred to in paragraph 1 shall be adopted by European Standardization Bodies, in accordance with the principles contained in the general guidelines for cooperation between the Commission and those Bodies.
- 3. The Commission, after consulting the Committee established by Article 5 of Directive 98/34/EC, may decide to publish in the Official Journal of the European Communities the references of European standards relating to products covered by this

Directive which were adopted by European Standardisation Bodies before the entry into force of this Directive.

4. Where a Member State or the Commission considers that a European standard referred to in Article 3(2) does not satisfy the general safety requirement of this Directive, the Commission or the Member State shall refer the matter to the Committee established by Directive 98/34/EC, setting out its reasons. After

## Article 3

- 1. Producers shall be obliged to place only safe products on the market.
- 2. Within the limits of their respective activities, producers shall:
- provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Provision of such warnings does not, however, exempt any person from compliance with the other requirements laid down in this Directive,
- adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present and to take appropriate action including, if necessary, withdrawing the product in question from the market to avoid these risks.

The above measures shall for example include, whenever appropriate, marking of the products or product batches in such a way that they can be identified, sample testing of marketed products, investigating complaints made and keeping distributors informed of such monitoring.

3. Distributors shall be required to act with due care in order to help to ensure compliance with the general safety requirement, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do receiving the Committee's opinion, the Commission shall notify the Member States whether or not the standard concerned or a part thereof has to be withdrawn from publication as referred to in Article 3(2) of this Directive.

Other obligations of producers and obligations of distributors
Article 5

1. Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. Provision of warnings does not, however, exempt any person from compliance with the other requirements laid down in this Directive.

Also within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, to enable them to be informed of risks which these products might present and to take appropriate action including, if necessary to avoid these risks, withdrawing the products in question from the market, adequately and effectively warning consumers of the risks posed by the products, or, in the last resort, recalling from consumers products already supplied to them when other measures would not suffice to prevent the risks involved. The measures shall for example include, whenever appropriate, marking of the products or product batches in such a way that they can be identified, sample testing of marketed products, investigating complaints made and keeping distributors informed of such monitoring.

2. Distributors shall be required to act with due care to help to ensure compliance with

not comply with this requirement. In particular, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks and cooperating in the action taken to avoid these risks.

the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, safeguarding and providing documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks.

- 3. Producers and distributors shall immediately inform the competent authorities of the Member States if they conclude that a product that they have placed on the market is dangerous. They shall in particular inform the authorities of the action taken to prevent risks to consumers. Specific requirements for this information are set out in Annex I. They shall be adapted by the Commission acting in accordance with the procedure referred to in Article 15(2).
- 4. Producers and distributors, within the limits of their respective activities, shall collaborate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The competent authorities shall define the procedures for such collaboration, including procedures for dialogue with the producers and distributors concerned on issues related to consumer product safety enforcement.

TITLE III Obligations and powers of the Member States

Article 5

Member States shall adopt the necessary laws, regulations and administrative provisions to make producers and distributors comply with their obligations under this Directive in such a way that Specific obligations and powers of the Member States

Article 6

1. Member States shall ensure that producers and distributors comply with their obligations under this Directive in such a way that products placed on the market are safe.

products placed on the market are safe. In particular, Member States shall establish or nominate authorities to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers to take the appropriate measures incumbent upon them under this Directive, including the possibility of imposing suitable penalties in the event of failure to comply with the obligations deriving from this Directive. They shall notify the Commission of the said authorities; the Commission shall pass on the information to the other Member States.

- 2. In particular, Member States shall establish or nominate authorities competent to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers and responsibility to take the appropriate measures incumbent upon them under this Directive.
- 3. The Member States shall define the tasks, organisation and powers of the authorities competent for the various product categories, risk aspects and surveillance activities, as well as the appropriate arrangements for the exchange of information, coordination and collaboration between such authorities and shall notify the Commission thereof, as well as any subsequent modification thereto. The Commission shall pass on such information to the other Member States.

## TITLE III Obligations and powers of the Member States Article 5

In particular, Member States shall establish or nominate authorities to monitor the compliance of products with the obligation to place only safe products on the market and arrange for such authorities to have the necessary powers to take the appropriate measures incumbent upon them under this Directive, including the possibility of imposing suitable penalties in the event of failure to comply with the obligations deriving from this Directive. They shall notify the Commission of the said authorities; the Commission shall pass on the information to the other Member States.

## Article 7

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by the date specified in Article 20(1) at the latest and shall also notify it, without delay, of any subsequent amendment affecting them.

## Article 6

1. For the purposes of Article 5, Member States shall have the necessary powers, acting in accordance with the degree or risk and in conformity with the Treaty, and in particular Articles 30 and 36 thereof, to

### Article 8

1. In order to achieve the objectives of this Directive and in particular for the purposes of Article 6, the competent authorities of the Member States shall have the necessary powers, and take the necessary action in

- adopt appropriate measures with a view, inter alia, to:
- (a) organizing appropriate checks on the safety properties of products, even after their being placed on the market as being safe, on an adequate scale, up to the final stage of use or consumption;
- (b) requiring all necessary information from the parties concerned;
- (c) taking samples of a product or a product line and subjecting them to safety checks;
- (d) subjecting product marketing to prior conditions designed to ensure product safety and requiring that suitable warnings be affixed regarding the risks which the product may present;
- (e) making arrangements to ensure that persons who might be exposed to a risk from a product are informed in good time and in a suitable manner of the said risk by, inter alia, the publication of special warnings;
- (f) temporarily prohibiting, for the period required to carry out the various checks, anyone from supplying, offering to supply or exhibiting a product or product batch, whenever there are precise and consistent indications that they are dangerous;
- (g) prohibiting the placing on the market of a product or product batch which has proved dangerous and establishing the accompanying measures needed to ensure that the ban is complied with;
- (h) organizing the effective and immediate withdrawal of a dangerous product or product batch already on the market and, if necessary, its destruction under appropriate conditions.
- 2. The measures to be taken by the competent authorities of the Member States under this Article shall be addressed, as appropriate, to:
- (a) the producer;
- (b) within the limits of their respective activities, distributors and in particular the party responsible for the first stage of

- accordance with the degree of risk and in conformity with the Treaty, and in particular Articles 28 and 30 thereof, to adopt appropriate measures with a view to: (a) organising appropriate checks on the safety properties of products, even after their being placed on the market as being safe, on an adequate scale, up to the final stage of use or consumption;
- b) requiring all necessary information from the parties concerned;
- (c) taking samples of products and subjecting them to safety checks;
- (d) subjecting product marketing to prior conditions designed to ensure product safety and requiring that suitable warnings be affixed regarding the risks which the product may present;
- (e) making arrangements to ensure that persons who might be exposed to a risk from certain products are informed in good time and in a suitable manner of the said risk by, inter alia, the publication of special warnings;
- (f) temporarily prohibiting, for the period required to carry out the various checks, verifications or safety assessments, anyone from supplying, offering to supply or exhibiting, certain products whenever there are precise and consistent indications that they could be dangerous;
- (g) prohibiting the placing on the market of dangerous products and establishing the accompanying measures needed to ensure that the ban is complied with;
- (h) organising or ordering, the effective and immediate withdrawal of dangerous products already on the market, the warning of consumers on the risks posed by dangerous products, the recalling from consumers of those products already supplied, and the destruction of the products in question under appropriate conditions, if necessary, in cases where action by producers and distributors to the same aims, in conformity to their obligation under this Directive, is not satisfactory or is insufficient.

| distribution on the national market;        | 2. In particular, the competent authorities    |
|---|--|
| (c) any other person, where necessary, with | shall have the necessary powers and take       |
| regard to cooperation in action taken to    | the necessary action, to apply with due        |
| avoid risks arising from a product.         | rapidity appropriate measures among those      |
|   | mentioned in paragraph 1(d) to (h), in the     |
|   | case of products posing a serious risk         |
|   | which requires rapid intervention.             |
|   | 3. The measures to be taken by the             |
|   | competent authorities under paragraphs 1       |
|   | and 2 shall be addressed, as appropriate, to:  |
|   | (a) the producer;                              |
|   | (b) within the limits of their respective      |
|   | activities, distributors and in particular the |
|   | party responsible for the first stage of       |
|   | distribution on the national market;           |
|   | (c) any other person, where necessary, with    |
|   | regard to cooperation in action taken to       |
|   | avoid risks arising from a product.            |
|   | Article 9                                      |
|   | 1. The approaches established by the           |
|   | Member States for operating effective          |
|   | market surveillance, including the working     |
|   | procedures and the procedures for              |
|   | exchanging information and coordination        |
|   | and collaboration between the various          |
|   | authorities concerned, shall aim at            |
|   | guaranteeing a high level of consumer          |
|   | health and safety protection.                  |
|   | 2. In order to achieve the objective referred  |
|   | to in paragraph 1, the Member States shall     |
|   | ensure that appropriate and effective means    |
|   | and procedures are put in place, which may     |
|   | include in particular:                         |
|   | (a) the establishment, periodical updating     |
|   | and implementation of sectoral surveillance    |
|   | programmes by categories of products or        |
|   | risks;   |
|   | (b) the follow-up and updating of scientific   |
|   | knowledge concerning the safety of             |
|   | products publicly available, periodical        |
|   | reports on surveillance activities, findings   |
|   | and results achieved;                          |
|   | (c) periodical reviewing and assessments of    |
|   | the functioning of the control activities and  |
|   | their effectiveness, and, if necessary,        |

|   | revision of the surveillance approach and                                    |
|---|--|
|   | organisation put in place.   |
|   | 3. The Member States shall ensure that                                       |
|   | consumers and other interested parties may                                   |
|   | present complaints to the competent  |
|   | authorities on product safety and on   |
|   | surveillance and control activities and that                                 |
|   | these complaints are considered, followed                                    |
|   | up as appropriate and answered. The  |
|   | Member States shall actively inform  |
|   | consumers and the other interested parties                                   |
|   | of the procedures established to that end.                                   |
|   | Article 10   |
|   | 1. The Commission shall promote the  |
|   | <u> </u>   |
|   | establishment and operation of a European Product Safety Network between the |
|   | 1  |
|   | authorities of the Member States competent                                   |
|   | for market surveillance of consumer  |
|   | products and involving also the  |
|   | Commission.  |
|   | 2. The Network shall cooperate with  |
|   | relevant bodies in product sectors covered                                   |
|   | by the legislation referred to in Article 1(2)                               |
|   | and shall have as its objectives, in   |
|   | particular, to facilitate:   |
|   | (a) the exchange of information on risk                                      |
|   | assessment, dangerous products, test   |
|   | methods and results, the recent scientific                                   |
|   | developments as well as other aspects  |
|   | relevant for control activities;   |
|   | (b) the establishment and execution of joint                                 |
|   | surveillance and testing projects;   |
|   | (c) the exchange of expertise and best                                       |
|   | practices and collaboration in training                                      |
|   | activities;  |
|   | (d) coordination at Community level of                                       |
|   | tracing, withdrawal and recall of dangerous                                  |
|   | products.  |
| TITLE IV Notification and Exchanges of        | Exchanges of information and rapid   |
| Information                                   | intervention situations  |
| Article 7                                     | Article 11   |
| 1. Where a Member State takes measures        | 1. Where a Member State takes measures                                       |
| which restrict the placing of a product or a  | which restrict the placing on the market of                                  |
| product batch on the market or require its    | products or require their withdrawal from                                    |
| withdrawal from the market, such as           | the market, or the recall from consumers of                                  |
| provided for in Article 6 (1) (d) to (h), the | those products already supplied, as  |

Member State shall, to the extent that such notification is not required under any specific Community legislation, inform the Commission of the said measures, specifying its reasons for adopting them. This obligation shall not apply where the measures relate to an event which is local in effect and in any case limited to the territory of the Member State concerned. 2. The Commission shall enter into consultations with the parties concerned as quickly as possible. Where the Commission concludes, after such consultations, that the measure is justified, it shall immediately inform the Member State which initiated the action and the other Member States. Where the Commission concludes, after such consultations, that the measures is not justified, it shall immediately inform the Member State which initiated the action.

provided for in Article 8(1)(d) to (h), the Member State shall, to the extent that such notification is not required under Article 12 or any specific Community legislation, inform the Commission of the measures, specifying its reasons for adopting them. Where the notifying Member State considers that the measures relate to an event which is local in effect and in any case limited to its territory, the notification will specify it. It shall also inform the Commission of any modification or withdrawal of such measures. The guidelines referred to in Annex II, point 8, shall define the contents and standard form for the notifications provided for in this Article. In particular the guidelines shall provide criteria for determining which measures related to purely local events must not be notified because they are not relevant for the aims of this Article. 2. The Commission shall forward the

2. The Commission shall forward the notification to the other Member States, unless it concludes, after examination, that the measure does not comply with Community law. In such a case, it shall immediately inform the Member State which initiated the action.

# TITLE V Emergency situations and action at Community level Article 8

1. Where a Member State adopts or decides to adopt emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of a product or product batch by reason of a serious and immediate risk presented by the said product or product batch to the health and safety of consumers, it shall forthwith inform the Commission thereof, unless provision is made for this obligation in procedures of a similar nature in the context of other Community instruments.

This obligation shall not apply if the effects

## Article 12

1. Where a Member State adopts or decides to adopt, recommend or agree with manufacturers, importers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk for the health and safety of consumers which requires rapid intervention, it shall immediately inform the Commission thereof through the Community Rapid Information System (RAPEX). The Member States shall also inform the Commission without delay of any modification or withdrawal of such

of the risk do not, or cannot, go beyond the territory of the Member State concerned. Without prejudice to the provisions of the first subparagraph, Member States may pass on to the Commission any information in their possession regarding the existence of a serious and immediate risk before deciding to adopt the measures in question.

- 2. On receiving this information, the Commission shall check to see whether it complies with the provisions of this Directive and shall forward it to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.
- 3. Detailed procedures for the Community information system described in this Article are set out in the Annex. They shall be adapted by the Commission in accordance with the procedure laid down in Article 11.

measures or actions.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, the notification shall indicate it taking into account the relevant criteria established in the guidelines referred to in Annex II, point 8. Without prejudice to the first subparagraph, Member States may pass on to the Commission any information in their possession regarding the existence of a serious risk requiring rapid intervention before deciding to adopt the measures or action in question.

- 2. On receiving this information, the Commission shall check whether it complies with the requirements applicable to the functioning of RAPEX, and shall forward it to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.

  3. Detailed procedures for RAPEX are set out in Annex II. They shall be adapted by the Commission in accordance with the procedure referred to in Article 15(2).
- 4. Access to RAPEX may be open to candidate countries, third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to modalities defined in these agreements. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Community.

#### Article 9

If the Commission becomes aware, through notification given by the Member States or through information provided by them, in particular under Article 7 or Article 8, of the existence of a serious and immediate risk from a product to the health and safety of consumers in various Member States and if:

#### Article 13

1. If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States requiring rapid action, it may, after consulting the Member States, adopt a decision, in accordance with the procedure laid down in Article 14(1), requiring Member States to take measures

- (a) one or more Member States have adopted measures entailing restrictions on the marketing of the product or requiring its withdrawal from the market, such as those provided for in Article 6 (1) (d) to (h);
- (b) Member States differ on the adoption of measures to deal with the risk in question;
- (c) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product and in a manner compatible with the urgency of the case, under the other procedures laid down by the specific Community legislation applicable to the product or category of products concerned; and
- (d) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure the protection of the health and safety of consumers and the proper functioning of the common market, the Commission, after consulting the Member States and at the request of at least one of them, may adopt a decision, in accordance with the procedure laid down in Article 11, requiring Member States to take temporary measures from among those listed in

Article 6

(1) (d) to (h).

- from among those listed in Article 8(1)(d) to (h) if:
- (a) Member States differ on the approach to deal with the risk;
- (b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product and in a manner compatible with the degree of urgency of the case, under other procedures laid down by the specific Community legislation applicable to the products concerned; and
- (c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.
- 2. Decisions referred to in paragraph 1 shall be valid for a period not exceeding one year and may be confirmed, under the same procedure, for additional periods of one year.

However, decisions concerning specific, individually identified products or batches of products, shall be valid without a timelimit.

- 3. Export from the Community of products for which Member States have been required to take measures among those listed in Article 8(1)(f), (g) and (h) shall be prohibited.
- 4. The Member States shall take all necessary measures to implement the decisions referred to in paragraph 1 within less than 10 days, unless a different period is specified in those decisions.
- 5. The competent authorities responsible for carrying out the measures referred to in paragraph 1 shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.

## Article 17

1. Member States shall adopt the laws, regulations and administrative provisions

#### Article 20

1. Member States shall bring into force the laws, regulations and administrative

necessary to comply with this Directive by 29 June 1994 at the latest. They shall forthwith inform the Commission thereof. The provisions adopted shall apply with effect from 29 June 1994.

- 2. When these measures are adopted by the Member States, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.
- 3. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the area covered by this Directive.

provisions necessary to comply with this Directive with effect from 1 January 2003. They shall forthwith inform the Commission thereof.

## Article 18

Decision 89/45/EEC is hereby repealed on the date referred to in Article 17 (1).

## Article 21

Directive 92/59/EEC is hereby repealed with effect from 1 January 2003 without prejudice to the obligations of Member States concerning the deadlines for transposition and for application of the repealed Directive as indicated in Annex III.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

## **General Product Safety Standards**

The following standards information is taken directly from the CEN web site: http://www.cenorm.be/sectors/consumers.htm

"In CEN, there is no specific "Consumer sector". This is quite normal because the range of consumer products is (too) wide."

"Also defining exactly a "consumer product" is not easy. However, one could define these products as any product intended for consumers or likely to be used by consumers, even if not intended for them. Products provided in the framework of a service to consumers are to be considered as consumer "products" too."

"Standards for consumer products are important: they are one of the means to prove that products are safe, that a product fulfils the "state of the art" of technology. As a result, manufacturers/distributors of products in compliance with a standard limit their **liability** in case of accidents."

## **CEN Is Writing Standards In The Following Fields:**

| Artificial climbing structures        |
|---------------------------------------|
| Barbecues                             |
| Child use and care articles           |
| Cycles                                |
| Domestic furniture                    |
| Educational furniture                 |
| Fireworks                             |
| Footwear                              |
| Gymnastic equipment                   |
| Jewelry and associated products       |
| Kitchen and bathroom furniture        |
| Leather products                      |
| Lighters                              |
| Mountaineering and climbing equipment |
| Office furniture                      |
| Oil lamps                             |
| Outdoor furniture                     |

| Paragliding equipment             |
|-----------------------------------|
| Playground equipment for children |
| Playing field equipment           |
| Roller sport equipment            |
| Safety of toys                    |
| Shopping Trolleys                 |
| Stationary training equipment     |
| Swimming pool equipment           |
| Textiles                          |
| Water slides                      |

Additionally, special projects are taking place on: People with special needs (e.g. elderly and disabled people), Child safety, and Product information.