Proposal for a directive of the European Parliament and of the Council on general product safety

(2000/C 337 E/15)

(Text with EEA relevance)

COM(2000) 139 final/2 — 2000/0073(COD)

(Submitted by the Commission on 15 June 2000)

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,

Having regard to the opinion of the Economic and Social Committee,

Whereas:

(1) Under Article 16 of Council Directive 92/59/EEC of 29 June 1992 on general product safety [1], 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.

(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.

[1] OJ L 228, 11.8.1992, p. 24.

(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 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 product-safety 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 above-mentioned 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 Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1], they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(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.

[1] OJ L 184, 17.7.1999, p. 23.

(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 [1].

(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,

[1] 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).

(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

1. For the purposes of this Directive, the Commission shall establish the mandates to the European standardisation 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 [1] . The Commission shall ensure coordination with the Regulatory Committee on Consumer Product Safety referred to in Article 14(1) of this Directive.

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 Standardisation bodies, in accordance with the principles contained in the general guidelines for cooperation between the Commission and those bodies.

---

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

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;

(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 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.

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 or 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.

ANNEX IV

CORRELATION TABLE

This Directive	Directive 92/59/EEC
1	1
2	2
3	4
4	—
5	3
6	5
7	5, second paragraph
8	6
9	—
10	—
11	7
12	8
13	9
14 and 15	10
16	12
17	13
18	14
19	15
20	17
21	18
22	19
Annex I	—
Annex II	Annex
Annex III	—
Annex IV	—