COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90) 259 final SYN 192

Brussels, 11 June 1990

Amended proposal for a

COUNCIL DIRECTIVE

concerning general product safety

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

Explanatory Memorandum

This amended version of the proposal for a Council Directive on general product safety[1] is hereby presented following the delivery of an opinion by the European Parliament.[2] It also takes account of the opinion of the Economic and Social Committee[3] and of the outcome of the discussions within the Council.

The amended proposal upholds the principles, concepts and basic elements of the original proposal which, in general, have been well supported not only by Parliament but also by the Economic and Social Committee:

- wide-ranging in scope (all products);

- complementarity vis-à-vis specific rules;

- obligations imposed on suppliers under the general safety requirement;

- obligations to be imposed and specific powers to be provided by the Member States in order to ensure compliance with the general safety requirement;

- procedures to be followed by the Member States for the notification of market restriction measures in general and for the rapid exchange of information in cases of emergency;

- intervention procedures and, where appropriate, adoption of decisions addressed, in the final instance, to the Member States in cases of emergency.

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1 OJ No C 193, 31.7.1989, p. 1.

2 Part-session March 1990, Report 3 II of 15 March 1990 (PE 139.694)

3 OJ No C 75, 26.3.1990, p. 1.

Following requests from all the bodies concerned and, in particular, from Parliament, the proposal has been restructured, simplified and clarified, so as to render the proposed rules more comprehensible and facilitate their implementation.

The Commission did not accede to Parliament's request to change the proposed instrument into a regulation. While it regards this proposal as genuinely interesting, it does not consider it attainable in view of the current situation.

Amended definitions of the terms "product" and "supplier" have been introduced in the text, prompted on the one hand by the opinion of Parliament and, on the other, with reference to the term "supplier", as the result of discussions at Council level.

The definition of "safe product" has been revised, although the risk acceptability criterion has been retained by agreement with Parliament, so as to take account of the relative and developmental nature of the concept. The amended definition introduces the positive approach requested by the Economic and Social Committee, as does the reference to the level of risks as a result of discussions within the Council and a special consideration taking account of the behaviour of children, as requested by Parliament.

Following requests from all the bodies concerned, the general safety obligation (Article 3) has now been established as incumbent, in the first instance, on suppliers.

The specific obligations which require suppliers to provide information with regard to acceptable but not insignificant residual risks and the monitoring of risks associated with the marketed products have been incorporated in the same Article 3 and worded more precisely, based largely on the opinion of Parliament and of the Economic and Social Committee.

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Following discussions within the Council, reference has also been made to the role of the distributors and retailers in this new Article 3, which incorporates the direct obligations imposed on the suppliers (former Articles 3, 4 and 6).

The new version of Article 4 formulates more precisely the references by which suppliers can discharge their duties and the authorities can assess the degree of compliance with such obligations. A clear reference is made to the role of national rules in the absence of Community rules following discussions within the Council and to recourse to Community voluntary standards as requested by all the bodies concerned.

Lastly, "the safety which users and consumers may reasonably expect" is added as an assessment criterion to be taken into consideration in the absence of other rules and as a supplement to the other specific criteria. This concept has been adopted in the light of the opinions of Parliament and of the Economic and Social Committee and the discussions within the Council.

The new versions of Articles 5 and 6 concerning the obligations and powers of the Member States have been set out more precisely than hitherto, incorporating in the text the essential points of former Annex 2 so as to ensure harmonization and permit the even-handed application of the general safety obligation. Here, too, the opinion of Parliament has been heeded, and account has been taken of the discussions within the Council. However, Parliament's call for a ban on exports of unsafe products has not been taken up on the grounds that, despite recognition of the problem, it was not felt that a solution could be found in the framework of this directive, which covers the marketing of products within the Community.

In the new versions of Articles 7 to 11 covering intervention at Community level, an effort has been made to separate and define the various procedures and the conditions of intervention, while at the same time focusing particular attention on emergency situations:

1. The general procedure for the notification of national measures taken for reasons of safety and affecting the marketing of products (Article 7(1)) no longer applies to the "draft" measures. More detailed conditions have subsequently been drawn up in accordance with the safeguard clauses under the "new approach" directives, and the principle of general recourse to the Management Committee has now been abandoned.

   Greater intervention in such cases, involving the extension of the Commission's powers and recourse to the Committee, as requested by Parliament, has been avoided because of the principle of subsidiarity. Furthermore, there are doubts about the feasibility of such an approach, which could lead to the fragmentation of available resources and have adverse effects on efforts to ensure efficient and concentrated intervention in cases of emergency.

2. The system of rapid exchange of information in emergency situations, whether real or imagined (Article 7(2)), is to be retained with the support of all the bodies concerned.

   In both instances, the Commission wishes to exclude notifications and information relating to situations where the effects are of a local nature and are invariably confined to the national territory. Despite a request by Parliament not to restrict these procedures and criticisms along similar lines from the Economic and Social Committee, such an extension would call into question the principle of subsidiarity and, as far as the Commission is concerned, would be untenable in practice.

3. As regards the procedure for action at Community level and for the possible adoption of decisions addressed to the Member States in the event of particular emergency situations ("grave and immediate risk"), the following points should be emphasized:

- Conditions governing initiation of the intervention procedure (Article 8): following the discussion in the Council, a new condition has been added, namely that one or more Member States should have decided to take measures to restrict the placing of a product on the market. Although this condition is not required in order to initiate the inquiry procedure, it is nevertheless necessary for the initiation of the decision-making procedure.

- Consultation and investigation procedure with the Member States (Article 9): as in the original proposal, the decision to initiate this procedure is a matter for the Commission. A number of drafting changes have been made, particularly in the light of discussions at Council level.

- Decision-making procedure (Articles 10 and 11): to be adopted by the Commission through a (so-called emergency) Management Committee in accordance with procedure II.a) of Council Decision 87/373 of 13 July 1987.[4] Also envisaged, through this Committee, is the adoption of detailed procedures for the system of rapid exchange of information.

  There are no significant changes vis-à-vis the original text, and the measures are still addressed to the Member States. Against this background, the Commission has not introduced Parliament's amendment whereby, under certain conditions, the Commission could adopt, in its own right, decisions that are directly applicable and that could call into question the balance of power with the Member States.

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4 OJ No L 197, 18.7.1987, p. 33.

For reasons of feasibility and priority, the Commission has not taken up the ›request by Parliament to extend these three actions beyond emergency situations on the grounds of feasibility or priority. Efficacity in these emergency cases must be guaranteed in order to protect the consumers and users of the products in general and to ensure confidence in the internal market and its proper functioning.

The same considerations apply with regard to an extension of the role of the Committee which would be concerned systematically with the problems of product safety. However, the Commission, as indicated in the recitals, is continuing to explore the possibility of setting up a non-statutory advisory committee, under its own authority, to represent the various interested parties.

Finally, by altering the recitals care has been taken to clarify that victims rights under the product liability directive are not affected by this directive.

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 of 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 therefore necessary to establish on a Community level a general safety requirement for any product placed on the market;

Whereas it is necessary that potential users are warned of any remaining risks;

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(1)

(2)

(3)

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Whereas, in the absence of more specific safety provisions covering the products concerned, the provisions of this Directive are to apply;

Whereas every effort must be made to refer to rules which, if observed, give credence to the assumption that the product in question complies with the general safety requirement and to assessment criteria for appraising product safety in the absence of such rules;

Whereas it is impossible to adopt Community legislation for every product which exists or may be developed; whereas there is a need for a broadly based, horizontal legislative framework 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 100A(3);

Whereas it is appropriate to supplement the duty to observe the general safety requirement by an obligation on economic operators to adopt suitable procedures for monitoring the safety of the products they deal with in the course of their business;

Whereas Member States must provide for authorities to control the safety of products, which have powers to take the appropriate measures;

Whereas Member States must ensure that their competent authorities give due consideration to reasoned complaints from the public concerning the safety properties of a product;

Whereas effective supervision of the safety of products requires the setting-up at a national and Community level of a system of rapid exchange of information in emergency situations in respect of the safety of a product; whereas it is appropriate to give the Commission the power to lay

down detailed rules for such rapid exchange system at Community level; whereas the procedure laid down by Council Decision .../.../EEC of ... on a Community system for the rapid exchange of information on dangers arising from the use of consumer products(4) has been adopted in this Directive and the abovementioned Decision has thereby been repealed;

Whereas it is necessary to oblige Member States to restrict the marketing of dangerous products or to order their withdrawal or recall from the market;

Whereas it is necessary for the preservation of the unity of the market to inform the Commission of any measure restricting the conditions of distribution or marketing of a product; whereas such measures can only be taken 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(5) and in Commission Decision 88/383/EEC of 24 February 1988 providing for the improvement of information on safety, hygiene and health at work;(6)

Whereas it is possible that Member States in applying the general safety requirement take different decisions with regard to a particular product; whereas such differences can constitute a barrier to intra-Community trade and in some cases an unacceptable difference in the protection of users and consumers;

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(4)

(5) OJ No L 109, 26.4.1983, p. 8.

(6) OJ No L 183, 14.7.1988, p. 34.

Whereas it is therefore necessary to provide for an adequate mechanism allowing for the adoption of measures applicable throughout the Community in order to cope with emergency situations of particular Community concern; whereas, by reason of their urgency, 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 efficiency, it is appropriate to provide for a management committee according to procedure II of Council Decision 87/373 of 13 July 1987;(7)

Whereas the Commission, acting in accordance with the powers vested in it, is continuing to look into the possibility of setting up an advisory committee on product safety to include representatives of the various interested parties, and in particular of the suppliers, users and consumers;

Whereas steps should be taken to protect the legitimate interests of the individuals concerned when doubts are publicly cast on product safety features;

Whereas it is necessary that Member States provide for appropriate means of redress in cases where irregular measures are adopted by national authorities;

Whereas the implementation of 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;(8)

Whereas the procedure for the adoption of measures applicable to imported products with a view to preventing risks to the safety and health of persons must comply with international obligations,

HAS ADOPTED THIS DIRECTIVE:

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(7) OJ No L 197, 18.7.1987, p. 33.

(8) OJ No L 210, 7.8.1985, p. 29.

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TITLE I - OBJECTIVES - SCOPE - DEFINITIONS

Article 1

1. This Directive lays down provisions for the safety of marketed products.

2. The provisions of this Directive apply insofar as there are no more specific provisions, in rules of Community law, governing the safety of the concerned products.

Article 2

For the purposes of this Directive:

(a) "Product" shall mean any manufactured, processed or agricultural product supplied whether for consideration or not in the course of a business, and whether new, used or reconditioned.

(b) "Safe product" shall mean any product which, during its foreseeable time of use, does not present any risk or only those reduced to such a level, taking account of the products use, considered as acceptable and consistent with a high standard of protection for the safety and health of persons

- given its composition, execution, wrapping, presentation and labelling, conditions of assembly, maintenance or disposal, instructions for handling and use and its direct or indirect effect upon or in combination with other products,

- when used for its intended use or in a manner which may reasonably be foreseen, having regard, inter alia, to any specific statement made by its supplier or on his behalf in that respect and , in particular, to the normal behaviour of 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 "not safe" or "dangerous".

(c) "Dangerous product" shall mean any product which does not meet the definition of "safe product" according to point (b) of the present Article.

(d) "Suppplier" shall mean:

- the manufacturer of the product, when he is established in the Community, and any person presenting himself as the manufacturer by affixing to the product his name, trademark or other distinctive mark;

- the manufacturer's authorized agent, when the manufacturer is not established in the Community, or, if no such agent exists, the importer of the product;

- distributors and other professionals in the supply chain insofar as their activities may affect the safety properties of a marketed product;

- the commercial supplier of used and/or reconditioned products.

TITLE II - GENERAL SAFETY REQUIREMENT

Article 3

1. Suppliers are under an obligation to place only safe products on the market. Member States shall incorporate in their legislation all necessary measures to ensure that suppliers meet this obligation.

2. In particular, within the limits of their respective activities, suppliers shall

   - provide the potential user or consumer with the relevant information to enable him to assess the risks presented by a product when such risks are acceptable as such but are not immediately obvious and are not insignificant, and to take precautions against these risks throughout the foreseeable time of use of the product; provision of a warning does not constitute a means of escaping the general safety requirement nor a defence when the product proves to be dangerous.

   - adopt appropriate measures to ensure suitable monitoring of the safety of the products, taking account of their particular characteristics, with a view to being properly informed of risks which these products might present, assessing this information and taking appropriate action including, if necessary, recalling the product in question or withdrawing it from the market to avoid these risks.

   The measures to be taken to monitor products specifically include, whenever appropriate, marking of the products or product lots in such a way that they can subsequently be identified, sample testing of marketed products and the institution of systematic procedures for assessing and investigating complaints made.

3. Distributors and other professionals in the supply chain, who are not suppliers are required to act with due care in order to contribute to ensuring compliance with the general safety requirement. In particular, within the limits of their respective activities, they shall participate in monitoring the safety of marketed products, for example by passing on information on product risks and cooperating in the action taken to avoid these risks.

Article 4

1. Suppliers shall be deemed to have complied with the general safety requirement when the product conforms

   - with the specific rules of Community law laying down the health and safety requirements which the product must satisfy in order to be marketed;

   - if there are no Community rules, with the specific rules of national law of the Member State on 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 order to assess the conformity of a product with the rules mentioned in paragraph 1, reference shall also be made to national voluntary standards giving effect to a European standard or, when they exist, Community technical specifications or, failing these, safety and health standards for the products concerned drawn up in the Member State in which the product is in circulation.

3. In the absence of any more specific rule, the conformity of a product or category of products with the general safety requirement shall be assessed by reference to the state of the art, to the state of scientific and technical knowledge, having regard to practical feasibility, and to the codes of good practice in respect of safety and health in the sector concerned and to the safety which users or consumers may reasonably expect.

4. Conformity of a product with the rules mentioned in paragraphs 1 and 2, shall not bar the competent authorities of the Member States from taking action 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 users or consumers.

TITLE III: OBLIGATIONS AND POWERS OF THE MEMBER STATES

Article 5

Member States shall take the necessary regulatory and administrative measures so that suppliers comply with their obligations under this Directive, to prohibit the placing of dangerous products on the market and to enable them to be withdrawn or recalled.

In particular, Member States shall

(a) establish and/or nominate authorities to control the compliance of products with the obligation to place only safe products on the market;

(b) ensure, at the same time, the technical competence and the impartiality of the authorities, where applicable on the basis of the relevant harmonized European standards;

(c) make the authorities known to the Commission; the Commission shall pass this information to the other Member States;

(d) make the authorities known to the public;

(e) ensure that the authorities collect and systematically analyse information on the real or probable existence of a risk associated with a product and data on accidents and harmful effects imputable to products;

(f) ensure that the authorities give due consideration to reasoned complaints about the safety properties of a product;

(g) ensure that the authorities have the necessary powers to take the appropriate measures imcumbent upon them under this Directive;

(h) provide, without prejudice to the common criminal law provisions made under national legislation, for suitable sanctions in the event of failure to comply with the obligations deriving from this Directive.

Article 6

For the purposes of Article 5 (g), the Member States have the necessary powers, acting in accordance with the degree of risk and in conformity with the Treaty and in particular Articles 30 and 36 thereof, to adopt appropriate measures with a view to

(a) organising appropriate checks on the safety properties of products, even after their first being placed on the market as being safe, on an adequate scale , up to the stage of end use or final consumption or, if appropriate, their disposal;

(b) requesting all relevant information from parties likely to be concerned;

(c) requesting samples of a product or a product line, seizure or sequestration of products and, if appropriate, obtaining access to commercial premises;

(d) ensuring compliance with the provisions concerning suitable monitoring of products;

(e) warning, in an appropriate form, of the risks arising from a product, in particular by public notices, distribution of notices to all persons liable to be exposed to the risk in question and by providing the products in question with warning notices to make them safe;

(f) imposing appropriate restrictions as to the conditions of distribution and marketing and, if appropriate, of disposal of a dangerous product;

(g) requesting appropriate changes in a product or product line in order to make it safe;

(h) temporary or definitive prohibition of the manufacture or marketing of a product;

(i) organising the withdrawal or recall of a dangerous product already on the market and, if appropriate, its destruction, under appropriate conditions;

(j) when there are strong and coraboratory indications that a product is dangerous and presents a risk of an immediate and grave nature,

- seizure of the product concerned at any stage of manufacture or distribution for the period, not exceeding three months, required to have the necessary analysis carried out to investigate the matter;

- serving of a notice prohibiting those on whom it is served, for a period ending not more than three months after the date of the notice as is specified therein, from supplying, offering to supply or exhibiting the product concerned.

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 supplier;

(b) within the limits of their respective activities, distributors and/or other professionals in the supply chain, and in particular the party responsible for the first stage of distribution on the national market, who are not covered by the definition of the supplier in Article 2 (d);

(c) when appropriate, to final users and/or consumers, or any other person in possession of the product, especially with regard to cooperation in the action taken to avoid risks.

TITLE IV - NOTIFICATION AND EXCHANGE OF INFORMATION

Article 7

1. Where a Member State has taken measures, pursuant to Article 6 (e) to (j), which restrict the placing of a product on the market or require its withdrawal from the market, the Member State shall, to the extent that such notification is not required under any specific Community legislation, immediately inform the Commission of any such measures, with the reasons for adopting them. This obligation shall not apply where the measures relate to an event which is local in effect, in any case limited to the territory of the concerned Member State.

   The Commission shall enter into consultations with the parties concerned as quickly as possible. When 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. When the Commission concludes after these consultations that the measure is not justified, it shall immediately inform the Member State which initiated the action and the manufacturer or his authorized agent established in the Community.

2. Where a Member State has information about the existence or the likely existence of a grave and immediate risk which has or may have effects outside its territory, it shall immediately inform the Commission thereof and of the measures it has taken or intends to take, unless equivalent procedures are required under specific Community legislation applying to the products or category of products in question.

The Commission shall ensure that such information is passed to the other Member States and they in turn shall inform the Commission of any outcome.

Specific detailed procedures for rapid exchange of this information between Member States and the Commission shall be adopted in accordance with the procedure laid down in Article 11 paragraphs 1 and 5.

TITLE V - ACTION AT COMMUNITY LEVEL

Article 8

Whenever the Commission has knowledge, whether through information provided or notification by the Member States, in particular under Article 7, of the possible existence of a grave and immediate risk related, directly or indirectly, to the safety properties of a product,

(a) which does or is likely seriously to affect, directly or indirectly, the safety and health of an indeterminate number of persons in more than one Member State; and

(b) which cannot be adequately dealt with, especially with a view to the urgency and/or complexity of the product safety issue in question, under the other procedures laid down under any specific Community legislation governing the product or category of products concerned; and

(c) which can only be eliminated effectively by adopting appropriate measures applicable throughout the Community, in order to ensure the best possbile protection of persons and the proper functioning of the Common Market,

The Commission shall either initiate the consultation and investigation procedure as set out in Article 9,

OR

(d) if one or more Member States has decided to take or implement one of the measures mentioned in Article 6 (e) to (j),

it shall ask the Member States to take appropriate temporary measures to prevent the risk, in accordance with the procedure laid down in Article 11.

Article 9

1. Within the limits arising from circumstances and from the urgency of the product safety issue in question, the Commission may decide to initiate a consultation and investigation procedure with the Member States to obtain further information on the nature and scale of the risk, its causes and possible means of prevention so that it can consider thoroughly whether it is necessary to adopt appropriate measures directly applicable throughout the Community.

2. When the Commission decides to initiate such a procedure, it shall immediately inform the Member States, providing a summary of the evidence available.

3. Upon request from the Commission, the Member States shall take the appropriate measures, in particular those mentioned in Article 6 (a) to (c), in order to obtain the necessary information.

   Member States shall inform the Commission of the findings and results of such measures.

4. The Commission shall inform the Member States of the results of the investigation.

Article 10

The Commission shall be assisted by a Committee on Product Safety Emergencies, hereinafter called "the Committee", composed of the representatives of the Member States and chaired by a representative of the Commission.

Article 11

1. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee 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, which shall apply immediately. However, if these measures are not in accordance with the opinion of the Committee, they shall be communicated by the Commission to the Council forthwith. In that event, the Commission may defer application of the measures which it has adopted for a period of five working days from the date of such communication.

   The Council, acting by a qualified majority, may take a different decision within the time limit referred to in the previous paragraph.

2. Any measure adopted under paragraph 1 of this article shall be valid for no longer than six months. It may be prolonged under the same procedure.

3. Member States shall take all necessary measures in order to implement the decisions adopted under this procedure within 10 days.

4. The competent authorities of the Member States which carry out measures adopted under this procedure shall, within one month, give to any party concerned an opportunity to submit its views, and shall inform the Commission accordingly.

5. The period for the adoption of detailed procedures of the rapid exchange of information system established in Article 7 paragraph 2 shall be one month.

TITLE VI - MISCELLANEOUS AND FINAL PROVISIONS

Article 12

Member States shall take all necessary measures to ensure that any information covered by profesional secrecy relating to the safety properties of a product, which has been revealed tc the competent authorities, is kept confidential, except for the information which must be made public in order to ensure effective protection of health and safety of persons, as may be necessary under the circumstances.

Article 13

This Directive shall be without prejudice to Directive 85/374/EEC of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products[1].

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[1] OJ No. L 210, 7.8.1985, p. 29.

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, shall state the exact grounds on which it is based. It shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits applying to such remedies.

The parties concerned, whenever feasible, shall 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 matter, such opportunity shall be given, in due course, after the measure has been implemented.

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 responsibility of the party concerned in the light of the national criminal law applying in the case in question.

Measures requiring the withdrawal of a product shall include provisions aiming to increase the readiness of any holder of such product, in particular distributors and end users or final consumers, to facilitate its withdrawal. These measures may, if appropriate, include replacement of the product or reimbursement of its cost.

2. Member States shall provide in their legislation that any person, natural or legal, who publicly calls into question the safety properties of a product or a category of products, for the sole purpose of increasing public awareness of health and safety problems, shall not be held liable

for the economic consequences which public debate might entail, provided such statements are intended to be truthful and accurate and are made in good faith.

3. Member States shall establish the necessary administrative and legal mechanisms for ensuring that suppliers of products, the safety of which is called into question in a manner not in conformity with paragraph 2, have appropriate means of redress.

4. 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, can be challenged before the courts.

Article 15

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

Article 16

1. Member States shall bring into force the laws, regulations and administrative provisions, including adequate sanctions, to comply with this Directive by 1 January 1991 at the latest. They shall forthwith inform the Commission thereof.

2. The provisions adopted pursuant to paragraph 1 shall make express reference to this Directive.

Article 17

Council Decision .../.../EEC of ..... on a Community system for the rapid exchange of information on dangers arising from the use of consumer products, is repealed.

Article 18

This Directive is addressed to the Member States.

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