COMMISSION OF THE EUROPEAN COMMUNITIES

COM(89) 162 final - SYN 192

Brussels, 7 June 1989

Proposal for a

COUNCIL DIRECTIVE

concerning general product safety

(presented by the Commission)

EXPLANATORY NOTE

I. General background

1. The initiative for this proposal goes back to the Commission's communication on a new impetus for consumer protection policy[1] where it was stated that product safety is a basic requirement and condition for the achievement of the internal market, and that, therefore, the need for the imposition at Community level of a general obligation on manufacturers to produce and market products which are safe, should be assessed. The Council, in its Resolution of 23 June 1986, has endorsed, amongst other, this objective of the new impetus programme[2].

   In further pursuing this objective the Commission, in its Communication on safety of consumers in relation to consumer products[3], has set up an inventory of existing national legislation in the area of general product safety, and has concluded that a legal instrument introducing, in particular, a general obligation on manufacturers, traders and importers to produce and market only safe products, should be submitted; this latter communication has been taken account of by the Council in its Resolution of 25 June 1987[4].

2. During the further preparation of the present proposal it has become apparent that the instrument to be developped should be viewed in a context somewhat broader than consumer protection only, both under political and legal aspects :

   a) There is, indeed, despite the success of the idea of "Completing the Internal Market by 1992", its consecration under the European Single Act and the generally satisfactory progress of legislative work, undertaken in this perspective, some residual uneasiness expressed by several quarters in Member States about what will be the practical consequences and results for everybody, once this target is reached. Such uneasiness is not strictly confined to consumerist circles, who, in principle, have joined by now the camp of the supporters - as have also done, in principle, trade unions' organizations.

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[1] COM(85) 314.

[2] OJ No C 167, 5.7.1986, p. 1.

[3] COM(87) 209.

[4] OJ No C 176, 4.7.1987, p. 3.

One of the major reasons for a certain uneasiness is the question of product safety. Product safety is already or will be governed, to a large extent, by Community legislation, adopted under procedures less known to and, hence, less discernable for the general public in Member States.

The complexity of the situation becomes even greater with the generalized application of the principles of equivalence and mutual recognition of other Member States' regulations and standards in product safety matters.

In particular, the legislative work started, on an accelerated scale, with a view to "Completing the Internal Market" and, in that context, the work for harmonization under the "New Approach", dealing with criteria for product safety, tends to explode into a mosaic of a multitude of texts of a very technical nature covering large product areas, which will give a fairly reasonable and complete picture when scrutinized by the specialists, but which may leave the average European citizen rather in a state of confusion.

A general legal instrument, establishing rather simple basic principles, such as proposed here, should help to overcome certain feelings of insecurity and some reluctance not only on the part of final consumers but equally on the part of workers and of professionals who all are users and consumers of whatever products freely circulate throughout the Common Market. The proposal is, therefore, designed to strengthen general confidence in the proper functioning of the internal market.

b) The notion of "consumer product" (in contrast to other products, mainly or exclusively designed for professional use and/or consumption) as a legal term is, for the purpose of establishing a general safety requirement, hardly operational for reasons which are set out, in more detail, below. Moreover, to make such a distinction in the present context, appears to be hardly defendable, even when putting aside technical difficulties of defining the scope of application. Indeed, with the ever growing division of labour between and even within industry sectors and with the increased complexity of products, there is no longer room for a general assumption that professional users or consumers of whatever kind of product are in a position to make their own assessment of the risks of a product, which is totally different from the situation of private/final end users or consumers. Differences which need to be made in the level of protection may be found, in more detail, in specific legislation, to which the present proposal refers in any event.

For similar reasons, the present proposal does not provide for any exemptions by product sectors and/or types of risk. The terminology used and, in particular, the notion of "unacceptable risk" is sufficiently flexible to cover any product, without unreasonably restricting its marketing and further development - including those products which are said to bear an "inherent" risk. Moreover, any such exemption by sectors would lead to the peculiar situation that the scope of application of the general instrument, as suggested here,

would be reduced, each time when a further product sector is to be covered, more or less comprehensively, by new "vertical" Community legislation.

c) Such assessment is confirmed by the analysis of national legislation of a horizontal type, on product safety, of which the Commission already has given an overview in the above Communication of 8 May 1987 (COM(87) 209). For the preparation of this proposal further studies on such legislation, as it is already in operation in a number of Member States (Spain, France, Germany, Netherlands, Portugal and the UK), have been undertaken.

3. The concept of the present proposal, as compared to the outlines given in earlier statements, has also been broadened in that it provides for a procedure for adopting, at Community level, measures applicable throughout the Community in emergency situations.

a) In specific product areas, governed by specific Community legislation - which are, perhaps, the ones less visible for a broad public -, the procedural and legislative machinery works quite satisfactorily in order to cope with such situations in a consistent way at Community level, although the results may sometimes be obtained rather through a well-established system of concertation and coordination between the Commission's and Member States' competent services than on the basis of a legal power for swiftly adopting such measures at Community level.

There are, however, large areas where such machinery is missing and/or the procedures available turn out to be insufficient if there are divergencies between the Member States as regards the proper line of action to be taken and, in the event, the adequate measure to be adopted. With a view to the achievement of the internal market such deficiencies become more and more apparent, and tend to give an impression of the Community as of a mighty institution which is, however, badly equipped to face all problems arising under the rules governing its own functioning.

Thus safeguard clauses, as now consecrated under Article 100a (5) of the Single European Act and systematically introduced into Community legislation drafted according to the "New Approach", provides for notification of safeguard measures, adopted by Member States' authorities, in respect of particular products governed by a specific text. Such notification is scrutinized by the Commission who then gives an opinion on its appropriateness which is communicated to other Member States. Whatever the Commission's opinion is, however, it remains without immediate consequences if Member States, in one way or the other, disagree with it. There is, in many areas, no adequate forum at Community level where such problems can be immediately dealt with together with all Member States and with a view to swiftly adopting consistent measures, applicable throughout the Community.

b) The present proposal is designed to provide for such a forum which, in fact, is highly needed for the functioning of the internal market and will thus apply to cases where Member States take different measures in situations covered by this Directive.

However, the procedure suggested is not meant and is not conceived as some sort of superstructure built over and above other procedures applicable in various specific product sectors governed by already existing or forthcoming Community legislation, but as an additional instrument reserved for rather extreme situations. The need for taking recourse to this instrument and the advantages it may offer in a given situation, will be assessed - under, of course, the responsability of the Commission as a whole- by each administrative unit of the Commission with regard to the particular product sector it is in charge of, and in respect of the specific product safety issue in question.

c) It is, in fact, not expected that such procedure needs to be initiated in many cases. Many "alerts", some of which have been given a rather large publicity in the recent past, may indeed not justify any other common approach at Community level than ensuring the most rapid flow, amongst Member States, of the most complete and most accurate information as possibly available -which the Commission, at present, tries to do, for example, within the Rapid Exchange System established under Council Decision 84/133 of 2 March 1984[5] and recently re-confirmed, for a limited period, by Decision of 21 December 1988[6].

Some of such "alerts" are, indeed, over-exaggerated, many of them can be adequately dealt with at a local or regional level, others are of such a clear cut nature that it can be expected that all national authorities concerned will react in the same way.

Differences in interpretation and application between the Commission and Member States, which are not likely to have an immediate and vital bearing on health and safety of users and consumers of the Community and on the functioning of the Common Market, may continue to be discussed and settled within the framework of other existing procedures, as those under Article 169 or Article 177 of the Treaty.

4. Taken as whole, the intention of the present proposal is not at all to build up a perfectionist regulatory machinery, but rather to summarize, in a general way, certain relatively simple principles, which anyway apply, in one way or the other, in the Member States and throughout the Community, and to give them a Community dimension.

II. Link with other Community legislation

1. Since the proposed text is not confined to "consumer products" for reasons which, partly, have already been explained under I. and which are set out, in more detail, below (see comments by

[5] OJ No L 70, 13.3.1984, p. 16.

[6] OJ No L 17, 21.1.1989, p. 51.

articles), the proposal links, in principle, with many areas of Community legislation, namely all legislation dealing with the harmonization of conditions of safety to be met by products for being put into free circulation and/or to be used at the workplace throughout the Community, including any "ancillary" professional activity which may affect the safety properties of a product throughout the entire production and distribution chain up to the stage of end use or final consumption and where necessary, of disposal.

a) This includes

- legislation laying down all necesary conditions to be met by technical products ("traditonal" approach to harmonization);

- legislation laying down "essential requirements" of such products ("new approach" to harmonization);

- specific legislation in the agricultural field (including veterinary and phytosanitary aspects);

- legislation mainly designed for the protection of workers which lays down "minimal requirements" according to Article 118A and/or regulates on specific safety questions in that area.

b) However, the proposed text, and in particular its essential rule - the general safety requirement - is not meant to interfere, in any way, with such legislation nor, in principle, to replace it. Its purpose is only to establish, as a basic residual rule of law, a general common denominator to all more specific legislation on product safety in any area, to which recourse can be taken where there are loopholes or inadequacies in existing legislation which cannot be mended, in the short run, or where such legislation is just not existing.

In areas already largely or, in principle, even totally covered by detailed regulatory rules, where, moreover, existing procedures allow for rapidly coping, in a consistent way, with emergency situations throughout the Community, the general safety requirement in itself may, indeed, hardly ever need to be brought into play. But the Community should not deprive itself, ab initio, of its potential application by establishing any sector-wise exemption to the general rule.

2. With regard to Directive 85/374/EEC on Product Liability[7] the present proposal constitutes a necessary complement. A general requirement upon manufacturers, importers and traders to produce and market only safe products, conceived as a public duty, will, in fact, add a further incentive for economic operators to comply with the general objective of product safety.

If Directive 85/374/EEC provides, indeed, for possibilities to obtain adequate compensation for damages to health and safety, these constitute, however, overall losses for national economies that should be avoided, to the extent possible, by adequate

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

measures of prevention. Moreover, cases where the said Directive and corresponding national legislation on the one hand and the present proposal on the other may be applicable, are not always the same.

It may suffice to point to Article 8 of the said Directive which allows for reducing or disallowing liability of a producer when a damage is caused both by a defect in the product and by the fault of the injured person. if, however, such a case reflects a large scale problem of inadequate behaviour of users or consumers, it may still give rise to an appropriate intervention, for public policy reasons, by competent authorities in order to prevent further injuries.

On the other hand, any measure taken by public authorities under the present proposal would not establish, in itself, an irrefutable proof that a corresponding claim can be made under product liability legislation, which is made expressly clear in Article 16 of this proposal.

III. Legal Basis

The basis for the proposal is Article 100a, as it is conceived as a corrolary to the "Completion of the Internal Market".

IV. General structure of the proposal

- Articles 1 and 2 covers objectives, scope and definitions.

- Articles 3 to 5 establish the general safety requirement to be applied to any type of product and to those activities which affect the safety properties of products, and contain some general criteria for risk assessment. For the full assessment of safety of a specific product, in a given case, reference is made, for the major part, to any more specific regulatory rules, governing the specific sector concerned and other more specific criteria.

- Articles 6 specifies, as part of such requirement a general duty for permanent monitoring of product safety (examples being given in Annex I).

- Articles 7 to 10 spell out, in a somewhat more detailed way, the obligations for Member States which follow from the implementation of the general safety requirement as regards the provision of public infrastructure, including powers for intervention against unsafe products (Article 7(c) and Annex 2) and exchange of information on product safety emergencies both at national and at Community level (Article 9).

- Article 8, in particular, provides for a notification mechanism.

- Article 11 to 14 introduce a Community procedure for the adoption of measures in emergency situations under conditions which are designed to limit it to rather extreme cases. This includes:

- a procedure for information and investigation (Article 12), to be initiated by the Commission under its own competences

- a procedure for adopting interim measures for the whole Community (Articles 13 and 14) according to the management committee variant of Council Decision 87/373 of 13 July 1987.

- Article 15 to 17 deal with miscellaneous subjects, including possibilities for redress and compensation.

V. Comment by articles

- Article 1 - Objectives
Defines the objectives and establishes the subsidiarity of the instrument.

- Article 2 - Definitions and Scope
Establishes the scope through the definition of the main terms used:

  - "Product" excludes, implicitly, any limitation to "consumer product" in the strict sense, for the following reasons:

    . there are large "grey zones" (example: do-it-yourself equipment), which would make a distinction defficult to operate; all vertical/sectorial directives, harmonising specific product sectors, or drafts do not make such distinction either;

    . most horizontal legislation in Member States do not make such distinction (in particular the French Law of 1983 despite its title);

    . in many cases such a limited approach would be inappropriate: the "real problem" may arise from specific parts, substances, semi-products etc. which are contained in a final product but which are not, as such, "consumer products"; measures taken against the (end)product alone may be both inadequate and disproportionate.

  - "Safe product" refers to the absence, taking into account all properties that may affect its safety, of unacceptable risk.

  The enumeration or properties to consider is illustrative and indicates that all aspects of a product should be taken into account; such enumeration can be found - in one way or the other - in various national legislations; the term "safety properties" has been introduced as a general cover for all these aspects.

  Concerning "unacceptable risk" despite its modest appearance, the term has been chosen with care. The term used in the Product Liability Directive of 1985 namely "the safety which a person is entitled to expect", has been avoided because of the possible difference between defective and unsafe products. The term applied here stems from terminology adopted by the UN-Economic Commission for Europe and published as an ISO-standard.

The term implies the idea that absolute safety cannot be required; it also implies the idea that the judgement to be made is an objective one, based on the general viewpoint of society, irrespective of the capacities of an individual supplier to comply with this requirement and of the particular expectations of a individual user/consumer; it further implies that the general standard can change, and that "unacceptability" of risk may, therefore, develop with time to represent a still higher degree of safety.

It should be noted that vertical/sectorial Community texts, in particular of the "new Approach" type, do not "qualify" the risk (danger) by any such term (see e.g. Art. 2 draft directive on machinery: "... placed on the market only if it does not endanger ..."). However, the underlying principle is, certainly, the same. In the context of a general instrument, it is preferable to make this principle express, since such text cannot rely, in the same way as vertical legislation, on more specific technical annexes or essential requirements and related standards adopted for agiven sector which can illustrate more clearly the concept as is done for example in the draft legislation on machinery[8].
Besides, some references are given for risk assessment, it should be noted that it was thought impossible to go any further as regards details and, in particular, to envisage anything like "essential requirements" as in vertical directives, bearing in mind the very broad scope of application of this Directive.

- As for the "suppliers" the emphasis is made on manufacturers/importers as main responsibles for products safety, but it is made clear that other economic operators are also involved within the limits of their activities.

Art. 3, 4 and 5 establish the safety principles to be enforced by Member States and including provisions for presumtion of respect of such principles.

- Article 3 - General product safety obligation on Member States
Establishes the general safety requirement to be enforced. It extends it to professional activities as they may affect products safety including, in the event, their disposal; a type similar approach is chosen by national legislations of this type. This does not mean, however, that the instrument covers services as such (as does the French Act of 1983).

- Article 4 - Completing the safety requirement.
It completes the general safety requirement in that it requires that warnings must be made in an appropriate way whenever a risk, which is acceptable as such, still potentially constitutes a significant risk for users/consumers above all if they are not informed.

- Article 5 - Presumption and assessment of conformity with the safety requirement

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[8] OJ No C 29, 3.2.1988, p. 1 - see Annex I 1.1.2(C) "eliminate or reduce risks as far as possible".

Refers for the purposes of assessing the safety of a particular product in a given case, in the first place to any more specific criteria which may have been adopted for or, at least, are generally recognised in the particular product sector concerned.

Only specific rules, as mentioned in Article 5(1), are considered as presumption of equivalence to the general safety requirement and, therefore, will generally supersede it as the lex specialis. However, in the absence of such rules, reference is made, in order not to leave the general safety requirement too open to arbitrary discretion, to some general means that allows the degree of safety to be examined in the light of practical and available technology.

- Article 6 - Obligations for suppliers
The measures needed to respect the safety requirement implies those as needed to assure that the supplier respect this duty and that necessarily includes permanent monitoring of the marketed products, to the extend appropriate to manage the occurrence of unacceptable risks.
No direct equivalent seems to exist in national legislation of the horizontal type to this specific duty to monitor product safety. However, a close ressemblance can be found in Art. 11-4 of the French Act of 1905 as amended by the Act of 1983.

However, such duty can easily be derived from the duty to observe the general safety requirement. It requires, in fact, nothing more than to take reasonable precautions in order to meet this requirement properly (this is, apparently, the approach of the French Act - see above). In particularly sensitive product areas duties of such a kind are already expressly stipulated in one way or the other under various legislations. Generalising the principle may be seen, at first sight, as a considerable broadening of the scope of application, and may be felt as an unwelcome burden by some businesses. But such generalization is relative. The provision only requires for "appropriate arrangements", appropriateness being in relation to the risks involved; an indicative list is given in Annex I of arrangements considered as appropriate depending of the circumstances.

The basic concept of the present proposal has recently been supported by the Economic and Social Committee who noted in an Opinion adopted by the plenary on 27 April 1988 (at 4.) that

> "In the Implementation of product safety along the production chain, from manufacturer through to retailer, the following factors must be taken into consideration:
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> 4.1. The role of the manufacturer in applying controls both during the production process and after the product is in general circulation.
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> 4.6. Systematic monitoring after goods have been sold onto the market, and checking up on consumer use and abuse wherever feasible."

- Article 7 - Obligations on national authorities, and necessary powers to enforce the essential requirement.
Besides laying down certain basic conditions to be fulfilled by Member States with regard to public infrastructure available for the control and surveillance in respect of the general safety requirement, and some specific task to be performed, including systematic collection of relevant data for preventive purposes and due consideration of public complaints, it introduces the need of adequate powers for the responsible authorities. While the list of the considered needed powers is set out as an indicative list in Annex 2, it is meant to systemize such powers and clarify their possible use, even where they exist in principle in respect of all relevant sectors.

Annex 2 sets up a detailed list of means for increased control and, where necessary, intervention which might be at the disposal of public authorities in Member States in order to prevent risks from unsafe products.

A specific interest lies in the details laid down in respect of recall (withdrawal) of unsafe products. Although safeguard clauses in vertical Community legislation, in particular in texts following the "New Approach", mention withdrawal from the market as a means for action to be taken by Member States' authorities against unsafe products (as to be assessed under the specific conditions laid down in the particular legislation), they do not give any details in that respect.

Article 7(2) makes it clear that compliance with whatever of the criteria for safety presumption established in Article 5, and in particular 5(1), cannot preclude the possibility of intervention by public authorities where a product turns out to be unsafe. This provision only generalizes a concept already underlying the safeguard clauses in various vertical Community legislation.

Article 8 - Notification of national measures when they have not a local effect.
It provides for a notification procedure in cases where no specific Community text applies and, therefore, notification of national measures already takes place under such instrument.

No mention is made of action to be taken by the Commission following a notification under this provision - in contrast to safeguard clauses under "vertical" directives -, since the Commission must keep a wide discretion, bearing in mind the very general scope of application of this text.

Article 9 to 14 deal with "Emergency situations" where grave and immediate risks are considered.

Article 9 - Information in emergency situations.
It establishes an obligation for Member States to effectively run systems of rapid exchange of information on product safety emergencies at national level, and in specific circumstances extends this obligation to a corresponding cooperation at Community level. Such provisions will put systems such as established under Council Decision 89/45/EEC of 21 December 1988[9]

[9] OJ No L 17, 21.1.1989, p. 51.

concerning consumer products a more general level and on a firmer legal basis.
It requires Member States to designate one single authority which is competent, at the national level, to deal with all matters dealt with under this article as regards Community cooperation and, moreover, as regards execution of measures adopted under procedures laid in Article 14 on emergencies at Community level.

Such concentration of administrative power is necessary both in order to ease the Commission's task in dealing with Member States and in order to ensure that any result of Community cooperation is efficiently taken into account. Such obligation cannot be considered as an interference with Member States' internal administrative organization, since it is justified and even indispensable with a view to the proper fullfilment of the objectives of the entire proposal; it finally follows from Article 5 of the Treaty.

Article 10 - National measures in emergency situations.
It establishes the obligation of the national authorities to restrict, as appropriate, the marketing of a product in cases of grave and immediate risk, limiting this action in time in the case such risk is only suspected while on reasonable grounds.

Article 11 - Triggering mechanism for initiating a procedure at Community level in emergency situations.
It establishes three conditions to initiate a procedure to investigate and eventually decide on measures applicable at community level. These conditions being the problem affecting more than one Member State and that it can not be tackled otherway neither legally under provisions of specific legislation (principle of subsidiarity) nor practically because of the Community dimension of the problem. The Commission may decide to initiate a consultation and investigation procedure or directly a decisional procedure.

Article 12 - Consultation and investigation procedure at Community level in emergency situations
It establishes, together with the objectives of such a procedure, as needed in some cases as a previous step both to proceed further concerning the need of Community measures and to define those, the measures that Member States may be required to adopt in order to fullfil the Commission request for further information.

Article 13 introduces the "Product Safety Emergencies" Committee.

Article 14 - Decisional procedure at Community level in emergency situatons
It sets out the procedure for adopting interim measures applicable throughout the Community according to the management committee variant of Council Decision 87/373 of 13 July 1987, that is considered as the most appropriate taking into account the need for rapid action at Community level and the necessary involvement of Member States.

Article 15 - Confidentiality. General clause to protect matters covered by professional secrecy.

Article 16 - Prejudice to product liability
While a close link exist between both areas, it must be made clear that any action taken for the purpose of prevention under this directive should not automatically constitue an irrefutable argument to claiming for damages.

Article 17 - Conditions to respect when impossing products marketing restrictions and to assure feasability of appropriate public claims on safety and of possible redress from suppliers.

Article 17(1) obliges decision makers to provide for statement of the reasons when restricting the placing of a product on the market or withdrawing a product from it, as well as to allow interested parties to be heard in such cases. Since in the case of a recall action a major problem is the effective organisation of such action, be it voluntary or compulsory, and that depends very much of the preparedness of holders of a product to render it for being replaced or repaired; the decisions mentioned should face that question and where necessary settle the question of how the cost should be shared.

Article 17(2) deals with public debate about product safety issues and is designed to bring about a clarification from a legal point of view, since recent case law from courts in several Member States shows that a number of doubts exist in that respect.

Article 17(3) and (4) establishes the need for economic operators to have the possibility of redressing either against abusive public safety claims or irregular measures taken by the authorities involving restriction of their products marketing.

Article 18 and 19 are standard articles except for the provision on adequate sanctions that in this case should be enforced to assure the respect of the general product safety requirement.

Annex I and 2 are mentioned as part of Article 6 on permanent monitoring and of Article 7 on powers of national authorities respectively.

Proposal for a

COUNCIL DIRECTIVE

concerning general product safety

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 produce and 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, namely that such products do not present any unacceptable risks and that potential users are warned of any remaining risks;

Whereas the provisions of the Directive are to apply without prejudice to specific rules of Community Law, especially legislation in the agricultural field and legislation on the safety and health of workers at the workplace, including consultation on those matters;

Whereas a large number of Community or national rules lay down specific requirements in respect of health and safety of persons for a particular product or product sector; whereas it must be presumed that products manufactured in accordance with such rules comply with the general safety requirement; whereas however such presumption does not bar competent national authorities from taking preventive measures in respect of a product or product sector presenting or likely to present an unacceptable risk for the safety and health of persons;

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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 monitor on a permanent basis the safety of the products they deal with in the course of their business;

Whereas Member States must provide for appropriate 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 on 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 it is necessary to oblige Member States to restrict the marketing of a product respresenting an unacceptable risk of an immediate and grave nature;

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 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 intracommunity trade and in some cases an unacceptable difference in the protection of users and consumers;

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 a particular Community concern; whereas because of its emergency nature, measures adopted under such procedure must be only of an interim nature and 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[4];

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

Whereas public awareness of product safety problems should be increased by facilitating public debate of such issues;

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 adoption of any measure under this Directive or under more specific legal instruments designed for the same purpose must not, in itself, prejudge further legal responsibility with regard to compensation for damages, in particular under national laws adopted pursuant to 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[5];

Whereas the adoption of any measures with regard to imported products for the purpose of preventing risks to the safety and health of persons are to be taken in conformity with international obligations,

HAS ADOPTED THIS DIRECTIVE:

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

Article 1

(1) This Directive applies to the safety of products from the time they are first placed on the market and throughout their foreseeable time of use.

(2) This Directive shall apply without prejudice to provisions adopted in the framework of more specific rules of Community law.

(3) This Directive shall apply without prejudice to other notification procedures in Community legislation and in particular 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[6] as well as Commission Decision 88/383/EEC of 24 February 1988 providing for the improvement of information on safety, hygiene and health at work[7].

Article 2

For the purposes of this Directive :

a) "Product" shall mean any manufactured product and agricultural product, and shall include

any part of it such as raw materials, substances, components and semi-finished products;

movables incorporated into immovables;

re-conditioned products or any other product which is not supplied as new insofar as such supply takes place in the ordinary course of a business;

b) "Safe product" shall mean a product that does not present, in particular in respect of its design, composition, execution, functioning, wrapping, conditions of assembly, maintenance or disposal, instructions for handling and use, or any other of its properties, an unacceptable risk for the safety and health of persons, either directly or indirectly, in particular through its effect upon other products or its combination therewith;

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[6] OJ No L 109, 26.4.1983, p. 8.

[7] OJ No L 183, 14.7.1988, p. 34.

c) "Unacceptable risk" shall be evaluated subject to the application of more specific rules in respect of health and safety as mentioned in Article 5, according to the following general criteria :

aa) the intended use or consumption of a product according to normal circumstances, including any specific representations made by its supplier or on his behalf in that respect, and any other reasonably foreseeable use or consumption.

bb) the foreseeable time of use.

Any malfunctioning or defectiveness of a product which does not affect its safety properties as such shall not be taken into consideration.

The feasibility of obtaining higher levels of safety or the availability of other products of the same category, presenting a less degree of risk, shall not constitute, as such, ground for considering a risk presented by a product as unacceptable.

d) "Supplier" shall mean :

- the manufacturer of a product;
- the importer into the Community from a third country;
- distributors and other professionals in the supply chain insofar as their activities may affect the safety properties of a marketed product.

e) "Foreseeable time of use" shall mean the time that can be reasonably expected a product may be used in normal circumstances and for the use for which it is intended.

Article 3

Member States shall take all necessary measures in order to ensure that only safe products are placed on the market, irrespective of the commercial conditions of such placing on the market.

These measures shall extend to such activities as may affect the safety of a product, in particular its treatment, processing, packaging, storage, transport, installation and, where necessary, its disposal.

Article 4

(1) The measures which Member States are required to take pursuant to Article 3 shall include those necessary to ensure that, where a product because of its nature or for technical and/or economic reasons presents a significant risk which is acceptable as such, such risk is appropriately indicated in order to make the potential user or consumer aware of such risk, and in a way which

a) takes into account, in particular,

- the intended use, consumption, packaging, transport and storage of a product according to normal circumstances, including any specific representations made by its supplier or on his behalf in that respect, and any other reasonably foreseeable use or consumption;

- the perception and knowledge that can reasonably be expected from the intended or potential user or consumer, and

b) ensures that any relevant warning can be duly perceived, where necessary at all stages of use, consumption and disposal, and, if necessary, throughout the foreseeable use time of a product.

(2) Indication of risk shall be made in such a way as to allow any intended or potential user or consumer to make his own assessment of the risk, before he acquires a product or is otherwise brought into a position to make use of it, when such indication is an important element for his decision on purchasing or using the product.

Article 5

(1) A product which has been manufactured in accordance with specific Community or national rules which lay down the relevant requirements in respect of health and safety that must be met by that product for being marketed, shall be presumed to comply with the obligation to place only safe products on the market.

(2) In the absence of any specific rules, compliance with the general safety requirement of a particular product or product family shall be examined having regard to the state of the art, the state of scientific and technical knowledge including its practical feasibility and good business practices in respect of safety and health in the product sector concerned.

Article 6

The measures which Member States are required to take in accordance with Article 3 shall include ensuring that the supplier of a product makes appropriate arrangements for permanent monitoring, such as mentioned in the indicative list in Annex 1, of the safety of the products supplied by him, with a view to being properly informed about any unacceptable risk which such products may be likely to present and to assess such information with a view to further avoiding such risk. In the case of distributors or professionals other than the manufacturer or importer the duty of monitoring shall extend only to their activities and insofar as they may affect the safety of the product.

Article 7

(1) Member States shall

(a) establish and/or nominate appropriate 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) ensure that the authorities have the necessary powers to take the appropriate measures incumbent upon them under this Directive ; an indicative list of such powers is set out in Annex 2;

(d) ensure that the authorities are in a position to take account of and, where necessary, collect relevant data, on a permanent and regular basis, from sources which may supply indications for the likely existence of any risk of products, in particular based on evidence from accidents, cases of sickness or any other personal injury,

- which are likely to be related to any of the properties of a product,

- which are of a serious nature and which are likely to recur and

- which are not due to an obvious or unforeseeable misuse of the product or the non-observance of an appropriate instruction or warning;

(e) ensure that the authorities give due consideration to reasoned complaints about the safety properties of a product, in particular from consumer organisations, business associations and workers as well as their representatives;

(f) notify the Commission of the authorities. The Commission shall communicate this information to the other Member States, and shall publish it in the Official Journal of the European Communities.

(2) Compliance of a product with any of the criteria for assessment established in Article 5, and in particular the specific rules mentioned in paragraph 1 shall not bar competent authorities of the Member States from adopting, under the applicable procedures, any of the preventive measures set out in this Directive, or any further measure provided for under specific legislation governing a particular product or product sector, where there is evidence that a product, despite such compliance, is or is likely to present an unacceptable risk.

Article 8

(1) Where a Member State intends to take or has taken measures, pursuant to Article 7 and 10, which restrict the placing of a product onto 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 governing the particular product or product sector concerned, immediately inform the Commission of any such measure, indicating the reasons for adopting it. This obligation shall not apply where the measure has only a local effect.

(2) National measures which have been notified according to paragraph 1 shall be examined pursuant to the procedure laid down in Article 14; the Commission may submit a draft of any appropriate measure.

Article 9

(1) Each Member State shall take all necessary measures to ensure that information about the existence or the likely existence of an unacceptable risk presented by a product marketed or likely to be marketed on their territory, in cases where such risk is or is likely to be grave and immediate, is rapidly exchanged between its own competent authorities with a view to gathering and assessing all relevant information in the most effective way.

(2) Where a Member State has information about the existence or the likely existence of a grave and immediate risk having not only local effects, it shall immediately inform the Commission thereof and of the measures it has taken or envisages to take, in particular those within the meaning of Article 10. The Commission shall, where appropriate, ensure the rapid transmission of such information to the other Member States.

This obligation shall not apply to products which, under other Community instruments, are the subject of equivalent notification procedures.

(3) Detailed procedures for the transmission of the information within the meaning of paragraph 2 shall be adopted by the Commission in agreement with the competent authorities of the Member States.

(4) Whenever the Commission has knowledge of the possible existence of a risk within the meaning of paragraph 1, without having received information pursuant to paragraph 2, the Member State concerned, upon request from the Commission, shall immediately supply all relevant information about the matter which such Member State disposes of or which it can obtain.

(5) Member States shall designate the competent authority which is entitled and adequately equipped to ensure effective cooperation with the Commission according to paragraphs 2 and 4 as well as the expeditious carrying out of measures adopted under the procedure laid down in Article 14. Member States shall inform the Commission thereof.

Article 10

(1) a) Where the appropriate authority in a Member State has reasonable grounds for suspecting that a product presents an unacceptable risk of an immediate and grave nature, it shall serve a notice prohibiting those on whom it is served, for such a period ending not more than three months after the date of the notice as is specified therein, from supplying, offering to supply, agreeing to supply or exposing the product concerned.

b) The notice referred to in (a) may impose requirements as regards labelling or other notifications accompanying the product, as a condition for the resumption of the supplying of the product on the market.

c) Any person having an interest in any product in respect of which a notice has been served may apply to the appropriate authorities for an order setting aside the notice.

(2) Where the appropriate authority in a Member State finds that a product presents an unacceptable risk of an immediate and grave nature it shall take all appropriate measures to withdraw those products from the market or to prohibit or restrict their being placed on the market.

Article 11

Whenever the Commission has knowledge, whether through information provided by Member States, in particular under Article 9, or by reason of a notification from Member States, in particular under Article 8, 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 adequately be dealt with, especially with a view to the urgency and/or complexity of the product safety issue in question, under other procedures for information, consultation, concertation and decision-making and related powers where so laid down under specific Community legislation governing the product or product sector concerned, and

c) which can only be coped with appropriately by adopting adequate measures applicable throughout the Community, in order best to ensure protection of persons and the proper functioning of the Common Market,

it shall either initiate the consultation and investigation procedure as set out in Article 12 or directly take appropriate temporary measures to prevent the risk involved, such as those mentioned in Annex 2 (2) d) to i) in accordance with the procedure laid down in Article 14.

Article 12

(1) Where the Commission decides to initiate a procedure under this Article, it shall immediately commmunicate such decision to the Member States with a summary of the evidence available.

(2) The purpose of the procedure is, within the limits imposed by the circumstances and the urgency of the product safety issue in question, to

- obtain full information about the nature and scope of the risk,
- identify its causes and assess possible means of prevention,
- examine the need for adopting appropriate measures applicable throughout the Community.

(3) Member States shall adopt, upon request from the Commission, any measures necessary and appropriate for the purpose of this procedure, in particular those mentioned in Annex 2 (2) a) b) and c) to obtain appropriate information. Member States shall communicate forthwith the findings and results of such measures to the Commission.

(4) The Commission shall communicate to the Member States the results of the investigation.

Article 13

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 the representative of the Commission.

Article 14

1. The representative of the Commission shall submit to the Committee a draft of the measure 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. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt 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 decided 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 this procedure shall be valid for no longer than six months. It may be prolonged under the same procedure.

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

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

Article 15

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

Article 16

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

Article 17

(1) Any decision adopted under this Directive and involving restrictions on the placing of a product on the market or requiring the withdrawal of a product 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 is not possible, in particular because of the urgency of the matter, such opportunity shall be given, in due course, after the implementation of such measure.

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.

(2) Member States shall provide in their legislation that any person, natural or legal, who publicly puts into question the safety properties of a product or a category of products, for the sole purpose of promoting public awareness of health and safety issues, shall not be held liable for the economic consequences which such public debate might entail, provided such statements are substantially relevant, made in good faith and without discrimination, represented in an objective way and supported by serious argument.

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

(4) Member States shall ensure that any irregular measure taken by the enforcement authorities, involving restrictions on placing a product on the market, can be reviewed by the Courts.

Article 18

(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 19

This Directive is addressed to the Member States.

Done at Brussels

For the Council

ANNEX 1

Illustrative list of appropriate arrangements for monitoring in the sense of Article 6

a) appropriate marking of a product or a lot of products allowing for identifying it at a later stage;

b) regular or random testing of a product in respect of its safety properties;

c) appropriate agreements with other suppliers and professional customers and with general business organizations of the product sector(s) concerned in order to receive and exchange, on a regular basis, relevant information on safety issues in the product sector(s) concerned;

d) systematic assessment and evaluation of complaints about a product or reasons for returns, even when they are not directly founded on its safety properties;

e) keeping of adequate records on a regular basis of any such arrangements and their results;

f) where necessary for effective monitoring, nomination of a person or service especially in charge of organising such arrangements and supervising their proper functioning.

ANNEX 2

Indicative list of powers of National Authorities

(1) Powers for the adoption of appropriate measures for :

- the organization of appropriate checks on the safety of products, even after their first being placed on the market as being safe, on an adequate scale and especially with a view to the remaining risk, up to the stage of end use or final consumption and, in the event, their disposal;

- the control on the respect of the provisions on permanent monitoring by suppliers.

(2) Powers for the adoption of adequate preventive measures such as

a) the request of all relevant information from parties likely to be concerned such as suppliers and where necessary, from any other natural or legal person;

b) the request of samples of a product or of a production line, seize or sequestrate products and, where necessary, the penetration into premises or any other locality for that purpose:

c) the increase of the number and scope of controls, checks, tests, analyses or the like which are normally foreseen for the particular product or product sector concerned, or the carrying out of such measures ad hoc;

(d) the publication through appropriate media and in an appropriate form of public warnings addressed to those parties who, in normal circumstances, can be supposed to be users or consumers of the product concerned, but where necessary, to the public in general as well;

(e) the request addressed to manufacturers, importers and, where necessary, to any other professional, and, in the event, to end users or final consumers as well, to disseminate adequate warnings to all persons likely to be exposed to the risk involved, including, where necessary, the public in general;

(f) the request addressed to manufacturers to add appropriate warning notices to the product in question; where necessary, such request may also be addressed to distributors or other professionals;

(g) the imposition of appropriate restrictions as to the conditions of distribution and marketing and, in the event, of disposal, of product;

(h) the request of appropriate changes in a product or production line or the prohibition, either temporarily or definitively, of its further manufacture or marketing or, in the case of raw material, substance, component, semi-product of any other part, the prohibition of its use, integration into or association with certain categories or types of products;

(i) the withdrawal of a product already placed on the market, - even where it is already in the possession of an end user or final consumer - and, where necessary, its destruction under appropriate conditions; according to the circumstances, Member States' authorities may

(aa) invite a manufacturer to voluntarily recall, in the most effective way, the product concerned;

(bb) order manufacturers to recall, in the most effective way, the product concerned;

(cc) seize the product concerned at any stage of the manufacturing process and the distribution chain, and, where necessary, at the premises or homes of end users or final consumers.

FINANCIAL SHEET

relating to the proposal for a Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning general product safety.

1. Budget line affected

Item 685 : Activities linked to the operation of a Community-level procedure on product safety and in particular to assess the need for Community-wide measures in the case of product safety emergencies and for the imposition and monitoring of such measures.

2. Legal basis

(a) Article 100a of the EEC Treaty added by the Single European Act
(b) Council Resolution of the 25 June 1987 on the Safety of Consumers [1]
(c) Communication of the Commission on Safety of Consumers in relation to Consumer Products of 8 May 1987 [2]
(d) Council Resolution of 23 June 1986 concerning the future orientation of the policy of the European Economic Community for the protection and promotion of consumer interests [3].

3. Proposal for classification as compulsory or non-compulsory expenditure

Non compulsory

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1 OJ No C 176, 4.7.1987, p. 3.
2 COM(87) 209 final
3 OJ No 167, 5.7.1986, p. 1.

4. Description and grounds for the action

4.1. Description

4.1.1. Aims of the proposal for a Directive

The Directive requires Member States to ensure that only products not presenting an unacceptable risk for the health and safety of users/consumers are allowed onto the market.

The Directive aims at creating basically uniform levels of safety and enforcement methods throughout the Community.

4.1.2. Features of the proposal for a Directive (especially those with financial implications)

Member States are to fulfill this duty by such measures as pre-and post marketing controls, control of the obligation for permanent monitoring by manufacturers and any other person responsible, and by establishment and effective operation of institutions or bodies for the control of compliance and conformity of products with requirements of the Directive.

Member States also have the obligation to gather certain information.

The Directive sets out measures which the authorities in Member States can take in respect of products, which either do not comply with specific Community or national safety requirements or which prima facie give reason to believe, despite such compliance, may present an unacceptable risk to the health and safety of persons.

Member States are to disseminate information between their own competent authorities about the existence or likely existence of an unacceptable risk presented by a product and notify the Commission when they have information about the existence or the likely existence of a grave and immediate risk related to the health and safety of persons presented by a product and where there is a reason to believe that the risk is not purely local. They shall also inform

the Commission of the measures they take or envisage taking. The Commission may also require information from the Member States in these circumstances.
The Commission is to ensure when appropriate the rapid exchange of such information by immediately forwarding it to the other Member States.

The competent authorities of Member States are to collect data on a permanent and regular basis which indicates the existence of products presenting an unacceptable risk to the safety and health of persons. Such information will provide a valuable tool for the establishment of policy and the proposal of measures.

4.1.3. The Directive aims to provide a rapid and uniform response to cases of products which present a grave and immediate risk to the health and safety of persons in cases which are not purely local.

In such cases the Directive aims at creating uniform levels of safety and uniform enforcement methods throughout the Community.

Where the Commission is notified by Member States or otherwise becomes aware of a product that actually or potentially presents a grave or immediate risk to the health and safety of persons in more than one Member State, it may instigate a consultation and investigation involving the obtention at Community level of information and data. If the Commission considers there is a need for adopting measures immediately applicable throughout the Community, it shall submit a draft of such measures to the Committee on Product Safety Emergencies. The Commission shall apply measures immediately but if these are not in accordance with the opinion of the Committee they shall be communicated to the Council which may take a different decision within five working days, and the Commission may defer application of the measures for a period of five working days.

4.1.4. Grounds

The action is justified on the legal grounds indicated under point 2. The financial implications are inherent in the application of the Directive.

5. Nature of expenditure and method of calculation

5.1. Nature of additional activities to be undertaken after adoption of the Directive

a) monitoring the application of the Directive;
b) collection and assessment of data when supplied by Member States and retransmission to other Member States;
c) operation of the Committee on Product Safety Emergencies;
d) adoption of measures where required due to the existence of a grave and immediate risk;
e) permanent and "ad hoc" experts meetings;
f) studies relating to the operation of the Directive;
g) taking of further harmonization measures.

5.2. Cost of activities mentioned in 5.1

The costs would be those normally associated with the activities mentioned in 5.1.

5.3. Calculation of expenditure

- In view of the nature of the activities, it is impossible to estimate the expenditure precisely.

- Costs are calculated on the basis of the "man/month" unit; at present, one unit is equivalent to 5,000 ECU

- The approximate figures given in 6.1. cover expenditures for additional activities indicated in 5.1. The expenditure for 1990 will be made for preparatory work. From 1991 onwards when the system at best, is in place, it has to be made progressively operative

until it is fully functioning by 1993. The figures are only given on indicative basis and subject to the annual decisions on the budget taken within the framework of the financial forecasts made under the Interinstitutional Agreement.

6. Financial impact of the action on appropriations

6.1. Schedule of commitment (non-dissociated):

	Year	ECU 000
- Item 685 (General product safety procedure)	1990	500
	1991	2.800
	1992	2.500
	Following years	3.800

7. Comments

None

8. Financial impact on staff appropriations

8.1. Staff needed solely for the execution of the action

From 1991, 6 full-time category "A" officials; 8 full-time "B" officials and 6 full-time "C" officials. 1 full-time "D" official.

The above personnel will be found by internal redeployment or in the context of the annual budget procedure.

8.2. Staff appropriations needed

From 1991 an estimated 630,000 ECU per year will be required.

IMPACT STATEMENT ON THE EUROPEAN CITIZEN

Proposal for a Council Directive relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning general product safety.

1. The proposition for a Directive will substantially improve the level of product safety in the Community. This is an essential concomitant of the far greater movement of goods to be expected with the completion of the Internal Market, and will itself assist in the expansion of such inter-state trade.

2. The Directive will accomplish the above objectives by requiring Member States to have a proper infrastructure on a national basis to discharge their responsibility to ensure compliance by producers with the requirements for products in the Directive bearing on the health and safety of consumers and by requiring Member States to gather information and disseminate it internally and through the Commission to each other, and thereby to ensure a more rapid intervention in cases of risks to health and safety arising from products.

3. The further requirement for the provision of information by Member States to the Commission facilitates the control by the latter of the application of intervention measures by the former, and therefore promotes the free movement of products between Member States.

4. The proposition for a Directive will enable the European Citizen to be protected throughout the Community far quicker in the case of serious risk to health or safety caused by a product sold or likely to be sold in more than one Member State, by the taking of common measures in each Member State concerned, in respect of such risks.

5. By avoiding the creation of barriers to trade arising from differences of interpretation and assessment of such risks and of the necessary measures to be taken in response, the measure will help assure free movement of goods, with the resulting benefits to the citizen.

COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT

Relating to the Proposal for a Council Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning general product safety.

I. The main reasons for introducing the measure, and thus the essential policy objectives are :

1) By establishing a common general requirement for safety, with which all products marketed within the Community must comply and by helping to coordinate measures taken in response, to protect the European citizen against injury or damage resulting from unsafe products, especially where such products are not at present regulated.

2) In particular by basically harmonising the information gathering and intervention methods available to Member States and by reinforcing the principle of free movement for products complying with Community or national health and safety requirements to encourage interstate trade whilst promoting the safety of products for the benefit of Europe's citizens.

3) By ensuring that each Member State disseminates information and data regarding the existence of unacceptable risks to the health and safety of persons presented by a product between its own competent authorities and, where such risk is grave and immediate and is likely to have more than only local effects it shall inform the Commission and further give to the Commission notice of the measures it has or intends to take to remove such risk which information the Commission shall, where appropriate, relay to the other Member States, to promote a uniform high level of safety in the Community.

4) By requiring Member States who take interventionist measures with regard to a product on the grounds laid down in the Directive, where the risks posed by such product are not likely to have a purely local effect, to immediately notify the Commission of any such measure and to indicate the reasons for adopting it to enable the Commission to control the uniform and non-discriminatory application of product safety criteria throughout the Community.

5) By establishing a procedure for action at Community level in cases of products involving an immediate and grave risk to the health and safety of a number of persons in more than one Member State, and by establishing a Committee on Product Safety Emergencies composed of representatives of the Member States it will be possible to :

   a. ensure an expeditious response to such risks throughout the Community - thus helping to raise the standard of living throughout the Community in accordance with Article 2 of the Treaty and ensure the high level of safety required by Article 100 A added by the Single Act.

   b. ensure a coordinated response, with the Member States either taking the same measures or, where it is established there is no risk, not taking any measures - or withdrawing those already taken in isolation. This is important for avoiding action taken under Article 36 of the Treaty, or under a safeguard clause contained in a vertical directive, on the grounds of safety or health, from impeding the free movement of goods and the proper functioning of the Internal Market.

6) By providing for the proper motivation of any decision taken by Member States in connection with the intervention powers set out in the Directive and by requiring producers to be informed of the means of appeal to encourage transparency and fairness of application of health and safety measures.

II. By such harmonization and increased protection to facilitate the completion of the Internal Market for products, by removing barriers to trade arising from products being permitted in certain Member States whilst being banned in others, and to strengthen the confidence of citizens in products originating from, or coming from, another Member State.

Action needs to be taken at EC level particularly as regards risks which are likely to effect more than one Member State :

a. to obtain a consistent judgement as to whether a product presents an actual or potential grave and immediate risk.

b. in order to reach such a judgement information concerning an investigation into actual or potential product hazards needs to be coordinated at the Community level.

c. the measures taken need to be the same in each Member State affected so as to avoid barriers to trade arising due to the inconsistency of the measures taken.

The consequences of non-intervention by the EC would be continued inconsistency of response by Member States, to cases of products which present an actual or potential grave and immediate risk to the health and safety of citizens in more than one Member State and an inacceptable delay in the taking of adequate uniform measures throughout the Community.

Action needs to be taken at EC level also :

a. - because safety criteria in Member States are widely different in respect of individual products or do not, in respect of some products, exist at all,

- and also because of the diversity of measures that may be taken to meet the problem of unsafe products.

These disparities will not be removed unless the EC approximates the underlying laws.

b. - so that the European citizen can be adequately protected as the flow of goods between Member States increases.

The consequences of non-intervention by the EC would be continued or increased division of the market and risk of injury and damage to the European citizen from unsafe products, thus failing to provide the full advantages to be expected from the completion of the Internal Market.

III. Features of the business in question

1) The proposal has implications for all manufacturing and processing industries, some businesses providing services to these industries and to retailers, and to wholesalers and retailers themselves.
Thus businesses of all types and sizes are involved, SMEs forming a large part of the market.

2) The measures proposed apply to all business irrespective of size, but the retail sector, where the percentage of SMEs is particularly high, are only expected to comply in respect of any activity exercised by them which may affect the safety properties of a product.

Responsible suppliers of all sizes already only produce and market goods they believe to be safe. No substantial procedural requirements of an administrative nature are made for them, except in relation to the need to monitor the safety of products after sale, which can be accomplished in a number of relatively simple and inexpensive ways, which can be incorporated into their existing manufacturing/marketing/after sales systems.

There are no special financial consequences for business, although the measures will encourage such businesses to keep proper records and data, where these are not already required by other Community or national measures, for example under the requirements of vertical directives. Management time would be taken up in complying with the information requests, but if proper data is kept by businesses this should not be great and in any event would only occur if there has been sufficient evidence of an actual or potential risk to health and safety to justify the obtention of such information in respect of that product

3) In that the European citizen will have increased faith in the safety of a product, irrespective of the Member State in which the product was first marketed within the EC and irrespective of the size of the supplier, the measures should considerably encourage purchases from SMEs and consequently their creation.

4) Such businesses are spread throughout the Community, but would affect regions largely concerned with farming and food production less, although the proposed Directive is applicable to the raw materials which form part of a manufactured product.

5) In general, by promoting safety standards and encouraging confidence in the products, sales should increase for businesses of all sizes and inter-Member State trade will be promoted, with a resulting increase in competition. The measures will also promote greater equality in the efforts made by firms to ensure safety, whereas previously firms who reduced safety standards may have had a cost-advantage.

IV. <u>What obligations does this measure impose on business</u> ?

The measures impose a requirement for products not to present an unacceptable risk for the safety and health of users/consumers. The obligation includes an obligation to permanently monitor the safety of the goods.

As the procedures involved in complying with the measures put forward in the Proposal can be adapted into their existing procedures, business should not be involved in substantial additional cost.

Once it is established or there is a strong reason to believe that a particular product does not comply with the general safety requirement or that despite such compliance it may be unsafe, Member States shall have powers of requesting information, taking samples, seizing or sequestrating products, and requesting the publication of warnings by the persons concerned. They may also request changes in a product or ban manufacture/marketing.

The proposals will only stop producers from producing unsafe goods.

Again, most Member States already control the safety of products - although the scope and methods vary - unless already harmonised for particular sectors or products by Community level legislation.

If the Proposal were not to go ahead, some businesses would continue to profit by cutting costs on safety to the detriment of the health and safety of Europe's citizens, thus unfairly distorting competition.

V. What indirect obligations are national, regional, local authorities likely to impose on business ?

1. Member States will have to extend their product safety control procedures and the competent authorities who execute them to embrace such products within the scope of the proposed Directive which are not at present subject to such controls.

2. Member States will be obliged to collect information and take interventionist measures as and when required by the Commission in cases of grave and immediate risk to health and safety which are not purely local.

3. Member States would also have to participate in the Management Committee (the Committee on Product Safety Emergencies) set up to consider proposals for measures made by the Commission in cases of grave and immediate risk to health or safety.

4. A small extra cost for business might result from the measures envisaged, most especially in connection with the permanent monitoring of the product, but also in the provision of information to the competent authorities where required by them.

5. There will also be a cost involved in complying with the requirements of Member States connected with the remedying of the risk to the safety and health of persons presented by the product.

6. Apart from the Member States themselves, testing laboratories and certification bodies would be involved in implementing the controls foreseen by the proposed Directive.

VI. 1. There are no special provisions in respect of SMEs and it is not desireable, given the aim and nature of the proposals, that they should be exempted.

2. The measures proposed apply to all businesses irrespective of size, but the retail sector, where the percentage of SMEs is particularly high, are only expected to comply in respect of any activity exercised by them and which may affect the safety properties of a product.

3. Insofar as the measures could stimulate increased demand for the products of SMEs, they will be stimulated by the Proposal.

VII. 1. <u>The likely effect of the proposal on the competitiveness of business</u>

Although the measures will represent a higher unit cost the fewer the products involved, this cost should be minimal as the measures proposed can in large measure be integrated into the normal manufacturing, marketing and after sales methods of the producers.

Companies which had previously had an unfair price advantage due to the adoption of a low safety level for their products, will be obliged to adopt at least the safety level required by the general safety requirement.

Greater faith in the safety integrity of products emanating from SMEs should promote sales of their products and enable them to compete more fully with larger suppliers.

The safety requirements of the proposed Directive, in principle, do not apply to goods exported out of the Community, but they would have to comply with existing international or bilateral agreements.

Goods coming into the Community from third countries will have to comply wilth the provisions of the proposed Directive, and so will not be able to gain a price advantage from having safety standards below those required of European Community manufacturers.

If the proposal were not to go ahead, some suppliers both inside and outside the Community, would continue to reap a price advantage from low safety standards.

2. What is the likely effect on employment ?

The measures will create new jobs in manufacturing and marketing business, especially in the field of test and quality control, where these factors are currently insufficiently covered by the supplier concerned.

The measures will also create new jobs with government inspection services and with testing laboratories and certification bodies.

If the proposal did not go ahead these jobs would not be created.

VIII. Consultation of the representative organisations

Consultation with experts from the national administrations of Member States, as well as with leading academics in the field of product safety from different Member States and also with members of national safety bodies concerned with the safety of products, have been systematically undertaken.

The Commission has had the benefit of Opinions from the Economic and Social Committee (ESC) (1) and the Consumer's Consultative Committee (CCC) (2) as well as from the Bureau Europeen des Unions de Consommateurs (BEUC) (3). All without exception, pronounced themselves in favour of the harmonisation measures proposed and that action in emergency situations be determined centrally, at Community level. Both the ESC (at point 7.8.) and BEUC (at p.14 final paragraph) pronounced themselves in favour of the Commission being empowered to decide measures necessary for dealing with the risk. The ESC (at point 7.8) also pronounced itself in favour of the Commission acting as central recipient of information from Member States.

By such consultations both employers and labour organisations have contributed to the concept of the Proposed Directive.

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(1) Opinion of 27 April 1988 - OJ N° C 175, 4.7.1988
(2) CCC/59/87 of 17.5.1988
(3) BEUC Suppl. Jur. N° 20 Feb. 1988