



COMMISSION OF THE EUROPEAN COMMUNITIES

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Green Paper

Liability for defective products

(presented by the Commission)

Summary

Since 1985, each producer is obliged to make good the damage to health, safety and property caused by a defective product, under the terms of Directive 85/374/EEC, the first instrument of a Community policy on producer liability. This Directive seeks to protect victims and promote improvements in product safety within the internal market through a regulatory framework which is as consistent as possible and based on a fair apportionment of the risks inherent in modern production.

The real challenge for this policy is to maximise its positive effects for consumers (and, in particular, to ensure the best possible compensation of victims), while keeping costs at the most reasonable level possible (and, in particular, not holding back industry's capacity for innovation and research). Since there is no such thing as zero risk (like the recent food crisis related to BSE and dioxin have shown), any society must adopt a system which is best suited to its development with a view to ensuring the best possible compensation of victims suffering damage from products. It is therefore essential to establish whether an instrument such as Directive 85/374/EEC is continuing to achieve its objectives in the light of the new risks which European society will have to face in the new millennium.

Approach of the Green Paper

Before contemplating any revision of the Directive, the Commission is proposing to consult all those parties concerned on the basis of this Green Paper in order to establish the impact of the Directive on victims and on the sectors of the economy concerned, and to reflect on the appropriateness and type of reform needed, with a view to ensuring greater legal certainty for the parties concerned. The announcement of this move (made during the parliamentary debate on Directive 1999/34/EC extending the rules on liability without fault to primary agricultural products) naturally aroused the interest of the economic operators, consumers and the public administrations. In a context which differs considerably from that in 1985, it is essential to establish whether the Directive is still effective and, if not, why and how to improve it. The Green Paper thus has two aims: (1) it allows to seek information which will serve to assess its application "in the field" in view of the experience of those concerned (in particular industry and consumers) and to establish definitively whether it is achieving its objectives; (2) it serves to "gauge" reactions to a possible revision as regards the most sensitive points of this legislation.

On the first point, it is more a matter of collecting information to assess how the Directive matches the objectives which it set out to achieve with regard to the various sectors involved: whether it ensures adequate protection for victims, whether it helps to discourage the marketing of dangerous products, whether it gives operators sufficient legal certainty to facilitate intra-Community trade, whether the competitiveness of European businesses is not being jeopardised by the Directive, whether the insurance sector has managed to cope with the risks tackled by the Directive, whether the authorities and consumer associations consider the Directive to be a useful instrument in their policies towards the victims of defective products, etc.

On the second point, all those concerned are invited to adopt a reasoned position as to the justification of any reform of Directive 85/374/EEC. Adoption of this Green Paper does not imply embarking on a legislative revision of its content at this stage. On the contrary, once the Commission has analysed the contributions received, it may well propose measures on this point in its second report on the Directive planned for the end of 2000. The "options for

reform” set out below are thus only guidelines for discussion - a basis for an open debate. This Green Paper does not prejudge the Commission’s position on the future of the instrument. Amongst other things, the guidelines for discussion concern the following aspects:

- the details of implementing the burden of proof imposed on the victims
- implementation of the exemption in the case of “development risks” and assessment of its possible abolition
- the existence of financial limits and their justification
- the ten-year deadline and the effects of a possible modification
- assessment of the insurability of risks deriving from defective production
- improved information on the settlement of cases deriving from defective products
- the supplier's liability
- the type of goods and damage covered.

In the EU, by comparison with the debate in the United States, Directive 85/374/EEC represents a compromise which reconciles the interests involved. The political resolve of the Member States, as embodied in the Directive, to have a balanced framework of liability governing relations between businesses and consumers, should not be underestimated. The Commission wishes to maintain this conciliatory approach. Any move to reform the Directive must *a priori* be guided by the balance resulting from its rules.

Finally, the Commission wishes the exercise to be guided by the transparency and effectiveness of the results. **In order to promote reflection and debate, it therefore wishes the replies provided to be based on facts, and not on mere positions of principle.** The Commission invites **any concerned party** to submit its written observations on the questions contained in this Green Paper within **four months of its adoption by the Commission.** Interested parties can reply to any questions they wish, even if some of the questions are aimed *a priori* at other types of operator. In addition, the Commission expects varying responses from the same sectors of the economy in the individual Member States: only such responses will enable it to assess the real impact of the Directive in the different Member States.

The Green Paper is accessible on the Internet (<http://europa.eu.int/comm/dg15/en/index.htm>). Those consulted can send their written observations to the Commission, by mail or similar, at the following address:

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and/or by e-mail (d3@dg15.cec.be). If they choose the latter, they are advised to send the electronic version in .html format. Observations received by e-mail **may be made public on the Internet, unless the party consulted explicitly requests otherwise.**

Follow-up to the Green Paper

Subsequent to the consultation, the Commission will assess the impact of the Directive and draw the appropriate conclusions for its possible reform. This will be the subject of a report to be presented **at the end of 2000** to the Community institutions, eventually accompanied by a duly motivated proposal for a revision.

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4. 1. INTRODUCTION

The right to compensation of a victim who has suffered damage through using or consuming a defective product, or through exposure to a defective product, is essential in a single market open to everyone. Since 1985, this right is recognised by the Directive on liability for defective products¹, under which any producer of a defective movable must make good the damage caused to the physical well-being or property of individuals. For instance, a child injured by the explosion of a soft drink bottle, an employee who loses a finger by using a defective tool, or a pedestrian knocked down by a car with defective brakes, enjoy this right, whether or not there is negligence on the part of the producer (principle of objective liability or liability without fault).

The policy of producer liability established by Directive 85/374/EEC concerns producers and victims directly. However, distributors, insurers, courts, public administrations and practitioners are involved in varying degrees in its application. The liability laid down by this Community legislation is a coherent framework which takes account of the various interests involved:

- on the one hand, those of individuals in coping with the risks to their health and physical and material well-being from a modern society marked by a high degree of technical complexity,
- on the other, those of producers in avoiding distortions of competition resulting from diverging rules on liability, and in reducing the impact of those differences on innovation, competitiveness and job creation.

This framework of liability is capable of ensuring the well-being of victims (by ensuring they are compensated and by discouraging the marketing of defective products) and of minimising the costs to industry so as to avoid excessive interference in their capacity for innovation, job creation and exporting. Through an equitable apportionment of the risks, the framework of the producer liability policy is made up of the following elements:

- liability without fault on the part of the producer in favour of the victim;
- burden of proof on the victim as regards the damage, the defect and the causal relationship between the two;
- joint and several liability of all the operators in the production chain in favour of the victim, so as to provide a financial guarantee for compensation of the damage;
- exoneration of the producer when he proves the existence of certain facts explicitly set out in the Directive;
- liability limited in time, by virtue of uniform deadlines;

¹ Council Directive of 25 July 1985 (85/374/EEC) (OJ No L 210 of 7.8.1985, p. 29) (full text is annexed)

- illegality of clauses limiting or excluding liability towards the victim;
- a high ceiling for financial liability, but optional for the Member States;
- regular review of its content in the light of the effects on victims and producers.

Defective services are not covered by Directive 85/374/EEC. As indicated in its Consumer Policy Action Plan for 1999-2001², the Commission intends to examine the need to reinforce the safety of services. On the basis of this analysis, the Commission will propose initiatives that will address both service safety and the liability of service providers. An in-depth consultation with business and consumers will determine the Commission's subsequent action.

1.1. Why a Green Paper?

This Green Paper is intended to prepare the report on the application of the Directive on producer liability planned for **the end of 2000**³. Further to the first report in 1995 (presented in a context marked by the very small number of cases of application due to the late implementation of the Directive⁴), this Green Paper initiates the second in-depth analysis of the implementation of Directive 85/374/EEC in a context which differs from that in 1985 and 1995, particularly because of the new impetus given to the policy for the protection of the health and safety of individuals after the "mad cow" crisis.

In the first report, the Commission had concluded that the lessons to be learnt from the implementation of the Directive were still limited. In 1995, the Member States had only a very limited case law in the field. In the light of the information available in 1995, the Commission had considered it unnecessary to submit any proposals for amendments. However, certain aspects of the Directive relating to consumer protection and the functioning of the internal market called for ongoing attention. This was the case, for instance, with the exclusion of unprocessed agricultural products. Subsequent to the "mad cow" crisis, and in accordance with Directive 99/34/EC, the Member States must now apply the rules of Directive 85/374/EEC to unprocessed primary agricultural products⁵.

² Communication from the Commission - "Consumer policy action plan 1999-2001" (COM(98)696 of 1.12.98).

³ The Commission has to report regularly to the Community institutions on the state of application of the Directive (see Article 21 - every five years on the general application of the Directive; Article 15(3) and 16(2) - ten years after notification of the Directive on development risks and the financial limit; and Article 18(2) - every five years on the revision of the amounts laid down in the Directive).

⁴ The Commission presented its first report on the application of the Directive on 13.12.95 (COM(95)617), based on an impact study carried out in 1994.

⁵ Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ No L 141 of 4.06.99.)

The Commission first of all proposes (*point 2 of the Green Paper*) to obtain the fullest possible information on the impact of the Directive on the proper functioning of the single market, the protection of health and safety, the competitiveness of industry and its capacity for innovation, and the financial sector (insurance). The objective is to establish (1) **what are the effects brought about by the application of the Directive, whether it has brought more benefits than costs, in particular as regards the protection of victims and the costs borne by business, and (2) how and to what extent the Directive is behind these effects.** Subsequently, it proposes to establish, on the basis of a number of guidelines for discussion (*point 3 of the Green Paper*), (3) **which aspects of the Directive should be reformed in order to increase its social benefits while keeping costs at a reasonable level.**

On the basis of the information and observations received, the Commission will then present its conclusions to Parliament and the Council in the application report to be adopted in 2000. This report will identify the shortcomings in the implementation of the current Directive and the fields which need to be improved. If the Commission considers that Directive 85/374/EEC has to be amended, a legislative proposal will be presented to that end. This Green Paper does not prejudge the Commission's position on the future of the instrument.

The choice of a Green Paper to prepare the report in 2000 is justified because of the scale and variety of the interests at stake. It was the Commission's intention that the assessment process should be governed by transparency, and that producers, consumers, insurers, practitioners and any other sector concerned should be able to make known their experience and views on implementation and the subsequent development of producer liability. **In this spirit of transparency, the replies will not be confidential and can be made public unless the participant in the consultation process explicitly requests otherwise.**

Apart from access to information on the application of the Directive⁶, the Green Paper invites operators to take part in the consultation on the future of the legislation under examination, with a view to gaining a better idea of the costs of any revision. The Green Paper thus fulfils the Commission's undertaking to consult the representatives of consumers, producers, distributors, insurers, public administrations and any other circles involved, before substantially revising the provisions of Directive 85/374/EEC. This commitment to transparency was entered into vis-à-vis Parliament and the operators involved when adopting Directive 99/34/EC extending the 1985 Directive to primary agricultural products⁷.

The consultation exercise launched with the Green Paper is also opened to operators, consumers and administrations coming from the countries which are candidates to accede to the EU.

⁶ When reference is made to "application of the Directive", this of course refers to application of the national measures implementing the Directive (e.g. the national transposing laws).

⁷ The Commission (see SEC(1998)2232 of 6.1.99) did not share the EP's favourable opinion, at first reading, of the revision of the Directive at the same time as its extension to the agricultural sector.

1.2 How to reply to it

The credibility and quality of the results of the consultation depend on the degree of involvement of the participants in this consultation. One of the difficulties in assessing the impact of the Directive remains the lack of reliable data because of the absence of an analysis methodology to measure its effects. To partly remedy this shortcoming, it is proposed that operators take account of the following parameters in order to contribute as effectively as possible to the exercise:

* The index of complaints (number and content of judgments, proceedings settled out of court, number of claims made, etc.)

The aim is to establish how the Directive is used in disputes of all types (legal proceedings, claims submitted for arbitration, claims lodged with insurers, etc.) Operators are invited to provide all types of information on this field.

* The availability of safe products on the market

It will be useful to know whether and how the Directive is one of the factors conditioning the market entry, maintenance and withdrawal of a product (for instance, has the producer decided to withdraw or not to market a product because of the risk of his liability being invoked?). At Community level, the accidents caused by a product and/or involving a product can be identified and quantified thanks to the former Community system, EHLASS - *European Home and Leisure Accident Surveillance System*. However, the former system could not identify the defective nature of the product in question. The new Community system for compiling information on injuries set up under the programme of Community action on injury prevention⁸ is looking into this approach in order to meet this need. However, it might be possible to find this information at national level⁹.

* The trend in costs, production and selling prices

The aim is to establish the real costs inherent in the system of liability, and the extent to which they are in fact passed on in the prices of products.

* Differentiation between markets

The aim is to establish whether and to what extent the differences between the liability schemes in force in the different export markets (inside and outside the EU) are taken into account by economic operators (e.g. change in the production process, supplementary insurance to cover new risks in the export market, etc.)

* Innovation/research

The aim is to learn about operators' experience in order to know how the Directive has influenced industry's capacity to innovate (e.g. has the Directive discouraged the development of a particular sector?).

⁸ OJ No L 46 of 20.02.99

⁹ According to the Spanish *Instituto Nacional de Consumo (informe Sistema EHLASS 1997, www.consumo-inc.es/Estudios)*, the Spanish victims surveyed stated that the cause of the accident was chance (45.2%), lack of attention (21.4%), their own negligence (15.4%), the action of a third party (7.0%), a design or production defect (2.8%), lack of information from the manufacturer (0.2%) and failure to follow the instruction manual (0.4%).

Using these parameters (or other equivalent ones), operators are invited to make known their experience and to reply to the questions in this Green Paper. In the field of producer liability, where the positions of principle are well-known, the Commission wishes to obtain factual practical information (if possible quantified) rather than mere declarations, so that it can justify its conclusions, particularly if they are to culminate in a substantial revision of the Directive.

2. WHAT ARE THE EFFECTS OF DIRECTIVE 85/374/EEC?

Evaluating the impact of the Directive means not just listing the cases brought before national courts or taken to arbitration, or even those on which the Court of Justice has pronounced¹⁰. The aim is more to assess how the Directive meets the objectives it set out to achieve with regard to the various sectors involved: whether it ensures adequate protection for the victims, whether it helps to discourage the marketing of dangerous products, whether it gives operators sufficient legal certainty to foster intra-Community trade, whether the competitiveness of European businesses is jeopardised by the Directive, whether the insurance sector has managed to cope with the risks covered by the Directive, whether the authorities and consumer associations regard the Directive as a useful instrument in their policies towards the victims of defective products, etc. To this end, the operators concerned and administrations are asked to answer the following questions.

2.1 The impact on the internal market

Applicable throughout the European Economic Area, and taken as a model by non-member countries (in particular those which have applied for membership of the European Union) (see annexes), the Directive on producer liability is a major element of the legal environment in which intra- and extra-Community trade is conducted. The Commission would like to know how those concerned view its impact in the light of their experience since 1985.

2.1.1 Community trade

In Directive 85/374/EEC, the current internal market, with its strong growth in intra-Community trade,¹¹ has a consistent and avowedly balanced framework of producer liability in Europe. It is intended to ensure adequate protection for victims, to promote trade in goods and to largely harmonise the conditions of competition in the internal market. The existence of harmonised legal conditions is intended to make trade easier, since the producer is in the same legal position no matter where his products are distributed.

¹⁰ The ECJ has issued two rulings on the Directive in actions against France (C-293/91, judgment of 13.1.93, ECR 1993, p. I-1) and the United Kingdom (C-300/95, judgment of 30.5.97, ECR 1997, p. I-2649).

¹¹ Since 1985, trade in products between Member States has increased significantly. In 1997, intra-Community trade in industrial goods was estimated at 31.5% of GDP (European Commission, *Report on the functioning of Community product and capital markets*, COM(1999)10 of 20.1.99).

Directive 85/374/EEC aims to harmonise to a large extent national law on producer liability. It does not contain any provision directly concerning conflicts of law. Despite the wide degree of harmonisation achieved by it, there are still divergences at national level. When a defective product causes damage in the Member State or it has been marketed within the internal market, the victim can be compensated under the uniform liability rules contained in the Directive. As regards the non-harmonised aspects, it is important that the victim and the producer establish which law is applicable. An intergovernmental convention was signed in 1973 to lay down the law applicable to product liability. However, most of the Member States are not parties to this agreement, which has been ratified only by Spain, Finland, France, Luxembourg and the Netherlands. In the absence of any other applicable instrument, conflicts of law relating to product liability are governed by the legislation of each Member State.

It must nevertheless be acknowledged that the legal certainty of the victim and the producer is far from being assured in this field, since the Directive is both incomplete and complementary to any other national producer liability scheme. In 1985, the disparity in legislation was perceived by the Community legislator as being such as to affect the level of intra-Community trade, so that it warranted an approximation of the legal conditions governing liability - an approximation which was partly achieved by Directive 85/374/EEC

On the one hand, the Directive does allow the Member States - in the case of certain points clearly defined in the Directive - to legislate differently in each Member State (see the options set out in Articles 15 and 16 of the Directive).

On the other hand, the general national law on liability based on fault, which naturally also applies to producers, is not harmonised and thus continues to apply. The situation in Spain illustrates this coexistence of the legal frameworks for producer liability which may well hamper the legal certainty of the parties in practice: on 4 October 1996, in a case involving the explosion of a bottle, the Spanish supreme court delimited the field of application of the transposing law of 1994 vis-à-vis the general consumer protection law of 1984, by ruling that the former establishes a special and closed system of liability, while the latter establishes a general system of quasi-objective liability with a reversal of the burden of proof. Although it did not apply it in the case in question (since the product was put into circulation before 1994), the Court ruled that the principle of liability under the law of 1994 extends to the distributor (which is the case only in the specific circumstances set out in Article 3(3) of the Directive) and entitles the victim to lodge the claim against one of the persons responsible, but not against all the persons jointly and severally (which runs counter to the principle of joint and several liability set out in Article 5 of the Directive)¹².

The Directive is only an initial step towards establishing a genuine producer liability policy at Community level. One of the reasons for reviewing it every five years¹³ is in fact to proceed towards greater harmonisation with a view to establishing a regulatory framework which is as comprehensive, coherent, balanced and effective as possible for protecting victims and ensuring legal certainty for producers. However, it would appear that the objective of greater harmonisation can only be achieved *a priori* by upholding the objective of total harmonisation in the present Directive (since no clause allows the Member States to adopt stricter rules under the Directive).

¹² TS Sala Civil, 4.10.96, No 778/1996 (RJ 1996-7034).

¹³ See the 18th recital of Directive 85/374/EEC on this point.

1. According to your experience, does the Directive properly function in practice?

☞ Given the importance for consumers and economic operators to rely on a stable legal framework of product liability, do you think it would be justified to modify the Directive?

☞ Has the disparity in legislation on producer liability - even potentially - discouraged the marketing in one Member State of products from another Member State?

☞ Where ordinary law has been applied rather than the Directive, what do you consider to be the reasons for this?

☞ Do you think the Directive should be revised to become the common and sole system of liability for defective products (deletion of Article 13 of the Directive)?

☞ Do you think that each Member State should be able to adopt stricter liability rules (introduction of a “minimum” clause in the Directive)?

2.1.2 The global context

In accordance with the principle of equality of treatment for products imported from non-member countries and put into free circulation in the Community, the legislation at stake applies *in toto* to imports. Products exported, on the other hand, are subject to the legislation of the country of distribution in which they may cause damage. The Directive thus helps to define the legal and economic environment for European operators in the global context, where the producer liability policies of many countries are equivalent to that set out in Directive 85/374/EEC, since it served as a model for Japan, Australia and Switzerland, in particular¹⁴. However, this equivalence is not total, and the conditions governing liability sometimes depend to a large extent on the legal framework of which they form part. On this point, the situation in the United States calls for a separate commentary.

In the United States, producer liability is framed by three elements: (1) the legal system encourages the parties to go to court (the level of damages awarded by juries, arrangements making it easier to search for proof, the “no win, no fee” principle under which victims who lose their case do not pay their lawyers any fees); (2) there is no uniform federal legislation¹⁵; (3) it is State legislators and judges who have set out the major principles governing liability (“warranty”, “negligence”, “strict liability”), -

¹⁴ For a comparative examination of legislation in the field, see OECD, *Product liability rules in OECD countries*, 1995. In Japan, the new law on product liability, in force since 1 July 1995, has been applied in a large number of cases (see www.law.kyushu-u.ac.jp/~luke/pllawcases.html).

¹⁵ Since the 1970s, the American federal legislator has been trying to establish a uniform and balanced legal framework for its large market. In May 1996, President Clinton blocked a federal bill passed by Congress. Subsequently, two bills were introduced in the Senate in 1997 (Bill S. 5 and Bill S.648), and one bill in 1998 (*Product Liability Reform Bill of 1998, US Senate, S.2236, 105th Congress*). The latter failed because of lack of agreement in the Senate.

principles which were approximated in practice under the “Restatement”¹⁶ (a kind of standard law drawn up by the American Law Institute).

In 1992, litigation involving producer liability was as follows in the 75 largest counties in the US: 12 763 cases of producer liability were decided; 358 cases went to a jury; 142 cases were won by the plaintiff. Of that total, the average award was 727 000 dollars, and compensation exceeded one million dollars in only 15.4% of the cases. The jury awarded punitive damages in only three of the 142 cases won by the plaintiff. The total for such damages, for the three cases, was 40 000 dollars¹⁷.

According to the *National Center for State Courts*, of the 19.7 million civil cases dealt with each year by state judges, 40 000 cases involve producer liability. Only 10% of victims take legal action to obtain compensation. Between 1965 and 1994, punitive damages were awarded in 379 cases (or 13 per year). In the United States, insurance costs for American businesses seem to be decreasing. Premiums fell between 1987 (\$4 billion) and 1993 (\$2.6 billion). The premium per \$100 cover is 26 cents¹⁸.

There is a great similarity between liability conditions in Europe and the United States, although there are some notable individual differences (the American rules concern the liability of the professional vendor, while the Directive applies only to the (real or apparent) producer, the importer and the distributor in the case of an unidentified producer; the period of liability in the EU is ten years, while the American legislation lays down a period of 18 years¹⁹). However, the lack of federal legislation laying down *inter alia* a ceiling for punitive damages is regarded by the Transatlantic Business Community as hampering trade between the EU and the United States. That is why the Community and business circles have always supported American efforts at reform.²⁰ Seen in this light, the European producer is better off, as the European Directive establishes a uniform and coherent framework of liability, without the most criticised elements of the American system (the role of the juries, punitive damages, etc.).

The truth is that, although the European and American legislations are very close in terms of principles, this is not the case with their practical application. Practical application of the European legislation does not appear to have the same results and consequences for those concerned as in the United States. The litigation involving the liability of the tobacco industry in Europe and the United States is a good example of this point. In Sweden, on the basis of liability without fault, Mrs Gustafsson had claimed compensation from the Swedish tobacco company *Swedish Match* for the damage caused to her health because of failure to provide information on the risks associated with tobacco, and in particular a warning of the risk of cancer. The case was rejected by a court in Stockholm in 1997. Upon appeal, the supreme court referred the case back

¹⁶ The principle of “liability without fault”, for instance, recognised in 1963, was adopted by most states and consolidated in the Institute’s “*section 402A of the Second Restatement of Torts*”. This Restatement was revised in the light of 30 years’ experience (ALI, *Restatement of the Law, Third, Torts: Product Liability*, xxxi, 382 pp., 1998).

¹⁷ US Department of Justice, Office of Justice Programs, Bureau of Justice Statistics Special Report, Civil Justice Survey of State Courts, 1992: *Civil Jury Cases and Verdicts in Large Counties* (July 1995).

¹⁸ The Public Citizen, *The Facts about Products Liability*, www.citizen.org.

¹⁹ See Section 107, Bill S. 2236. The federal period of 18 years already applies to the aerospace sector by virtue of the *General Aviation Revitalization Act* of 17 August 1994 (49 U.S.C. § 40101).

²⁰ Transatlantic Business Dialogue, *Statement of Conclusions, 1998 CEO Conference*, Charlotte, 5-7 November 1998 and *TABD Mid Year Report*, Washington, D.C., 10 May 1999.

on a point of procedure. The tobacco company, however, considered that the case was politically motivated and unfounded²¹. Two similar cases were lodged against *SEITA* in France by victims of tobacco addiction²².

In contrast, litigation against the tobacco industry in the United States has met with unparalleled success, *inter alia* on the basis of the companies' liability for selling defective products²³. This litigation has increased because of the cases brought by the state authorities to recoup the medical expenditure incurred by their health services for smokers²⁴.

2. Do you think that the Directive weakens the position of European businesses vis-à-vis their foreign competitors because of the conditions governing liability for defective products?

☞ What are the main reasons for this, and how can it be avoided?

☞ What is the impact on European businesses of exporting products to markets with stricter legislation (or legal practice), such as the United States (in terms of costs, production methods, insurance, level of litigation, etc.)?

2.2. Protection of public health and safety

The Commission believes that public health and safety must be afforded the most effective and best protection possible within the internal market. The Directive helps to increase the level of protection against defective products for two reasons: it is a "sword of Damocles" which encourages producers to do their best to produce without unnecessary risks to health (it thus complements the regulatory measures and checks to prevent the marketing of defective products), and once these preventive measures

²¹ Swedish Match, Press Release, 14 May 1998, www.swedishmatch.sv/news.

²² In December 1996, two victims of tobacco addiction brought legal proceedings against the French manufacturer for failure to provide information on the dangers of *Gauloises* cigarettes. Invoking the manufacturer's liability without fault, the victims claimed damages and interest of FRF 2 668 090 and FRF 1 158 499 respectively (see *Le Monde*, 20, 27 and 28 December 1996).

²³ Tobacco litigation is currently marked by both damage awards in first instance, although these judgments are frequently overturned on appeal (on 30 March 1999, for instance, Philip Morris was ordered to pay \$81 million to the family of a smoker who had died of cancer, the largest sum yet awarded until the verdict of 7.07.99 in the Engle class action), and by out-of-court settlements (in the *Broin v. Philip Morris, et al.* class action, for example, the representatives of the flight attendants and the tobacco companies reached an agreement which, amongst other things, makes the burden of proof easier for each individual victim initiating legal proceedings and establishes a \$300 million fund for medical research - see www.cnn.com/US/9903/30/tobacco.trial.02/)

²⁴ It took a settlement reached in November 1998 between the producers and the American authorities to put an end to the cases brought by the state administrations, estimated at \$206 billion. That still leaves legal proceedings brought by the victims either individually or as class actions (see www.tobaccoresolution.com). It is only recently that the sickness insurance scheme in France has approached the tobacco industry to demand the reimbursement of the sums incurred in treating the consequences of tobacco addiction. The local sickness insurance fund in Saint-Nazaire decided in February 1999 to bring charges against all companies distributing their products in France (see www.lemonde.fr, 17.2.99).

have failed and accidents have happened (since there is no such thing as zero risk), it allows the victims to obtain redress from the producers.

3. What percentage of victims has been compensated either on the basis of ordinary liability law or on the basis of application of the principles of Directive 85/374/EEC?

☞ In the case of application of the Directive, was it easy to obtain the compensation awarded in terms of speed and efficiency?

Doubts have been expressed recently about the Directive's effectiveness in attaining its objectives, and there have been calls for its content to be revised. At the first reading of Directive 99/34/EC, Parliament called for a substantial revision of Directive 85/374/EEC so that it better meets the objective of protecting health and safety²⁵. At the second reading, however, this call for a revision did not receive the majority needed for the Directive to be amended on the occasion of its extension to primary agricultural products²⁶.

The Commission has taken note of these criticisms and is preparing to examine their justification on the basis of the results of this Green Paper. The Community's experience when adopting the Directive, and that of other countries which are currently debating producer liability (as in the United States), show that arriving at a balanced framework for producer liability calls for a serious and in-depth debate on the advantages and drawbacks of each rule governing liability.

If producer liability policy is to be strengthened, this must be done by building on the strengths of Directive 85/374/EEC, and in particular on its balanced approach to the apportionment of risks. That does not rule out improving it in order to make it more effective, provided the solutions chosen are equally balanced. As the Commission has had occasion to recognise in general terms, "consumer policy must therefore ensure an equitable reconciliation of consumer interests and the interests of other stakeholders [...] consumers themselves can recognise and accept such compromise because they are not only consumers but taxpayers, employees and beneficiaries of public policies too"²⁷. This reconciliation of interests also applies to the Directive and its further development (see point 3 of the Green Paper as regards justifying its reform and maintaining the balance).

4. How has the Directive impacted on the victim's interests because of the balance established in the Directive?

☞ Should the Directive be amended to give greater protection of victims' interests, even if this involves changing its present balance?

²⁵ Opinion of 5.11.98(OJ No C 359 of 23.11.98).

²⁶ Decision of 23.03.99 on the common position EC No 3/1999 (OJ No C 177 of 22.06.99).

²⁷ Communication from the Commission - "Consumer Policy Action Plan 1999-2001", (COM(98)696 of 1.12.98, p.4.)

Knowing how to compensate the victims of a defective product, and who should compensate them, is a matter for both the private and the public domains, since it is the victims and the producers who have to settle the problem of compensation for damage by applying the rules of liability, such as those in Directive 85/374/EEC. Drawing on the liberal tradition of the civil codes of the 19th century, the Directive is in fact part of the civil law on extra-contractual liability or liability under the law of tort. This socio-economic approach is the reason why the state intervenes only in specific - even exceptional - cases where society has been obliged to "assume" the task of compensating victims in view of the catastrophic nature of the problem²⁸. Without prejudice to exceptional situations, the situation of the victims also comes under the heading of social protection (after a domestic accident caused by a defective product, for instance, the social security scheme generally covers the medical expenses, earnings during sick leave, etc., before any approach to the producer responsible by the victim). One of the reasons why litigation under Directive 85/374/EEC has not reached the same proportions as in the United States appears to be the widespread existence of social security schemes in Europe: the greater the likelihood of being covered by social security, the less incentive there is to claim the producer's liability. In this respect, producer liability is regarded as an instrument for compensation which is complementary to the other ways in which the victim can obtain redress²⁹.

5. In your experience, how do you assess the relationship between the possibilities to award damages to the victim by Directive 85/374/EEC and those of the social security schemes?

☞ Can you indicate any cases in which the social security schemes took proceedings against the producer on the basis of the rights conferred upon the victim under Directive 85/374/EEC, after having covered his expenses?

☞ Can you indicate any cases in which the producer liability scheme set up by Directive 85/374/EEC was insufficient to fulfil its compensatory role, so that it was then necessary to fall back on the solidarity of society as a whole to compensate the victims?

²⁸ This was the case in France (where the national authorities regarded compensation of the haemophiliacs infected with the HIV virus as a public problem to be resolved by means of a compensation fund) and in Spain (in the rapeseed oil case, the second chamber of the Spanish supreme court ordered the state on 26.9.97 (see *Actualidad Juridica. Aranzadi 313 de 16/10/97* and *La Ley de 05/11/97*) to pay damages to all the victims of the poisoning as having subsidiary liability under civil law). In Denmark, Law No 40 of 14.6.85 also set up a compensation fund for the victims of blood marketed by Novo Nordisk A/Z, subsequent to the judgment of the *Østre Landsret* of 14.2.85 (confirmed by the judgment of the *Højesteret* of 3.10.96 -Case No I 155/1995, I 156 /1995, I 157/1995) which found the producer not liable in the absence of negligence (as the law transposing Directive 85/374/EEC was not applicable).

²⁹ This is set out explicitly in the Belgian legislation of 1991 (Article 14), under which the beneficiaries of a social security scheme must first take advantage of the rights deriving from such a scheme. If there are any damages not covered, the victim must then enforce his rights as a victim vis-à-vis the producer under his liability.

2.3. The effects on industry and the insurance sector

Because of the very nature of producer liability (one single defective product can give rise to numerous cases or “mass litigation”), application of Directive 85/374/EEC gives rise to direct and indirect costs for operators: premiums for product liability insurance, capital reserves and financial guarantees to cover any compensation, damages with interest actually paid out under an out-of-court settlement or a court decision, fees for lawyers and experts, time and energy involved in defending against the charges, loss of value of the brand or shares in the company found guilty, etc. However, it is quite difficult to put an exact figure on these costs and to assess their impact on competitiveness, commercial and financial capacity, innovation and research efforts, design, manufacturing and packaging methods, and on job creation by businesses producing in Europe³⁰. The Commission very much wants to establish to what extent application of the Directive is affecting industry.

6. Are you aware of any cases of defective products in which the Directive was actually applied and how this affected your activities?

6. Have you undertaken any research or studies on the Directive’s potential impact on your activity?

With regard to the cover for risks associated with defective products, there are schemes to cover such eventualities set in an individual (product liability insurance policies) or collective basis (e.g. the “Pharma Pool” for the German pharmaceutical industry, or the “Läkemedelsförsäkringen”, set up by the pharmaceutical industry and Swedish insurers.) The Directive leaves it to the Member States to regulate the extent to which industry should be covered for these risks, although the implementation of the Directive in certain countries includes a requirement for financial cover: in Austria, the producer and importer must take out cover for product liability in the form of an insurance policy or in any other appropriate form³¹ (a similar requirement is planned but not implemented in Spain³²).

It is equally difficult to put a figure on the degree to which the insurance market is affected by the Directive in terms of the number of claims covered by a “product liability - defective products” guarantee, the level of premiums, the amount of compensation paid, etc. The insurance sector is invited to provide information on the impact of implementation of the Directive on the insurance sector.

³⁰ The reform of the American law is justified, amongst other things, by the high costs of the present system (see US Senate, *Report No 105-32 of 19.6.97 on the Product Liability Reform Act of 1997, Bill S. 648, p. 3*: “the US tort system is by far the world’s most costly tort system...A study conducted by the insurance industry in 1989 – the Tillinghast study – estimated the current overall annual cost of the US tort system at a staggering \$117 billion.”) *Produkthaftungsgesetz*, § 16.

³¹ Article 30, Law 26/1984, of 19 July (BOE No 176 of 24.7.84), in the wording of the second final provision, Law 22/1994, of 6 July (BOE No 161 of 7.7.94). This provision empowers the government to prescribe producer liability insurance and the establishment of a fund for personal damages (death, poisoning, bodily injuries).

7. Have you any data - if possible with figures and broken down by year - on the number of claims which the insurance sector has dealt with after accidents caused by defective products since 1990?

☞. If so, is it possible to know whether the guarantee given by the insurer is related specifically to the producer's liability under Directive 85/374/EEC?

☞. Is it possible to know whether the insurance market has seen an increase in demand for this type of guarantee after application of the Directive and, if so, what has been the impact on costs for the sector (in terms of compensation paid) and for the beneficiaries (level of premiums)?

☞. In the claims made, what was the percentage breakdown by type of defect (defect in design, manufacturing and/or information)?

3. IS A REVISION OF DIRECTIVE 85/374/EEC JUSTIFIED?

In this part of the Green Paper, the Commission calls on all those involved to take a reasoned stance concerning the justification for any revision of Directive 85/374/EEC. The idea is not at this stage to undertake a legislative revision of its content. On the contrary, once the Commission has analysed the implementation of the directive on the basis of the contributions to be received, it may propose actions on this matter in its second report on the directive scheduled for the end of 2000. Consequently, the "revision options" mentioned below are solely guidelines for open discussion, without prejudice to any future Commission initiative.

3.1 Maintaining the balance

As recent political discussions on extension to the agricultural sector have shown, the policy of product liability provokes conflicting views on the part of producers and consumers. Victims want the greatest protection at the lowest cost, while producers ask in particular for ceilings and for the shortest possible liability period.

It is not easy to reconcile the interests involved. Sometimes, neither industry nor consumer representatives can fully back up their interests on various points of the discussion (costs of the system and its repercussions on the prices of goods, length of legal procedures, lack of predictability, effect on undertakings' capacity for innovation and development, impact on their external competitiveness, etc).

The way in which the debate on product liability has gone in the United States confirms this analysis. In the Senate the advocates of reform have put forward the view that "the present [US product liability] system adversely affects producers, product sellers, consumers and individuals injured by products. Reform by the states cannot fully address the problems with the current product liability system. Reform at the federal level is urgently needed", while the opponents of reform take the view that "before we make dramatic changes in product liability law, we should, at the least, have information to demonstrate that the current system needs fixing. It is not achieving its purpose of fairly and properly compensating victims of defective products, or of deterring the marketing of unsafe products. As each additional piece of objective data becomes available, it becomes more clear that the system is working.

The number of non-asbestos product liability cases is actually declining, punitive damages are a rare occurrence, and compensatory awards are reasonably related to the cost of the injuries involved^{32bis}."

In the EU, by comparison with the debate in the United States, Directive 85/374/EEC represents a compromise reconciling the interests at stake. The Member States' political determination, set out in the provisions of the directive, to have a balanced framework of liability governing relations between firms and consumers must not be underestimated. The Commission is keen to see this conciliatory approach retained. Any attempt to revise the directive should be guided *a priori* by a balance which is rooted in the following principles:

- the producer's civil liability is (1) **objective** (no need to prove the fault), (2) **relative** (the producer is exempt from liability when he proves the existence of certain facts, these facts being subject to re-examination (see below, for example, "development risks"), (3) **limited in time** (the producer is not liable for an indefinite period, even though the practical arrangements for this principle deserve to be re-examined, especially the period of cessation of liability) and (4) **liability that cannot be waived** at the wish of the parties;

The courts in the Member States have shown their attachment to the principle of no-fault liability recognised by the directive, even before its transposition into positive law. In 1989, the Swedish Supreme Court in a case dealing with food poisoning (salmonella) considered the principle of no-fault liability; it was accepted for the first time, and this solution was reinforced by the act of 1992. In 1989, in the *Halcion* case (a tranquilliser that has been very popular on the American market since it was approved in 1982) the Dutch Supreme Court had anticipated the implementation of the transposition bill in the Netherlands by applying the idea of "defect" to the sedative in question³³.

It is in France that such a legal approach has been most in evidence, because of the lack of any legislative transposition for ten years. The situation there was marked by very complicated jurisprudence on guarantees for hidden defects, on the basis of which judges gradually moved towards the terms of the directive. Jurisprudence of this kind, however, has not absolved France of its obligation to transpose the directive. Indeed, in 1993 it was censured by the Court of Justice for failure to transpose the directive within the period laid down (30 July 1988). In the absence of any transposition, the Commission had decided in March 1998 to refer the matter to the Court a second time for non-implementation of the 1993 order, asking for a daily fine of ECU 158 250 to be imposed in accordance with Article 171 of the Treaty of Rome. Following this decision by the Commission, France adopted on 19 May 1998 Law No 98-389 in order to comply with its obligations. This law applies, among others, to primary agricultural products and products derived from the human body. However, it is the view of some commentators that transposition of the entire directive, including the possibility of development risk exemption, would have represented a step backwards. This issue of development risk exemption has been at the centre of discussion in France and explains, to some extent, the delay in transposing the directive.

^{32bis} US Senate, *Report No 105-32*, pp. 2, 44, 71, 75.

³³ HR 30.6.89 No 13 564, NJ 1990/652.

Lastly, it was the Cour de Cassation which, a few months before the adoption of the transposition bill in France, gave implicit effect to the directive in adopting its definition of fault with regard to a product (by affirming the liability of a laboratory concerning the damage caused by the non-digestible coating of a medicinal product on the grounds that the producer is required to provide a product which ensures the safety that can be legitimately expected³⁴). On 28 April 1998 the Court explicitly interpreted the Civil Code (Articles 1147 and 1384) in the light of the directive to affirm that every producer is liable for damages caused by a defect in his product, with regard to victims who are both directly and indirectly affected, without the requirement to distinguish whether they are contracting or third parties. Consequently, a blood transfusion centre, providing tainted plasma, was declared liable not only with regard to the direct victim but also with regard to the family for the non-material damage caused³⁵.

- (5) **it is the victim's task to prove** that damage has occurred, that the product was defective and that there is a causal relationship between the defect and the damage suffered. This principle applies even if the conditions of proof are subject to re-examination (see below "burden of proof"). The "defective" nature of a product is determined by the lack of safety which the general public is entitled to expect, given the circumstances of the product and the occasion³⁶. In the event of there being several producers who are liable, the liability remains (6) **joint and several** (allowing the victim to approach any of those liable without prejudicing his right of complaint). This absolves the victim of the need to approach all those who are jointly liable in order to be fully compensated.

8. Do you agree that the six principles listed above constitute the basis that needs to be maintained in order not to upset the internal balance of Directive 85/374/EEC?

3.2 Ideas for possible reform

Consumer trust is vital for the success of firms and, consequently, for the proper operation of the internal market. Measures to bolster trust are vital for producers' prosperity, and any extra costs that are incurred are generally offset by the overall benefit accruing from greater consumer trust in the market. The Commission, in implementing its consumer policy action plan³⁷, is acting to bolster this trust. In this

³⁴ Cass. 1ere civ., 3 March 1984, *SA Les Laboratoires Léo c. Scovazzo et a.* [order No 432 P]. Counsel M. Sargos had asked the court to follow the directive, on Article 6.

³⁵ Cass. 1ere civ., Cts C c. Centre régional de transfusion sanguigne de Bordeaux [order No 736 P+B+R].

³⁶ The directive does not follow the criterion of "reasonable alternative design (RAD) requirement" to define design fault. This criterion was followed in the latest version of "Restatement" in the United States, insofar as a product is defective if these risks could have been avoided if the producer had designed the product differently. It is up to the victim to prove that there was such an alternative design.

³⁷ Communication from the Commission "Consumer policy action plan 1999-2001", (COM(98)696 of 1.12.98.)

regard, it hopes to ensure that Directive 85/374/EEC has the necessary effectiveness to bolster consumer trust. If analysis of how the directive is applied shows that this is not the case, it will propose the necessary amendments.

Already, politicians, operators and experts have highlighted several aspects of the directive as deserving special analysis with a view to possible reform:

Burden of proof

Without prejudice to the principle whereby the burden of proof lies with the victim, there is a need to look at the arrangements for its application. The fact of the victim having suffered an accident is not enough to bring an action against the producer within the meaning of the directive. The victim must prove that the damage is the result of a defect in the product. This burden may be great when such proof turns out to be technically complicated and/or expensive on account of the expert opinions required. The directive does not define a standard of required proof for a complaint to succeed. The trickiest task for the victim is always to convince the producer (or the judge in the case of a dispute) of the existence of a defect and of the link between this defect and the damage suffered, while noting that usually there is a lack of balance between the two with regard to access to information (the producer is in a better position than the victim to detect how the problem occurred since he controls the process of production). In this situation, making proof easier turns out to be a way of improving the situation of the victim, especially in cases where it is difficult to track down the origin of the damage. The difficulties involved in proof (origin of the product, defect, causal relationship) increase when it comes to products that are ingested or no longer available (e.g. food, medicinal products).

There are several options:

- 1) To infer a causal relationship when the victim proves the damage or defect, or the defect when the victim proves the existence of damage resulting from a product.

In the first case decided in Belgium on the basis of the directive, the judge ruled that the explosion of an aerated beverage bottle was indeed evidence of an abnormal feature of the product which was incompatible with the safety that consumers were entitled to expect. The defect could be deduced from the abnormal behaviour of the product, according to the judge, in determining the proof that the victim had to bring. The producer had to consider the probable conditions of use of the product. Consequently, in the case of a beverage that was supposed to be consumed cold throughout the year, the producer had to consider the effects of temperature variations on the structure of the glass³⁸.

During the debate about extending Directive 85/374/EEC to primary agricultural products, the European Parliament eventually decided not to endorse the proposal from

³⁸ Case *Riboux v S.A. Schweppes Belgium*, 21.11.96, Civ. Namur, 5e. ch.

its relevant committee to make any presumption with regard to the appearance of damage in the case of a "typical course of events"³⁹.

2) To establish the degree or standard of necessary proof of the three elements required by Article 4 of Directive 85/374/EEC (damage, defect, causal relationship). It is not a question of including a presumption of proof in the directive, but of establishing that the victim should prove these three elements to a high degree of probability, without the standard needing to be very high (for example, it would be sufficient for probability to be above 60%). However, this option proves complicated in practice.

During the debate on extension, the European Parliament, on the basis of a proposal from the relevant committee, examined the possibility of requiring that it be necessary only for the causal relationship to be "sufficiently probable". Parliament, however, rejected this idea⁴⁰.

3) To impose on the producer the obligation to provide all useful documentation and information so that the victim can avail himself of concrete facts to prove his case.

4) With a view to facilitating the victim's burden of proof, to make the producer bear the costs of expert opinion under certain circumstances: for example, the victim could ask the judge for the producer to advance the costs incurred in the proof proceedings, on condition that the victim reimburse the costs (plus any interest) in the event of failure.

In Italy there exists an example akin to this possibility. Article 8.3. of the 1988 decree transposing Directive 85/374/EEC allows the judge to order the producer to advance the costs of expert opinion if it is likely that the damage has been caused by a defect in the product.

9. Do you think that the experience of implementing the directive justifies its being amended in order to make easier to determine the burden of proof? How?

One special problem affecting the burden of proof concerns determining the identity of the producer when the same product is made by several producers (for example, a medicinal product manufactured under licence by several laboratories). Indeed, in some cases, the victim would be able to prove the damage, the defectiveness of the product and the causal relationship, but would not however be able to identify the producer of the product that caused the damage. According to the directive, in this case the buyer will have no possibility of recourse.

A solution to this problem, for which there is no provision in the directive, would be to follow the principle of "market share liability" that exists in American law (see

³⁹ European Parliament, *report by the Committee on the Environment, Public Health and Consumer Protection*, (ROTH-BEHRENDT report, doc. A4-0326/98, accessible at <http://www.europarl.eu.int/plenary/en/default.htm>), amendment No 3.

⁴⁰ European Parliament, *ROTH-BEHRENDT report*, amendment No 12.

DES case in the Netherlands)⁴¹. The American theory of "market share liability" is used in particular with regard to liability involving medicinal products. The plaintiff is required solely to prove that there is a link between the damage and the incriminated product, without indicating the manufacturer's name. It is enough for a firm to enjoy the profits from the sale of the product for its liability to be invoked. The plaintiff will thus be able to involve several producers on account of their link with the incriminated product. He will be able to ask for the full amount of damages and interest from the most solvent defendant, regardless of his degree of liability. The latter can then claim against his competitors. The payment of the damages will then be shared among all the producers according to their market share.

10. Would "market share liability" be feasible in Europe for this type of cases?

Development risks

Technological innovation has given rise to increasingly complicated product design and manufacturing processes, the long-term effects of which cannot be foreseen with certainty. This lack of certainty in connection with the state of the art raises the existence of "development risks", one of the most controversial aspects of the debate on product liability.

The extent of the problem of "development risks" needs to be circumscribed: in accordance with Article 7(e) of Directive 85/374/EEC, the producer of a defective product is absolved of liability if he can establish that the objective state of technical and scientific knowledge, at its most advanced level, at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered. If it is to be a valid argument against the producer, the relevant knowledge must have been available when the product was put into circulation⁴². An initial evaluation of the practical application of this waiving of liability indicates that it is not so easy to prove that the defect could not be detected on the basis of the knowledge that was available when the product was marketed.

In 1995 the German Bundesgerichtshof gave its first ruling on the basis of the directive and found that the waiving of liability under Article 7(e) of the directive did not apply to manufacturing defects (but solely to design defects)⁴³. The case concerned the explosion of a recycled mineral water bottle. The state of the art made it possible to know that the type of bottle in question contained microscopic fractures that caused explosions. The Court ruled that a bottle with such a fracture had a manufacturing

⁴¹ HR, 9.10.92, No 14 667, NJ 1994/535. This case is the follow-up to the legal battle in the United States, conducted mainly in California (*Sindell v Abbott Laboratories*, 607 P. 2ed 924 (Cal.), *cert. denied*, 449 US. 912 (1980)), dealing with the medicinal product diethylstilbestrol (a female hormone against miscarriages, and a source of cancer among children of women who have taken it). The Supreme Court in California ruled that any producer who had placed this trademarked product on the market was liable to the extent of his market share, the reason being to avoid any problems in tracing the origin of the product.

⁴² *Commission v the United Kingdom*, C-300/95, judgement of 30.5.97, ECR [1997], p. I-2649, point 29.

⁴³ BGH, 9.5.95, VI ZR 158/94 and NJW 1995, 2162.

defect for which the producer was held liable. The Austrian Oberste Gerichtshof has also ruled on "development risks"⁴⁴.

In the Belgian case mentioned earlier, the producer offered no evidence of abnormal use of the bottle nor any other evidence for which there is provision under Article 7 of the directive. In particular, the judge ruled that, whatever the quality checks the defendant claimed to have implemented, he did not offer any proof of the "absolute impossibility" of detecting the existence of the defect that caused the damage.

Exemption from liability in the case of "development risks" has been at the centre of parliamentary debate in France on the transposition of the directive since 1990. On 9 July 1996, in connection with the "contaminated blood" affair⁴⁵, the Cour de Cassation ruled on the applicability of this exemption before the transposition of the directive. It stated that the blood transfusion centre was required to provide products that were untainted, without being able to claim exemption from liability for any reason other than external cause, and that the internal defect of the product, even if undetectable, did not constitute for the supplier an external cause. The supplier tried to invoke the exemption clause under Article 7(e), to counter the application of this principle, in spite of the lack of transposition in France. The Court replied that, even if the judge was required to interpret domestic law in the light of the purpose and text of the directive, it was on condition that the latter was binding on the Member State and did not allow any option in adapting national law to Community law. The Court added that the directive actually prescribed nothing on the matter, since Article 15(1)(b) allowed the Member States the option of deciding whether or not to introduce exemption for development risks. Following the adoption of Law No 98-389, the new Article 1386-12 of the French Civil Code confirmed this jurisprudence, by making no provision for producers of products derived from the human body to be able to claim exemption for development risks⁴⁶.

In 1985, European lawmakers dealt with the problem provisionally: exemption was possible for a period of ten years, although the Member States had the option of abolishing it unilaterally. Under Article 15(3) of the directive, it had been agreed that the Commission would assess whether producers should be liable for "development risks" after the transition period.

The sensitive nature of the issue became apparent during the parliamentary debates on extending the directive to primary agricultural products. A large majority of MEPs were not in favour of abolishing the exemption without an assessment of its effect. The two amendments seeking to change the arrangements for "development risks" did not get the support of a majority of the Chamber⁴⁷. Already in 1979, when the original Commission proposal (which did not contain such an exclusion) was considered, the European Parliament was divided on the matter. Although it had proposed excluding these risks, it had nevertheless recommended examining, after a

⁴⁴ OGH, 20.6.91, 6 Ob 568/91 (relevant jurisdiction); OGH, 30.6.92, 7 Ob 581/92, *ecolex* 1992, 842 (exploding Coca Cola bottles); OGH and *ecolex* 1992, 842 (liability of distributor); OGH, 11.11.92, 1 Ob 644/92 (unslaked lime); OGH, *ecolex* 1994, 384 (damage caused by component to final product); OGH and JBI 1995, 592 (liability if importer); OGH and JBI 1996, 188 ("development risks").

⁴⁵ Cass. Iere civ., *Cts X... c. GAN Incendie accidents et autres*, [order No 1395 P].

⁴⁶ Article 13, Law No 98-389 of 19 May.

⁴⁷ Opinion of 5.11.98 (OJ C 359, of 23.11.98)

transitional period, the advisability of transferring, wholly or in part, generally or for certain risks only, the producers' liability to a guarantee fund, with a view to insuring both consumers and producers against this kind of risk⁴⁸.

The question is whether the abolition of the exemption clause in Article 7(e) would have very damaging consequences for the manufacturing and/or insurance sectors. In this respect, the experience of countries where there is no exemption (as in Luxembourg, Finland and Spain in the case of food and medicinal products, Germany for pharmaceutical products and France for products derived from the human body and for those marketed before May 1998) ought to help in assessing whether and how liability for development risks involves insurmountable consequences for producers at the European level. The removal of this exemption clause could create problems with regard to the insurability of such risks, because of the lack of criteria on which to assess the probability of a risk, the existence of which is not known when the product is put on the market⁴⁹. However, if a risk is too great to be covered by an insurer, will it not be equally insurmountable for consumers?

In view of the fact that the Commission does not have all the information that is needed to conclude that liability for "development risks" would be insurmountable for producers, it has called on operators to provide accurate information on the application of the exemption in order to make an objective assessment (1) whether the removal of the exemption would discourage producers from innovation, especially in the sectors that are most sensitive in this regard (e.g. pharmaceuticals) and (2) whether it would still be feasible to insure this kind of risk in the insurance market.

11. Do you have information about the actual application of the exemption clause in case of "development risks" (Article 7(e) of the directive)?

☞ Have you any information on specific extra costs incurred by industry in countries where producers are liable for development risks?

☞ Do you think that producers should be liable for "development risks"?

☞ Should damages caused by development risks be borne by society as a whole (by means of a compensation fund using government revenue) and/or by the manufacturing sector in question (by means of a fund to which those in the sector contribute)?

Financial limits

⁴⁸ Opinion of 26.4.79 (OJ C 127 of 21.5.79).

⁴⁹ In this connection, the deputy secretary-general of the European Insurance Committee said in 1996: "The resulting conclusion is that the insurability of development risk poses a serious problem, and if European lawmakers, in their desire to harmonise civil liability for products, stopped it from being a reason for exemption in the future, it is certain that there would be an immediate upheaval in relations between producers and their insurers" (LEGRAND, B: "L'impact de la directive sur l'industrie des assurances", *La directive 85/374/CEE relative à la responsabilité du fait des produits : dix ans après*, Louvain-la neuve, 1996.).

A producer's liability is not unlimited in financial terms under the current directive. The threshold indicated in Article 9 allows a producer not to compensate the victim for damage to property with a lower threshold of ECU 500. Council Directive 85/374/EEC formally refers to ECU as a historical value⁵⁰. With regard to the current directive and contrary to the opinion of some Member States⁵¹, the Commission is of the opinion that this threshold is not optional. There is provision in Article 16, on the other hand, for the possibility (not the obligation) to fix a maximum ceiling for product liability in the case of damage to persons caused by identical items with the same defect. This ceiling is set at ECU 70 million (an amount which, in practice, is seldom reached) but may be higher. Only Germany, Spain and Portugal have provided for such a limit.

As for the threshold, the lawmakers had justified it in 1985 on the grounds of wanting to avoid improper court cases against producers under the directive, by restricting its field of application to material damage above a certain amount. This justification should be revised if experience provides no reason for believing that its removal would result in a surge of cases against producers, with the interests of SMEs kept in mind in this regard. On the other hand, the Article 16 limit is a transitional and exceptional solution, since no-limit liability ought to be revised, following a transitional period of ten years (see in this regard Article 16.2 of the directive). This explains why the limit has not been introduced in most Member States.

In its opinion on extending the Directive 85/374/EEC to primary agricultural products, Parliament had initially supported the idea of removing the threshold of € 500 and increasing the option for a ceiling to € 140 million. The question is whether the existence of financial limits is strictly justified, especially with regard to the Article 16 ceiling (which only three Member States have adopted).

12. Do you have any information on the percentage of cases involving material damage of less than € 500?
- ☞. Would you modify the Directive as regards the € 500 threshold and/or the optional upper limit of € 70 million?
- ☞. If you have opted for product liability with regard to development risks (question 11), do you think that there is justification for keeping the optional upper limit for this kind of risk?

Prescription and liability periods

A producer's liability is not unlimited with regard to time. According to Articles 10 and 11 of the directive, a producer's liability ceases ten years (term of extinction of liability) from the date on which the product was put into circulation, unless there are any claims or proceedings pending. During this ten-year period, if a person suffers

⁵⁰ The reference is not to the euro but to the ecu, the currency that was used before 1999; the value of the ecu in national currencies is that fixed on 25.07.85 (see Article 18, Directive 85/374/EEC).

⁵¹ There is no threshold in the French and Greek laws.

damages because of a defective product, he must claim for the recovery of damages within three years after the date on which he became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer (prescription period). Liability limited in time is justified mainly on grounds of fairness: for producers, no-fault liability involves a heavier burden than that laid down in the usual systems of contractual and extracontractual liability. This must be offset by a limitation in time so that technological innovation is not discouraged and insurance cover is available.

The prescription period is not always fully understood when it comes to its application. On 21 June 1996, the civil chamber of the Spanish Supreme Court ruled, in a case dealing with compensation for a garage mechanic's loss of a finger when using a defective spanner, that the directive had no horizontal effect between private parties in accordance with Community jurisprudence *Faccini Dori* and that, consequently, it was not applicable to the product that had been put into circulation before the entry into force of the implementing law. In this particular case, the judge added that, even if the 1994 law had been applicable *ratione temporis*, the proceedings were prescribed in view of the fact that the accident had occurred three years after the spanner had been purchased. But the fact is that, according to the directive, the prescription period for instituting proceedings begins from the day on which the plaintiff became aware of the damage, defect and the identity of the producer, and not from the date on which the product was purchased⁵².

With regard to the time limit for instituting proceedings (three years), there is no *a priori* reason for thinking that the limit should be changed. On the other hand, it turns out that the liability limitation of ten years might not be enough to cover circumstances in which damage appeared after ten years (which is what the European Parliament had advocated in proposing an extension of the time limit to 20 years for "hidden defects")⁵³. But the matter needs to be looked at again to see if such is the case. On the other hand, a longer period of liability involves a greater financial burden for producers and insurers. It is in any case useful to note that there is a difference on this matter between Directive 85/374/EEC and Council Directive 92/59/EEC of 19 June 1992 on general product safety⁵⁴. In the case of the former, a producer's civil liability for damage caused by a defective product ceases ten years after the date on which the product was put into circulation. However, Directive 92/59/EEC requires producers to place only safe products on the market. The idea of a safe product, as laid down in Directive 92/59/EEC, includes a reference to the foreseeable period of a product's use, which can of course be greater than ten years.

⁵² TS Sala Civil, 21.6.96 (RJ 1996/6712). The directive is also referred to in an order of 21.1.90 (RJ 1990-69) on the liability of the distributor concerning a defective bathroom cabinet (Article 3.3); order of 23.5.91 (RJ 1991-3784) on the liability of a car manufacturer. The Supreme Court usually rules in connection with legislation on consumer protection (Law 26/1984), which establishes liability with regard to a consumer's use and consumption of a product (order of 23.6.93, RJ 1993-5380). When the proper implementing conditions are satisfied, the courts will apply Law 22/94 of 6 July from 8 July 1994, instead of Articles 25-28 of the 1984 law (vid. SAP Tarragona, 18.07.98, n. 347/1998).

⁵³ Opinion of 5.11.98 (OJ C 359, of 23.11.98).

⁵⁴ OJ L 228 of 11.8.92, p. 24.

13. Does the time limit of ten years need to be changed, either generally or specifically for certain products or sectors?

☞ Should and could that change be borne in terms of cost by industry, especially SMEs, and the insurance market?

Insurance requirement

As already stated, the directive does not require producers to have any kind of financial cover, and in particular it does not impose any requirement to take out liability insurance for an amount that is adequate to cover any damage caused by a defective product. At the moment, it is up to the Member States to decide on the terms of such a requirement, unless there are cross-sectoral agreements between industry and insurers (e.g. in the field of pharmaceuticals). Operators' experience can help the Community to justify whether it should act in this regard by demanding from producers a financial commitment, either individually or collectively, to ensure that victims will be compensated, especially in connection with damages caused by identical items with the same defect, as referred to in Article 16 of the directive.

It is not always easy to arrive at voluntary arrangements. The Government in Denmark endeavoured to persuade members of the pharmaceutical industry to agree on setting up a compensation fund like the one in Sweden (and Finland). In view of the impossibility of reaching a quick agreement, Parliament had to pass legislation in 1995 on compensation for damages caused by medicinal products, which allowed consumers, regardless of any proof of fault or liability, to obtain compensation for personal injury caused by medicinal products obtained after 31 December 1995 by contacting a fund managed by the patient insurance association. This fund is financed by reducing reimbursement of medicinal products from 75% to 74.7% and from 50% to 49.8%.

14. Are you aware of any cases whereby lack of insurance made it impossible for victims to obtain reimbursement for damages?

☞ Do you think that there is a need to require producers to have insurance cover for risks linked to production or, alternatively, to encourage voluntary arrangements between producers and the insurance market?

More transparency

The lack of transparency and information concerning cases in which the liability provisions of Directive 85/374/EEC have been applied is a disrupting factor when it comes to looking at the implementation of the directive, especially with regard to the way in which victims have actually been compensated (amount of compensation, duration of claim procedure, difficulties in proving their case, etc). There is no provision in the directive for any means of making its implementation more transparent, apart from the regular assessment by the Commission. There is no obligation on producers to keep records of claims against them; nor are the national authorities obliged to keep track of the number of cases reported.

Directive 92/59/EEC on general product safety, setting up a system of notification and exchanges of information between the Member States and the Commission to deal

with the withdrawal of unsafe products from the market, does not make it possible to remedy this shortcoming. In spite of the obligation on a producer to provide consumers with the relevant information on the risks inherent in a product and to take appropriate action including, if necessary, withdrawing the product from the market to avoid such risks, the legislation imposes no obligation requiring specific information on the actual application of Directive 85/374/EEC.

The question is not an easy one, given producers' concern to keep business matters confidential. There are, however, ways that allow such information to be disseminated. Experience in the United States shows information on the issue of product liability is increasingly available as a result of two kinds of initiative.

Firstly, there are research undertakings ("jury verdict reporters") that exist to elicit and disseminate information on the number of cases, amount of compensation, products and people involved, courts dealing with the case, etc. This kind of economic venture is becoming very widespread thanks to the Internet.

This commercial activity does help the fact-finding work of the attorneys representing parties to disputes, for example by making available extracts of the latest decisions in a particular field or by categorising the kind of compensation paid. The *National Association of State Jury Verdict Publishers* is the organisation of American publishers who collect information directly from attorneys involved in such cases. A wide range of services is available on request (search for cases by category of product or damage, recent cases, lists of experts, review of out-of-court settlements, statistical analyses, etc)⁵⁵.

Secondly, lawmakers have imposed on producers the obligation to announce cases involving defective products and to notify the *Consumer Product Safety Commission*. Producers (and importers as well) have to notify this authority of circumstances in which a product that has allegedly caused death or serious injury is the subject of at least three court cases, as soon as the cases have been settled by a ruling in favour of the plaintiff or as the result of an out-of-court agreement⁵⁶.

15. Do you think that the directive needs to be revised in order to include means of increasing the transparency of the way in which operators apply the rules, especially by identifying the cases involving defective products that are still on the market?

Supplier's liability

Formal notification of supplier: Article 3(3) of Directive 85/374/EEC states that where the producer of a defective product cannot be identified, the supplier of the

⁵⁵ See www.juryverdict.com.

⁵⁶ Section 37 of the Consumer Protection Safety Act (15 USC Sec. 2084, "Notification of settlements or judgments").

product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same applies in the case of a product imported into the Community, if this product does not indicate the identity of the importer, even if the name of the producer is indicated. The victim is therefore obliged to notify the supplier formally, so that he can within a reasonable time provide details of the producer or previous supplier. This procedure of "formal notification" is justified inasmuch as the directive lays down as a principle that it is the producer who is liable for damage caused by a defect in his product.

Experience shows, however, that the method of formally notifying a supplier of his liability can vary tremendously depending on the Member State, and this does not seem to be very satisfactory in view of the aims of the directive. In Italy, for instance, a supplier has three months in which to supply the required information (producer's name and address). The victim is responsible for making a written request for the information, by informing the supplier of the product in question and the date and place of its acquisition. The victim cannot refuse to let the supplier check the product⁵⁷. In Germany the time limit for communicating the required information is restricted to one month⁵⁸, and in Belgium the time limit will be decided by the court⁵⁹. The Commission asks those involved in the consultation to submit what they know on this point.

Extent of supplier's liability: The directive puts forward as a principle that it is the producer who is liable for the damage caused by a defect in his product. Article 3(1) defines a producer as "the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer". By way of exception, a professional acting as simple supplier is liable in only three cases: when he is the importer of the product into the Community - within the meaning of Article 3(2) of the directive - and, in certain circumstances, when the producer of the product cannot be identified by the victim of the damage caused by the product or when the identity of the aforementioned importer is not indicated on the product: Article 3(3). In other words, and apart from the limited instances referred to, the liability of professionals acting as simple suppliers is not governed by the provisions of Directive 85/374/EEC. In order to invoke the possible liability of the supplier, the victim of the damage caused by the defective product must use the system governing liability laid down in the legislation of the Member State in question. As a rule, it is the general system of extracontractual fault liability.

As for Directive 92/59/EEC on general product safety, it states that producers shall be obliged to place only safe products on the market⁶⁰, and it includes in its definition of producer other professionals in the supply chain, insofar as their activities may affect the safety properties of a product placed on the market. The question thus arises as to whether the no-fault liability system introduced in 1985 by Directive 85/374/EEC

⁵⁷ Article 4, Decree-Law of 24 May 1988.

⁵⁸ §4 Produkthaftungsgesetz 1989.

⁵⁹ Article 4.2 of the Law of 25 February 1991.

⁶⁰ See Article 2(b) of Directive 92/59/EEC for the definition of a safe product.

should not be applicable to every professional in the product supply chain, when his activities have affected the safety properties in question of a product placed on the market, such as, for instance, specific activities involving repackaging, transport or storage. The Commission asks those involved in the consultation to comment on this point.

16. Should the victim prove that he provided the supplier with the opportunity to inform him of the identity of the producer, at the risk of having his claim declared inadmissible, and, on the other hand, should the supplier inform him of the identity of the producer within a maximum time limit (e.g. three months)?

17. Should the Directive be applicable to any professional in the product supply chain when his activities have affected the safety properties in question of a product placed on the market?

Products covered by the directive

The directive applies only to products (namely material movables, whether for private use or not, including electricity).

Having excluded defective services (for which the Commission is considering a possible specific initiative⁶¹), the Commission has received questions on whether real estate property should be included in the scope of the directive, insofar as there is no constructor liability system at Community level.

17. Do you think that the directive needs to be extended to cover real estate property?

Damage covered by the directive

Article 9 of Directive 85/374/EEC refers to damage caused by death or personal injury, as well as damage to property, provided that it is intended for non-professional use, with the exception of the defective product itself⁶².

Examples of non-application of the directive in the case of damage to the defective product can be found in Portuguese jurisprudence: in the ruling of 26 October 1995 by the Supremo Tribunal de Justiça in a case dealing with the repair of a vehicle after an accident, the Portuguese Supreme Court held that the dealer of SEAT cars built in Spain was not liable under Decree-Law 383/89 by virtue of the fact that he was considered the "producer" and that the damage had been caused to the product itself⁶³. On 23 May 1995, in another case dealing with the repair of a vehicle damaged by fire, the judge disregarded the national legislation implementing the directive on the

⁶¹ Communication from the Commission - "Consumer policy action plan 1999-2001" (COM(98)696 of 1.12.98).

⁶² Product compensation is covered by the legislation on sales guarantees (see Directive 99/44/EC on after-sales guarantees, OJ No L 171, of 7.07.99).

⁶³ Acórdão No 87.397, Col. De Jur., 1995, III-84.

grounds that the decree-law was not applicable at the moment when the product in question was placed in circulation and that it did not cover damage caused to the product itself⁶⁴.

Non-material damage (any damage not affecting property, moral damage, mental suffering, etc) is not at present covered, even though most national legislations take it into account. In its opinion at the first reading of Directive 99/34/EC, the European Parliament recommended including mental suffering in the scope of the directive, although at the second reading Parliament failed to secure the majority needed to amend the directive accordingly.

Another issue concerns damage caused to products intended normally for professional or commercial use, which are not covered by the directive. This means that when property in an office is destroyed by fire caused by a defective product, the owner (whether a firm or a professional) cannot invoke the directive against the producer to claim compensation for damage. The reason for this is that the directive covers damage to only one type of property: consumer goods. However, there is nothing in principle to prevent the directive being applied to help other types of victim, such as professionals.

In France the law transposing the directive also covers damage to property intended for non-private use (commercial goods).

18..Should the directive cover other damage caused by defective products, such as non-material damage, moral damage, mental suffering and/or damage to property intended for professional use, which would allow firms, and especially SMEs, to invoke the directive against producers of defective goods?

Access to justice

In addition to the ongoing initiatives concerning consumers' access to justice, announced by the Commission in its consumer policy action plan (implementation of the directive on injunctions, out-of-court settlement of disputes, recovery of legal expenses incurred by consumers in enforcing their rights, measures to make it easier for consumers to take legal action collectively, etc)⁶⁵, the question is whether the implementation of Directive 85/374/EEC requires special measures to improve victims' access to justice. In this connection, two measures need to be considered: injunctions and group actions.

Community legislation does not afford victims the opportunity to apply for an injunction when consumers' health and safety are harmed by a dangerous or defective product: the directive on injunctions for the protection of consumers' interests⁶⁶ does not cover the field of Directive 85/374/EEC. However, it may be useful to see if a

⁶⁴ Recurso No 7653, Col. De Jur. 1995, III-113.

⁶⁵ COM(98) 696 of 1.12.98, p. 21.

⁶⁶ Directive 98/27/EC of the European Parliament and of the Council of 19 May 1998, OJ L 166/51 of 11.6.98.

solution similar to that proposed in Directive 98/27/EC is called for, in addition to a victim's right to compensation under Directive 85/374/EEC. In fact, according to Directive 92/59/EEC, a product can be withdrawn from the market only on order of the public authorities and not of private individuals.

On the other hand, Community legislation does not cover group actions in this field either, even though this is a means that is often used in cases of product liability, albeit without any guarantee of success.

An example of multi-party action in this field is shown by the *benzodiazepines* case in the United Kingdom, which involved 5 000 separate proceedings against Roche Products Ltd and John Wyeth and Brother Ltd for damage caused by the tranquillisers, Valium and Ativan. The case depended on the financial support of the Legal Aid Board, which subsequently withdrew its funding on account of the costs that such a case involved. Seventy plaintiffs nevertheless continued the proceedings, until their cases were struck out in a High Court judgement on 19 July 1996⁶⁷.

In the United States there is a special procedure, which has never been used much in Europe. If it is likely that a case will become almost impossible to conduct because there are so many plaintiffs or defendants who may be required to appear, one or more plaintiffs may be selected to represent the others if questions of fact or of law are of common interest to all of them. These are known as "class action suits". The party that is selected to represent the others must have certain typical features that make him the ideal representative. The judgement delivered at the end of a class action suit serves as *res judicata* for all the parties who had elected to participate in the representative action, and also for anyone else who suffered the same kind of damage but who had not explicitly indicated his wish not to participate in the action⁶⁸.

However, American courts are demonstrating increasing caution with regard to class action suits. According to the Federal Rules of Civil Procedure, these suits are possible on condition that the class represented in the action is "certified", i.e. identified. When a case involves a producer's liability, the court must ensure that the group is very large and has the same questions of fact and law, that the representatives of the group are serving and defending the group's interests in an appropriate manner, that the individual arguments are less significant than the collective arguments and, lastly, that a class action suit is the most suitable means of action when compared with other ways of settling the dispute⁶⁹. The Supreme Court showed this kind of "legal scepticism" in the dispute concerning asbestos⁷⁰. The Court did not acknowledge the common identity of the group of asbestos victims because of the lack "common" interest in the case in question. This decision confirms a growing reluctance among American courts involved in "mass tort litigation" against the tobacco or asbestos industries.

⁶⁷ See details at www.gidleigh.com/alert

⁶⁸ Rule 23 of the US Federal Rules of Civil Procedure: "...the judgment, whether favorable or not, will include all members who do not request exclusion;"

⁶⁹ Rule 23 of the US Federal Rules of Civil Procedure.

⁷⁰ *Amchem Products Inc. v Windsor*, 117 S.Ct. 2231 (1997), delivered on 25 June 1997.

In Europe, although some national systems allow cases to be grouped (as in France, where group actions allow consumers' individual interests to be pooled - and this has to be distinguished from collective actions or injunctions, the purpose of which is to serve the general interest rather than individual interests), there has been a legal procedure which seems somewhat similar to class action suits only in Portugal since 1995 (Law No 83/95 on people's action).

19. Should Community legislation provide for court proceedings or out-of-court dispute resolution means, specially set for the implementation of Directive 85/374/EEC?

☞ Would injunctions, provide a solution⁷¹?

☞ Would it be feasible to introduce better arrangements for the common representation of similar interests, like the group actions in France and the people's actions in Portugal?

Other

There are a number of issues relating to liability for defective products which are not dealt with by Directive 85/374/EEC. These include the liability of the management and workers of the firm producing the product, criteria to evaluate damage and arrangements for compensation, apportionment of responsibility among those who are jointly and severally liable, and so on. The Commission asks those parties involved to identify any additional topics that might warrant legislative action at Community level and to give the reasons for such action.

⁷¹ This could be done by including the 1985 Directive in the list of Directive 98/27/EC on injunctions.

Annex 1 : Directive on liability for defective products

Transposition in domestic law

Member State	Adoption	Entry into force	Liability for defective agricultural products (art. 15.1.a)*	Liability for development risks (art. 15.1.b)	Financial ceiling (art. 16)
Belgium	Law of 25.2.91	1.4.91	NO	NO	NO
Denmark	Law No 371 du 7.6.89	10.6.89	NO	NO	NO
Germany	Law of 15.12.89	1.1.90	NO	NO	YES
Greece	Law 2251/1994 (replacing decree-law of 1988)		YES	NO	NO
Spain	Law No 22/1994 du 6.4.94	8.7.94	NO	NO (apart from food and medicinal products)	YES
France	Law No 389-98 du 19.5.98	23.5.98	YES	NO (apart from products derived from the human body)	NO
Ireland	Law No 28 of 1991	16.12.91	NO	NO	NO
Italy	Decree-Law No 224 of 24.5.88	24.5.88	NO	NON	NO
Luxembourg	Law of 21.4.89, amended by Law of 6.12.89	2.5.91	YES	YES	NO
Netherlands	Law of 13.9.90	1.11.90	NO	NO	NO
Austria	Law No 99 of 21.1.88, amended by Law No 95 of 11.2.93, Law No 917 of 29.12.93 and Law No 510 of 12.7.94	1.7.88	NO (apart from GMOs)	NO	NO
Portugal	Decree-Law No 383 of 6.11.89	21.11.89	NO	NO	YES
Finland	Law No 694 of 17.08.90, amended by Law No 99 of 8.1.93 and Law No	1.9.91	YES	YES	NO

* Following the adoption of Directive 99/34/EC, the Member States are obliged to extend Directive 85/374/EEC to primary agricultural products.

	879 of 22.10.93				
Sweden	Law No 18 of 23.1.92, amended by Law No 1137 of 3.12.92 and Law No 647 of 10.6.93	1.1.93	YES	NO	NO
United Kingdom	Law of 15.5.87	1.3.88	NO	NO	NO

Annex 2 : Directive on liability for defective products

Alignment of non-Member States' laws

State	Adoption	Entry into force	Liability for defective agricultural products (art. 15.1.a)	Liability for development risks (art. 15.1.b)	Financial ceiling (art. 16)
Iceland	Law No 25 of 27.3.91	1.1.92	YES	NO	YES
Liechtenstein	Law of 12.11.92	1.5.95	NO	NO	NO
Norway	Law No 104 of 23.12.88, amended by Law No 62 of 25.11.91	1.1.89	YES	YES	NO
Malta	(draft law)	--	--	--	--
Cyprus	Law No 105 of 1995	1.1.97	NO	NO	NO
Estonia	(draft law)	--	--	--	--
Hungary	Law No 10 of 16.2.93, amended by Law No 25 of 16.3.98	1.1.94	NO	NO	NO
Poland	(draft law)	--	--	--	--
Czech Republic	Law No 59 of 5.3.98	1.6.98	NO	NO	NO
Slovenia	Law of 6.3.98	28.3.98	YES	NO	NO
Bulgaria	Law of 18.3.99	3.7.99	YES	NO	YES
Latvia	Law of 8.10.96	8.10.96	NO	NO	NO
Lithuania	(draft law)	--	--	--	--
Slovakia	(draft law)	--	--	--	--
Romania	(draft law)	--	--	--	--
Turkey	Law of 23.2.95	8.9.95	NO	NO	NO

Annex 3 : Legislation of non-Member States on liability for defective products

State	Adoption	Entry into force	Liability for defective agricultural products (art. 15.1.a)	Liability for development risks (art. 15.1.b)	Financial ceiling (art. 16)
Australia	Trade Practices Amendment Act 1992 (24.6.92)	9.7.92	YES	NO	--
Israel	Defective Products (Liability) Law 1980	1.9.80	NO	NO	--
Japan	Product Liability Law (1.7.94)	1.7.95	NO	NO	NO
United States***	S 2236 (federal bill tabled on 25.6.98 and rejected on 9.7.98)		--	--	--
Brazil	<i>Codigo de defesa do Consumidor</i> (11.9.90)	11.3.91	--	--	NO
Switzerland	Federal law on liability for defective products of 18.6.93	1.1.94	NO	NO	NO

*** In the absence of a harmonised federal law, civil liability for defective products is a matter of States law.

Annex 4

85L0374

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

(Official Journal L 210 , 07/08/1985 p. 0029 - 0033)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

Whereas liability without fault should apply only to movables which have been industrially produced; whereas, as a result, it is appropriate to exclude liability for agricultural products and game, except where they have undergone a processing of an industrial nature which could cause a defect in these products; whereas the liability provided for in this Directive should also apply to movables which are used in the construction of immovables or are installed in immovables;

Whereas protection of the consumer requires that all producers involved in the production process should be made liable, in so far as their finished product, component part or any raw material supplied by them was defective; whereas, for the same reason, liability should extend to importers of products into the Community and to persons who present themselves as producers by affixing their name, trade mark or other distinguishing feature or who supply a product the producer of which cannot be identified;

Whereas, in situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them; whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;

Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances;

Whereas the protection of the consumer requires that the liability of the producer remains unaffected by acts or omissions of other persons having contributed to cause the damage; whereas, however, the contributory negligence of the injured person may be taken into account to reduce or disallow such liability;

Whereas the protection of the consumer requires compensation for death and personal injury as well as compensation for damage to property; whereas the latter should nevertheless be limited to goods for private use or consumption and be subject to a deduction of a lower threshold of a fixed amount in order to avoid litigation in an excessive number of cases; whereas this Directive should not prejudice compensation for pain and suffering and other non-material damages payable, where appropriate, under the law applicable to the case;

Whereas a uniform period of limitation for the bringing of action for compensation is in the interests both of the injured person and of the producer;

Whereas products age in the course of time, higher safety standards are developed and the state of science and technology progresses; whereas, therefore, it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product; whereas, therefore, liability should expire after a reasonable length of time, without prejudice to claims pending at law;

Whereas, to achieve effective protection of consumers, no contractual derogation should be permitted as regards the liability of the producer in relation to the injured person;

Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible;

Whereas, to the extent that liability for nuclear injury or damage is already covered in all Member States by adequate special rules, it has been possible to exclude damage of this type from the scope of this Directive;

Whereas, since the exclusion of primary agricultural products and game from the scope of this Directive may be felt, in certain Member States, in view of what is expected for the protection of consumers, to restrict unduly such protection, it should be possible for a Member State to extend liability to such products;

Whereas, for similar reasons, the possibility offered to a producer to free himself from liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered may be felt in certain Member States to restrict unduly the protection of the consumer; whereas it should therefore be possible for a Member State to maintain in its legislation or to provide by new legislation that this exonerating circumstance is not admitted; whereas, in the case of new legislation, making use of this derogation should, however, be subject to a Community stand-still procedure, in order to raise, if possible, the level of protection in a uniform manner throughout the Community;

Whereas, taking into account the legal traditions in most of the Member States, it is inappropriate to set any financial ceiling on the producer's liability without fault; whereas, in so far as there are, however, differing traditions, it seems possible to admit that a Member State may derogate from the principle of unlimited liability by providing a limit for the total liability of the producer for damage resulting from a death or personal injury and caused by identical items with the same defect, provided that this limit is established at a level sufficiently high to guarantee adequate protection of the consumer and the correct functioning of the common market;

Whereas the harmonization resulting from this cannot be total at the present stage, but opens the way towards greater harmonization; whereas it is therefore necessary that the Council receive at regular intervals, reports from the Commission on the application of this Directive, accompanied, as the case may be, by appropriate proposals;

Whereas it is particularly important in this respect that a re-examination be carried out of those parts of the Directive relating to the derogations open to the Member States, at the expiry of a period of sufficient length to gather practical experience on the effects of these derogations on the protection of consumers and on the functioning of the common market,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The producer shall be liable for damage caused by a defect in his product.

Article 2

For the purpose of this Directive 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity.

Article 3

1. 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

Article 4

The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

Article 5

Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.

Article 6

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- (a) the presentation of the product;
- (b) the use to which it could reasonably be expected that the product would be put;
- (c) the time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.

Article 7

The producer shall not be liable as a result of this Directive if he proves:

- (a) that he did not put the product into circulation; or
- (b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or
- (c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or
- (d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or
- (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or
- (f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Article 8

1. Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party.

2. The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.

Article 9

For the purpose of Article 1, 'damage' means:

- (a) damage caused by death or by personal injuries;
- (b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property:
 - (i) is of a type ordinarily intended for private use or consumption, and
 - (ii) was used by the injured person mainly for his own private use or consumption.

This Article shall be without prejudice to national provisions relating to non-material damage.

Article 10

1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

2. The laws of Member States regulating suspension or interruption of the limitation period shall not be affected by this Directive.

Article 11

Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.

Article 12

The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability.

Article 13

This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.

Article 14

This Directive shall not apply to injury or damage arising from nuclear accidents and covered by international conventions ratified by the Member States.

Article 15

1. Each Member State may:

(a) by way of derogation from Article 2, provide in its legislation that within the meaning of Article 1 of this Directive 'product' also means primary agricultural products and game;

(b) by way of derogation from Article 7 (e), maintain or, subject to the procedure set out in paragraph 2 of this Article, provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

2. A Member State wishing to introduce the measure specified in paragraph 1 (b) shall communicate the text of the proposed measure to the Commission. The Commission shall inform the other Member States thereof.

The Member State concerned shall hold the proposed measure in abeyance for nine months after the Commission is informed and provided that in the meantime the Commission has not submitted to the Council a proposal amending this Directive on the relevant matter. However, if within three months of receiving the said information, the Commission does not advise the Member State concerned that it intends submitting such a proposal to the Council, the Member State may take the proposed measure immediately.

If the Commission does submit to the Council such a proposal amending this Directive within the aforementioned nine months, the Member State concerned shall hold the proposed measure in abeyance for a further period of 18 months from the date on which the proposal is submitted.

3. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect that rulings by the courts as to the application of Article 7 (e) and of paragraph 1 (b) of this Article have on consumer protection and the functioning of the common market. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal Article 7 (e).

Article 16

1. Any Member State may provide that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million ECU.

2. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect on consumer protection and the functioning of the common market of the implementation of the financial limit on liability by those Member States which have used the option provided for in paragraph 1. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal paragraph 1.

Article 17

This Directive shall not apply to products put into circulation before the date on which the provisions referred to in Article 19 enter into force.

Article 18

1. For the purposes of this Directive, the ECU shall be that defined by Regulation (EEC) No 3180/78 (1), as amended by Regulation (EEC) No 2626/84 (2). The equivalent in national currency shall initially be calculated at the rate obtaining on the date of adoption of this Directive.

2. Every five years the Council, acting on a proposal from the Commission, shall examine and, if need be, revise the amounts in this Directive, in the light of economic and monetary trends in the Community.

Article 19

1. Member States shall bring into force, not later than three years from the date of notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof (1).

2. The procedure set out in Article 15 (2) shall apply from the date of notification of this Directive.

Article 20

Member States shall communicate to the Commission the texts of the main provisions of national law which they subsequently adopt in the field governed by this Directive.

Article 21

Every five years the Commission shall present a report to the Council on the application of this Directive and, if necessary, shall submit appropriate proposals to it.

Article 22

This Directive is addressed to the Member States.

Done at Brussels, 25 July 1985.

For the Council

The President

J. POOS

(1) OJ No C 241, 14. 10. 1976, p. 9 and OJ No C 271, 26. 10. 1979, p. 3.

(2) OJ No C 127, 21. 5. 1979, p. 61.

(3) OJ No C 114, 7. 5. 1979, p. 15.

(1) OJ No L 379, 30. 12. 1978, p. 1.

(2) OJ No L 247, 16. 9. 1984, p. 1.

(1) This Directive was notified to the Member States on 30 July 1985.