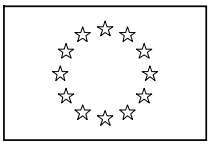

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 31.1.2001
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REPORT FROM THE COMMISSION

on the Application of Directive 85/374 on Liability for Defective Products

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TABLE OF CONTENTS

1. BACKGROUND

Since 1985, the Directive on liability for defective products[1] introduced in the Community the principle of objective liability or liability without fault. According to it, any producer of a defective movable must compensate any damage caused to the physical well-being or property of individuals, independently whether or not there is negligence on the part of the producer.

1.1 Introduction

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 contributing to the well-being of consumers (by ensuring that victims 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, due to diverging national rules.

The Directive on product liability contains the following main elements:

- liability without fault of the producer;

- 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, 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;

- illegality of clauses limiting or excluding liability towards the victim.

In view of the different legal traditions, the Directive accepts that Member States derogate from the common rules ("options") with regard to three points by:

- including unprocessed agricultural products in its scope of application;

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[1] Council Directive of 25 July 1985 (85/374/EEC), OJ No L 210 of 7.8.1985, p. 29

- not exonerating the producer 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;

- by fixing a financial ceiling of not less than 70 million Euro for damage resulting from death or personal injury and caused by identical items with the same defect.

The Directive recognised that the harmonisation could not be total at that stage. It, therefore, foresees that the Commission presents every five years a report to the Community institutions on the general application and, if necessary, shall submit appropriate proposals to it (Article 21). According to Article 15(3) and 16(2), the Commission reports on development risks and the financial limit ten years after notification of the Directive. Every five years, it examines the question of revising the amounts laid down in the Directive (Article 18(2)).

The first report[2] was presented in 1995. It is considered that the Directive is generally perceived to have been an important piece of legislation. It has contributed towards an increased awareness of and emphasis on product safety. The Commission had concluded that experience is still limited and would only develop slowly. In 1995, the Member States had only a very limited case law in the field. On the basis of the information available at that stage, the Commission had considered it not appropriate 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 by the majority of Member States.

In the aftermath of the "mad cow" crisis, the Commission presented a proposal to extend the principle of liability without fault for defective products, as foreseen under Directive 85/374, to primary agricultural products and game. Directive 99/34[3] now obliges the Member States to extend the scope of strict product liability to unprocessed primary agricultural products.

1.2 The Green Paper

During the first reading of Directive 99/34, the European Parliament called for a substantial revision of the existing product liability system. Although the Commission did not share this view, it promised to open a wide discussion with all interested parties in the form of a Green Paper, which would prepare the second report on the application of Directive 85/374.

The Green Paper on Liability for defective products was adopted in July 1999.[4] It aimed at collecting information from all interested parties, in particular economic operators, consumers, insurance companies and public administrations on two points:

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2 The Commission presented its first report on the application of the Directive on 13.12.1995 (COM(95)617), based on an impact study carried out in 1994. This study is published on the Internet: www.europa.eu.int/comm/internal_market/en/goods/liability/index.htm.

3 OJ No L 141 of 4.6.1999, p. 20

4 COM(1999) 396 final of 28.7.1999

- as to how the 1985 Product Liability Directive has worked in practice and

- as to what extent it should be modified.

This document was intended to promote reflection and debate. An important part of the Green Paper called on all those involved to take a reasoned stance concerning the justification for any revision. This section addresses a wide range of issues: they include those points the European Parliament had raised in the discussion on Directive 99/34, such as burden of proof, development risks, mental damages, the threshold, prescription limit and the financial limit; they also consider other questions like the question of more transparency, supplier's liability or access to justice. The "options for revision" mentioned in chapter 3 of the Green Paper should guide the open discussion, without prejudice to any future Commission initiative.

The Commission invited the parties to provide replies which are based on facts, and not on mere positions of principle.

1.3 Reactions to the Green Paper

The Commission received some 100 comments to the Green Paper. They emanate from four different groups:

– national and European consumer organisations,

– national industry associations as well as national and European unions representing sectors of industry concerned (in particular pharmaceuticals, cars, insurance, chemicals, agricultural products, electrical equipment),

– public administrations of Member States (Austria, Denmark, Germany, Finland, France, Netherlands, Greece, Portugal, Spain, United Kingdom) and other European countries (Iceland, Norway, Slovenia, Switzerland),

– bodies specialising in product liability (e.g. Pan-European Organisation of Personal Injury Lawyers, US Defense Research Institute, Special Committee on European Product Liability Law).

As indicated in the Green Paper, the observations received were made public as far as confidentiality was not explicitly requested, and are available at the following internet address: http://europa.eu.int/comm/internal_market/en/goods/liability/replies.htm. A consultant made a summary of two-thirds of the replies which can be found at the same address.

The Economic and Social Committee adopted on 1 March 2000 an opinion on the Green Paper.[5] The European Parliament voted a resolution on the Green Paper at its session of 30 March 2000.

The present application report considered the information and observations received to the Green Paper as well as any other relevant information available. Generally it follows the structure of the Green Paper: chapter 2 gathers the (mainly) factual

[5] OJ No C 117 of 26.4.2000, p. 1

information on the practical application of Directive 85/374; chapter 3 assesses the information and arguments stakeholders put forward in view of the issues for discussion (the report's assessment is highlighted with grey colour); chapter 4 finally draws conclusions from the two previous chapters.

2. PRACTICAL EFFECTS OF DIRECTIVE 85/374/

The Green Paper proposed in chapter 2 to assess, under different angles, how the Directive meets the objectives it set out to achieve: the internal market, the protection of public health and safety and the effects on industry and the insurance sector.

2.1 The impact on the internal market

The Directive on producer liability constitutes a significant element of the legal environment in which intra- and extra-Community trade is conducted. The Commission asked those concerned to comment on its impact in the light of their experience since 1985, both with regard to its functioning in relation to Community trade and to the position of Community companies in relation to competitors from third countries.

2.1.1. The functioning of the Directive in practice

Many observations indicate that the Directive functions properly in practice. This is considered to be due to the fact that it has created a well-balanced and stable legal framework which takes into account the concerns of both the consumers and the producers. However, it is important to note that only little information about the application exist and statistics, if available, are not complete.

In most Member States, the national rules implementing the Directive are applied alongside other liability regulations in the majority of the cases. In Austria nearly all product liability cases are solved on the sole basis of the system provided by the Directive. Plaintiffs use other liability systems (contractual or tort law) mainly because they provide for compensation which is more protective (it covers namely damages under 500 Euro, non-material damages, damages to the defective product itself and to property intended for professional use; prescription periods are longer). In Germany case law constantly interprets applicable provisions of tort law in such a way that they come close to a no-fault based liability. Another reason for parallel application is that the "traditional" legislation is better known given that settled case law exists.

This co-existence of different product liability rules, which is permitted under Article 13 of the Directive, is perceived in various ways: the variety of rules has not discouraged the marketing of products in the Community, nor has it had any effect on insurance companies; it permitted a higher level of consumer protection which, on the other hand, might restrict the application of the rules under the Directive.

For these reasons, most of the observations are opposed to the Directive becoming the common and sole system of liability for defective products, but in favour of maintaining the present situation under Article 13.[6]

It was also asked whether each Member State should be able to adopt stricter liability rules with regard to the provisions of the Directive by introducing a "minimum clause". For some, such a minimum clause should be introduced given that all other Directives in the field of consumer protection follow this model. Another group of replies disagree with this proposal: such a provision would decrease the level of harmonisation which results from the Directive in its present form and create potential obstacles to the free movement of products.

2.1.2 The position of European businesses vis-à-vis their foreign competitors

It seems that the Directive does not weaken the position of European businesses in the global context. Foreign companies selling their products on the European market must also respect Community provisions. In their assessment of third countries, European industry notes that they don't encounter difficulties in those countries the product liability legislation of which follows the principles introduced by the Directive (such as Australia, Japan, Switzerland, Norway and others).

The situation in the United States is considered to constitute a particular case and to have an important impact on European businesses. The answers confirm the way in which the Green Paper assessed the legal framework of which US product liability law forms part: the trial by juries, the "no win, no fee" principle, the awarding of high punitive damages, the possibility of class actions are elements that encourage victims to go to court. This is claimed to create a climate of unpredictability of the outcome for producers. Due to this different situation, European companies, namely small and medium-sized ones, claim that they refrain to some extent from exporting their products to the United States. Another consequence is that they have to pay higher insurance premiums and to face a considerably higher level of litigation. According to figures presented by the Belgian industry, the US legislation renders exports from Europe to the United States two times (for textiles and steel), five times (for food stuffs) and ten times (for pharmaceuticals) more expensive than exports to other countries. These figures have not been assessed and verified by the Commission.

2.2. Protection of public health and safety

The Directive helps to increase the level of protection against defective products for two reasons: first, it encourages producers to do their best to produce safe products by complementing the regulatory measures of a given product group or those following the Directive on General Product Safety 92/59 and second, once these preventive measures have failed and accidents have happened, it allows the victims to obtain redress from the producers.

The first question addressed by the Green Paper in this respect concerned the compensation of victims. It is said that product liability cases have been mostly dealt

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[6] A preliminary ruling procedure, currently pending with the Court of Justice, concerns the interpretation of Article 13 (case C-183/00, González Sánchez).

with under traditional systems and much less under the legislation transposing the Directive. In Finland, the Consumer Complaint Board registered between 1.1.1993 and 22.11.1999 71 cases; 46 cases were decided on the basis of the Product Liability Act and 25 cases on the basis of the Finnish Consumer Protection Act. In Portugal, 200 claims were made since the date of the Directive's implementation; their legal basis is not indicated. In the UK, the number of cases is low.

There are only few reported Court cases based on the Directive: a recent case in Ireland, 2 cases in Italy, 3 cases in the UK, 3 or 4 cases in Belgium, Sweden and Finland, 20 to 25 decisions in Austria, some 30 decisions in Germany, 19 judgements in Portugal, no decision yet in France, Greece and Luxembourg.

The number of product liability cases seems to be relatively low. In the vast majority (90%, according to the German and Dutch insurers) these claims are settled out of court, in particular when the facts (i.e. the defect, the damage and the causal link) are clear. Business recognises the benefits of settling genuine, validated claims by avoiding the length and costs of litigation. In these cases, liability is not an issue and all that remains to discuss is compensation. While some consider the out-of-court settlement a mechanism which functions well, consumer organisations criticise it since the details of the settlement often remain confidential and because producer and insurers have an inequitably advantageous position.

Given the high number of out-of-court settlements, it is said that victims are compensated in general quickly and efficiently. With regard to cases brought before the national courts, the question of a swift solution is more a question of the speed and efficiency of the national systems of civil procedure than of the adequacy of the substantive law. Spanish procedural law is said to be very formal and strict concerning the submission of evidence.

Another question of the Green Paper concerned the impact of the Directive on the victim's interests. The number of claims based on defective products seems not to have increased. It is stated that the level of product safety increased considerably since the Directive was adopted in 1985. This situation results from the existence of a high safety level ensured by a strict regulatory framework, namely in certain product sectors, such as pharmaceuticals, chemicals, machinery, electrical equipment, while the other sectors are covered by the Directive 92/59 on General Product Safety. Industry is said to take into account these safety features in design, production, labelling and post-marketing systems and uses extensively good practice standards. The replies confirm that the Directive on Product Liability has a deterrent effect on manufacturers and suppliers and gives them a strong incentive, alongside the obligations under the afore-mentioned safety regulations, to improve the safety level.

The view of industry is that the Directive found the right balance between the protection of victims and the interests of producers. Consumer organisations disagree on this point and call for several changes. Several Member States (Germany, the Netherlands, Austria and the UK) state in their comments that at the moment there is no concrete information which could justify any changes of the Directive in favour of the consumers. Another group of Member States (France, Finland, Denmark, Greece

and Portugal) indicate areas where some changes could be made; however, in certain cases, no arguments are given.[7]

The observations reveal some differences among the Member States as far as the relationship between the national social security systems and the compensation awarded according to the Directive is concerned. As a general rule, a person injured by a defective product receives a payment under the social security schemes, independent of the existence of a liable person and as a counterpart to his contributions to the insurance scheme. Compensation of the victim under the Directive is additional to this payment. The level and scope of social security provisions in Europe is generally high, but differs between Member States. It is unclear whether in those cases where a large proportion of the damages are covered by these schemes victims initiate compensation proceedings.

In some Member States, such as the Netherlands[8] and Scandinavian countries[9], social security schemes do not have the possibility to take proceedings against the producer of a defective product. In other countries (as for example in Austria, the United Kingdom[10] or Italy), social security schemes have such a possibility, but have not yet used it in practice on the basis of the rights conferred upon the victim under the Directive. No figures exist with regard to the number of cases in those Member States where the social security actually took redress against the producer.[11]

It was also asked whether cases existed where the producer liability scheme set up under Directive 85/374 was insufficient to fulfil its compensatory role so that it was necessary to fall back on the solidarity of society as a whole to compensate victims. Those few replies addressing this point confirm the information contained in the Green Paper (blood transfusions in France, rape-seed oil case in Spain, blood products in Denmark). In Germany haemophiliacs were infected with the HIV virus by contaminated blood products during the period of 1980 to 1993 and a compensation fund was established.[12] Several Member States (Germany, France, Denmark, United Kingdom, Sweden, Italy, Finland and Austria) enacted legislation under which schemes administered by governments provide compensation payments to persons with vaccine-associated injuries. They are financed by the general public except for Denmark, Sweden and Finland where manufacturers contribute to a insurance fund.

2.3. The effects on industry and the insurance sector

The Green Paper asked industry whether it were aware of any cases of defective products in which the Directive was actually applied and how this affected its activities. There were very few claims of this nature which were normally covered by the company's insurance policy. Activities may have been affected in so far as companies had to insure higher risks.

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7 Where replies identify specific shortcomings of the present system, they are discussed in the relevant part of chapter 3 of this report.

8 Article 197 of Book 6 of the Civil Code

9 The introduction of a redress mechanism is at present under discussion in Sweden.

10 Social Security (Recovery of Benefits) Act 1997

11 In France one case is known, in Portugal none; in Germany few cases are known.

12 BGBl. I 1995, 972

The pharmaceutical sector indicates that the introduction of a comprehensive regulatory system since 1965 lead to an increase in costs. However, no figures are given with regard to the Directive's impact.

No research or studies have been undertaken on the Directive's potential impact on companies' activities.

Another set of questions was specifically addressed to the insurance sector. It asked for data on the number of claims it had dealt with after accidents caused since 1990, whether the guarantee given by the insurer is related specifically to the producer's liability under the Directive and whether demands for this type of guarantee increased since the Directive applied and its impacts. Insurance policies seem to have risen in Austria up to 100% since the law transposing the Directive was passed. In Germany, however, the number of demands introduced for product liability policies did not increase considerably. The reason was that the majority of companies already had taken appropriate cover, prior to the Directive and following the case law of German courts which developed stricter liability standards for producers. The same situation prevailed in most of the other Member States.

The Directive's impact on costs is difficult to assess because many other factors and developments influenced the level of compensation paid, the amounts of cover sought and the premiums collected. At European level no statistics exist which break down the type of liability (negligence or no fault-based liability) or the type of defect. This is due to the fact that product liability statistics are neither systematically collected at this level nor collected in such detail by all individual insurers. They are collected at national level by a few of the smaller markets. On the basis of this data approximately 60 to 70% of settled claims are based on manufacturing defects and 1 to 11% concern design defects.

3. ASSESSMENT OF ISSUES DISCUSSED WITH A VIEW OF POSSIBLY AMENDING DIRECTIVE 85/374

3.1 Maintaining the balance

Political discussions on earlier occasions and again the contributions to the Green Paper show that the policy of product liability provokes conflicting views on the part of producers and consumers. Victims want the highest level of protection at the lowest cost, while producers ask in particular for ceilings and for the shortest possible liability period.

Directive 85/374 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 expressed its wish in the Green Paper to see this conciliatory approach retained. Accordingly, any proposal to revise the directive should take into account the balance which at present 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 victim's rights and obligations are:

(5) **he has 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 (the conditions of proof are subject to re-examination (see below "burden of proof") and

(6) **joint and several** liability (allowing the victim to approach any of those liable without prejudicing his right of complaint).

The Green Paper asked whether the said six principles constitute the basis that needs to be maintained in order not to upset the internal balance of the Directive. Some of the comments agree that the six principles constitute a fair balance of the interests involved and should be maintained, whereas others would wish to see some modifications introduced.

3.2 Issues for a possible future reform

Earlier political discussions, stakeholders and experts have highlighted several aspects of the directive as deserving special analysis with a view to possible reform. The Green Paper explained the issues at stake for each point and, when possible, indicated "options" which should be considered as guidelines for open discussion, without prejudice to any future Commission initiative.

3.2.1 Burden of proof

According to the Directive, the injured party is required to prove the damage, the defectiveness of the product and the causal link between the defect and the damage suffered. In practice it may be difficult to prove that a product was defective and/or that a causal link exists. This can be due to the technical complexity of the product concerned, the high costs for the necessary expert opinions or the disappearance of the product concerned (e.g. foodstuffs, pharmaceutical products).

Without prejudice to the general principle whereby the burden of proof lies with the victim, the Green Paper asked whether its application should be facilitated. It indicated four "options":
- 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;

- to establish the degree or standard of necessary proof of the three elements required;
- 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;
- to make the producer bear the costs of the expert opinion under certain circumstances.

Replies are divided on this issue. One group believes that the current system is adequate, since problems had not been cited. If the producer had to provide proof that the product was safe, there was a risk that a large number of actions would be brought by consumers without due reason. This group rejects the idea of introducing a liability based on presumption. Since each product liability case needs to be decided on its merits, presumption would not be a suitable instrument.

Another group considers that the use of presumptions is a useful means in law to put the onus on the more informed person with the relevant insight in order to prove to the Court why the product should not be considered to be defective. A similar argument could be made for causation. It would be unfair to oblige the victim to cover evidential costs when it is clear that the defective product was the only possible cause of the victim's injury.

The situation in Member States in this area differs to some respect. It indicates, however, that national Courts have already developed ways to facilitate the burden of proof.

- In **Sweden** it is for the judge to assess the causal relation, particularly in technically complex cases. The burden of proof had been reduced by the courts in certain situations ("probability").

- In **Finland**, under the principle of the free assessment of evidence, the judge can take into account the difficulty of establishing the defect in a product or a causal relation.

- In **Germany**, according to the law on civil procedure, the Court is free to assess and judge evidence in the individual case. Causality was established in several cases on the basis of *prima facie* proof, when damage arose in the normal course of events.

- When the product disappeared (e.g. an exploding bottle) and when it was difficult to find the origin of the defect, in **Spain** judges based their decisions on assumptions.

- Judges in the **Netherlands** used the power to overthrow the burden of proof in exceptional cases, e.g. in the case of the defect in the product.

- In **Denmark**, the requirements of proof depend on each case and are decided by the judge. There are several judgements where consumers had been unable to furnish proof and where the court had asked the producer to provide rebuttal evidence.

- According to legal practice in **France** and **Belgium**, the defect of a product can be proven in any way, by evidence and by probability. The judge can infer the causal link ("the equivalence of conditions").

- In the **United Kingdom** the simple balance of probabilities test (this means at least 51%) is applied to issues of damage, defect and causation.

There is limited experience with regard to relieving the victim's financial burden of advancing the costs for expert opinions. Under UK Civil Procedure Rules 1999 the Court is obliged to ensure that parties are as far as practicable put on an equal footing; it also has the power to give directions about the payment of a jointly instructed expert's fees and expenses. According to existing German law, the producer is obliged to pay the expenses insofar as the damage is regulated out of court or if the producer is ordered to pay damages. In case of financial difficulties, the victim can apply for legal aid. The Italian transposing decree 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.

Finally, the national rules on discovery vary widely between Member States. Where such rules provide for excessively limited disclosure of documentation or information prior to or in the course of litigation, a denial of access to justice could be the possible result. The English Civil Procedure Rules 1999 are cited as a balanced approach with regard to the disclosure of information by both claimants and defendants at an early stage of a dispute. Other liability rules under German law oblige the producer to provide documentation and information if specific conditions are met. This obligation applies when sufficient indications for the causation of damage exist and factual circumstances falling within the ambit of the producer are necessary for the victim to establish the proof. In cases where the producer does not provide this information, the burden of proof can be reversed.[13]

In general, national administrations know of no practical problems due to the rules on burden of proof. This conclusion concerns also the situation of foodstuffs or pharmaceuticals which is recognised as being specific.[14] In Germany, it is presently being discussed how to overcome some difficulties with regard to pharmaceutical products. In this case, consideration might be given to introducing the right of the user to have certain facts mentioned on the product or on the packaging leaflet concerning the side-effects of pharmaceutical products, since this was necessary for bringing legal action.

The Green Paper then addressed the special problem of determining the identity of the producer when the same product is made by several producers and asked whether "market share liability" were feasible in Europe for this type of cases.

The concept of "market share liability" is rejected by nearly all the contributions. Product liability is based on the individual responsibility of the person who causes

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13 § 35 of the Law on biotechnology (Gesetz zur Regelung von Fragen der Gentechnik), BGBl I 1999, 1080: Liegen Tatsachen vor, die die Annnahme begründen, daß ein Personen- oder Sachschaden auf gentechnische Arbeiten eines Betreibers beruht, so ist dieser verpflichtet, auf Verlangen des Geschädigten über Art und den Ablauf der in der gentechnischen Anlage durchgeführten oder einer Freisetzung zugrundeliegenden gentechnischen Arbeit Auskunft zu erteilen, soweit dies zur Feststellung, ob ein Anspruch nach § 32 besteht, erforderlich ist. Die §§ 259 bis 261 BGB sind entsprechend anzuwenden.

14 In Germany nearly all cases concerning pharmaceuticals could be solved on the basis of the *prima facie* rule.

damage. The said concept would make persons liable although they are not involved in the damage and thus deviate from a fundamental principle of liability. In this situation it would be extremely difficult to ensure risk as underwriters would not be able to assess or quantify their exposure until after the case has been concluded. The Directive introduces the liability of the supplier under Article 3(3) in case the producer cannot be identified. This guarantees that the victim has a defendant against whom he can introduce a claim.

Furthermore, Article 3 of the Directive gives a wide definition of a producer. This can lead to joint and several liability of producers (Article 5). The Dutch Supreme Court developed the following rule for the DES case:[15] if it is established that the victims' damage is the result of a particular product, each of the producers who had placed that product on the market during the period in which the damage occurred can be liable for the full amount of the damage.

It seems that no other similar cases exist and that there is no need for introducing this concept. Also in the United States, where this concept originated, the application is limited and the courts have refused its application due to practical difficulties of definitions.

3.2.2 Development risks

Under Directive 85/374 a producer is exempt from liability when he proves the existence of certain facts. One of the exemptions concerns the so-called "development risks". The European Court of Justice interpreted the relevant provision in the following way: 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 circulation[16].

Given the controversial debate, the Community legislator in 1985 did not settle this issue definitely, but provisionally: exemption was possible for a period of ten years, and 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 the effect that rulings by the courts as to the application of Article 7(e) and of Article 15(1)(b) have on consumer protection and the functioning of the internal market. In the light of this assessment it was to be decided whether producers should be liable for "development risks" after the transition period.

After implementation, in some Member States the producer is liable also in case of development risks. In Luxembourg and Finland the scope of liability concerns all types of products. Other countries limited this liability to specific product sectors: Spain in the case of food and pharmaceutical products and France for products derived from the human body and for those marketed before May 1998. In Germany

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15 See Green Paper, p. 23, footnote 41.

16 *Commission v the United Kingdom*, C-300/95, judgement of 30.5.1997, ECR [1997], p. I-2649, point 29.

the producer's liability in cases of development risks existed since 1978 in the area of pharmaceutical products.[17]

In this context, the Green Paper asked whether and how liability for development risks involves insurmountable consequences for producers at the European level, by discouraging them from innovation, especially in the sector of pharmaceuticals, and whether it would be feasible to insure this kind of risk in the insurance market.

Industry's replies put forward a number of arguments in favour of maintaining the exemption based on development risks. In their view this kind of liability would prevent scientific progress, the development and innovation of new products. Linked to the specific features of the pharmaceutical sector, the product launch of innovative bio-tech products could be delayed or prohibited. The degree of unforeseeable risk in so-called "orphan drugs", i.e. those designed to treat rare diseases, would be comparatively higher than with other medicines because the clinical testing is limited to a small number of patients. Introducing such a liability could lower the standard of care to which the pharmaceutical industry works since producers could be made liable notwithstanding the fact that they have applied the highest existing level of scientific knowledge.

Insurers stress the difficulties which will result in pricing a product liability insurance that covers development risks. Given the unforeseeable and unknown risk, it would be very difficult to cover it and insurers might exclude it in their policies.

Other replies, namely those from consumer organisations, stress the fact that strict liability is based on the recognised principle under which the person taking benefits from a dangerous activity should compensate the disadvantage of other persons. Consequently, the producer should be held liable also in case of damages due to any undetectable risk.

Some information is available with regard to the five Member States where, partially or in general, the producer is liable for development risks.

Finland: The Government regarded cases of development risks as very rare and introduced producer liability in this case since there was no justification for consumers having to bear these risks. In practice, the level of insurance premiums increased, the additional costs being negligible. At a public hearing organised by the Ministry of Justice in November 1999, it had been noted that there had been no cases of development risks.

Luxembourg: Case law existing before the Directive was adopted made producers also responsible for development risks. The option had been used to maintain this situation. Specific problems due to this system are not known.

Spain: Introducing liability for development risk for foodstuffs and pharmaceuticals is explained by the fact that these sectors are of greatest public sensitivity and the occurrence of these risks is likely in this area. The financial impact on industry (insurance premiums) is not known.

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[17] The Directive recognised the existence of this specific liability system and authorised the co-existence with the Directive, see Article 13 and the 13th recital.

France: Under the traditional liability system, an undetectable defect was not grounds for exonerating the producer. Owing to ethical considerations, the transposing law made the producer liable for development risks with regard to the elements and products of the human body. Although it is known that insurance companies had difficulties with this provision, no specific data is available.

Germany: Strict liability including development and production risks with regard to pharmaceutical products had already existed before the adoption of the Directive. Given the direct impact on the human body medicines have, the Law on Pharmaceuticals provided for this solution. The inclusion of liability for development risks is combined with financial ceilings (liability is limited to 500 000 DM in any individual case and 200 million DM for each pharmaceutical or 12 million DM for each product per year in the case of annuities). No data on the practical impact is available and very little case law exists.

Very little data is available on what practical impact the introduction of producer liability in case of development risks would have for industry and insurers. No detailed research on the rulings of national courts with regard to the application of the exemption clause related to development risks exists. The few cases known seem to indicate that in practice it is not so easy for the producer to prove that the defect could not be detected on the basis of the knowledge that was available when the product was marketed and, thus, waive his liability. The occurrence of damages due to a development risk seems to be most likely in the following sectors: pharmaceutical products, chemical substances, genetically modified organism and foodstuffs.

The Green Paper asked whether damage caused by development risks should 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.

Replies are divided on this point. Some contributions are in favour of introducing a compensation fund in the most sensible sectors. Past experience has shown that, with damage on a large scale, public intervention was inevitable and public funds were set up to assist those suffering damage (see the cases mentioned above under point 2.2 - HIV etc). It is questionable whether this intervention should not constitute the exception. Therefore, the idea of establishing a fund by companies of the manufacturing sector concerned should be first envisaged. Other comments suggest that the question of compensation funds should be left to the individual Member States.

Compensation funds set up by industry exist in few countries. In Germany, due to the liability limit of 200 million DM per product, manufacturers of pharmaceuticals and insurers agreed to establish the “Pharmapool”. Manufacturers pay a percentage of turnover based on three risk categories into a pool comprising all of the German insurers of pharmaceutical companies. In return, the insurers collectively guarantee the cover. Since its existence, this pool made one payment of 55 million DM in the case compensating haemophiliacs with HIV alleged to be caused by blood products. Premiums were reduced in 1981 since no claims were introduced against the pool.

A voluntary scheme for injuries caused by pharmaceuticals was established in Sweden in 1978. The scheme is financed by a percentage of the manufacturers’ sales

and administered by insurance companies. This scheme was established on the basis that manufacturers would not be expected to reimburse the National Social Security Scheme of any payments it had made to injured persons.

A voluntary Pharmaceutical Insurance Scheme exists also in Finland since 1990. An aggregate upper limit of 100 million Mk per year is set for epidemic injuries.

Danish legislation provides for compensation of personal injury caused to individuals by pharmaceuticals, regardless of any proof of fault or liability, if the products were obtained after 31 December 1995. A compensation fund is managed by the patient insurance association and financed by reducing State reimbursement of medicinal products individuals have bought. Two claims were introduced during the period of 1998 and 2000.

On the basis of information available it seems that the said compensation funds intervened very rarely and, if so, for minor damages.

3.2.3 Financial limits

The Green Paper addressed two issues under this heading: First, according to Article 9 of the Directive, the producer does not have to compensate the victim for damage to property which is lower than ECU 500. This threshold or deductible was introduced in 1985 in order to avoid litigation in an excessive number of cases.[18] Stakeholders were asked to provide any information on the percentage of cases involving material damage of less than € 500.

One group of replies proposes to abolish the € 500 limit. Consumers would often suffer damages to property which are below this threshold and therefore lack compensation in these cases. Contributions contain limited data: in Finland 71 cases were brought before the Consumer Complaint Board between 1.1.1993 and 22.11.1999; 13 out of these cases involved damage to property of less than € 500.

Another group argues that the current regime should be maintained. The limit would be reasonably modest and would not unduly disadvantage consumers. Judicial costs related to this category of claims would be disproportionately high. In most cases, the damage would be covered by the consumer's home insurance policy.

The limited data available seems to indicate that a removal of the deductible might result in a higher number of cases against producers, also small and medium size enterprises. This could be prevented by encouraging out-of-court solutions for small claims.

The second issue concerns the possibility left to Member States under Article 16 (1) of the Directive 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 € 70 million. In 1985 lawmakers considered this limit as transitional and agreed that the Commission should assess the effect of using this option on consumer protection and the functioning of the internal market after a period of ten years (Article 16(2)). In the

[18] See 9th recital of the Directive.

light of this assessment it should be decided whether this financial ceiling should be removed.

Three Member States (Germany, Spain and Portugal) have adopted financial ceilings.

In **Germany**, the setting-up of a financial ceiling of DM 160 million was explained by the fact that liability without fault needed to be limited. Under the specific regime for pharmaceutical products the financial ceiling is DM 200 million. There are no known cases in which the financial ceiling would not have been enough.

In **Spain**, the ceiling is PTS 10 500 million. So far, no cases are known were this limitation left injured persons without compensation.

In **Portugal**, legislation set a financial limit at ESC 10 000 million. No data on the application is available.

The little information seems to indicate that the financial ceilings which exist in three Member States are high enough in order to cover any claims for compensation. No data exists which would show that the use of the option under Article 16 (1) of the Directive by these Member States has any major impact on the functioning of the internal market.

3.2.4 Prescription and liability periods

The liability of a producer extincts ten years from the date on which the product was put into circulation, unless there are any claims or proceedings pending (liability period). A person who wants to bring a claim against a producer for damages due to a defective product must bring his claim 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). This limitation of liability is mainly justified by the fact that strict liability puts a higher burden on producers than liability under the traditional systems of contractual or extra-contractual liability. Therefore, the liability period is limited in order not to discourage technological innovation and to allow insurance cover.

The Green Paper asked whether the time limit of ten years needed to be changed, either generally of specifically for certain products or sectors and whether the costs resulting from such a change should and could be borne by industry and the insurance market.

One group of replies thinks that the ten-year limit should be maintained. Their arguments relate to the need for legal security, problems to get insurance cover in case of longer periods or at least an increase in insurance premiums. Another point is that, since it is easier for the victim to get compensation under strict liability, the time limit is justified and the victim has the possibility to take redress against the producer for longer periods (up to 30 years) under other liability systems.

Another group of comments suggest to extend the limit, at least with regard to particular product sectors (such as foodstuffs, pharmaceuticals, agricultural products or products intended for especially long-use). These sectors are identified to bear latent injury where the damage might result a long time after the product was put on

the market.[19] Other proposals consist in beginning the ten-year period by the date on which the product was first supplied to the consumer or extending the limit to the foreseeable period of the product's use.

The Directive 92/59 on general product safety[20] requires that only safe products are put on the market. In this context, the notion of a safe product refers to the foreseeable period of a product's use. It is to be noted, however, that Directive 92/59 and Directive 85/374 have a complementary function: the first instrument ensures that only safe products are put on the market (prevention); the second instrument establishes the rules under which personal injury and damage to property caused by a defective product are compensated (compensation). Therefore, it is justified to deal with the issue of time-limit in relation to the producer's liability in a different way than in relation to the general safety of products.

There is no information on practical cases in relation to the effect of the ten-years time-limit, nor concrete data on the financial impact on industry and the insurance sector if the time-limit was extended.

3.2.5 Insurance requirement

Producers are currently not required to have any kind of financial cover; they are not required to take out liability insurance for an amount that is adequate to cover any damage caused by a defective product.

The Green Paper asked about the experience in this regard, in particular whether any cases are known where lack of insurance cover left victims without compensation and whether there is a need for further action in this relation.

A group of contributions considers that the producers themselves should decide on the question of insurance. The arguments are twofold: there are no known cases where compensation could not be provided due to the lack of insurance cover and obligatory insurance for all product sectors would make the manufacturers of products with low risk pay a part of the financial burden of more dangerous products. Some comments favour the introduction of a mandatory insurance in those sectors which insurance companies have recognised as risk sectors.

On the basis of the information available, it seems that the absence of a specific provision on insurance cover did not lead to any practical problem. It should be further assessed whether in practice manufacturers of those sectors where the liability risk is high already seek on their own insurance cover or whether there is a need for further action.

3.2.6 Transparency

The Directive currently does not foresee any means of making its implementation more transparent by instituting a mechanism covering information with regard to

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19 A case occurred in France where a pharmaceutical was taken by pregnant women and which caused physical damage to their children which appeared, however, at the age of sexual maturity.

20 OJ No L 228 of 11.8.1992, p. 24.

product liability cases. Producers are not obliged to keep records of claims against them, nor are the national authorities obliged to collect the cases reported.

The Green Paper asked whether the Directive should provide for means of increasing transparency of the way in which operators apply the rules, in particular by identifying the cases involving defective products that are still on the market.

With regard to the question of ways to identify defective products that are still on the market, some replies propose to set up a system requiring producers of defective products to provide a central body with all the relevant information. Another group of comments refer to Directive 92/59 on general product safety. This Directive and the national implementing measures are considered to be the means of guaranteeing that only safe products are placed on the market and that, should unsafe products be found on the market, they are withdrawn or recalled.

A number of contributions disagree with the idea of publishing the details of product liability cases. Two main arguments are raised: detailed information on specific cases could in some instances weaken the consumer's position when negotiating the amount of compensation; increased information about product liability cases could lead to a number of ungenuine claims.

It needs to be further analysed whether the obligation of the producer under the Directive 92/59 with regard to post-marketing, in particular recall and withdrawal of unsafe products, is correctly implemented.

3.2.7 Supplier's liability[21]

The Green Paper addressed under this title two points: the notification procedure in relation to the supplier and the supplier's liability.

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

The Green Paper asked whether the supplier should inform the victim of the producer's identity within a maximum time limit.

Many contributions consider that a fixed time limit could be justified because the indication of "reasonable time", as currently stated, could be interpreted in different ways in the Member States. While some propose a limit of one month, it is three months for others.

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[21] The Directive uses in Article 3 (3) the term "supplier" within the meaning of a person distributing a product put on the market to the consumer. The present report follows this definition.

It seems that Member States apply the indication of “reasonable time” with small variations. No data is available on the practical effects of these differences. At this stage, there is no clear evidence for a need for harmonisation.

Extent of supplier's liability: The Directive is based on the principle that it is the producer who is liable for the damage caused by a defect in his product. Article 3(1) of the Directive 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)).

The Green Paper asked whether the Directive should 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.

A group of replies refer to Directive 92/59 whereby the definition of producers includes other professionals in the supply chain, insofar as their activities may affect the safety properties of a product placed on the market. This means that professionals in the supply chain are also obliged to ensure that only safe products are marketed and to participate in post-marketing measures. The liability rules under Directive 85/374 should be extended in this sense. The contributions do not always clearly indicate whether the supplier’s liability should be unlimited (i.e. the supplier would be liable also if it concerns a manufacturing defect) or only limited to specific activities of the supplier involving e.g. repackaging, transport or storage.

Another series of comments rejects the idea of introducing supplier’s liability. The main argument is that it is difficult to see how the principle of no-fault based liability can be applied to the supplier. If the supplier was liable for any defect due to storage or transport, such a liability would come close to the concept of fault-based liability. Other problems would consist in identifying the liable person (the producer or the supplier) and proving the defect if it is a defect falling within the supplier’s sphere. The approach adopted in the Directive 85/374, based on the production and marketing of defective products, does not justify full liability of the supplier, i.e. also in the case of a defect existing at the moment of commercialisation.

As already mentioned above, Directive 92/59 has the objective of prevention and Directive 85/374 has the role of compensation. Although these functions are complementary, it does not mean that in all respects the rules applicable need to be the same. This is true for the question whether the obligations suppliers bear under the Directive on general product safety can be transposed *ipso facto* to the area of product liability. The objective underlying Directive 85/374 is that the producers shall be liable for defective products independently of any fault. Suppliers are liable only in case that the producer cannot be identified. Thus, the Directive recognises the exceptional situation of the supplier’s liability.

The number of cases where a product defect results from the activity of a supplier seem to be relatively limited (mainly in the area of foodstuffs and agricultural products); no concrete data is available in this regard. No information is available whether consumers were left without compensation in this specific situation or whether they could turn themselves against the producer. A fundamental change in shifting the liability to the supplier in other situations than the ones foreseen by Article 3(3) of the Directive does not seem justified at this stage.

3.2.8 Products covered

The Directive applies only to products[22] and covers all material movables, whether for private use or not, including electricity.

The Green Paper asked whether real estate property should be included in the scope of the Directive.

Comments are in general negative on this point. Specific legislation on liability for buildings exists in several Member States. In other Member States rules of contractual law ensure that a person can seek compensation in case that there is a problem with a building. The Directive envisages the producer's liability for defects in products which are industrially mass-produced. Accordingly, the Directive covers construction products which are incorporated into an immovable. However, real estate property constitutes an individual service and requires different rules.

On the basis of data available it does not seem appropriate to make the Directive apply to real estate property.

3.2.9 Damage covered

The Directive currently refers in Article 9 to damage caused by death or personal injury, as well as damage to property, provided that it is intended for non-professional use. The defective product itself[23] is not covered.

The Green Paper addressed three issues in this respect:

Non-material damage (any damage not affecting property, moral damage, mental suffering, etc) is not at present covered by the Directive, even though most national legislation takes it into account. Stakeholders were asked whether the Directive should cover also non-material damage.

Contributions are divided on this point. It is confirmed that national laws on strict liability in most Member States already cover non-material damage. However, differences exist with regard to the definitions and the practical application (e.g.

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22 For defective services the Commission is considering a possible specific initiative, see Communication from the Commission - "Consumer policy action plan 1999-2001" (COM(98) 696 of 1.12.1998).

23 Product compensation is covered by the legislation on sales guarantees (see Directive 99/44/EC on after-sales guarantees, OJ No L 171 of 7.7.1999, p. 12).

amount of compensation awarded in this respect). In Germany, discussions have started in order to extend damage which is compensated according to the national law on strict liability to non-material damage resulting from suffering.

The replies do not give sufficient detail in order to be able to assess what practical impact national rules providing for compensation of non-material damage and the fact that they have a different scope and are applied in different ways have on the functioning of the internal market as well as on the protection of the consumer. This issue needs to be further examined before any conclusions can be made.

The Green Paper also asked whether damage caused to products intended normally for professional or commercial use should be covered by the Directive and, thus, professionals should be protected in case of damage.

The position of comments in this regard is in general negative. The main argument is that one of the Directive's objective is the protection of the consumer and products other than consumer goods should not be covered. In practice professional users had either a means of redress under contractual law or any damage would be covered by a business insurance policy.

On the basis of data available it does not seem appropriate to amend the Directive on this point.

Only few contributions address the issue whether damage to the defective product itself should be covered. Damage to the defective product itself was said to be covered by contractual arrangements.

On the basis of data available it does not at this stage seem appropriate to include this type of damage.

3.2.10 Access to justice

The Directive contains no special provisions on the victims' access to justice in its current version. The injured person has to use national remedies.

The Green Paper put the question whether special measures to improve victims' access to justice should be introduced by providing for injunctions, special mechanisms for out-of-court proceedings and/or class actions.

A number of contributions consider the power given to the national authorities under Directive 92/59 to withdraw any dangerous product sufficient for the protection of consumers. They think that there is no need for an individual's right on injunction.

While some replies are in favour of giving further thought to alternative dispute mechanisms, others consider that the out-of-court proceedings currently in existence are functioning well since the majority of claims are solved in this way. There are objections on formal grounds (lack of Community competence under Article 95 EC with regard to the harmonisation of rules on civil procedure) against group actions. Another negative argument in this respect relates to the fact that rules on legal proceedings should not be created for a specific sector, as this same problem arises in all consumer-related areas.

There is some information on the situation in most of the Member States with regard to group actions. It can be summed up as follows:

In **Portugal**, popular legal action exists whereby the Public Prosecutor's Office and consumers' organisations can intervene in cases of injury to private individuals.

In **Austria**, civil procedural rules allow the victim to pass on his/her liability claim to a consumers' association.

In **Belgium**, plaintiffs with similar but separate claims can institute proceedings before the same court and then ask the court to handle their claims at the same hearing, without joining them.

In **Greece,** legal action by consumer groups is possible.

In **Denmark**, the rules on legal proceedings allow popular legal actions to be brought in all consumer-related areas.

In **France**, legislation exists which enables consumer associations to defend the civil interests of consumers. This does, however, not include actions for compensation for a group of injured persons. Consequently, there are no actions similar to the "class actions" in the United States.

In **Germany**, in the event of a series of accidents, there is a "trial action" which will subsequently form the basis of compensation between industry and the injured persons.

In **Ireland**, the rules of court provide a procedure whereby one or more of persons having the same interest in a single claim may bring or defend the claim on the behalf of all those interested.

In **Italy**, consumers' associations can defend consumers' interests, but cannot act on behalf of injured persons.

In **Finland**, a few years previously, the question of popular legal action had been examined. The consumer ombudsman can assist individuals before the court; the trial costs can be entirely covered by a special budgetary fund.

In the **Netherlands**, multi-party action is possible under the Group Actions Act from May 1994.

In **Spain**, consumers' associations can bring a legal action on behalf of one of its members. An amendment of the rules on court proceedings will make it possible to bring joint actions, as from January 2001.

In **Sweden**, rules concerning popular legal action are being considered, and a proposal might be put forward in the future.

In the **United Kingdom**, multi-party action can be brought in the courts in England and Wales[24] under a rule of civil procedure on group litigation. Under this procedure one or more individuals can act in a representative capacity and bring proceedings on behalf of others where they have the same interest.

At this stage, there is no indication that action concerning access to justice specifically with regard to product liability cases would be appropriate.

3.2.11 Other

Some contributions advance additional points which should be reflected further. The issues concern some points where the Directive leaves Member States to define certain legal concepts (such as "putting into circulation"[25]) or where, due to an apparent lack of clarity in the Directive, Member States seem to have taken diverging national transposition laws. Another point relates to the use of a defective product in the supply of a service. Finally, the question is raised whether the Directive should contain provisions concerning conflicts of law (defining the jurisdiction and the applicable law).

These issues need further consideration. They would not require in principle a modification and might be dealt with either in relation to the transposition control of the Directive or in the context of an exchange of information between Member States on the practical application of certain provisions.

4. CONCLUSIONS

The Commission concluded in its First Application Report in 1995 that experience was still limited and was only likely to develop slowly. The impact study[26] on which the report based its conclusions and to which it referred, explained the different reasons why experience would be little.

In view of this situation, the Commission thought it appropriate to issue a Green Paper on product liability for the following reasons: this document would address the various points on which factual information is needed and would trigger a large and substantial debate in this respect. The Commission received a large number of contributions which shows the great interest in the subject matter.

The Green Paper had invited the stakeholders to provide the Commission with factual information on the practical application, rather than mere positions of principle, in order to enable it to justify its conclusions, in particular if they were to lead to a substantial amendment of the Directive.

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24 The Scottish Law Commission rejected the idea of introducing such a rule.

25 A preliminary ruling request, currently pending with the Court of Justice, addresses inter alia this point (case C-203/99, Veedfald).

26 See footnote 2.

On the basis of the information available at present which results from the contributions to the Green Paper as well as other documents received, one can summarise the situation prevailing in the Member States as follows:

- there is still limited experience with regard to the application of the Directive. This is mainly due to two factors: the Directive was lately transposed in some Member States and, according to the possibility given to Member States under Article 13 of the Directive, national contractual or extra-contractual law or a specific liability regime is applied in parallel;

- the scarce information available has not permitted to identify any major problems with the application of the Directive;

- a cost-effective framework should be maintained preserving the balance between the interests of both consumers and producers.

Globally, the factual situation is not different compared to the situation prevailing in 1995 when the Commission presented the first report. The Commission is of the opinion that any modifications to the Directive should be grounded on objective factual bases. The information available at the present stage is not sufficient to draw firm conclusions. Therefore, the Commission considers that it would be premature to envisage any changes to the current liability system under Directive 85/374.

The Commission intends, however, to take a number of follow-up actions which are twofold: on the one hand, it envisages measures which are directly linked to the issue of product liability, with short and medium-term objectives; on the other hand, measures in other fields which are complementary to product liability are either already under way or will be taken up in the near future.

4.1 Follow-up measures which are directly linked to product liability

The Green Paper purported to collect as much factual information on the functioning of the Directive as possible. Despite the active participation of a large number of the interested parties in this exercise, difficulties in gaining a full picture of the situation in the Member States still remain. In view of the continuous process of assessing the application of the Directive in the Community, means need to be explored by which the present information gaps can be filled in the short-term. A reflection on ways for greater harmonisation of product liability at Community level in the medium-term should also be initiated.

4.1.1 Short-term actions

The Commission is of the opinion that a pragmatic and efficient tool of data-collection could be the setting-up of a expert group on product liability, similar to the idea of an “observatory” the Social and Economic Committee had put forward in its opinion on the Green Paper. This expert group would involve all the interested parties such as experts from national administrations, specialised lawyers and academics, representatives from different industry sectors and the insurance area as well as consumers’ associations.

The expert group would gather information in relation to all the Member States in particular on the legal application of the Directive, on recent case law and changes in national legislation having an impact on product liability (such as issues concerning the access to justice). In addition, the data exchanged could be published on the Internet in order to increase transparency.

The Commission considers that the establishment of such a expert group would not only be a practical way of filling information gaps, but also a forum to continuously discuss issues related to product liability. The specific details of the expert group and its functioning will be defined in the beginning of the year 2001.

Another question concerns the collection of information related to the availability of safe products on the market. A Community injury data-collection and information system has already existed since 1993 under the former EHLASS (European Home and Leisure Accident Surveillance System) system. In the past, this system did not identify the number of injuries caused by a defective product because all types of accidents involving a product were collected. Under the programme of Community action on injury prevention,[27] a new Community system for compiling information on injuries has been set up. Product and services safety indicators will be developed. The feasibility of integrating additional information in particular dealing with accidents caused by defective products will also be approached.

Furthermore, the information received from the interested parties during the discussion on the Green Paper needs to be completed by other expert opinions. The Commission intends to launch a study on the assessment of the economic impact of strengthening the current liability system under Directive 85/374.

The Directive in its current version attributes a specific role to the Commission when assessing the impact of the Directive with regard to the options left to the Member States regarding the exemption to liability for development risks and the financial limit (see Article 15(3) and 16(2) of the Directive). Given that the impact of these two options on the functioning of the internal market and the protection of consumers at present cannot be measured sufficiently, the envisaged study should focus on these issues.

The objective of the study would be to assess the economic impact for industry, insurance companies, consumers and society as a whole (in particular via social security schemes) of introducing producer liability also in case of development risk and of eliminating maximum financial limit for serial incidents. This analysis should be as fact-based as possible.

The results of the study should enable the Commission to have a realistic evaluation of the costs and benefits of strengthening the current liability system.

4.1.2 Medium-term actions

The lawmakers in 1985 thought that the Directive was only an initial step towards establishing a genuine producer liability policy at Community level. They introduced

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[27] OJ No L 46 of 20.2.1999, p. 1

a review of it at regular intervals (five years) in order 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 guaranteeing legal certainty for producers.

At this moment, reflection could start with whether greater harmonisation between the different liability systems currently existing would be advisable and, if this was the case, what means would be feasible.

Indeed, for the time being, the Directive does not affect any rights the injured person may have according to contractual or non-contractual (negligence/tort) liability or a special liability system existing in July 1985 (Article 13). This means that the Directive sets common rules on strict liability which Member States have to implement and from which they cannot deviate by adopting stricter provisions. The injured person can, however, base an action against the manufacturer of a defective product under other product liability systems which may exist in the different Member States, provided the specific conditions necessary for their application are met.

This possibility of allowing the co-existence of different liability systems might be one factor which could explain the limited number of practical cases brought before national courts on the basis of national rules implementing the Product Liability Directive.

In principle it would seem that the injured party could more easily bring actions based on strict liability provisions rather than under other provisions; in particular, he/she does not have to show the fault or negligence of the producer as is the case under contract or tort law. An absence of fault would seem to exclude the liability of the producer under another system. Contributions to the Green Paper, however, indicate that in practice, at least in some Member States, actions are based in parallel on different systems, and not only on the strict liability provisions.

Moreover, case-law in several Member States tends to interpret the producer's liability under fault-based liability systems in an extensive way with the result that in practice the difference between fault-based and strict liability systems is getting blurred. In this situation and given that fault-based liability systems generally provide for a larger scope of consumer protection parallel applications are a practical consequence.

In some Member States, strict liability rules used to be only exceptionally applied and the principle introduced by the Directive therefore constituted a novelty for these legal systems. In this situation one would assume that the position of the injured person suing the producer of a defective product has improved.

At present no assessment is possible as to the real impact of the co-existence of national laws transposing the Directive with other liability systems. Therefore, the Commission will launch a study which should analyse and compare the practical effects of the different systems applicable in all the Member States on the bringing of claims for defective products (i.e. the national laws implementing the Product Liability Directive, the national laws on contractual obligations, the national laws on extra-contractual obligations and specific liability laws). One important aspect of the study would be to analyse on what points the different systems diverge from each

other (in particular with regard to conditions and scope of application, rules on burden of proof, products and damages covered, exemptions of the producer, prescription and liability periods, financial limits, levels of damages awarded, access to justice).

A second part of the study would look into the future of product liability legislation. It would address the question of whether a uniform product liability system could be introduced in the Community on the basis of the present situation in the Member States. In this context, the study should look at the different initiatives existing with regard to the law of obligations, such as the Lando Commission, the European Group on Tort Law and the European Centre on Tort and Insurance Law (Europäisches Zentrum für Schadenersatz- und Versicherungsrecht) in Vienna.

This study would enable the Commission to have a complete overview of all the applicable product liability laws and their practical application in all the Member States. On the basis of the results of this study, the Commission could assess the practical effect of the strict product liability provisions under Directive 85/374 and the need and feasibility of introducing - at medium-term - a common and sole liability system for defective products.

4.2 Follow-up measures in other areas which are complementary to product liability

The Commission is committed to achieving a high level of consumer protection against product-related risks. In this context, the provisions of Directive 85/374 on product liability are one major element. Two other areas play a complementary role: Directive 92/59 on General Product Safety and specific Community legislation governing the safety of products are of paramount importance since their correct application ensures that only safe products are put on the market and, therefore, minimises the risk that any liability claims due to a defective product occur. Access to justice issues are another important element in providing compensation to consumers in general and, more particularly, to the victim of an injury caused by a defective product. Any actions taken in the past addressed these questions in general and did not envisage specific actions for product liability matters. The present situation confirms the soundness of this approach.

Another area important in relation to product liability is environmental liability which concerns the allocation of responsibility for damage caused to the environment.

The Commission already took and intends to take further actions in these areas, as described below, and considers that these measures will help to foster product safety, guarantee consumers fair access to justice as well as a well-conserved environment.

4.2.1 Amendment to Directive 92/59 and enforcement of other Directives related to product safety

The General Product Safety Directive 92/59 and other Directives related to product safety have established an elevated level of consumer protection in the Community.

The past experience has shown some weaknesses in the provisions of the Directive 92/59 and the review of its application identified additional needs of consumer

protection. Therefore, the Commission adopted on 29 February 2000 a Proposal for revision of Directive 92/59.[28]

Several of the proposed amendments to Directive 92/59 enhance the preventive aspect of product safety by reinforcing the effectiveness of market surveillance. In this respect, the obligations for producers and distributors needed to be completed:

- producers and distributors, the latter within the limits of their respective activities, have to pass on information on product risk, safeguard and provide documentation necessary for tracing the origin of products, inform national authorities immediately if a product put on the market is dangerous and they have to inform these authorities of the action taken to prevent risks to consumers. This information will help market surveillance authorities to trace the products concerned, verify whether other products present the same risk, take any necessary measures and inform the authorities of the other member States as appropriate.

- producers and distributors have to collaborate with the national authorities on action taken to avoid the risks posed by products they supply or have supplied. This will enable swift tracing of dangerous products during emergency situations and organising their withdrawal.

- in addition to the withdrawal of dangerous products from the market when this is necessary to prevent risks to consumers, producers have to recall products already supplied to the consumers when other means would not suffice to prevent the risks involved.

- producers have to adequately and effectively warn consumers of the risks posed by the products that have already been sold to them.

Another set of amendments are proposed with a view of strengthening market surveillance and enforcement powers of the Member States. These measures aim to:

- ensure that effective, proportional and dissuasive sanctions are applied as necessary;

- ensure that systematic and co-ordinated market surveillance approaches are put into place by all Member States;

- ensure that the market surveillance systems work in a transparent manner and are open to consumers and other stakeholders;

- provide for a periodic assessment by the Commission of the results achieved by the market surveillance systems of the Member States;

- set-up a framework for systematic collaboration between the enforcement authorities of the Member States;

- reinforce the enforcement powers of competent authorities, namely in relation to:

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[28] COM(2000) 139 final/2 of 15.6.2000

- recall of dangerous products already supplied to consumers, and adequate consumer information on the risks posed to them;

- temporary prohibition of the placing on the market of certain products, pending verification and assessment of their risks;

- rapid action, in case of serious risks requiring immediate or rapid intervention, and removal of limitations on the circulation of information on such risks.

Market surveillance is an essential tool for the enforcement of Community legislation on product safety (with regard to, inter alia, pharmaceuticals, chemicals, cosmetic products, medical devices, machinery and electrical equipment). It is worth recalling the fact that market surveillance must allow to verify that the provisions of applicable Directives have been complied with in each Member State on the same basis. This guarantees both a high level of protection for consumers and users, and supports the free movement of goods in the internal market by eliminating unfair competition and non-compliant products. Member States' authorities have an obligation to organise and carry out market surveillance in an effective way (i.e. adequate infrastructures and resources). In order to ensure that market surveillance is as effective as possible, the Commission encourages administrative co-operation between national authorities.

4.2.2 Initiatives with regard to access to justice

Since the eighties, with the continuing development of the internal market, the Commission has faced a new challenge: to promote more effective and efficient access to justice in view of the cross border dimension of the problem. In its Green Paper on "Access of consumers to justice and the settlement of consumer disputes in the Single Market", the Commission set out a number of proposals aimed at resolving individual and collective cross border disputes. This led to the adoption of Directive 98/27 on injunctions for the protection of consumers' interests[29] to allow qualified entities (e.g. consumer associations) to seek injunctions where there has been an infringement of one of the Directives related to consumer protection enumerated in the annex and which harms the collective interests of consumers. In addition, the Commission published a "Consumer Guide in the Single Market" and a "Guide to Legal Aid in the European Union".

The Commission has also been supporting for several years, a network of Consumer "Euroguichets" which aim to support and give advice to consumers on access to justice in cross border cases. Finally, the Commission adopted, in 1996, an "Action Plan on consumer access to justice and the settlement of consumer disputes in the internal market" which highlighted the need for Community action in regard to the settlement of consumer disputes.

In the light of the consultations surrounding these initiatives the Commission adopted in 1998 a "Communication on the out-of-court settlement of consumer disputes". This Communication contains two features designed to improve access to justice for

[29] OJ No L 166 of 11.6.1998, p. 51

individual consumers: a consumer complaint form and Recommendation 98/257/EC[30] laying down the principles applicable to out-of-court procedures for the settlement of consumer disputes.

These two initiatives were aimed at addressing this issue through promoting access to simple, swift, effective and inexpensive legal channels for resolving disputes. Member States were requested to notify the Commission of all out-of-court bodies which applied the principles of the Recommendation and these where placed on the Commission website. As the follow up the Commission adopted on 17 March 2000 a "Working Paper on the creation of the EEF-Net" to provide a background and framework to create a network of European out-of-court consumer dispute resolution schemes: the European Extra-Judicial Network (EEJ-Net).

The EEJ-Net will utilise all existing alternative dispute resolution (ADR) schemes notified to the Commission by Member States as complying with the principles within Recommendation 98/257/EC. Member States have undertaken to establish national contact points (or 'Clearing Houses').[31] If a consumer has a dispute with an enterprise he can then contact his Clearing House for advice and support to assist him in filing a complaint with an out-of-court body where that enterprise is located. In cross-border disputes the Clearing House will address existing barriers to seeking extra-judicial redress such as language differences and lack of information and then pass the complaint through the network to the appropriate out-of-court body.

The Commission further announced in its consumer policy action plan 1999-2001 a number of initiatives concerning consumers' access to justice.[32] In line with this action plan, it published in February 2000 a Green Paper on Legal Aid in Civil Matters[33] in cross-border litigation. The Commission will adopt at the beginning of the year 2001 a Communication on widening access to justice for consumers, which will build on existing Community initiatives and provide criteria to promote greater choice and flexibility for using out-of-court resolution schemes.

Since Article 65 EC came into force in May 2000 the competence of the Community has been extended to cover judicial co-operation generally. Therefore, these initiatives should be seen in the wider framework of co-operation in ensuring citizens better access to justice.

By the year 2001, the Commission will issue a Green Paper on alternative dispute resolution (ADR) and a Working Paper on recovery of legal expenses and lawyers fees. Other areas where the Commission intends to launch initiatives concern measures to make it easier for consumers to take legal action collectively and the definition of the applicable law to non-contractual obligations.

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30 OJ No L 115 of 17.4.1998, p. 31

31 See Council Resolution of 25 May 2000 on a Community-wide network of national bodies for the extra-judicial settlement of consumer disputes, OJ No C 155 of 6.6.2000, p. 1.

32 COM(98) 696 of 1.12.1998, p. 21

33 COM(2000) 51 of 9.2.2000

4.2.3 Initiatives with regard to environmental liability

The Commission adopted in February 2000 a White Paper on environmental liability[34] with a view to introducing a framework directive on environmental liability. This future liability regime will provide for liability for damage to the environment as such, next to covering traditional damage (damage to persons and goods) which is caused by dangerous or potentially dangerous activities. It will have to ensure coherence and consistency with Directive 85/374. In this regard, it is necessary to determine the applicable regime in cases where there could be an overlap between Directive 85/374 and the future environmental liability regime. This question needs particular reflection as far as genetically modified organisms (GMOs) are concerned. Directive 85/374, as amended by Directive 99/34, establishes already liability for damage caused by GMOs to persons and property. The future environmental liability regime should in any event supplement this by covering damage to the environment caused by GMOs.

* * *

The Commission will continue to monitor the implementation and effects of the Directive 85/374 in view of its requirement in Article 21 to submit periodic reports to the Council and Parliament. Based on the findings of this report, it intends to set up a forum for a continuous dialogue and exchange of information between the interested parties with regard to product liability issues. The results of two studies will complete the information available at present and allow the Commission to assess the need and the feasibility of developing a strengthened Community liability system for defective products. In parallel, the Commission will propose supporting actions in the area of general product safety, access to justice for consumers and environmental liability.

[34] COM(2000) 66 of 9 February 2000

FINANCIAL STATEMENT

1. TITLE OF OPERATION

Report on the application of Directive 85/374 on Liability for Defective Products

2. BUDGET HEADINGS INVOLVED

B5-3001

3. LEGAL BASIS

Article 21 of Directive 85/374 on Liability for Defective Products foresees that the Commission reports every five years to the Council on the application of the Directive.

4. DESCRIPTION OF OPERATION

4.1 General objective

At the present stage only limited information is available on the actual impact the Community legislation on product liability has on the internal market and the consumer protection. The present report identifies information gaps with regard to the application of product liability legislation in all the Member States which need to be filled.

4.2 Period covered and arrangements for renewal

The duration of the action is limited to five years.

According to Article 21 of Directive 85/374, the Commission will present in 2005 a report to the Council on the application of the Directive and, if necessary, submit appropriate proposals to it.

5. CLASSIFICATION OF EXPENDITURE OR REVENUE

5.1 Non-compulsory expenditure

5.2 Differentiated appropriations

6. TYPE OF EXPENDITURE OR REVENUE

Purchases of studies.

7. FINANCIAL IMPACT

7.1 Method of calculating total cost of operation (relation between individual and total costs)

Operational expenditure (cost of studies) will amount to EUR 0,5 million.

All expenditure on incidental activities mentioned in the report in other areas than those being directly linked with product liability have been or will be the subject of separate financial statements.

7.3 Operational expenditure for studies, experts etc. included in Part B of the budget

Commitment appropriations EUR 0,5 million (at current prices)

	2001	2002	2003	2004	2005	2006	Total
Studies	0,5	0	0	0	0	0	0,5
Total	0,5	0	0	0	0	0	0,5

7.4 Schedule of commitment and payment appropriations

EUR million

	2001	2002	2003	2004	2005	2006	Total
Commitment appropriations	0,5	0	0	0	0	0	0,5
Payment appropriations							
Studies	0,21	0,29	0	0	0	0	0,5
Total	0,21	0,29	0	0	0	0	0,5

8. FRAUD PREVENTION MEASURES

The rules and procedure governing procurement of goods and services for the Communities will be strictly complied with, in accordance with the financial regulation applicable to the general budget of the European Communities, the regulation on modalities for the implementation of the financial regulation and internal rules.

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1 Specific objectives; target population

Product liability legislation has a major impact on manufacturers and suppliers of products as well as important consequences for consumers, therefore even small modifications to the existing product liability framework, although limited, can have an important effect. Studies appear to be the most efficient way of achieving a consistent analysis of the situation across all the 15 Member States.

9.2 Grounds for the operation

The Commission is assessing the functioning of the internal market throughout the Community. Only limited information is at the present stage available on the actual impact the Community legislation on product liability has on the internal market and the consumer protection. The aim of the present actions is to gather lacking information by having recourse to the help of external expert knowledge. These actions form part of the on-going assessment of the functioning of the internal market legislation. They will highlight whether the legislation is achieving its objectives and functions correctly and whether any changes are needed.

9.3 Monitoring and evaluation of the operation

This forms part of the ongoing monitoring of the Internal Market and more particularly of the functioning of Directive 85/374 on which the Commission is obliged to report every five years.

10. ADMINISTRATIVE EXPENDITURE (SECTION III, PART A OF THE BUDGET)

The mobilisation of required administrative and human resources is covered by the existing resources of the managing service.

10.1 Effect on the number of posts

Type of post		Staff to be assigned to managing the operation		Source		Duration
		Permanent posts	Temporary posts	Existing resources in the DG or department concerned	Additional resources	
Officials or temporary staff	A B C	0.54 0.16		0.54 0.16		
Other resources						
Total		0.7		0.7		

10.2 Overall financial impact of additional human resources

EUR

	Amounts	Method of calculation
Officials Temporary staff Other resources (indicate budget heading)	378.000	0,7 (two-third official per year) x EUR 108.000 x 5 years
Total	378.000	

10.3 Increase in other administrative expenditure as a result of the operation

EUR

Budget heading	Amounts	Method of calculation
A 7030 General meetings	111.500	(10 private experts x EUR 790 + 5 experts from national administrations x EUR 650 = 11.150) x 2 meetings x 5 years
Total	111.500	