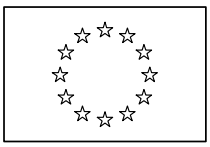

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REPORT FROM THE COMMISSION TO THE COUNCIL, THE EUROPEAN PARLIAMENT AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Third report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999)

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(Text with EEA relevance)

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1. INTRODUCTION

In accordance with Article 21 of Directive 85/374[1] ('the Directive'), the Commission must review the efficiency of the product liability legal framework on a regular basis. The first report COM(1995) 617 was presented in 1995. The second review exercise was launched with a Green Paper on Product Liability adopted in July 1999, COM(1999) 396 final, leading to the second report published on 31 January 2001, COM(2000) 893 final.

This third report has taken due account of the results of the last two studies carried out for the European Commission[2], the outcome of meetings with interested parties and their responses to a questionnaire sent at the end of 2005.

As it was requested by Council Resolution of 19 December 2002 on amendment of the liability for defective products Directive (2003/C 26/02), this report also considers the issue of suppliers' liability.

As an overall conclusion, the report will demonstrate that the Directive works by and large in a satisfactory way and that there is no need for amendments at present. Also, that there are some circumstances where the application of the national laws leads to different outcomes, but without affecting the functioning of the Internal Market. Those circumstances will continue to be closely monitored by the European Commission.

2. BACKGROUND

Since 1985, the Directive 85/374/EEC on liability for defective products introduced in the Community the principle of 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 of whether there is negligence on the part of the producer or not. Directive 99/34/EC extended the scope of this kind of product liability to unprocessed primary agricultural products.

This legislation applies to any product marketed in the European Economic area and is of direct concern to consumers and producers alike. By striking a fair balance of risk among these two groups, this legislation aims to unite consumers' interests with Single Market policies (namely free exchange of goods and elimination of competition distortions).

The Directive on product liability contains the following main elements:

– liability without fault of the producer;

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[1] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 21, 07.08.1985 p. 29 – 33) as amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 (OJ L 141, 4.6.1999, p. 20 – 21) and corrected by Corrigendum (OJ L 283, 6.11.1999, p. 20). The date for implementation of the Directive was 25 July 1988.

[2] LOVELLS, *Product liability in the European Union*; 2003; and FONDAZIONE ROSSELLI, *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products*; 2004.

– 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;

– a 500 € threshold regarding damages suffered in order to avoid litigation in an excessive number of cases;

– 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 some points by:

– 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 EUR for damage resulting from death or personal injury and caused by identical items with the same defect.

3. APPLICATION OF DIRECTIVE 85/374/EEC DURING 2001 – 2006

The Council and the Commission, as well as the informal working groups organized by the latter institution have taken a number of actions during this period. The Council adopted a Resolution and the Commission called for two studies to evaluate several aspects of the day-to-day implementation of the Directive. Moreover, two different working groups were set up in 2003 to bring together the opinions of professional and academic experts of recognized standing.

Last but no least, it has to be underlined that the European Commission continues to closely monitor the process of implementation and application of the Directive in the EU. Directive 85/374/EEC has been transposed and is being put into application in the twenty five Member States.

3.1. Council Resolution of 19 December 2002 on the amendment of liability for defective products[3]

In this Resolution, the Council considered that there was a need to assess whether the Directive should be modified in such a way as to allow for national rules on liability of suppliers to be based on the same grounds as the liability system in the Directive concerning liability of producers.

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[3] Council Resolution of 19 December 2002 on amendment of the liability for defective products Directive (OJ C 26, 4.4.2003, p. 2 - 3).

3.2. The Lovells Report (published in 2003)

This study was carried out on behalf of the European Commission in order to analyse and compare the practical effects of the different systems applicable in Member States of the European Union regarding procedural aspects of claims for defective products.

The report showed that for the first time there was some collective experience of the Directive being used in almost all Member States. The overall conclusion of the report was that the Directive can be seen to offer, at least to the extent that it was uniformly implemented and interpreted, a common level of protection for consumers and a common basis for liability of producers. The research also showed that the predominant (although not universal) view is that the Directive, and the product liability system to which it belongs, strike an appropriate balance on the whole between producers/suppliers interests and those of consumers. Moreover, it demonstrated that there was no uniform call for major reform of the Directive from any particular category of persons affected by its terms. Indeed, it was developments in more general areas, such as access to justice, procedural reforms and perceived changes in the "claims culture" that were seen by many (and in particular producers and insurers) as presenting a risk of upsetting the prevailing balance.

It is worth noting that whilst most consumer representatives and a minority of other participants suggested that the Directive did not strike an appropriate balance, no single deficiency was cited. This does not, of course, discount the validity of the views expressed, but it does make it difficult to conclude that the Directive is fundamentally flawed in any significant respect.

The broad acceptance of the main provisions of the Directive is a remarkable achievement given the nature of the reforms introduced by it and the controversy that has surrounded the history of its adoption and implementation. Furthermore, the research undertaken in the course of this report revealed no clear and consistent call from within the EU for significant reform of the Directive. Indeed, many participants have urged that there be no reform at all. In particular, a number of them suggested that it would be better to await the outcome of developments in other areas, which might have an impact on the practical operation of product liability systems and may affect the Directive. These include developments at an EU level in areas such as product safety regulation, access to justice and consumer protection in general.

3.3. The Fondazione Rosselli Report (published in 2004)

This study was carried out on behalf of the European Commission in order to analyse the economic impact of the Development Risk Clause (DRC) as provided by Art 7(e) of Directive 85/374/EEC on Liability for Defective Products. This clause excludes liability for damage caused by a defect that could not be foreseen given the technical and scientific knowledge available at the time the product was developed.

The interpretation of Art 7(e) has created difficulties and given rise to different interpretations between various courts: see for example cases on infected blood: *A v National Blood Authority* (1999) English High Court re blood infected with Hepatitis C, and *Hartman v Stichting Sanquin Bloedvoorziening* (1999) Amsterdam District Court re HIV, which reached seemingly opposing conclusions.

The DRC was defined in order to establish a satisfactory compromise between the need to stimulate innovation on the one hand and consumers' legitimate expectations for safer products on the other. The crucial argument of the current debate on the DRC is that removing this clause would stifle innovation.

The findings presented in this report seem to indicate that the often-used argument of the Development Risk Clause being a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and consumers' interests is well-founded and is based on the following:

– the DRC protects incentives to innovate in reducing the innovation-related risks, by not diverting resources from R&D to insurance policies and by pushing firms to align to state of the art knowledge;

– the DRC is probably one key factor in determining the relative stability of product liability insurance costs in European industry and keeping litigation at a reasonable level;

– in a strict liability regime, companies in high-tech / high risk sectors would find it very difficult to obtain a reasonable insurance policy which covers their developmental risks.

The combination of these factors lead Fondazione Rosselli to conclude that the costs of letting the producers innovate within a strict liability environment would be extremely high, and would affect consumers in the long term. In effect, both the Lovells and Rosselli studies conclude that such a defence should be maintained.

3.4. Conclusions of the meetings held with the working groups (2003/2004) and conclusions extracted from the questionnaire prepared by the European Commission (2005/2006)

The Economic and Social Committee in its opinion on the 1999 Green Paper advanced the idea of an observatory to monitor the functioning of the Directive. Two working groups have been created: one of experts designated by national authorities and another of stakeholders. They assist the Commission in its task of keeping existing legislation in the product liability field under constant review. The focus of the first meetings was primarily on the results of the two studies carried out on behalf of the Commission (the "Lovells study" and the "Rosselli study").

Stakeholders and experts are generally in favour of maintaining the balance struck by the Directive between competing interests. No demand for major reforms has been advanced. Nevertheless, a few members have voiced their concern regarding differing interpretations given to certain provisions of the Directive by national courts which might be, in their opinion, capable of creating distortion of competition across Member States. All participants agreed that decisive help to eliminate these inconsistencies might come from the case law of the European Court of Justice, which is more and more frequently called on to adjudicate on references for preliminary rulings coming from national courts.

On the other hand, by means of a questionnaire, the European Commission asked at the end of 2005, whether the members of the aforementioned working groups believed that there were any significant changes of circumstances since the 2001 report was published.

Among the stakeholders and national experts, the Directive is largely perceived as positive and beneficial to consumers. The broad majority of the responses received, indicate the absence of any significant change in EU law since 2001. Most of the participants can be labelled as "generally satisfied with the current situation" and many of them do not see any reason at all for amending the Directive[4]. The only point of concern has been the 500 EUR threshold, where some ask for clarifications; while others for its abolition. This might be a topic on which future discussion and monitoring could be based.

3.5. Judgments of the Court of Justice

Since 2001 and to the drafting this report, the Court of Justice has ruled on nine different occasions relative to Directive 85/374/EEC.

The Court of Justice offered some guidance on the concept of 'damage' in the case Veedfald (C-203/99); referred to some issues on the national measures of transposition in the cases against France (C-52/00), Greece (C-154/00) and Spain (C-183/00); idem in the case Skov Æg (C-402/03) and gave a definition of the concept *'put into circulation'* in the case Declan O'Byrne (C-127/04).

Finally, in one of its most important judgements[5] on this subject the Court of Justice underlined the fact that "…the limits set by the Community legislature to the scope of the Directive are the result of a complex balancing of different interests. As is apparent from the first and ninth recitals in the preamble to the Directive, those interests include guaranteeing that competition will not be distorted, facilitating trade within the common market, consumer protection and ensuring the sound administration of justice." In line with this ruling, the European Commission recalls that the founding principles of Directive 85/374/EEC achieve a delicate balance between the interests of claimants, manufacturers and their insurers. Shifting or removing these founding principles such as causation – article 4, prescription periods – articles 10 & 17, the development risk exemption – article 7, would mean that the interrelationships between these parties would upset this balance leading to adverse economic effects and diminishing the level of consumer protection.

Therefore, one of the foremost priorities for the European Commission is to continue to closely follow developments in case law and in the practical operation of product liability systems.

4. FURTHER WORK

Certain aspects of the Directive concerning the protection of consumers and the functioning of the Internal Market require continued monitoring and could even be subject to further clarification. Differences on the interpretation of these concepts by national courts can sometimes lead to disparities in the judicial application of certain aspects of this Directive

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4 For instance, only three stakeholders oppose to the actual formulation of Art. 7(e) (development risk clause); only five stakeholders and just one Member State have requested the creation of a EU-wide compensation fund.

5 Judgment of the CJ in case C-154/00 (Commission of the European Communities v Hellenic Republic) of 25/04/2002, paragraph 29.

from one Member State to another, but there is little evidence that those disparities create significant barriers to trade or distortions to competition in the EU[6].

At this stage it should be noted that the Lovells report had already underlined that the Directive does not fully harmonise product liability laws throughout the EU such that, in any Member State, consumers and producers/suppliers could expect the same outcomes in similar circumstances. Indeed, at the time the Directive was adopted, it was intended to provide for limited harmonisation only, whilst at the same time "[opening] the way towards greater harmonisation". Nevertheless, taking into account the conclusions of the report, total harmonisation in the broadest sense is not only unrealistic, but also not necessary in view of the limited impact (if any) that its absence would have on the Internal Market.

In the light of the above, the following legal concepts constitute areas where the European Commission proposes that close and regular monitoring takes place:

– **the burden of proof (Art. 4);**

Questions relating to the burden of proof continue to be controversial, and of real practical significance. There remains a perception on the part of some consumer representatives that consumers are unfairly disadvantaged by the burden of having to prove defect and/or causation in product liability claims. The concern mainly arises from perceived difficulties in proving claims due to a lack of legal or other resources needed to investigate them properly, or to an inability to gain access to essential information. Such problems are seen to be particularly acute in relation to highly technical products, or where the alleged injuries are of a complicated nature.

Producers and insurers, on the other hand, are concerned that any relaxation of the rules relating to the burden of proof might have the effect of encouraging "spurious claims". Indeed, some producers suggested that there should be a greater obligation on claimants to substantiate claims in the early stages of proceedings.

The difficulties which claimants may have in proving fault have been redressed to varying degrees in several Member States. In Portugal and Austria, for example, there is a presumption of fault in the event of non-fulfilment of a contractual obligation, in which case the burden of proof shifts to the defendant to prove the absence of fault.

In a number of Member States, national courts have been prepared to infer the existence of fault from the fact that the product is defective. Examples of this practice have been reported in cases in the Netherlands and Ireland. In such cases, there is effectively a reversal of the burden of proof, with a requirement for the defendant to present evidence to convince the court that he was not at fault, notwithstanding the defective condition of the product. This is also seen in Denmark. Similarly, the Supreme Court in Spain has established in many judgments that the claimant has only to prove the damage and the causal link between the defendant's activity and the damage; fault is presumed unless the defendant can prove a high level of due diligence. In many cases the defendant will only be exonerated if he can prove the intervention of a fortuitous event or *force majeure*, or the exclusive fault of the claimant or a third party. In Italy, in the case of injury caused by "hazardous" products, the burden rests

[6] As conclusion #4 in the Lovells Report literally states.

on the defendant to prove that all suitable measures had been taken to prevent the damage if the defendant wishes to avoid liability.

– **the concept of defect (Art. 6);**

The Directive prescribes an "expectations" test for defect - that is, a product is said to be defective if it does not provide the safety that a person is entitled to expect. The subjective nature of the "expectations" test means that this principle is incapable of precise definition. This leads to some very practical questions about matters such as whether it is appropriate for a court to undertake a risk/benefit analysis when assessing what a person is entitled to expect, and the extent to which the actual conduct of a producer (such as the degree of care taken, or not taken) is ever relevant in this context. These questions have arisen in reported cases but have yet to be finally resolved by the courts in any Member State. For example, in the aforementioned case *A and Others v National Blood Authority*, the English High Court said that the conduct of the defendant is not a factor to be taken into account when considering whether a product is defective. However, in the subsequent case of *Sam Bogle and others v McDonald's Restaurants Ltd*, the English High Court cited, as a relevant consideration, the steps taken by McDonalds to train its staff in relation to the safe service of hot drinks to customers.

Uncertainty also surrounds the question of what is required to prove "defect". In some cases, courts seem to have decided that it is sufficient that the claimant merely prove that the product failed and that such failure resulted in injury. In a case decided by the Tribunal de grande instance of Aix en Provence in France, the claimant was injured when a glass window in a fireplace exploded in circumstances where the precise cause was unknown. The Tribunal said that the intervention of the product at the time of the harm was sufficient and that the claimant did not have to prove the precise cause of the accident to prove that the product was defective.

In a similar case in Belgium involving an exploding soft drink bottle the claimant was not required, under the Directive, to prove “the exact nature of the defect, in particular as regards all its technical aspects”.

This is in contrast to the approach of the courts of the United Kingdom in *Richardson v LRC Products Ltd* (which involved a condom that broke during use) and *Foster v Biosil* (which involved a silicone breast implant that ruptured *in situ*). In both of these cases, the product failed, but the cause of the failure was unknown. Unlike the decisions in France and Belgium, the United Kingdom court in each case decided that, under the Directive, the claimant bore the onus of proving the nature of the alleged defect, and not merely that the product had failed. As the claimants were not able to prove what had caused the failure, the claims were unsuccessful.

– **the development risks defence (Art. 7(e));**

Member States, by Article 15(1)(b), have had the option to exclude the defence in their implementing legislation, but only Finland and Luxembourg have chosen to do so. Although the Court of Justice has provided some explanation of the scope of the defence[7], its precise

[7] Judgment of the Court (Fifth Chamber) of 29 May 1997. Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland. Case C-300/95. *European Court reports 1997 Page I-0264.*

scope remains uncertain Indeed, there appears to have been only one reported example of where the defence has been used successfully, namely the Sanquin Foundation case in the Netherlands. In this case, suppliers of blood contaminated with HIV were able to rely on the defence in circumstances where there was not a reliable screening test available to them at the time of supply. It is interesting to note, however, that a court of the United Kingdom decided in a subsequent case that the defence was not available in similar circumstances.

– **the minimum threshold (Art. 9);**

This provision is subject to different interpretations in the Member States. In most Member States, including Austria, Denmark, Finland, Germany, and Italy, the threshold is treated as a "deductible", in that the amount of damages awarded to a successful claimant (for property damage) is reduced by the specified amount. In some other Member States, such as the Netherlands and the United Kingdom, the threshold is treated as a minimum amount, such that, provided the claim exceeds that minimum, the full amount of damages is recoverable. In Spain, the amount is expressed in the implementing legislation to be a deductible but in practice the courts treat it as a threshold, such that the amount has never actually been deducted from any award.

The lower threshold is clearly an issue in Finland in particular, where a number of participants suggested that it should be abolished.

– **the defence of regulatory compliance;**

Some stakeholders, and in particular representatives of the pharmaceutical industry, have argued strongly for the introduction of a defence of regulatory compliance, which would apply to a product whose safety was closely regulated, provided that the product complied fully with the applicable regulations.

– **novel products, design defects and failure to warn.**

Some stakeholders, mainly in the producers category, suggested that the "strict liability" standard under the Directive was inappropriate for dealing with liability arising through design defects or injuries attributed to "informational defects" such as a failure to warn.

5. CONCLUSIONS

After having taken into account the information obtained regarding the application of the Directive, the Commission does not consider it necessary, at this stage, to submit any proposal for its amendment. More specifically regarding the Council Resolution of 19 December 2002 on the amendment of the liability for defective products Directive, the opinion of the European Commission is that if the Resolution were given effect, this would mark a departure from the objective of harmonisation of product liability laws under the Directive.

Nevertheless, it should not be underestimated that further harmonisation can also be achieved by accomplishing the highest possible common grounds of interpretation of the legal concepts of the Directive. This can be achieved using:

– The case law of the Court of Justice of the European Communities.

– The power of control of the European Commission (examination of national transposing measures, possibility of starting infringement procedures for incorrect application).

– Continuous analysis within the working groups.

In this sense, the Commission proposes the continuation during 2007 of the examination and discussion within the working groups, referred inter alia to the concepts mentioned in point 4 above ("Further work") with the objective of analyzing the existing Community legal framework with regard to liability for defective products. As experience in the use of the Directive grows, discrepancies existing in the operation of the Directive between Member States may assume greater practical significance, in which case some intervention by the Commission may be warranted.

The Commission, in accordance with Article 21 of the Directive, must present periodic reports to the Council and the Parliament. It will, therefore, continue to monitor the implementation and the effects of the Directive and evaluate any eventual need for future amendments in its next report on the application of Directive 85/374/EEC.