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

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

(Text with EEA relevance)

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CONTENTS

1. INTRODUCTION

The purpose of Directive 85/374/EEC (hereinafter "the Directive")[1] is to approximate the laws of the Member States concerning the liability of the producer for damage caused by defective products. The Directive introduces the principle of liability without fault on the part of the producer, whereby any producer of a defective movable must compensate any damage caused to the physical well-being or property of an individual, irrespective of whether or not there is negligence on the part of the individual.

This Directive applies to any product[2] marketed in the European Economic Area, i.e. in the Member States of the European Union, Norway, Liechtenstein and Iceland. It provides that compensation for material damage shall be limited to goods for private use and consumption with a 500 euro threshold. It sets out the period of limitation and forbids clauses limiting or excluding the liability of the producer. This Directive provides that the producer is exonerated if he proves the existence of certain facts, such as not having put the product into circulation, the defect being due to compliance of the product with mandatory regulations issued by the public authorities, or the state of scientific or technical knowledge at the time when the producer put the product into circulation not allowing him to detect the existence of the defect.

Directive 85/374/EEC does not affect the rights of the injured party under legal provisions on contractual or non-contractual liability or special liability arrangements existing at the time when this Directive was notified[3]. Moreover, it shall not prejudice compensation for non-material damage pursuant to national legislative provisions.

In accordance with Article 21 of the Directive, the Commission must regularly review the effectiveness of the legal framework governing product liability. The Commission has already drawn up three reports on the application of this Directive[4].

This is the fourth report on the application of the Directive. It covers the period 2006-2010 and analyses the application of the Directive in the 27 Member States. To this end, the Commission sent a questionnaire to the Member States and the members of informal advisory groups requesting information, in particular concerning the issues raised in the previous report.

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1 Council Directive 85/374/EEC of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 21, 7.8.1985, p. 29), 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) and corrigendum (OJ L 283, 6.11.1999, p. 20)

2 Directive 99/34/EC extended the scope of Directive 84/374/EEC to include agricultural and fishery products. In contrast, nuclear energy is expressly excluded from the basic directive.

3 The Court of Justice of the European Union has on a number of occasions ruled that the provisions laid down in the Directive do not preclude the application of other systems of contractual or non-contractual liability based on other grounds (see, for example, CJEC judgment of 10 January 2006 in Case C-402/03, [2006] ECR I-199).

4 COM(1995) 617, 13 December 1995. COM(2000)893 of 31 January 2001 and COM(2006) 496 of 14 September 2006.
(http://ec.europa.eu/enterprise/policies/single-market-goods/documents/liability/index_en.htm)

2. THIRD REPORT ON THE APPLICATION OF DIRECTIVE 85/374/EEC: 2001-2005

The third report on the application of Directive 85/374/EEC concluded that the Directive managed to strike the balance between consumer interests and internal market policies. In its general conclusion, the report confirmed that the implementation of the Directive was on the whole satisfactory and that no amendments were necessary. Even if the application of national legislation sometimes led to discrepancies, these did not affect the functioning of the internal market.

In order to intervene where discrepancies at national level require action at European Union level, the Commission proposed that the functioning of the Directive continue to be examined, in particular in respect of the impact of the provisions on the burden of proof, defences or the threshold of 500 euros for material damage sustained.

3. APPLICATION OF DIRECTIVE 85/374/EEC: 2006 - 2010

During the period in question, the Commission monitored the transposition and implementation of the Directive in the Member States.

In most Member States, the national provisions implementing the Directive are generally applied alongside other regulations on contractual, non-contractual or other types of liability. The coexistence of different product liability rules, which is permitted under Article 13 of the Directive, is considered positive because the range of rules allows consumer protection to be improved.

The data collected for the drafting of this report show that some Member States, including Austria, France, Germany, Italy, Poland and Spain, recorded an increase in the number of product liability cases brought under national laws transposing the Directive. In some of the Member States, there was both an increase in the absolute number of cases brought on the grounds of product liability in the last few years and an increase in the relative use of the Directive against cases brought on the grounds of civil or contractual liability.

The increase in the number of product liability cases brought in recent years is thought to be mainly due to external factors such as greater consumer awareness and better organisation of consumer groups or improved means of accessing information. In contrast, it would seem that the costs of the action discourage this type of proceedings in some Member States, for example the United Kingdom.

This having been said, the swift resolution of a case brought before the national courts depends on the thoroughness and effectiveness of national systems of civil law. In cases where liability is not called into question (i.e. the defect, damage and causal link are clear), these claims are settled out of court, which contributes to the injured party being compensated quickly for the damages sustained[5].

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[5] Austria and Latvia, for example, have reported a number of out-of-court settlements, including a case where a baby fell off a baby-change table which had folded up (€ 1 500); burns to a person's legs after the handle broke off a fondue set (€ 2 500); pains and symptoms of poisoning after consuming a dish

3.1. Judgments of the Court

The Court of Justice of the European Union (hereinafter "the Court") has continued to specify the arrangements of Directive 85/374/EEC thus contributing to removing the differences in interpretation. The Court has repeatedly ruled on the linkage of this Directive to national transposition arrangements. It has ruled on the overall degree of harmonisation of Directive 85/374/EEC which prevents Member States from, for example, establishing more favourable arrangements for consumers in respect of the period of limitation. It also confirmed that Member States are free to maintain different systems for liability and for strict or no-fault liability whereby the liability of intermediaries may be equivalent to that of the producer in the event of negligence or fault.

Between 2006 and 2010 the Court handed down rulings on six occasions concerning Directive 85/374/EEC. On two occasions, judgments were delivered in the Court's second referral procedure (Article 260 TFEU, ex Article 228 TEC).

3.1.1. Preliminary rulings (Article 267 TFEU)

In *Skov v Bilka Lavrishvareus*[6], the Court ruled that Directive 84/374/EEC must be interpreted as precluding national rule under which the supplier of a defective product is answerable, beyond the cases listed exhaustively in Article 3(3) of that Directive, for the no-fault liability which the Directive establishes and imposes on the producer. However, the Court specified that the Directive does not preclude a national rule under which the supplier is answerable without restriction for the producer's fault-based liability.

In *Declan O'Byrne v Sanofi*[7], the Court ruled on the notion of the "putting into circulation" of the product within the meaning of Article 11 of the Directive and when the limitation period of the liability action for defective products starts to run. It also specified that a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed.

The Court again clarified its interpretation of Article 11 of the Directive in the *Aventis Pasteur SA v OB*[8] judgment, ruling that this article must be interpreted as precluding national legislation, which allows the substitution of one defendant for another during proceedings, from being applied in a way which permits a "producer", within the meaning of Article 3 of that Directive, to be sued, after the expiry of the period prescribed by that article, as defendant in proceedings brought within that period against another person. However, it then made clear that Article 11 must be interpreted as not precluding a national court from holding that, in the proceedings instituted within the period prescribed by that article against the wholly owned subsidiary of the "producer", within the meaning of Article 3(1) of Directive 85/374, that producer can be substituted for that subsidiary if the court finds that the putting into circulation of the product in question was, in fact, carried out by that producer.

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containing millet contaminated by thorn apple seeds (€ 1 000), or serious injury following a fall from a defective armchair (€ 5 000).

6 CJEU - Judgment of 10 January 2006 in Case C-402/03 [2006] ECR I-199.

7 CJEU - Judgment of 9 February 2006, Case C-127/04 [2006] ECR I-1313.

8 CJEU - Judgment of 2 December 2009, Case C-358/08 [2009] ECR I-11305.

Lastly, the Court also provided further information regarding the supplier's liability. In that respect, Article 3(3) of the Directive must be interpreted as meaning that, where the person injured by an allegedly defective product was not reasonably able to identify the producer of that product before exercising his rights against the supplier of that product, that supplier must be treated as a "producer" for the purposes, in particular, of the application of Article 11 of that Directive, if it did not inform the injured person, on its own initiative and promptly, of the identity of the producer or its own supplier.

In *Moteurs Leroy Somerc v Dalkia France*[9], the Court of Justice ruled that the Directive must not be interpreted to mean that it does not preclude the interpretation of domestic law or the application of settled domestic case-law according to which the injured party may seek compensation for damage to an item of property intended for professional use and employed for that purpose where that injured party simply proves the damage, the defect in the product and the causal link between that defect and the damage.

3.1.2. Direct actions (Articles 258 and 260 TFEU)

In its judgment of 25 April 2002 in *Commission v French Republic*[10], the Court noted that France had failed to correctly transpose Directive 85/374/EEC. Given that the Court's judgment had only been partially implemented, the Commission had brought a second referral procedure under Article 260 of the TFEU (ex Article 228 TEC).

Its decision of 14 March 2006 in *Commission v French Republic*[11], the Court concluded that by continuing to regard the supplier of a defective product as liable on the same basis as the producer where the producer cannot be identified, even though the supplier has informed the injured party within a reasonable time of the identity of the person who supplied him with the product, the French Republic had not taken the all necessary implementing measures set out in the judgment of 25 April 2002 as regards the transposition of Article 3(3) of Directive 85/374/EEC. The Court ordered the French Republic to comply with the Directive and pay a penalty of 31 650 euros for each day of delay in taking the necessary measures to ensure full compliance with the judgment of 25 April 2002, as from the date of the delivery of the new judgment. France, which had to pay a penalty amounting to a total of 795 600 euros, fully complied with the new judgment.

In a judgment of 5 July 2007, *Commission v Kingdom of Denmark*[12], the Court deemed that the Kingdom of Denmark had failed to fulfil its obligations in respect of the transposition of Directive 85/374/EEC by adopting and maintaining in force provisions which made intermediaries in the distribution chain liable under the same conditions as a manufacturer, contrary to Article 3(3) of that Directive. Following this Decision, Denmark took the necessary measures to bring its legislation into line with the Directive.

3.2. Information provided by national experts and advisory groups

Using the same methodology as for the third report, the Commission invited the national authorities and interested parties who are members of the informal advisory groups to express

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9 CJEU - Judgment of 4 June 2009, Case C-285/08 [2009] ECR I-4733.
10 CJEU - Judgment of 25 April 2002, Case C-52/00 [2002] ECR I-3827.
11 CJEU - Judgment of 14 March 2006, Case C-177/04 . [2006] ECR I-2461.
12 CJEU - Judgment of 5 July 2007, Case C-327/05 [2007] ECR I-93.

their opinions on the application and effectiveness of the Directive during the reference period. The task was to assess the practical impact of the Directive and the issues raised in the previous report, the different interpretations of which by national courts could at times lead to differences in the application of the Directive from one Member State to another.

This report summarises the data collected by the Commission in particular concerning the burden of proof, defence of regulatory compliance, development risk defence and the question of the 500 euro threshold for material damage.

– **Burden of proof (Article 4)**

Directive 85/374/EEC provides that the burden of proof for damage, the defect and causal relationship between the two lies with the injured party. The purpose of this Directive is not to harmonise Member States' national procedural rules, which vary not only as regards substantive law, but also the standard of proof required.

The Lovells study on product liability in the European Union[13] and the Commission's third report on the application of the Directive already pointed out that case-law in this area varied; there were differences between the decisions of various Member States and even between decisions of the courts within a single Member State.

In the light of the information available, we also note differences in terms of the evidence needed to prove a defect. In some courts, for example, in Belgium, France, Italy or Spain, it is enough for the plaintiff to prove that the product did not fulfil the function for which it was intended. In other countries, such as Germany or the United Kingdom[14], the plaintiff must prove the precise nature of the product's defect in more detail. The same information also shows that the Austrian Supreme Court has developed a body of settled case-law which reconciles these two positions.

Some national authorities (including those of Bulgaria, Italy, Malta, Latvia, Slovakia or Sweden) are, however, of the opinion that injured parties face considerable difficulties in proving that the damage was caused by the product's defect. Such difficulties are mainly due to the costs involved in obtaining an expert opinion. In order to overcome this problem, some Member States believe that the Directive should be amended so as to include a presumption of the producer's liability or a mechanism to reverse the burden of proof.

This provision continues to be a bone of contention between the representatives of the interested parties (consumers, producers, suppliers, insurers or legal practitioners). Consumers emphasise the difficulty, in particular due to the economic costs, of furnishing proof of the defect of certain highly technical products as well as proving the causal link between the defect and the damage when such damage is complex in nature. In order to better guarantee consumer protection, they believe the burden of proof should be reversed.

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13 Lovells. Product liability in the European Union – A report for the European Commission – (The Lovells Report) 2003. (http://ec.europa.eu/enterprise/policies/single-market-goods/documents/liability/index_en.htm).

14 Nevertheless, the English Court of Appeal ruled that the appellant did not have to prove the precise mechanism by which the product was defective in order to establish the producer's liability in *Ide v. ATB sales* (2008, WECA Civ 424).

As for the producers and insurers, they believe that the requirement to prove the causal link between the damage and the product's defect is fundamental to the balance between producers' interests and consumer interests guaranteed under the Directive. They also believe that relaxing the rules for the burden of proof would encourage consumers to take legal action for minor damage. According to legal practitioners, plaintiffs are able to establish the causal link between the defect and damage on the basis of the rules of evidence in the various Member States. This is proved by the increasing number of claims for compensation arising from a defective product.

– **Defence of regulatory compliance (Article 7(d))**

Directive 85/374/EEC establishes that the producer shall not be liable if he proves that the defect is due to compliance of the product with mandatory regulations issued by the public authorities.

On the basis of the information available, the Commission notes that there is very little case-law on this ground of defence. In this connection, the Hungarian authorities have indicated that this type of case mainly relates to vehicles and medical products. In the first instance, Hungarian case-law rarely establishes the producer's liability pursuant to the national law transposing the Directive, but as regards medicines and other medical products (in particular blood products), the producer's liability is, as a general rule, decided on by the courts. According to the Slovak authorities, consumers rarely exercise their rights to compensation in this context. They usually request other rights be enforced, such as the right to withdraw, request a discount on the purchase price or have the defect repaired.

The representatives of the pharmaceutical industries in Europe take the view that the liability system laid down in the Directive does not sufficiently take into account the fact that the medicinal products sector is very strictly regulated. In their opinion, the fact that the use of medicine is generally subject to external examination by health professionals (including doctors, nurses or pharmacists) and that the producer does not have any control over the way in which medicines are prescribed or administered should be taken into account when analysing the defect of the product and the producer's liability.

– **Development risk defence (Article 7(e))**

Directive 85/374/EEC provides that the producer's liability is not affected when the state of technical knowledge at the time when he put the product into circulation was not such as to enable the defect to be discovered. On this point, the Member States are permitted to take measures by way of derogation[15].

According to the information available, the Commission notes that national courts differ as to whether this defence applies to all types of defect. For example, the German Supreme Court ruled that Article 7(e) never applies to manufacturing defects. Other courts, for example in the Netherlands and the United Kingdom, disagree with this interpretation. Furthermore, despite the judgment of the Court of Justice of the European Union in *Commission v United*

[15] Fondazione Rosselli. Analysis of the Economic Impact of the Development Risk Clause as provided for by Directive 85/374/EEC on liability for defective products. 2004. According to this report, only Finland and Luxembourg have excluded this defence from their legislation. (http://ec.europa.eu/enterprise/policies/single-market-goods/documents/liability/index_en.htm).

Kingdom[16], there still seems to be some doubt as to the way in which the courts should interpret the clause "*the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered*".

Based on the above-mentioned information, the Austrian Supreme Court ordered that this liability exclusion clause may apply to a situation in which a certain risk has been discovered only by the expert appointed by the court through a series of tests as part of proceedings, and which was not known to the experts prior to the start of proceedings and the marketing of the product.

Today, some Member States have also shifted liability for development risks onto the producer. For example, in Finland and Luxembourg this liability applies to all types of product. In Spain, this defence does not apply in actions brought for pharmaceutical products and foodstuffs intended for human consumption. In other countries, this clause does not apply to certain products and under certain circumstances (for example, in France).

Some national authorities (including those in Bulgaria and Malta) believe that the provision laid down in Article 7(e) of the Directive needs to be reviewed in order to remove this exclusion of liability. In their opinion, removing this defence would contribute to the internal market functioning better. Other authorities (including those in Greece, Italy, Lithuania and the United Kingdom) believe that this clause contributes to maintaining a balance between encouraging the putting into circulation of innovative products and consumer protection as it reduces the insurance costs for companies. This defence encourages technical and scientific innovation without, however, increasing the final cost of the products.

Representatives of the industry and insurance companies believe that the exclusion of this defence would slow down innovation and the development of new products and increase insurance costs. In their opinion, the fact that this exclusion has not had any significant impact in either Luxembourg or Finland is due to the size of the markets. However, consumer representatives would be in favour of removing this liability exclusion clause. They stress that strict liability is based on the principle that persons making a profit from dangerous activities must compensate for damage caused. The producer should therefore be held liable even if the damage sustained is the result of a risk that was impossible to detect.

Some representatives from pharmaceutical companies criticise the position taken in French case-law whereby development risk for identical products put into circulation between 1988 and 1998 (date of the transposition legislation) may not be invoked. Their view is that this position is not in line with the Directive in that the ground for exclusion from liability cannot be accepted or rejected depending on the date of the putting into circulation of products that are identical.

– **500 euro threshold (Article 9)**

Directive 85/374/EEC applies to damage caused to an item that is for private use or consumption other than the defective product itself and with a lower threshold of 500 euros. The third report noted that this threshold was interpreted in different ways by national courts.

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16 CJEU - Judgement of 29 May 1997, C-300/95 [1997] ECR I-2649.

Some national authorities are now expressing a certain preference for reducing, or even removing, the threshold in order to guarantee more effective consumer protection. In particular, the Romanian authorities suggested setting a threshold of between 200 and 500 euros and allowing Member States to fix the amount that best matches the prices in their respective countries.

As regards the parties concerned, the representatives of the industry believe that the current threshold should at least be maintained in order to establish the compensation for strict liability from a given level of damage and to avoid a pile-up of claims for minor material damage, in particular those filed against small and medium-sized enterprises. Furthermore, they believe that this threshold should be raised in order to match it to inflation. Consumer representatives are calling for the threshold to be removed in order to allow compensation for all material damage sustained.

3.3. Other issues concerning the application of the Directive

– Access to the courts

Directive 85/374/EEC does not contain specific provisions in respect of access to the courts for injured parties. Injured parties have to use national legal solutions.

The Commission recalls that the development of the internal market requires easy access for consumers to the courts in cross-border cases.

In this context, substantial progress has been made in the field of judicial cooperation in civil matters, in particular as regards alternative dispute resolution and procedures for small claims.

– Collection and exchange of information

Since 2001, the Commission has had a group of national experts (Expert group on liability for defective products) which assists it in collecting information that is useful and/or necessary to check whether the Directive operates in a satisfactory manner and, if not, to examine the problems identified. This group has not met since 2004. Most Member States believe that it is not necessary to hold periodic meetings to exchange information, but rather feel that the group should meet if the need for a specific discussion arises. However, the new Member States are on the whole in favour of having regular meetings to exchange information.

As regards the collection of information, the *Product Liability Forum of the British Institute of International and Comparative Law* has a database on liability for defective products. This database can be accessed online and contains information regarding legislation and judicial decisions concerning Directive 85/374/EEC in all Member States[17].

4. CONCLUSION

Directive 85/374/EEC is not aimed at fully harmonising all aspects of legislation on liability arising from defective products in the EU. Moreover, the Court of Justice of the European

[17] www.biicl.org/plf

Union, through its case-law, makes a key contribution towards defining the scope of this Directive and ensuring its correct and uniform implementation.

In the light of the information available, the situation regarding the application of Directive 85/374/EEC is similar to that stated in the previous report. It would, however, seem that the number of liability claims made on the basis of the Directive has increased in some Member States, moreover, there has been an increase in the number of out-of-court settlements for compensation reached between the injured party and the person who caused the damage.

In general, the Directive is seen as achieving a balance between consumer protection and the producers' interests. Most contributions to this report confirm the fact that Directive 85/374/EEC is an instrument that offers the real possibility of filing a claim for appropriate remedy and compensation for damage caused by a defective product.

On the whole, national experts and interested parties recognise the importance of having a balanced liability instrument governing relationships between companies and consumers and feel that the Directive strikes this balance by reconciling the said interests. However, the interested parties also have differing opinions about the Directive as regards the effectiveness of certain provisions, in particular those concerning the burden of proof, defence of regulatory compliance, the development risk defence or the 500 euro threshold. Overall, however, these differences had already been noted in the previous report.

In general, consumers would like more protection at a lower cost, which would mean, for example, removing the threshold. In contrast, producers and insurers mention the risk of increasing the number of claims for minor damages and are therefore in favour of increasing the threshold. These two differing stances are also reflected among the national experts.

It would therefore seem that Directive 85/374/EEC contributes to maintaining the balance between the producers' interests and consumer interests as regards liability for defective products. The Commission takes the view that the differences that may arise do not create significant trade barriers or distort competition in the European Union. In particular, the Commission believes that injured parties can establish the causal link in cases where a defective product causes damage irrespective of the differences between national procedural rules. Similarly, it also noted that, from the information available on the impact of provisions for defences or the 500 euro threshold, it is possible to conclude that the Directive provides a common level of consumer protection and a common basis for the producers' liability for defective products.

Taking into account that the information available is not sufficiently fact-based and that any amendment to one or more provisions has an effect on the overall balance of this Directive, the Commission is of the opinion that it is premature to propose a review of the Directive at this stage.

Between now and the next report, the Commission will follow any development likely to affect the balance, where necessary using an in-depth evaluation involving national experts and interested parties, in order to identify the problems and find solutions that are acceptable to the majority of stakeholders.

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The Commission would ask the European Parliament, the Council and the European Economic and Social Committee to take note of this report.