OPINION OF ADVOCATE GENERAL TRSTENJAK

delivered on 8 September 2009 [1]

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I — Introduction

1. This reference for a preliminary ruling from the House of Lords concerns the interpretation of Article 11 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. [2] The referring court asks the Court of Justice to clarify in particular whether and under what conditions the producer of a product may, by a substitution of parties, be made a defendant in an action in which the injured person has mistakenly asserted his rights under that directive against a supplier of the product, if the action was brought before the expiry of the 10-year limitation period provided for in Article 11 of Directive 85/374 but the application to substitute the defendant was made only after the expiry of that 10-year period.

2. A special feature of this reference for a preliminary ruling is that the question has already been referred to the Court — albeit in a different formulation — by the High Court of Justice of England and Wales, Queen's Bench Division, as the lower-instance court in the same proceedings, and answered by judgment of 9 February 2006, *O'Byrne*. [3] Since the House of Lords, as the appellate court in the same case, is uncertain as to the precise extent of the answer given by the Court, it has referred the question to the Court for another preliminary ruling.

2 — OJ 1985 L 210, p. 29.
3 — Case C-127/04 [2006] ECR I-1313.

II — Legal framework

A — *Community law*

3. Article 1 of Directive 85/374 provides that '[t]he producer shall be liable for damage caused by a defect in his product'.

4. Article 3 of Directive 85/374 reads:

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

...

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

5. Article 11 of Directive 85/374 provides:

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

B — *National law*

6. The United Kingdom transposed Directive 85/374 by means of Part I of the Consumer Protection Act 1987, which came into force on 1 March 1988.

7. That act also inserted a new section 11A in the Limitation Act 1980, subsection 3 of which provides:

'An action to which this section applies shall not be brought after the expiration of the period of 10 years from the relevant time …; and this subsection shall operate to extinguish a right of action and shall do so whether or not that right of action had accrued, or time under the following provisions of this Act had begun to run, at the end of the said period of 10 years.'

8. Under section 35 of the Limitation Act 1980, the substitution of a defendant in the course of an action is in principle prohibited after the limitation period has expired. Exceptionally, however, rules of procedure may give the courts power to allow such a change of parties after the expiry of the limitation period.

9. Rule 19.5(3)(a) of the Civil Procedure Rules provides for such a possibility of substituting a party after the expiry of the limitation period where proceedings have been brought by mistake against the wrong person. The national courts have a broad discretion in applying that provision. In doing so they take into account that the defendant will lose the liberating effect of limitation, so that an

application to substitute a defendant will, even where all the conditions laid down are satisfied, be granted only if this is just in the circumstances of the case.

III — Facts and reference for a preliminary ruling

A — *Facts*

10. The respondent in the main proceedings was vaccinated as a child in a medical practice in the United Kingdom with the HIB vaccine, the producer of which was the French company Pasteur Mérieux Sérums et Vaccins SA, which later changed its name to Aventis Pasteur SA ('APSA'). The vaccine was distributed in the United Kingdom by the English company Mérieux UK Limited, a wholly-owned subsidiary of APSA. In 1994 APSA set up a joint venture with Merck Inc. Mérieux UK Limited was converted into a subsidiary of the joint venture, and subsequently changed its name to Aventis Pasteur MSD ('APMSD').

11. The vaccine administered to the respondent was part of a consignment of a number of units of HIB vaccine sent by APSA to APMSD on 18 September 1992. On 22 September 1992 the consignment arrived at APMSD, which duly paid APSA the invoice for the consignment.

12. At an unknown date — probably in late September or early October 1992 — part of the consignment, including the vaccine given to the respondent, was sold by APMSD to the Department of Health and delivered to a hospital designated by the department, which in turn supplied the vaccine to the doctor's surgery where the respondent was vaccinated on 3 November 1992.

13. The respondent subsequently suffered severe brain damage. In his view, the damage was caused by the vaccine, which is said to have been defective.

14. On 2 November 2000 the respondent commenced proceedings against APMSD. In the particulars of claim served on 1 August 2001, he alleged that the vaccine had been produced by APMSD and was defective. APMSD replied in its defence, served on 29 November 2001, that it was merely the

distributor of the vaccine administered to the respondent. On 17 April 2002, in reply to a request to that effect, APMSD identified Pasteur Mérieux Sérums et Vaccins SA as the manufacturer.

15. On 16 October 2002 the respondent brought separate proceedings against APSA, seeking damages on the basis that APSA was the producer of the vaccine. In this second action APSA admitted that it was the producer of the vaccine but submitted that the action against it was statute-barred. It said that the product had been put into circulation when it was sent on 18 September 1992 to APMSD, which received it on 22 September 1992. The limitation period of 10 years under section 11A(3) of the Limitation Act 1980 had therefore expired on 22 September 2002 at the latest.

16. In addition to the new action against APSA, the respondent applied on 10 March 2003 in the first action against APMSD for APMSD to be substituted as defendant by APSA. In support of that application, the respondent submitted that when bringing the first action in November 2000 he had mistakenly believed that APMSD was the producer of the vaccine. In opposition to the application, APSA contended that, in so far as national law permitted such a substitution of parties after the expiry of the 10-year limitation period, it was incompatible with Article 11 of Directive 85/374. The respondent denies this.

B — *First reference for a preliminary ruling and the* O'Byrne *judgment*

17. In those circumstances the High Court of Justice of England and Wales, Queen's Bench Division, stayed the first action, which was then pending before it, and referred three questions to the Court for a preliminary ruling. The High Court sought clarification in particular on when, in a case such as that in the main proceedings, the product was to be regarded as being put into circulation within the meaning of Article 11 of Directive 85/374 (first question), whether proceedings brought by mistake against an undertaking other than the producer could be treated as 'proceedings against the producer' within the meaning of Article 11 (second question), and whether in those circumstances Article 11 permitted a producer to be substituted as a defendant, with the permission of the court, if the relevant proceedings had been commenced before expiry of the 10-year period but the substitution of defendants was applied for only after expiry of the period (third question).

18. In answer to those questions, the Court ruled in *O'Byrne* that:

'1. Article 11 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 is to be interpreted as meaning 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.

2. When an action is brought against a company mistakenly considered to be the producer of a product whereas, in reality, it was manufactured by another company, it is as a rule for national law to determine the conditions in accordance with which one party may be substituted for another in the context of such an action. A national court examining the conditions governing such a substitution must, however, ensure that due regard is had to the personal scope of Directive 85/374, as established by Articles 1 and 3 thereof.'

C — *Reference for a preliminary ruling by the House of Lords*

19. Following the *O'Byrne* judgment, the High Court of Justice of England and Wales, Queen's Bench Division, on 20 October 2006 allowed the respondent's application for a substitution of parties, on the ground that APMSD had been mistakenly named as defendant instead of APSA. APSA appealed to the Court of Appeal, which dismissed the appeal on 9 October 2007. The House of Lords gave APSA leave to appeal.

20. In the appellate proceedings the House of Lords has to decide whether it is consistent with Directive 85/374 for the laws of a Member State to allow the real producer to be substituted as a defendant in a case such as that in the main proceedings. This question was already submitted to the Court in the second and third questions of the first order for reference, and was answered in the *O'Byrne* judgment. In determining the precise extent of the answer given, however, the House of Lords found itself confronted with serious difficulties of interpretation.

21. In those circumstances the House of Lords decided to stay the proceedings before it and refer the following question to the Court for a further preliminary ruling:

'Is it consistent with the European Product Liability Directive for the laws of a Member State to allow substitution of a new defendant to a claim brought under the directive after the 10-year period for enforcing rights under Article 11 of the directive has expired in

circumstances where the only person named as a defendant in proceedings instituted during the 10-year period was someone who does not fall within Article 3 of the Directive?'

IV — Procedure before the Court

22. The order for reference of 11 June 2008 was received at the Court on 5 August 2008. In the written procedure, the respondent and the appellant in the main proceedings and the Commission submitted observations. At the hearing on 30 June 2009, the representatives of the respondent and the appellant in the main proceedings and the Commission made submissions.

V — Submissions of the parties

23. APSA observes that Directive 85/374 is based on a complex balancing of interests. To compensate the no-fault liability of the producer, the directive provides for certain defences and other protective machinery for the producer. In this connection Article 11 provides that the consumer's rights under the directive are in any event extinguished on the expiry of a period of 10 years from the date on which the producer put the product into circulation. The only possibility of interrupting the running of that period is the institution of proceedings against a producer within the meaning of Article 3. Since Directive 85/374 intends a complete harmonisation of the matters it regulates, the definition of a producer in Article 3 is exhaustive. In view of the fact that APMSD is not a producer within the meaning of Article 3, the action brought against APMSD did not stop the 10-year limitation period running. The rights of the injured person were therefore extinguished on the expiry of that period, so that he could no longer claim those rights in proceedings against APMSD as the original defendant or against APSA as a new defendant.

24. In the view of the respondent in the main proceedings, Directive 85/374 does not preclude a national rule of procedure under which the supplier of a product against whom an action has been brought before the expiry of the 10-year limitation period laid down in Article 11 may in exceptional circumstances be substituted as defendant by the producer of the product, even if the application for a substitution of parties is not made until after the expiry of the 10-year limitation period. Such a rule is to be regarded as consistent with the directive in particular when the substitution of parties presupposes that the claimant intended *ab initio* to assert his rights against a producer, and the national courts can refuse the application for a substitution of defend-

ants if the new defendant did not have knowledge, before the expiry of the 10-year period, of the claimant's intention to assert his rights against a producer.

25. In the Commission's view, the referring court is essentially seeking to know whether, in the context of the main proceedings, a substitution of defendants which is permitted under national law is consistent with Directive 85/374 if the injured person has, before the expiry of the 10-year limitation period, by mistake brought his claim not against the producer within the meaning of Article 3(1) of the directive but instead against a supplier who is to be classified as a producer within the meaning of Article 3(3), and applies for the substitution of defendants only after that 10-year period has expired. It submits that the answer should be in the affirmative.

VI — Legal assessment

26. By its reference for a preliminary ruling, the referring court asks the Court to answer a question which has already been asked in the same case by the lower court, the High Court of Justice of England and Wales, Queen's Bench Division, and has been answered by the Court in the *O'Byrne* judgment. [4]

27. Although the first *O'Byrne* judgment is a binding decision of the Court, whose binding effect extends not only to the referring court but to all courts which have to give judgment in the same case, a second reference of the same question in the same proceedings is permissible. [5] According to settled case-law, such a second reference may be justified in particular when the national court encounters difficulties in understanding or applying the judgment, when it refers a fresh question of law to the Court, or when it submits new considerations which might lead the Court to give a different answer to a question already ruled on. [6] It is in principle for the national court to decide whether the preliminary ruling already delivered has given it an answer that is adequate for deciding the case, or whether it considers a further reference to be necessary. [7]

28. In this context, I shall first analyse below the *O'Byrne* judgment. I shall then take that analysis as the starting point for working out a proposed answer to the question referred for a new preliminary ruling.

4 — Cited in footnote 3.

5 — Rengeling, H.-W., Middeke, A. and Gellermann, M., *Handbuch des Rechtsschutzes in der Europäischen Union*, Munich, 2003, § 10, paragraph 87.

6 — Case 14/86 *Pretore di Salò* [1987] ECR 2545, paragraph 12, and order in Case 69/85 *Wünsche* [1986] ECR 947, paragraph 15.

7 — See Dauses, A.,'P — Gerichtsbarkeit der EU', in *Handbuch des EU-Wirtschaftsrechts* (ed. Dauses, M.), P. II, paragraph 224 (EL 23).

A — *First reference for a preliminary ruling and the* O'Byrne *judgment*

1. First question: the time when a product is put into circulation

29. In the *O'Byrne* judgment, the Court first had to decide whether, where a product is sold by a producing undertaking to a distributing subsidiary which then sells it to a third party, Article 11 of Directive 85/374 is to be interpreted as meaning that the product is put into circulation at the time when it is transferred from the producing undertaking to the subsidiary or at the time when the subsidiary transfers it to a third party.

30. In answering this question, the Court emphasised that the provision in Article 11 of Directive 85/374 setting a time-limit for the injured person's rights is of a neutral character. The establishment of the time-limits within which the injured person's action must be brought must therefore satisfy objective criteria. [8]

31. The Court then stated the principle that a product must be considered as having been put into circulation within the meaning of Article 11 of the directive when it leaves the production 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. It is not generally important in that regard that the product is sold directly by the producer to the user or to the consumer or that the sale is carried out as part of a distribution process involving one or more suppliers. [9]

32. Where, however, the links between a producer and a supplier are so close that the latter is in reality involved in the production process, the concept of producer within the meaning of Article 11 of the directive also includes that supplier, and the product is not regarded as put into circulation merely by being transferred to the supplier. It is for the national courts to assess whether such a close link exists. [10]

2. Analysis of the Court's answer to the first question

33. In answer to the first question, the Court stated essentially that a product is in principle regarded as being put into circulation from the time when the producer transfers it to a supplier. If the producer and the supplier are so closely connected, however, that the supplier really forms part of the production

8 — *O'Byrne*, cited in footnote 3, paragraph 26.

9 — Ibid., paragraphs 27 and 28.

10 — Ibid., paragraph 29 et seq.

process, the supplier is also to be classified as a producer within the meaning of Articles 7 and 11 of Directive 85/374. In such a case the product is regarded as not being put into circulation until the time when the supplier who is to be classified as a producer transfers it to a third party.

34. Because the concept of producer used in Articles 7 and 11 of the directive refers to the statutory definition of a producer in Article 3, the Court basically opted in *O'Byrne* for a functional interpretation of the concept of producer within the meaning of Article 3. To ascertain the precise extent and meaning of that functional interpretation, I shall first describe the various categories of producers under Article 3 and then explain which category of producer the Court was referring to. I shall then show how this functional interpretation fits into the limitation rule in Directive 85/374.

(a) The multi-layered concept of producer under Article 3 of Directive 85/374

35. For determining the personal scope of Directive 85/374, the legislature proceeded from a complex, multi-layered concept of producer, which is described in Article 3 and comprises four different categories of producer:

(1) the producer *stricto sensu* who produces the finished product, a raw material or a component part (first half of Article 3(1));

(2) the quasi-producer who holds himself out as the producer by putting his name, trade mark or other distinguishing feature on the product (second half of Article 3(1));

(3) the importer who imports the product into the Community for distribution in the course of his business (Article 3(2));

(4) the supplier who supplies the product, if the producer (or, in the case of an imported product, the importer) cannot be identified and the supplier does not within a reasonable time state the identity of the producer or importer or the person who supplied him with the product (Article 3(3)).

36. By emphasising in the *O'Byrne* judgment that an entity which is formally a part of the distribution chain may as a result of its involvement in the process of manufacturing the product be regarded functionally as a producer, the Court impliedly but unmistakeably referred to the category of producers *stricto sensu* within the meaning of the first half of Article 3(1). Only the producer *stricto sensu* operates a process for manufacturing a product and is therefore in a position to arrange the process in a way which involves other entities.

37. The functional interpretation in *O'Byrne* of the concept of producer thus relates to the category of producer *stricto sensu* within the meaning of the first half of Article 3(1) of Directive 85/374. The other categories of producer, by contrast, are not concerned by this functional interpretation of the concept of producer.

38. It is for the national courts to determine whether a supplier of a product is to be classified functionally in the particular case as a producer within the meaning of the first half of Article 3(1) of Directive 85/374. In this connection the Court has, however, already explained in *O'Byrne* [11] that, when assessing whether the producer and a supplier are so closely connected that the supplier is really part of the production process, it is in principle immaterial whether or not the producer and the supplier are distinct legal persons. It is equally irrelevant whether the producer *stricto sensu* has invoiced the products to the entity concerned and whether the latter has paid the purchase price like any other purchaser. It is also irrelevant who held the property rights in the products at what time. On the other hand, it is relevant whether the undertakings carry on different manufacturing activities or are undertakings one of which, the subsidiary, acts solely as distributor or holder of the product produced by the parent company.

39. In the light of those principles, for the classification of a supplier as a — functional — producer of a product within the meaning of the first half of Article 3(1) of Directive 85/374, what is decisive is the answer to the question whether the producer, after transferring the product to the supplier who is formally part of the distribution chain, retains de facto control over the product transferred. [12] That will be the case in particular where the supplier does not determine his conduct in the market autonomously but follows the instructions of the producer by whom he is controlled.

11 — Ibid., paragraphs 30 and 31.

12 — To this effect, see also Advocate General Geelhoed in his Opinion in *O'Byrne*, cited in footnote 3, point 43, in whose view the criterion must be control or the abandonment of control over the product. See also Viney, G. and Jourdain, P., *Les conditions de la responsabilité*, 3rd edition, Paris, 2006, p. 881; Jourdain, P., 'Responsabilité civile. Responsabilités spéciales. Produits défectueux', RTD civ. 2006, p. 331, 333.

40. The question of the transfer of factual control over a product must be answered by the national courts in the context of an assessment of the individual case and with particular attention being paid to the production and distribution process operated by the producer. It must not be overlooked, however, that with transactions within a group the transfer of a product does not normally involve a loss of control, especially where — as in the main proceedings — the supply is made by the producer to a wholly-owned subsidiary.

41. Where a product is passed on by the producer to a wholly-owned subsidiary which forms part of the distribution chain, it may thus be presumed that the producer retains control over the product until the subsidiary has sold the product to a person or entity outside the group. This presumption can be rebutted. Economic reality is far too complex for it to be possible, without taking account of the specific circumstances, to confirm that a producer does not lose de facto control over a product when he transfers it to an entity within the group. Counter-proof that control has been lost and also proof of the exact time when the product was transferred within the group are, however, to be provided by the producer, who bears the burden of proof and the concomitant risk of the consequences of the failure to provide proof. To avoid the producer being able in this connection to glean a procedural advantage from relations within the group which are not transparent to the consumer, the requirements to be met by this counter-proof must moreover be set high.

42. If counter-proof of loss of control in the context of a transfer within the group is not brought, a supplier who is a wholly-owned subsidiary of the producer and has received a product from the producer is to be classified, together with the parent company, as a producer of that product within the meaning of the first half of Article 3(1) of Directive 85/374.

(b) The time when the limitation period under Article 11 of Directive 85/374 starts to run in the light of the functional interpretation of the concept of producer

43. Giving a functional interpretation to the concept of producer within the meaning of the first half of Article 3(1) of Directive 85/374 takes due account of the compromise brought about by the directive between the interests of consumers and those of producers. That is evident primarily in connection with the determination of the time when the limitation period under Article 11 of the directive starts to run, to which the High Court's first question related.

44. As regards rules on limitation, Directive 85/374 provides for a twofold temporal limit on the producer's liability for products.

45. First, Article 10(1) contains a limitation period of three years, which starts running from the day on which the injured person became aware, or must have become aware, of the damage, the defect and the identity of the producer. Although that limitation period is relatively short, the fact that it runs only from the date of knowledge — or negligent lack of knowledge — of the crucial facts that give rise to the claim carries with it the possibility that the period will not start running until many years after the first use of the products. Furthermore, under Article 10(2), the laws of the Member States on the suspension or interruption of limitation periods are applicable to this period.

46. In addition to this 'variable' three-year limitation period, Article 11 of the directive provides for a 'fixed' 10-year limitation period which starts to run from the day on which the product was put into circulation, can be interrupted only by the bringing of proceedings against the producer, and leads to the extinguishment of the injured person's rights under the directive. [13]

47. Although the Court emphasised in *O'Byrne*, referring to the 10th recital in the preamble to Directive 85/374, that this 10-year limitation period creates legal certainty in the interests of all concerned, and in that sense is neutral, it cannot in my view be overlooked that in the overall context of the directive Article 11 also, and above all, has a neutralising effect in favour of the producer.

48. As Advocate General Geelhoed correctly said in his Opinion of 2 June 2005 in the *O'Byrne* case, [14] Directive 85/374 aims to protect the consumer by providing for no-fault liability of the producer — but with

13 — Because the rights conferred by the directive are extinguished on expiry of the 10-year period under Article 11, this period is generally classified in legal writing not as a limitation period but as an 'extinctive' period which, by reference to concepts of national law, is described inter alia as 'von Amtwegen zu beachtende Ausschlussfrist' (Graf von Westphalen, F., *Produkthaftungshandbuch*, Vol. 2, 2nd edition, Munich, 1999, § 79, paragraph 15), 'vervaltermijn' (Dommering-van Rongen, L., *Productaansprakelijkheid*, Amsterdam, 2000, pp. 92 and 93), or 'délai d'extinction' (le Tourneau, Ph., *Droit de la responsabilité et des contrats*, 6th edition, Paris, 2006, paragraph 8461). Such use of concepts developed for the purposes of national law brings with it a risk, however, that the principles of procedural law indwelling in those concepts may flow indirectly into the interpretation of Article 11 of the directive. Moreover, the 10th recital in the preamble to the directive refers expressly to 'a uniform period of limitation for the bringing of action for compensation'. In this context, the Court in the judgment in *O'Byrne*, cited in footnote 3, and Advocate General Geelhoed in his Opinion in that case both rightly described the 10-year period under Article 11 of Directive 85/374 as a limitation period, that term being understood in the Community law sense.

14 — Opinion of Advocate General Geelhoed in *O'Byrne*, cited in footnote 3, point 29.

possible defences — in cases in which damage is caused by a defect in his product. This classification of the producer's liability as no-fault liability is immediately apparent from the second recital in the preamble to Directive 85/374, which states that liability without fault on the part of the producer is the sole means of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production. [15] Classification as no-fault liability is confirmed by an analysis of the wording and scheme of the directive. Thus the damage which is to be compensated is consistently described as caused by a defect in the product, without any reference to negligent conduct or breach of duty on the part of the producer. [16] In this connection, under Article 6 of Directive 85/374, the legitimate expectation of the consumer, rather than a duty of care to be complied with by producers, applies as the criterion for deciding whether a product is defective. [17]

49. The producer's no-fault liability is limited in time and is extinguished, in accordance with Article 11 of Directive 85/374, at the latest on the expiry of 10 years from when the product was put into circulation. This 'fixed' 10-year period is justified primarily on the ground that no-fault liability represents a greater burden on the producer than liability under the usual rules of contractual and non-

15 — See only on this point Borghetti, J.-S., *La responsabilité du fait des produits. Etude de droit comparé*, Paris, 2004, paragraph 434, pp. 432 and 433.

16 — See only Taschner, H.C., 'Product liability: basic problems in a comparative law perspective', in *Product Liability in Comparative Perspective* (ed. Fairgrieve, D.), Cambridge, 2005, p. 155, 161, who emphasises that Article 4 of Directive 85/374 presupposes as elements only damage, a defect and a causal link, with the producer's conduct being irrelevant. The producer's liability is accordingly not 'fault-based' but 'defect-based'.

17 — Yet the question of the classification in legal theory of the producer's liability has led to a particularly lively debate between legal writers, especially in German legal writing, in which not only a classification as no-fault liability but also classifications as liability based on risk, as a combination of various elements of fault-based and no-fault liability, depending on the type of defect, or as a mixture of risk-based liability and no-fault liability for defective products have been suggested (see only Oechsler, J., in Staudinger, *Kommentar zum Bürgerlichen Gesetzbuch*, Buch 2, Berlin, 2002, Einl zum ProdHaftG, paragraph 27). In other legal systems too, the question of the legal nature of the producer's liability has been answered in the most diverse ways in the context of national legal systems, inter alia with the use of the terms 'responsabilité quasi objective', 'responsabilité mixte' (le Tourneau, Ph., cited in footnote 13, paragraph 8350) or 'responsabilité de plein droit' in French writing, 'risicoaansprakelijkheid' (van Empel, M. and Ritsema, H.A., *Aansprakelijkheid voor producten*, 2nd edition, Deventer, 1992, p. 53) and 'risicoaansprakelijkheid met schuldelementen' (Dommering-van Rongen, L., cited in footnote 13, p. 36) in Dutch writing, 'objectieve aansprakelijkheid met eerbiedigend karakter' in Belgian writing (Wuyts, D., 'Productaansprakelijkheid: een Richtlijn voor (n)iets?', TBBR 2008, p. 3, 7). In this debate it is, however, generally overlooked that Directive 85/374 introduced a Community law rule on liability to which the concepts of liability developed for national law cannot simply be applied. Since in accordance with the wording, purpose and structure of Directive 85/374 fault is precisely not a condition of liability, the liability laid down in that directive must be classified in Community law as no-fault liability (correctly stated in Taschner, H.C. and Frietsch, E., *Produkthaftungsgesetz und EG-Produkthaftungsrichtlinie*, Munich, 1990, 2nd edition, Art. 1 Richtl., No 2. See also v. Bar, C., *Gemeineuropäisches Deliktsrecht*, Vol. II, Munich, 1999, paragraph 391, who describes this liability very subtly as based on a system of strict attribution).

contractual liability. In order not to restrict technical progress, [18] to keep the additional burden on the producer within bounds, and to make it possible to insure against the risk of liability, [19] the legislature found it necessary to set a time-limit on the no-fault liability and to guarantee producers a fixed terminal date that was uniform throughout the Community.

50. In the overall scheme of Directive 85/374, the 10-year upper limit for the producer's liability in Article 11 must therefore be regarded as a counterweight to the non-fault-based character of this product liability. It follows directly that a displacement of the starting date of the limitation period necessarily has an effect on the directive's balancing of the interests of producers and consumers. If the limitation period starts running at a later date, it is not only the protection of the consumer that is increased, but also the producer's risk of liability. If, on the other hand, the limitation period starts running at an earlier date, the protection of the consumer is reduced and — in parallel — so is the producer's risk of liability.

51. To prevent an unjustified shortening of the limitation period to the detriment of consumers, the Court in *O'Byrne*, interpreting the expression 'put into circulation' as the event which starts the period running, focused primarily not on the physical transfer of the product by the producer to another entity but rather on the manufacturing process operated by the producer and the control exercised in that context. The transfer of the product to a subsidiary company which is formally part of the distribution chain does not count as a putting into circulation if the transfer is a purely internal transaction within the group and the producer does not lose control over the product.

52. The Court accordingly used a functional interpretation of the concept of producer within the meaning of the first half of Article 3(1) of Directive 85/374 to avoid the possibility of the limitation period starting to run as a result of internal transactions within the group, even though the product had not yet left the producer's sphere of control. A converse interpretation would have had the consequence that producers would be given a tool for shortening the 10-year limitation period significantly by storing and keeping

18 — Although under Article 7(e) of the directive the producer is not liable 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 the defect to be discovered, the producer bears the burden of proof and consequently also the risk of the consequences of the lack of proof in relation to this defence. The defence can therefore only partly remove the risk of holding back innovation which is inherent in no-fault liability for products. In this context, the 11th recital in the preamble to Directive 85/374 rightly points out that products age in the course of time, higher safety standards are developed and the state of science and technology progresses, so that it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product.

19 — In the relevant legal literature, reference is made in particular to the possibility of insuring against the risk of liability for products as the main reason for introducing the 10-year limitation period under Article 11 of Directive 85/374; see Borghetti, J.-S., cited in footnote 15, pp. 491 and 492; van Wassenaer van Catwijck, A., *Productenaansprakelijkheid in Europees verband*, 2nd edition, Zwolle, 1991, p. 104; and Kullmann, H.J., *Produkthaftungsgesetz*, 2nd edition, Berlin, 1997, p. 149.

products within the group, [20] which would in turn have led to a disturbance of the balance struck by the directive between the interests of producers and consumers.

3. Second and third questions: substitution of a producer as defendant during the proceedings

53. By the second and third questions on which the Court had to give a preliminary ruling in *O'Byrne*, the national court sought essentially to know whether national law can give the courts discretion to treat an action brought by mistake against a person other than the producer as 'proceedings against the producer' within the meaning of Article 11 of Directive 85/374 (second question), and whether Article 11 allows a national rule in this connection under which the producer may, by way of a substitution of parties, be made a defendant in proceedings which were started by mistake against another undertaking before the expiry of the 10-year period, even though the application for substitution was made only after the expiry of that period and no other legal proceedings in relation to the product concerned have been brought against the producer within the time-limit (third question).

54. In its answer to these questions (which it examined together) the Court started by observing that the directive does not state which procedural rules are to be applied when an injured party brings an action for liability for defective products and makes an error as to the identity of the producer. It is therefore for national procedural law to determine the conditions in accordance with which one party may be substituted for another in the context of such an action. [21]

55. The Court then pointed out that the directive seeks to achieve a complete harmonisation in the matters it regulates, and the determination in Articles 1 and 3 of the class of persons liable must be regarded as exhaustive. In that context, other persons may be regarded as producers only in the cases exhaustively listed in Article 3. [22]

56. In the light of those considerations, the Court reached the conclusion, in answer to the second and third questions, that in a case such as that in the main proceedings it is as a rule for national law to determine the conditions under which one party may be substi-

20 — To similar effect, Advocate General Geelhoed in his Opinion in *O'Byrne*, cited in footnote 3, point 48 et seq.

21 — *O'Byrne*, cited in footnote 3, paragraph 34.

22 — Ibid., paragraphs 35 and 37.

tuted for another. A national court examining the conditions governing such a substitution must, however, ensure that due regard is had to the personal scope of the directive, as determined by Articles 1 and 3. [23]

4. Analysis of the Court's answer to the second and third questions

57. A thorough analysis of the *O'Byrne* judgment leads me to the conclusion that the answer given by the Court to the second and third questions, in particular the requirement that when examining the conditions for a substitution of parties the national court must ensure that due regard is had to the personal scope of Directive 85/374, is open to two quite different interpretations.

58. On the one hand, the judgment could be interpreted to the effect that a substitution of parties — valid under national law — can satisfy the requirements of Directive 85/374 if the 'substituted' defendant falls within the personal scope of Directive 85/374 and the proceedings were brought by mistake — and hence in good faith — but in good time against an undertaking other than the producer, even though the application for a substitution of parties was made only after the expiry of the 10-year limitation period. The High Court evidently took this interpretation as the basis for its decision of 20 October 2006 to allow the respondent's application for a substitution of parties. A majority of the House of Lords also appears to be inclined to this interpretation.

59. Although this first interpretation can be reconciled with the wording of the operative part, in my view the *O'Byrne* judgment contains several indications that the Court reached the contrary conclusion.

60. This second interpretation is supported by an overall analysis of the *O'Byrne* judgment with particular attention to the Court's reformulation of the second and third questions. The Court amalgamated the two questions to make one, and answered it to the effect that the conditions for a substitution of parties are as a rule for national law to determine, but the national courts may not extend the personal scope of the directive when examining those conditions.

61. That reference to the obligation to have due regard to the personal scope of Directive 85/374, in answer to the second question, excluded the treating of an action brought by mistake against an undertaking

23 — Ibid., paragraph 39.

other than the producer as 'proceedings against the producer' within the meaning of Article 11, because this would imply that an undertaking which did not fall within the concept of producer within the meaning of Article 3 would be classified as a producer, in disregard of the personal scope of Directive 85/374.

62. This negative answer to the second question implies, for the same reasons, that the third question must be answered in the negative. Because the action brought by mistake against an undertaking other than the producer cannot be classified as 'proceedings against the producer', it does not interrupt the limitation period within the meaning of Article 11 of Directive 85/374, and the claims against the real producer — if no separate proceedings have been brought against him — are extinguished on expiry of the 10-year limitation period. In this context, the possibility is excluded of the producer subsequently being substituted as a defendant in proceedings that are already in progress in which the claims which are now extinguished were brought against another undertaking. Otherwise the action against an undertaking other than the producer would be treated de facto as proceedings against the real producer, which the Court ruled out in its answer to the second question.

B — *The reference for a preliminary ruling by the House of Lords*

1. Introductory remarks

63. By its reference for a preliminary ruling of 11 June 2008, the House of Lords essentially requests a fresh examination of whether a substitution of defendants would be compatible with Directive 85/374 in the circumstances of the main proceedings. In formulating the question the House of Lords assumed that the supplier APMSD originally sued in the main proceedings cannot be classified as a producer within the meaning of Article 3 of Directive 85/374 and that the application for a substitution of parties was not made until after the expiry of the 10-year limitation period in Article 11 of the directive.

64. APSA has submitted, however, that it has not yet been finally clarified in the main proceedings whether APMSD can be classified as a producer within the meaning of Article 3 of Directive 85/374. Nor has it been decided whether the bringing of proceedings against APSA on 16 October 2002 took place before or after the expiry of the 10-year period under Article 11 of the directive. In reliance on the documents in the case, the Commission in particular submits in this connection that APMSD should be classified as a producer within the meaning of Article 3 of the directive and that the question should be reformulated accordingly.

65. Although the Court is not called on itself to evaluate the facts of the main proceedings, it can still give the referring court any guidance that would be helpful to it in resolving the main proceedings, having regard to the particular facts of the case.

66. In this context, I shall start by analysing the question in the formulation chosen by the House of Lords. I shall then examine the premisses from which the House of Lords started and their possible consequences for the answer to the question.

2. Impossibility of substituting a producer as a defendant after the expiry of the limitation period under Article 11 of Directive 85/374

67. The central question which must be dealt with in the answer to the reference by the House of Lords is whether and under what conditions national law can give an injured person the possibility, after the expiry of the limitation period defined in Article 11 of Directive 85/374, of making the producer a defendant in proceedings which were brought by mistake against a supplier before the expiry of the limitation period, and in that way bringing claims under the directive in proceedings against the producer.

68. In my opinion, such a substitution of the producer as a defendant when he has been released by the expiry of the 10-year limitation period is incompatible with Directive 85/374.

69. It should be pointed out, to begin with, that according to settled case-law Directive 85/374 aims at a complete harmonisation of the laws, regulations and administrative provisions of the Member States. The discretion available to the Member States in regulating liability for defective products is determined entirely by Directive 85/374 itself and must be inferred from its wording, purpose and structure. [24]

70. It is also settled case-law of the Court that Article 13 of Directive 85/374, which provides that any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when the directive is notified will continue to

24 — Case C-285/08 *Moteurs Leroy Somer* [2009] ECR I-4733, paragraphs 20 and 21; Case C-402/03 *Skov and Bilka* [2006] ECR I-199, paragraphs 22 and 23; Case C-52/00 *Commission* v *France* [2002] ECR I-3827, paragraphs 16 and 24; Case C-154/00 *Commission* v *Greece* [2002] ECR I-3879, paragraphs 12 and 20; and Case C-183/00 *González Sánchez* [2002] ECR I-3901, paragraph 25.

exist, cannot be interpreted as leaving it open to the Member States to maintain a general system of product liability different from that provided for in the directive. [25]

71. Directive 85/374 accordingly lays down not only the lower but also the upper limits of the no-fault liability of the producer, [26] and the limitation rule in Article 11 must indisputably be classified as a definition of the temporal upper limit of liability.

72. An interpretation of Article 11 of Directive 85/374 in accordance with its wording and structure demonstrates unmistakeably here that the rights against the producer which the injured person derives from the directive were intended to disappear altogether on expiry of the 10-year period provided for in that provision. In the various language versions of the provision, the disappearance of the rights is expressed inter alia by the terms 'prenehajo', 'erlöschen', 'shall be extinguished', 's'éteignent', 'se extinguirán', 'si estinguono' and 'komen te vervallen'. The wording of that provision thus gives no ground for supposing that the rights deriving from the directive could be revived for any reason after they have been extinguished.

73. The interpretation to the effect that coming to the end of the limitation period under Article 11 of Directive 85/374 leads to the irrevocable disappearance of the rights which the injured person derives from the directive in relation to the released producer furthermore corresponds to the Court's case-law on the aims pursued by the directive.

74. The Court, referring to the first recital in the preamble to Directive 85/374, has consistently held that the directive aims not only to avoid differences in levels of consumer protection but also to ensure undistorted competition between economic operators and to facilitate the free movement of goods. [27]

75. As those three legislative aims exist alongside each other, the protection of consumers does not enjoy priority in the context of Directive 85/374 over the other two aims, [28]

25 — *Moteurs Leroy Somer*, paragraph 22, *Skov and Bilka*, paragraph 39, *Commission* v *France*, paragraph 21, *Commission* v *Greece*, paragraph 17, and *González Sánchez*, paragraph 30, all cited in footnote 24.

26 — Directive 85/374 does not, however, exclude the application of differing national rules of contractual or non-contractual liability, if they are based on other grounds. See Magnus, U., 'Die Produkthaftung des Zwischenhändlers vor dem EuGH', GPR 2006, p. 121, 123, who rightly emphasises in this connection that the directive should not be regarded as regulating the entire complex of product liability and constitutes merely a partial regulation — although effecting a complete harmonisation in that respect — of that problem by means of no-fault liability.

27 — *Moteurs Leroy Somer*, paragraph 29, *Commission* v *France*, paragraph 17, *Commission* v *Greece*, paragraph 13, and *González Sánchez*, paragraph 26, all cited in footnote 24.

28 — See Schaub, R., 'Abschied vom nationalen Produkthaftungsrecht? Anspruch und Wirklichkeit der EG-Produkthaftung', ZEuP 2003, p. 562, 570; Schroeter, U., 'Zur historischen Auslegung sekundären Gemeinschaftsrechts und deren Grenzen am Beispiel der Produkthaftungsrichtlinie', ELR 2006, p. 296, 297; Whittaker, S., 'Form and Substance in the Harmonisation of Product Liability in Europe', ZEuP 2007, p. 858, 866; Bacache, M., 'La loi nº 98-389 du 19 mai 1998, 10 ans après', Resp. civ. et assur. 2008, étude 7, paragraph 2.

in contrast to what is the case with many other directives relating to consumers. [29] The purpose of Directive 85/374 is to bring about a fair division of risks between the injured person and the producer, as is expressly confirmed inter alia in the seventh recital in the preamble. [30]

76. In this context the Court has consistently held that national consumer protection rules which go beyond the requirements of Directive 85/374 are, in the light of the complete harmonisation aimed at, contrary to the directive. [31]

77. As I have already shown, the aim of the 10-year limitation period under Article 11 of Directive 85/374 in this connection is to guarantee producers a fixed date on which their no-fault liability ends. The additional burden on the producer is not only kept in bounds as a result, the risk of liability also becomes easier to insure against. [32]

78. Those two aims can be achieved only if the start and the end of the 10-year period are

29 — In *Commission* v *France*, paragraph 18, *Commission* v *Greece*, paragraph 14, and *González Sánchez*, paragraph 27, all cited in footnote 24, the Court rightly emphasised that several directives concerning consumers expressly provide that the Member States may adopt or maintain more stringent provisions for the protection of consumers in the field covered by the directive, and thereby secure a higher level of consumer protection. Compare Article 8 of Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours (OJ 1990 L 158, p. 59), Article 8 of Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (OJ 1993 L 95, p. 29), Article 14 of Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts (OJ 1997 L 144, p. 19), and Article 8(2) of Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (OJ 1999 L 171, p. 12).

30 — According to the seventh recital in the preamble to Directive 85/374, a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances.

31 — *Commission* v *France* and *Commission* v *Greece*, both cited in footnote 24, are regarded as leading judgments. In those judgments the following were held to be contrary to the directive: the extension of the concept of damage as a result of the failure to apply the lower threshold of EUR 500 in Article 9(b) (*Commission* v *France*, paragraph 26 et seq. and *Commission* v *Greece*, paragraph 34), the unrestricted application of producer's liability to the supplier in relation to the consumer (*Commission* v *France*, paragraph 36 et seq.), and the introduction of additional conditions for the exemptions from liability under Article 7(d) and (e) (*Commission* v *France*, paragraph 42 et seq.). In later cases the following were held to be contrary to the directive: a provision under which a supplier has to take on the producer's liability in relation to the consumer (*Skov and Bilka*, cited in footnote 24; confirmed by Case C-327/05 *Commission* v *Denmark* [2007] ECR I-93) and the restriction of the possibility of the producer being freed from liability under Article 3(3) to cases in which the producer remains unidentified (Case C-177/04 *Commission* v *France* [2006] ECR I-2461).

32 — See point 47 et seq. above.

treated in the same way throughout the Community. The running of the limitation period is determined in Article 11 of Directive 85/374 on the basis of objectively ascertainable criteria: the period runs from the time when the producer puts the product into circulation, and lasts for 10 years. To prevent the laws of the Member States in relation to the suspension or interruption of limitation periods from leading to different national forms of the 10-year period, the legislature additionally laid down an exhaustive list of grounds for interrupting the limitation period in Article 11, so that only the bringing of proceedings against the producer can lead to an interruption of that period. Bringing an action against a person other than the producer does not therefore lead to an interruption of the 10-year period. [33]

79. From a systematic point of view, this exhaustive regulation of the grounds for interrupting the limitation period under Article 11 of Directive 85/374 is a very clear indication that the rights deriving from the directive which have been extinguished in accordance with Article 11 can no longer be asserted in legal proceedings, not even by means of a substitution of parties — effective in national law — in the course of proceedings that are already on foot against a supplier. If an injured person whose rights in relation to the producer have already been extinguished could make that producer a defendant in another action in which the same rights are being asserted against a supplier, a new ground for interrupting the limitation period would effectively be created: in that case the bringing of proceedings against an undertaking that was mistakenly thought to be a producer would de facto be capable of also interrupting the limitation period in relation to producers. The upper temporal limit of liability for producers in Article 11 would thereby be broken through, and that is excluded in the light of the complete harmonisation of the field which is the aim of Directive 85/374.

80. My conclusion is that a national rule under which an injured person can by means of a substitution of parties make a producer who, as a result of the expiry of the limitation period under Article 11 of Directive 85/374, is released from liability in accordance with that directive a defendant in proceedings in which claims under that directive were brought by mistake but in time against another undertaking is not compatible with Directive 85/374.

33 — In his Opinion in *O'Byrne*, cited in footnote 3, point 58, Advocate General Geelhoed rightly emphasised that the 10-year period is not interrupted if the injured person mistakenly brings proceedings against a person who is not the producer within the meaning of Article 3. Compare also Taschner, H.C. and Frietsch, E., cited in footnote 17, Art. 11 Richtl., paragraph 8, who point out that if during the proceedings it turns out that they were brought against the wrong person, the claim against the real opponent is extinguished; see also Kullmann, H.J., cited in footnote 19, p. 152.

3. Analysis of the premisses of the question referred by the House of Lords and their consequences for the application of Directive 85/374

(a) Limitation under Article 11 of Directive 85/374 and substitution of defendants before the expiry of the limitation period

81. As I have already stated, APSA submits that the assumptions on which the reference for a preliminary ruling is based, namely that APMSD is not a producer within the meaning of Article 3 of Directive 85/374 and that APSA was sued for the first time only after the expiry of the 10-year limitation period, have not yet been decided in the main proceedings. Furthermore, the Commission clearly inclines to the view that APMSD is to be classified as a producer in accordance with Article 3(3), so that it suggests that the question referred should be reformulated to take account of that circumstance.

(i) Running of the limitation period under Article 11 of Directive 85/374 in a case such as that in the main proceedings

83. Under Article 11 of Directive 85/374, the injured person's rights deriving from that directive are extinguished on the expiry of a period of 10 years from the date when the producer put the product into circulation.

82. Because the Court can provide the referring court with any information that will be of use to it in deciding the main proceedings, I shall make the two basic assumptions of the House of Lords the subject of a more detailed examination, and in so doing show how the running of the limitation period under Article 11 of Directive 85/374 is as a rule to be determined in a case such as that in the present main proceedings, and how a substitution of a producer as defendant is to be assessed in the light of the directive if the application for substitution is made before the expiry of the limitation period. I shall then discuss the consequences the classification of a supplier such as APMSD as a producer within the meaning of Article 3 of Directive 85/374 would have in a case such as that in the main proceedings.

84. The question of the determination of the precise time when a product is put into circulation was already put before the Court by the first reference for a preliminary ruling by the High Court of Justice, and was answered unambiguously in the *O'Byrne* judgment.

85. The Court held that a product is not put into circulation until 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. [34] In this context, the transfer of the product to a subsidiary company which is formally part of the distribution chain is not a putting of the product into circulation if the transfer is a purely internal transaction within the group and the producer does not thereby lose control over the product. [35]

86. If the national courts in the end confirmed in the main proceedings that APSA and APMSD were so closely linked that APMSD could not determine its conduct autonomously with regard to the vaccine in question, the vaccine supplied to APMSD would not have been put into circulation until the time when APMSD sold it to a third party.

87. In this connection it appears from the order for reference that the date on which APSA sent the vaccine to APMSD was determined very precisely in the main proceedings. The vaccine was dispatched on 18 September 1992 and reached APMSD on 22 September 1992. The precise date on which APMSD sold the vaccine to the Department of Health is not certain, on the other hand. According to the referring court, that sale took place on a date 'likely to be in late September 1992 or early October 1992'. Finally, the respondent was vaccinated with the vaccine on 3 November 1992.

88. On 16 October 2002 the respondent commenced proceedings against APSA, asserting his rights deriving from Directive 85/374.

89. If the 10-year limitation period for APSA started running only when the vaccine was transferred to the Department of Health, the precise date of the sale of the vaccine by APMSD to the Department of Health would have to be ascertained, in order to determine the starting date of the limitation period. Leaving aside the question whether in that case the 10-year limitation period in relation to APSA would not already have been interrupted by the bringing of the action against APMSD, [36] the proceedings brought against APSA on 16 October 2002 would in any event have been initiated before the expiry of the 10-year period if the vaccine was not put into circulation until a sale to the Department of Health on or after 16 October 1992. [37]

34 — *O'Byrne*, cited in footnote 3, paragraph 32.

35 — See point 39 et seq. above.

36 — See point 109 et seq. below.

37 — Although Directive 85/374 does not expressly lay down the method of calculating the limitation period, this too must — in the light of the complete harmonisation aimed at — be done uniformly throughout the Community. It would appear appropriate, in the light of the aims pursued by that directive, to adopt the method of calculation which is the basis of a number of Community acts, under which the day on which the event which starts the period running takes place is not included, in accordance with the maxim *dies a quo non computatur in termino* (see merely Articles 80 and 81 of the Court's Rules of Procedure). That would guarantee in particular that consumers can make full use of the period allowed them (see Case 152/85 *Misset* [1987] ECR 223, on Articles 80 and 81 of the Rules of Procedure of the Court of Justice). The period under Article 11 of Directive 85/374 accordingly ends in principle at the end of the day in the 10th year which bears the same number as the day on which the product was put into circulation.

90. Even if the precise time of the sale of the vaccine to the Department of Health which started the period running could no longer be ascertained, but could merely be confined to the period between 22 September 1992 — the date when the vaccine was received by APMSD — and 3 November 1992 — the vaccination of the respondent — the bringing of the action against APSA on 16 October 2002 would in any case have interrupted the limitation period in good time. If APSA put forward a limitation defence, it would have to prove the date of putting the vaccine into circulation. [38] If APSA as producer could merely confine that date to a certain period starting more than 10 years before the date of bringing proceedings but ending less than 10 years before that date, APSA as producer would bear the burden of proving and the associated risk of not proving the precise point at which time started running. [39] In the absence of a precise determination of the time of putting into circulation, the proceedings of 16 October 2002 would in such a case too have been brought against APSA in time in any event, thus interrupting the limitation period against APSA.

(ii) Possibility of substituting the producer as a party before the expiry of the limitation period under Article 11 of Directive 85/374

91. Directive 85/374 is silent as to what procedural rules are to be applied when an injured person wishes to put forward claims under that directive against a producer. If national procedural law provides for the possibility of replacing the defendant in an already pending action by another defendant, and thereby asserting against the new defendant the rights that have been claimed, such a substitution of defendants must in principle be regarded as a permissible form of bringing proceedings against the producer.

92. As long as the limitation period under Article 11 of Directive 85/374 has not yet expired, the producer can therefore, by means of a substitution — valid under national procedural law — of defendants, be made a party to other proceedings in which claims for damages based on product liability have been brought by mistake against another undertaking.

38 — See Taschner, H.C. and Frietsch, E., cited in footnote 17, Art. 11 Richtl., paragraph 4; Dommering-van Rongen, L., cited in footnote 13, p. 173.

39 — See Schmidt-Salzer, J., *Kommentar EG-Richtlinie Produkthaftung*, Vol. 1, Heidelberg, 1986, Art. 11, paragraph 14; Borghetti, J.-S., cited in footnote 15, paragraph 512, p. 492, especially footnote 271; Graf von Westphalen, F., cited in footnote 13, § 79, paragraph 17.

93. The same must apply where the injured person has interrupted the limitation period under Article 11 of Directive 85/374 by bringing a separate action against the producer. Since the effect of this interruption of the limitation period goes beyond the specific proceedings, it would be compatible with Directive 85/374 if the producer, following the first action, could by means of a substitution of parties — valid under national procedural law — be made a defendant in another action in which the same claims had been brought by mistake against another undertaking.

(b) Consequences of classifying a supplier as a producer within the meaning of Article 3 of Directive 85/374

94. It is apparent from the submissions of the parties and the information in the documents in the case that the national courts have not yet ruled in the main proceedings on the classification of APMSD as a producer within the meaning of Article 3 of Directive 85/374. Against that background, I shall now address the conditions for and consequences of classifying a supplier such as APMSD as a producer within the meaning of the first half of Article 3(1) or Article 3(3) of the directive.

(i) Classification of a supplier as a producer within the meaning of the first half of Article 3(1) or Article 3(3) of Directive 85/374

95. According to the functional interpretation of the concept of producer on which the Court based its judgment in *O'Byrne*, an entity which distributes a product falls within the concept of producer *stricto sensu* within the meaning of the first half of Article 3(1) of Directive 85/374 if the producer and the supplier are so closely linked that the producer, after transferring the product to the supplier, retains de facto control over the product transferred. [40] If the national courts were ultimately to find in the main proceedings that there was such a close link, APMSD would consequently have to be regarded, together with APSA, as a producer within the meaning of the first half of Article 3(1) of Directive 85/374.

96. Moreover, under Article 3(3) of Directive 85/374, any supplier of a product is treated as its producer if the producer cannot be identified and the supplier does not inform the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product.

97. Classification of a supplier as a producer within the meaning of Article 3(3) of Directive 85/374 is thus a possibility in cases in which the injured person was unable to

40 — See point 39 et seq. above.

establish the identity of the producer within the meaning of Article 3(1) of the directive. In view of the clear wording of that provision, however, mere ignorance of the identity of the producer is not enough. The injured person must additionally show that he was not able to ascertain the identity of the producer. [41] The directive leaves open the reason why the producer is not known to the injured person, so that it is for the national courts to decide whether the producer of the product could or could not have been identified in the particular circumstances of the case. [42]

98. The application of Article 3(3) of Directive 85/374 also presupposes that the supplier has not informed the injured person within a reasonable time of the identity of the producer or his own supplier. Although the directive says nothing further as to how the period within which the supplier must answer is to be calculated, it may be assumed that that period starts to run from the time when the injured person raises claims under the directive against the supplier. To prevent a supplier from making it more difficult or even — in view of the expiry of the 10-year limitation period — completely impossible for the injured person to bring proceedings against the producer, by delaying the identification of the producer, it must be assumed that the period in which the supplier must identify the producer or his own supplier runs at the latest from the time when the injured person formally demands compensation from the supplier by reference to the product liability rules, whether by a formal demand or by bringing judicial proceedings. The period will start to run only if the demand is sufficiently specific with respect to the product.

99. A supplier can avoid being classified as a producer under Article 3(3) of Directive 85/374 only by identifying the producer or his own supplier. If the supplier is aware of the identity of the producer or of his own supplier, the statement that he is not himself a producer is not enough to release him from liability. Rather, the supplier is required, even without being requested to do so by the injured person, to communicate all the necessary information within the reasonable time. [43]

41 — See only Dommering-van Rongen, L., cited in footnote 13, pp. 92 and 93.

42 — It will usually be a case of unlabelled products or products with no accompanying information on the packaging or in instructions for use; see Taschner, H.C. and Frietsch, E., cited in footnote 17, Art. 3 Richtl., paragraph 24.

43 — See Tascher, H.C. and Frietsch, E, cited in footnote 17, Art. 3 Richtl., paragraph 28; Dommering-van Rongen, L., cited in footnote 13, p. 93. Problematic in this context are national transposing provisions which require a request to identify the producer or the supplier's own supplier, such as Paragraph 4(3) of the German Produkthaftungsgesetz (reply within one month from the request for identification), section 2(3) of the English Consumer Protection Act 1987 (reasonable time from the request for identification), or section 2(3) of the Irish Liability for Defective Products Act 1991 (reasonable time from the request for identification). See Hodges, C.,'Product liability of suppliers: the notification trap', ELRev 2002, 27(6), p. 758, 764.

(ii) Consequences of classifying a supplier as a producer within the meaning of the first half of Article 3(1) or Article 3(3) of Directive 85/374

100. If in the main proceedings the national courts were ultimately to reach the conclusion that APMSD should be classified as a producer within the meaning of the first half of Article 3(1) or Article 3(3) of Directive 85/374, APMSD would, in accordance with the provisions of that directive, be liable as producer for the damage caused by a defect in the vaccine.

101. In view of the fact that the injured person brought proceedings against APMSD on 2 November 2000 on the basis of product liability and served the particulars of claim on 1 August 2001, the limitation period under Article 11 of Directive 85/374 would have been interrupted, in relation to APMSD, in good time.

102. Moreover, such a classification of APMSD as a producer would not rule out the bringing of proceedings additionally against APSA. In the event of claims under the directive being brought against several producers, Article 5 of the directive expressly provides that they are jointly and severally liable to the injured person, without prejudice to the provisions of national law concerning rights of contribution or recourse.

103. It would have to be borne in mind, however, that bringing proceedings against one of several producers within the meaning of Article 3 of Directive 85/374 interrupts the limitation period under Article 11 of the directive in principle only in relation to the producer against whom the proceedings are brought. However, even in this limitation context, the consequences of the functional interpretation of the concept of producer within the meaning of the first half of Article 3(1) of Directive 85/374 must not be disregarded. [44]

104. Although in accordance with the scheme of Directive 85/374 all producers who are involved in the manufacturing process are jointly and severally liable to the consumer if the finished product is defective, the limitation period in Article 11 of the directive is in principle to be ascertained separately for each producer involved.

105. In its written observations, the Commission proposes a different interpretation, according to which the bringing of proceedings against a supplier who is to be classified as a producer within the meaning of Article 3(3) of Directive 85/374 could interrupt the limitation period under Article 11 in relation to a producer within the meaning of the first half of Article 3(1). Such an interpretation, however, would have the effect that bringing proceedings against a producer within the meaning of Article 3 would interrupt the running of the 10-year limitation period against all other producers within the

44 — See point 109 et seq. below.

meaning of Article 3. That approach runs counter to the aims of Directive 85/374, ignores the case-law of the Court, and was qualified by the Commission at the hearing.

106. It should be pointed out, first, that in *O'Byrne* the Court, in interpreting the putting into circulation which sets the limitation period running, focused on the manufacturing process operated by a specific producer for a specific product. In this connection a producer of a component part or a supplier to be classified as a producer (of a component part) who sells his component part to another producer of a component part or of the finished product as a rule puts it into circulation, so that his limitation period under Article 11 of the directive starts to run from that time. [45] If several producers or suppliers to be classified as producers form part of a chain of value creation, the time when the limitation period starts running must be ascertained separately for each producer. If, then, proceedings brought against one producer or supplier to be classified as a producer interrupted the limitation period in relation to all the other producers and suppliers to be classified as producers involved, regardless of whether they were ever made parties to the proceedings or even became aware of them, that could scarcely be reconciled with the approach followed in *O'Byrne* of examining the particular individual case.

107. In addition, it should be remembered that the 10-year limitation period under Article 11 of Directive 85/374 is basically intended to guarantee producers a fixed end date for their no-fault liability. [46] That temporal limitation of liability is also based on considerations of proof, since the defences for the producer of the component or finished product provided for in Article 7(e) (development risk) and (f) (non-defective component) require proof relating to the state of the product at the time of putting into circulation. Because producers bear the burden of proof and the risk of failure to prove, while the defence becomes more and more difficult to prove with the passing of time, it would run counter to the balance of interests struck by Directive 85/374 if the 10-year limitation period for all producers involved in a chain of value creation could be interrupted by the bringing of proceedings against another producer or supplier to be classified as a producer, and consequently without their knowledge, especially as such proceedings can be particularly long drawn out.

108. In my opinion, the bringing of proceedings in due time against a supplier cannot therefore have the effect of interrupting the limitation period in relation to a producer within the meaning of Article 3(1) of the directive, even if the national courts were to take the view that the supplier should be classified as a producer within the meaning of Article 3(3) of the directive.

45 — See on this point Graf von Westphalen, F., cited in footnote 13, § 79 paragraph 18; Kullmann, H.J., cited in footnote 19, p. 151; Wuyts, D., cited in footnote 17, paragraph 41; Dommering-van Rongen, L., cited in footnote 13, pp. 173 and 174; and van Empel, M. and Ritsema, H.A., cited in footnote 17, p. 83.

46 — See point 47 et seq. above.

109. If, by contrast, the national courts were to reach the conclusion in the main proceedings that a supplier such as APMSD was, because of its involvement in the manufacturing process operated by APSA, to be regarded together with APSA as a producer within the meaning of the first half of Article 3(1) of Directive 85/374, the bringing of proceedings in due time against APMSD would indeed have the effect of interrupting the limitation period in relation to APSA.

110. The decisive point here is the fact that a supplier who is sufficiently closely involved in the manufacturing process operated by the producer is to be classified together with the producer as a producer within the meaning of the first half of Article 3(1) of the directive. Because those two entities are to be regarded, in the light of the functional interpretation of the concept of producer, as one producer within the meaning of the first half of Article 3(1), the limitation period must also run in the same way for both entities.

111. In this connection the Court in *O'Byrne*, after carefully weighing up the interests of consumers and producers, synchronised the starting point of the 10-year limitation period under Article 11 of Directive 85/374 for the producer *stricto sensu* and the supplier who forms part of the manufacturing process by reference to the date on which the supplier puts the product into circulation. In the context of the same balancing of interests, the running of the limitation period must also be uniform.

112. Since the running of the limitation period under Article 11 of the directive is interrupted only by the bringing of proceedings, a uniform limitation period for the producer and supplier who are to be regarded together as a producer within the meaning of the first half of Article 3(1) presupposes that the bringing of proceedings against the supplier interrupts the running of the 10-year limitation period not only in relation to that supplier but also in relation to the producer in whose manufacturing process the supplier is involved.

113. Accordingly, my conclusion is that classification — to be assessed by the national courts — of the supplier of a product as its producer has the consequence that that supplier is liable under Article 1 of the directive for the damage caused by a defect in the product, regardless of whether he is classified as a producer within the meaning of Article 3(1) or a producer within the meaning of Article 3(3) of the directive. Classification of a supplier as a producer within the meaning of the first half of Article 3(1) of the directive has the further consequence that the 10-year limitation period for the producer in whose manufacturing process the supplier is involved does not start to run until the time when the supplier puts the product into circulation. At the same time, proceedings brought against that supplier will in that case

interrupt the running of the limitation period under Article 11 of the directive in relation also to the producer in whose manufacturing process the supplier is involved.

released from liability as a result of the expiry of the limitation period under Article 11 of the directive.

4. Summary

114. In the light of the above considerations, I conclude that a substitution of parties, valid under national procedural law, by which a producer is substituted as a defendant in proceedings concerning claims under Directive 85/374 constitutes a form of bringing proceedings against that producer which is compatible with that directive, provided that the producer was not, at the time of the application for substitution of parties,

115. If the national courts were in addition to reach the conclusion in the main proceedings that APMSD should be classified as a producer within the meaning of the first half of Article 3(1) or Article 3(3) of Directive 85/374, APMSD would also be liable under Article 1 of the directive for the damage caused by a defect in the product. Classification of APMSD as a producer within the meaning of the first half of Article 3(1) would have the further consequence that the bringing of proceedings against APMSD would interrupt the running of the limitation period under Article 11 of the directive in relation also to APSA, in whose manufacturing process APMSD was involved.

VII — **Conclusion**

116. I therefore propose that the Court should give the following answer to the House of Lords:

A national rule which, in the context of an action concerning claims brought under 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, allows the defendant supplier to be replaced by the producer by

means of a substitution of parties is compatible with that directive, provided that the producer was not, at the time of the application for substitution of parties, released from liability as a result of the expiry of the limitation period under Article 11 of Directive 85/374.

If a supplier is to be classified as a producer within the meaning of Article 3 of Directive 85/374, he is liable under Article 1 of that directive for the damage caused by a defect in the product. Classification of the supplier as a producer within the meaning of the first half of Article 3(1) of Directive 85/374 has the further consequence that the bringing of proceedings against that supplier interrupts the running of the limitation period under Article 11 of that directive in relation also to the producer in whose manufacturing process the supplier is involved.