OPINION OF ADVOCATE GENERAL LÉGER

delivered on 2 October 1997 *

1. The High Court of Justice, Queen's Bench Division, has referred to the Court for a preliminary ruling three questions on the interpretation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1] ('the directive').

Legal framework

Community law

Directive 91/414

2. In substance, the Court is asked to determine whether the provisions of that directive are to be interpreted as meaning that they permit a Member State to authorise the importation into its own territory of a plant protection product (or, hereinafter, 'the product') coming from a State belonging to the European Economic Area ('an EEA State') or from a third country on account of its 'identicality' with a product already authorised in that Member State and to provide for the issue of a marketing authorisation for the imported product following a 'simplified' authorisation procedure. In other words, the questions put to the Court concern the Community legislation applicable in the matter of marketing authorisations for parallel imported plant protection products.

3. The purpose of Directive 91/414/EEC is to lay down uniform rules on the conditions and procedures for the granting of marketing authorisations for plant protection products.

4. Its main aim is to protect humans, animals and the environment against the risks and hazards of the uncontrolled use of those products. [2] It is further intended to eliminate the barriers to the free movement of those goods. [3]

* Original language: French.

1 — OJ 1991 L 230, p. 1.

2 — Fourth, ninth and tenth recitals.

3 — Fifth and sixteenth recitals.

5. To that end, the Community legislature adopted provisions designed to harmonise national rules governing the conditions and procedures for the granting of marketing authorisation for plant protection products. [4]

6. Article 1(1) provides: 'This directive concerns the authorisation, placing on the market, use and control within the Community of plant protection products in commercial form and the placing on the market and control within the Community of active substances intended for a use specified in Article 2(1).'

7. Article 2 defines the various terms relevant to the application of the directive. Thus, Article 2(1) states that 'plant protection products' means 'active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user' and which are intended for specific uses. Article 2(4) defines 'active substances' as 'substances or micro-organisms including viruses, having general or specific action ... against harmful organisms or ... on plants, parts of plants or plant products'. Article 2(5) provides that 'preparations' are 'mixtures or solutions composed of two or more substances of which at least one is an active substance, intended for use as plant protection products'. Article 2(10) states that 'placing on the market' corresponds to 'any supply, whether in return for payment or free of charge, other than for storage followed by consignment from the territory of the Community or disposal. Importation of a plant protection product into the territory of the Community shall be deemed to constitute placing on the market for the purposes of this Directive'. Article 2(11) provides that 'authorisation of a plant protection product' is the 'administrative act by which the competent authority of a Member State authorises, following an application submitted by an applicant, the placing on the market of a plant protection product in its territory or in a part thereof'.

8. According to Article 3(1) of the directive, the Member States must prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with the directive, except where the intended use is covered by Article 22. [5] It is apparent from the order for reference that Article 22 is not relevant to the present case.

9. Article 4 of the directive provides for the conditions which a plant protection product must satisfy in order to be authorised. In particular, its active substances must be included in the list in Annex I.

4 — Sixth and seventh recitals.

5 — This provision concerns the procedure which the Member States must follow in order to authorise experiments or tests for research or development purposes involving the release into the environment of an unauthorised plant protection product.

10. The conditions for inclusion of the active substances in Annex I are set out in Articles 5 and 6 of the directive. Article 5(1) points out, in particular, that an active substance may only be included in Annex I if, *in the light of current scientific and technical knowledge*, it may be expected that plant protection products containing the active substance will fulfil certain conditions. [6]

11. *No active substance has yet been included in Annex I.*

12. Until a list of authorised active substances is adopted, transitional and derogating measures have been established by Article 8 of the directive for obtaining, reviewing and withdrawing marketing authorisations for those products, a provision which is relevant to this case. I will return to it later.

13. The first subparagraph of Article 9(1) of the directive provides: 'Application for (marketing) authorisation of a plant protection product shall be made by or on behalf of the person responsible for first placing it on the market in a Member State to the competent authorities of each Member State where the plant protection product is intended to be placed on the market'. Article 9(2) stipulates that every applicant is required to have a permanent office within the Community.

14. Article 10 of the directive [7] concerns the mutual recognition [8] by the Member States of marketing authorisations for plant protection products. The first and second indents of Article 10(1) provide that a Member State to which an application is made for a marketing authorisation of a plant protection product already authorised in another Member State must:

'— *refrain from requiring the repetition of tests and analyses already carried out* in connection with the authorisation of the product in that Member State, and to the extent that agricultural, plant health and environmental (including climatic) conditions relevant to the use of the product are comparable in the regions concerned,

and

— to the extent that the uniform principles have been adopted in accordance with

6 — Thus, emphasis is laid, in Article 5(a) and (b) of that provision, on the residues and use of those active substances, consequent on application consistent with good plant protection practice, not having any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

7 — Emphasis added.

8 — See the sixteenth recital.

Article 23, [9] where the product contains only active substances listed in Annex I, *also authorise the placing of that product on the market in its territory*, to the extent that agricultural, plant health and environmental (in particular climatic) conditions relevant to the use of the product are comparable in the regions concerned'.

The relevant national law

The 1994 Control Arrangements

15. Restrictions and exceptions to the principle of mutual recognition are strictly defined by Articles 10 and 11 of the directive.

16. Annex II to the directive relates to the requirements for the dossier to be submitted for the inclusion of an active substance in Annex I, and Annex III to the requirements to be fulfilled for the dossier to be submitted for the marketing authorisation of a plant protection product.

17. As stated above, the list of active substances included in Annex I has not yet been drawn up. Accordingly, the provision for the automatic recognition by a Member State of those products already authorised by another Member State is not yet applicable.

18. The 1994 Control Arrangements, [10] which entered into force on 14 March 1994, were drawn up pursuant to the Control of Pesticides Regulations 1986, [11] introduced on 6 October 1986. The 1994 Control Arrangements extended the previous system, which only concerned parallel imports coming from the Member States, to cover those *coming from countries which are not members of the European Community*. They maintain the provision under which it is for the parallel importer to certify that the imported product is identical to the master product.

19. Furthermore, that legislation provides, in substance, that no person may advertise, sell, supply, store or use pesticide product in the United Kingdom unless the Ministers have jointly given in respect of it a provisional or full approval under Regulation 5 of the Control of Pesticides Regulations and all relevant conditions are complied with.

9 — That is a year after the date of notification of the directive.

10 — Otherwise hereinafter referred to as 'the national legislation at issue'.

11 — S. I. No 1510.

20. *Master product* is defined as being a United Kingdom approved product to which identicality is claimed and which is not itself a parallel import. Moreover, *an imported product* is *deemed to be identical to a master product* if the active substances in the imported product and the master product are manufactured by the same company (or by an associated undertaking or under licence) and are the same within certain limits. Those products are also deemed to be identical if the formulation of the imported product and that of the master product is produced by the same company (or by an associated undertaking or under licence) and any differences in the nature, quality and quantity of the components are deemed by the authority responsible for issuing marketing authorisations to have no material effect on human and animal health, on the environment generally or on the efficacy of the product. Finally, where the imported product is manufactured under licence, information on its source and specification may be required to prove identicality with the master product.

21. Clause 6 provides that the file to be submitted in support of an application for marketing authorisation must contain, first, a covering letter giving the name of both the master product and the imported product and the type of approval sought and, secondly, evidence that the product to be imported is identical, according to specific criteria, to the United Kingdom master product. This may either be a sample of the original label of the product to be imported or a copy of the label of the product for which the importer is seeking approval to import.

22. Clause 9 provides that the authority responsible for marketing authorisations may require the provision of such additional information as it considers necessary in support of an application.

Facts and procedure

23. The British Agrochemicals Association Limited ('the applicant') is a limited company which currently represents 39 members of the agrochemical manufacturing industry. It challenges, before the national court, the legality of the 1994 Control Arrangements governing the issuing of marketing authorisations for imported pesticides. The action is directed against the Ministry of Agriculture, Fisheries and Food ('MAFF'), which is responsible, in particular, for the safety of pesticides marketed in or imported into the United Kingdom.

24. In support of its application, the applicant claims that the 1994 Control Arrangements are in breach of the directive by allowing an imported product onto the market on the basis that it is identical to a master product already approved in the United Kingdom following tests, even though the components of the master product differ in their nature, quality and quantity from the imported product. It submits that the directive does not provide for the issuing of a marketing authorisation following a speedy procedure on the ground that the formulation of the master product and the imported product is identical. Rather, the directive puts in place a

rigorous and binding system which assumes that all marketing authorisations are issued after checking the safety, quality and efficacy of the plant protection product by means of properly documented tests, analyses and trials.

25. MAFF, for its part, considers that the issuing of marketing authorisations for plant protection products which have been the subject of a parallel import is not governed by the provisions of the directive. Articles 3, 4 and 9 of the directive harmonise only the rules relating to applications for authorisation to place such products on the market *for the first time*. On the other hand, that elaborate procedure is not gone through where those products are already authorised. The 1994 Control Arrangements thus do no more than provide a simplified way of allowing onto the United Kingdom market imported products that are identical to master products already approved in the United Kingdom and available on the United Kingdom market. They do not call in question in any way the rigorous and binding system put in place by the directive since the purposes of the two instruments are different.

26. The national court considered that the solution of the dispute required an interpretation of the relevant Community provisions and referred the following questions to the Court of Justice for a preliminary ruling:

'1. Does Directive 91/414/EEC of 15 July 1991 as amended allow a Member State to permit the placing on the market of a plant protection product imported from another EEA State or from a third country because the Member State considers that product to be identical to a master plant protection product which has already been authorised by that Member State pursuant to Article 4(1) or 8(2) of the directive, when the imported product is deemed to be identical to the master product if:

(i) the active ingredient in the imported product is manufactured by the same company (or by an associated undertaking or under licence) as the active ingredient of the master product and is the same within variations accepted by the registration authority; and

(ii) the formulation of the imported product is produced by the same company (or by an associated undertaking or under licence) as that of the master product and any differences in the nature, quality and quantity of the components are deemed by the registration authority to have no material effect on the safety of humans, domestic animals, livestock, wildlife or the environment generally or on efficacy?

2. Does Directive 91/414/EEC of 15 July 1991 permit a Member State to allow a plant protection product imported from another EEA State or from outside the EEA onto the market as identical (as defined in 1 above) to a master product without any analysis of the actual contents of the imported product prior to placing on the market?

3. If the answer to 1 above is in the affirmative, does Article 9(2) of Directive 91/414/EEC of 15 July 1991 permit a Member State to allow a plant protection product imported from countries outside the EEA onto the market when the importer or person placing the product on the market is a person without a permanent office within the EEA?'

The first and second questions

27. By its first question, the national court is asking the Court, first, to *determine whether*, in the present case, *Articles 4 and 8 of the directive concern the parallel import procedure.* In order to do so the scope of those provisions must first be defined. Secondly, the Court must *state whether*, in the present case, *Community law precludes the criteria chosen by the national legislation at issue in order to establish whether an imported product is 'identical' to a master product.*

28. The second question clarifies Question 1(ii). It is a question of determining whether the authority competent for the issuing of marketing authorisations for plant protection products may authorise a product imported from an EEA State or a third country to be placed on the market on the basis that the components of the imported and master products are identical — according to pre-established criteria — without any previous comparative tests on those components.

29. Although the national court does not make it clear, I assume that the imported product was duly placed on the market of the State of origin. [12]

1. *Scope of Articles 4 and 8 of the directive*

A — *States subject to the directive*

30. Since, in principle, only the Member States are bound by the directive, the rules applicable to trade between the Community and third countries are governed, on the one hand,

12 — Otherwise, contrary to what is unanimously accepted by the national court and the various interveners, in particular in the replies to the questions put by the Court, it would not be a case of a parallel import which presupposes that the imported product has been marketed on the market of the State of origin, that is to say was authorised to be sold.

by Article 110 and the first paragraph of Article 234 of the EC Treaty [13] and, on the other, by the international agreements to which the Community has acceded, such as the General Agreement on Tariffs and Trade ('GATT'), [14] and the Agreement on the European Economic Area ('EEA Agreement') adopted by Decision 94/1/ECSC, EC of the Council and the Commission of 13 December 1993. [15]

31. So far as concerns the EEA States, Article 8(1) of the EEA Agreement provides: 'The free movement of goods between the contracting parties shall be established in conformity with the provisions of this agreement'.

32. Annex II of the EEA Agreement, [16] which deals with technical regulations, standards, testing and certification, was revised by Decision of the EEA Joint Committee No 7/94 of 21 March 1994 amending Protocol 47 and certain Annexes to the EEA Agreement [17] (hereinafter 'Decision No 7/94'), which entered into force on 1 July 1994, [18] which expressly provides that Council Directive 91/414, amended by Commission Directive 93/71/EEC of 27 July 1993, [19] is applicable throughout the EEA.

33. Finally, after 1 July 1994, the issuing within an EEA State of a marketing authorisation for a plant protection product is subject to the strict observance of the requirements of the directive.

34. There could be a problem for the national court in deciding which law is applicable at the relevant time. It is for the national court to determine, in accordance with its own domestic law and all the evidence before it, under which body of provisions the case before it must be decided.

35. Two possibilities are open to it:

— it can consider that Decision No 7/94 is applicable; in that case, since the situation of a product imported in parallel from an EEA State or from a Member State is

13 — See, in particular, Joined Cases 21/72 to 24/72 *International Fruit Company and Others* v *Produktschap voor Groenten en Fruit* [1972] ECR 1219: 'in so far as under the EEC Treaty the Community has assumed the powers previously exercised by Member States in the area governed by the General Agreement [on Tariffs and Trade], the provisions of that agreement have the effect of binding the Community' (paragraph 18), and also Joined Cases 37/73 and 38/73 *Diamantarbeiders* v *NV Indiamex et Association de fait De Belder* [1973] ECR 1609, paragraphs 5 to 9.

14 — Council Decision 80/271/EEC of 10 December 1979 concerning the conclusion of the Multilateral Agreements resulting from the 1973 to 1979 trade negotiations, which are applicable in the present case (OJ 1980 L 71, pp. 1 and 90). That decision was replaced by Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ 1994 L 336, p. 1).

15 — Decision on the conclusion of the Agreement on the European Economic Area between the European Communities, their Member States and the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation (OJ 1994 L 1, p. 1).

16 — Cited above, p. 263.

17 — OJ 1994 L 160, p. 1.

18 — Articles 2 and 3 of Decision No 7/94.

19 — OJ 1993 L 221, p. 27.

identical, the rules which govern the parallel import of a product coming from a Member State will also apply to the parallel importation of a product coming from an EEA State ('Possibility One');

— it can consider that Decision No 7/94 is not applicable; in which case, since the situation of a product imported in parallel from an EEA State is comparable to that of a product imported in parallel from a third country, the principles governing international trade relations, contained in the Treaty and international agreements, such as the GATT Agreements, will, as I stated above, be applicable rather than the provisions of the directive ('Possibility Two').

B — *Scope* rationae materiae

(a) Possibility One

36. As we have seen, Article 3(1) of the directive provides: 'Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with this Directive ...'.

37. For a transitional period and until Annex I establishing the list of active substances which the Community permits to be included in plant protection products is drawn up, those requirements may be found in Article 8.

38. Article 8(1) of the directive provides that the Member States may 'authorise, for a provisional period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market two years after notification of this Directive ...'. Article 8(2) states essentially that 'a Member State may, during a period of 12 years following the notification of this Directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive'.

39. Finally, I would again point out that the first paragraph of Article 9(1) of the directive mentions, moreover, that the application for the marketing authorisation for plant protection products must be made *by or on behalf of the person responsible for first placing it on the market in a Member State* to the competent authorities of each Member State where the plant protection product is intended to be placed on the market.

40. It is clear from the wording itself of those provisions — as the law stands at present — [20] that *those full, detailed and therefore necessarily binding procedures relate only to a first application to place on the market a plant protection product not yet authorised in the Member State in which marketing authorisation is sought.*

41. That reading is, moreover, in keeping with the dual objective pursued, which is to ensure that a product placed on the market is completely *safe* and to facilitate the free movement of goods.

42. Nevertheless — *and I must stress this point* — the system put in place rests on the assumption that *each Member State will observe strictly and scrupulously all the provisions of the directive.*

43. I consider that, in this regard, the judgment in *Scotia Pharmaceuticals* is perfectly capable of being transposed to the present case. [21] In that case, it was necessary to examine Community legislation concerning marketing authorisations for medicinal products for human use [22] and to determine the extent of the discretion reserved to the competent national authorities.

44. The Court, having regard to the essential aim of that legislation — *namely the placing on the market of a medicinal product whose efficacy, harmlessness and quality are proven* —, ruled that the competent national authority *does not have any discretion to relax or derogate from the conditions laid down by Directive 65/65.* [23]

45. Given the manifold aims of the legislation on medicinal products, [24] the Court thus chose to give priority to the aim of protecting public health.

46. Faced with a comparable choice — the free movement of goods and the probable risks to public health — the Court confirmed the position taken in the *Scotia Pharmaceuticals* case in the order which it made on 12 July 1996 in *United Kingdom* v *Commission.* [25] The United Kingdom had asked the Court to make an interim order suspending the operation of Commission Decision 96/239/EC of 27 March 1996 on emergency

20 — See points 11 and 17 of this Opinion.

21 — Case C-440/93 *R* v *Licensing Authority of the Department of Health, ex parte Scotia Pharmaceuticals* [1995] ECR I-2851.

22 — Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20).

23 — *Scotia Pharmaceuticals*, cited above, paragraph 24.

24 — See, on that point, my arguments in *Scotia Pharmaceuticals*, cited above, and in Case C-201/94 *Smith & Nephew and Primecrown* (hereinafter referred to as 'the judgment in *Smith & Nephew*') [1996] ECR I-5819.

25 — Case C-180/96 R [1996] ECR I-3903.

measures to protect against bovine spongiform encephalopathy ('BSE'). [26] That decision prohibits the United Kingdom from exporting to the other Member States and to third countries cattle and products obtained from bovine animals because of the risk they pose for public health.

47. The United Kingdom maintained, in particular, that there was no scientific basis for the ban on exports (paragraph 47 of the order).

48. The Court observed that, even though it was not absolutely certain that BSE could be transmitted to human beings, there existed a serious risk. Accordingly, the Court refused to grant the application, pointing out that the interests of the protection of public health (paragraphs 89, 90 and 92) had to prevail over other considerations, in particular, the principle of the free movement of goods within the Community. The Court underscored the fact that 'it cannot but recognise the paramount importance to be accorded to the protection of health' (paragraph 93 of the order).

49. That having been said, assuming that each Member State observes *strictly* those requirements with regard to the granting of marketing authorisations for plant protection products, the marketing authorisation granted for such products under a harmonised procedure is a guarantee of safety, efficacy and quality throughout the Community. There can therefore be no justification for restricting the free movement of those products.

50. That is why Article 10 of the directive [27] provides for the mutual recognition of authorisations. Nevertheless, as the law now stands, [28] that principle is not altogether applicable.

51. In the light of the preceding arguments, since the procedures laid down in both *Articles 4 and 8 of the directive* apply only *where a plant protection product being placed on the market for the first time* is not yet authorised in the Member State in which marketing authorisation is sought, I consider that the *practical effect of the directive* would be *undermined if those procedures* had to be used each time a marketing authorisation is sought for *a product displaying properties and characteristics identical to those of a product already authorised by that Member State.* To decide otherwise would amount to requiring the issuing of two marketing authorisations for the same product, contrary to the wording and objectives of the directive.

26 — OJ 1996 L 78, p. 47.

27 — Set out in point 14 of this Opinion.

28 — *Ibidem*, points 11 and 17.

52. Apart from the reasoning based on the analysis of the provisions of the directive and of its aims, I consider that the decision of the Court in *Smith & Nephew*, cited above, is perfectly capable of being transposed to the present case.

53. In *Smith & Nephew*, the Court was asked to interpret the provisions of Directive 65/65, as amended by Council Directive 87/21/EEC, [29] relating to the conditions to be fulfilled and the procedure to follow in order to obtain a marketing authorisation for a medicinal product for human use. In particular, the Court was asked whether — *in circumstances similar to those of the present case* — the mandatory provisions laid down by Directive 65/65 also applied to applications for marketing authorisations for parallel imports of medicinal products from other Member States. [30]

54. The Court observed that the primary purpose of Directive 65/65 was to ensure that 'when a proprietary medicinal product is marketed, *public health is safeguarded* by means which cannot hinder the development of the pharmaceutical industry or trade in medicinal products within the Community' [31] and that, to that end, it 'requires that a series of documents as well as precise, detailed information be produced as a pre-condition to the granting of a marketing authorisation, *even where the proprietary medicinal product in question is covered by a marketing authorisation granted by the competent authority of another Member State*'. [32]

55. Subsequently, on the basis of the *De Peijper* case, [33] the Court stated that the objective of safeguarding public health '... justifies such stringent measures only in regard to proprietary medicinal products which are being put on the market for the first time', [34] and concluded that 'the provisions of Directive 65/65 concerning the procedure for issue of marketing authorisations cannot apply to a proprietary medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a *parallel import* of a product already covered by a marketing authorisation in that other Member State. In such a case, the imported proprietary medicinal product cannot be regarded *as being placed on the market for the first time in the Member State of importation*'. [35]

(b) Possibility Two

56. So far as third countries are concerned, not only does the directive not apply in their territory, but no harmonisation of the conditions for granting marketing authorisations

29 — Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36).

30 — Judgment in *Smith & Nephew*, cited above, paragraph 19.

31 — *Ibidem*, emphasis added.

32 — *Ibidem*, emphasis added.

33 — Case 104/75 *De Peijper* [1976] ECR 613.

34 — *Smith & Nephew*, paragraph 20.

35 — *Ibidem*, paragraph 21, emphasis added.

for plant protection products has been carried out at international level in the context of the GATT Agreements.

57. The procedure for the issue of marketing authorities laid down in Articles 4 and 8 of the directive cannot therefore be applied as far as Possibility Two is concerned.

58. In conclusion, as far as the first part of the first question is concerned, I submit that the marketing authorisation procedures provided for by Articles 4 and 8 of the directive are not applicable to the factual situation referred to by the national court.

59. The national court's questions concern the interpretation of the directive's provisions. If I were to restrict myself to the wording of those questions, and conclude that the procedures for granting marketing authorisations for plant protection products have no bearing on parallel imports, I could not go any further in examining the questions.

60. However, the Court has consistently held that the nature of the preliminary ruling procedure is based on the assumption that the Court takes account of the real purpose of the questions raised by the national court, as it emerges from an analysis of the order for reference, and is not strictly limited by their wording. [36]

61. It seems to me that, by its questions, the national court is seeking to ascertain whether, beyond the directive, Community law and, in particular, the rules relating to the free movement of goods within the Community preclude provisions such as those specified by the national court.

2. The Community law criteria enabling parallel imports of plant protection products to be placed on the market

(a) Possibility One [37]

62. The *De Peijper* case, cited above, provides some guidance for the national court. In that case, the Court was asked, first, whether the provisions which make the granting of marketing authorisations for plant protection products for human use subject to the production of the same particulars and analyses as those enabling a national authority to issue a marketing authorisation for a master product, in order to ascertain *that the product parallel imported from* a Member State and

36 — See, in particular, Case 16/65 *Schwarze* v *Einfuhr- und Vorratsstelle Getreide* [1965] ECR 877.

37 — See point 36 of this Opinion.

the master product were identical, derogated from the rules on the free movement of goods within the Community and in particular from Article 36 of the Treaty. Secondly, the criteria which the imported products were to meet in order to be adjudged identical to the master product were to be examined in the same way. As we see, the circumstances which the Court was called upon to consider are comparable to Possibility One.

63. The Court held that the public health objective cannot be legitimately relied upon by a national authority in support of restrictive measures adopted against pharmaceutical products coming from other Member States where *the master products and the imported products are identical in every respect.* The criteria enabling such identicality to be found were laid down in that judgment.

64. The Court thus stated that parallel importation involves '*a pharmaceutical product prepared in accordance with a uniform method of preparation and qualitative and quantitative composition ... in every respect similar to a product in respect of which the public health authorities of the Member State into which the first product has been imported already possess the documents relating to the method of preparation and also to the quantitative and qualitative composition*' [38] and in respect of which '*the public health authorities of the importing Member State already have in their possession, as a result of importation on a previous occasion, all the pharmaceutical particulars relating to the medicinal preparation in question and considered to be absolutely necessary for the purpose of checking that the medicinal preparation is effective and not harmful*'. [39]

65. The Court held that that requirement is observed [40] even where 'the process of manufacture and the qualitative and quantitative composition of the medicinal preparation imported by the parallel importer coming from another Member State are different from those of the medicinal preparation bearing the same name and in respect of which the authorities of the Member State into which it has been imported already have these data' [41] *provided that* 'the differences between the one and the other product are of such minor importance that it is likely that the manufacturer is applying or introducing ... these differences with the conscious and exclusive intention of using these differences ... in order to prevent or impede the possibility of the parallel importation of the proprietary medicinal product'. [42]

66. Consequently, since the present case concerns applications for the placing on the market of *products likely to pose a risk to the health of humans*, the stringency of the requirement laid down in *De Peijper* should at the very least be maintained.

38 — *De Peijper*, paragraph 10.

39 — *Ibidem*, paragraph 21. See also paragraph 25: '... parallel importers are very often in a position to offer the goods at a price lower than the one applied by the duly appointed importer for *the same product ...*'.

40 — *Ibidem*, paragraphs 34 to 36.

41 — *Ibidem*, paragraph 33.

42 — *Ibidem*.

67. In the present case, the essential aim of Directive 91/414 is to ensure the use of plant protection products which offer a high standard of protection of human and animal health and of the environment. The Court so held in its judgment in *Parliament* v *Council*. [43]

68. Furthermore, the Community legislature has provided that the implementation of the directive and the adaptation of its annexes must be carried out in the light of 'advances in technical and scientific knowledge'. [44] The need to take into account that factor is systematically pointed out by the Community legislature in the various legal instruments introduced in the field of the authorisation for the marketing of pharmaceutical products. [45] The Court has not failed to point out the need to observe that requirement, for in paragraph 21 of *Scotia Pharmaceuticals*, cited above, it held that:

'... the competent authority may also use its power of assessment to ascertain whether or not the applicant seeking an authorisation, and consequently the expert who prepared the documentation supporting the application, *took account of current technical developments and scientific progress* and whether or not he or she was satisfied that the scientific publications, on the basis of which the application for authorisation was submitted under the abridged procedure, were still up to date'.

69. It is common ground that not only has scientific progress made it possible to refine ever more research and knowledge in fields such as that of comparative tests to establish whether two plant protection products are identical, but also that development of technology makes it easier to carry out such tests.

70. Finally, the Court stated in *Scotia Pharmaceuticals*, cited above, that '*the abridged procedure in no way relaxes the requirements of safety and efficacy which must be met by medicinal products*'. [46] By analogy, I consider that the procedure which must be followed in the case of parallel imports of plant protection products cannot result in the introduction onto the market of products capable of presenting a hazard for human health.

71. That is why I maintain that it would be hard to justify any reduction in the stringency of the requirement laid down in *De Peijper* in 1976, confirmed recently by the

43 — Case C-303/94 *Parliament* v *Council* [1996] ECR I-2943, paragraphs 24, 25 and 28.

44 — See the twenty-fourth recital in the preamble to and Article 5 of the directive.

45 — For example, Article 9a of Council Directive 65/65, cited above, as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36); the first paragraph of Article 14 of Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1); similarly, the first paragraph of Part 1(A) of the Annex to Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ 1981 L 317, p. 16).

46 — Paragraph 17, emphasis added.

judgment in *Scotia Pharmaceuticals*, for checking whether products are identical.

72. The Court's judgment in *Smith & Nephew*, cited above, [47] expressly refers to *De Peijper* and specifically reproduces paragraph 10 thereof. It is for this reason that I consider that it must be interpreted in the light of those arguments.

73. Finally, in order to deal specifically with the concern expressed by the national court in its second question, according to the judgment in *De Peijper*, [48] it is not absolutely necessary to carry out tests again if the national authority already has in its possession the scientific particulars which were delivered to it with the first application for placing on the market. Moreover, the authority could possibly, in coordination with the authority of the Member State where the imported product originates, obtain information to supplement the information provided by the importer. [49] That comparative examination should be easily accomplished since the two products were authorised in countries which comply with the procedure for the issue of marketing authorisation provided for by the directive.

74. It is therefore for the national court to determine whether the competent authority has displayed special vigilance when assessing the identicality of the two products. The national authority must establish, *having compared the results of similar tests and analyses* which are relevant and up to date, account being taken of scientific progress and technical developments, that *the products under comparison are indeed identical in every respect.* That is so if those products have the same components — in particular as regards not only the active substances but also the proportion of active substances to other substances; if they have the same effect on plants and are used in the same proper way (having regard to whether conditions as to agriculture, plant health and environment, in particular climatic conditions, relevant to the use of the products are comparable in the regions concerned in the State of origin and in the State of importation); if they have the same harmless side-effects and, in any event, if they likewise have no harmful side-effects on humans, animals and the environment. In other words, it is a question of ensuring that, in all those various respects, the differences between the two products are negligible.

75. Moreover, although it is necessary that the components of the imported product and of the master product should be created by the same company, that criterion is not sufficient. The fact that the two products were manufactured by the same company or by a company belonging to the same group does not necessarily mean that the two products are identical.

47 — Paragraph 23.
48 — Paragraph 32.
49 — *Ibidem*, paragraph 27.

76. If, after the examination has been carried out, it is found that the imported product does not fulfil the criteria as set out, it cannot be considered to have already been placed on the market of the Member State of importation, in which case the conditions listed in the directive for the issuing of a marketing authorisation for such a product must be strictly observed.

(b) Possibility Two [50]

77. The Treaty, in particular Article 110 and the first paragraph of Article 234 thereof, and the GATT Agreements preclude any unjustified barrier to international trade. [51] I am therefore of the view that the solution set out under Possibility One may be adopted in the case of a plant protection product imported from a third country where that product is identical to a plant protection product already on the market in the Member State of importation.

78. The main difficulty lies in the fact that the imported plant protection product will have been authorised in a State which does not follow the same procedure and which does not necessarily require the same tests, analyses and documents before issuing a marketing authorisation.

79. Without harmonisation of those procedures by international agreements, it is for each Member State to define the relevant rules and to ensure that it does not adopt measures which unjustifiably restrict world trade. I believe that those requirements would be complied with if the State of importation treated products imported from third countries in the same way as it treats Community products.

80. Consideration of the first question leads me to the conclusion that the rigorous procedure and conditions provided for by the directive are required only if the plant protection product has never been placed on the market in the Member State of importation. On the other hand, in the case of a parallel import, according to the judgment in *De Peijper*, the national authority of that Member State must ascertain that the products compared are indeed identical in every respect, according to previously defined criteria. Moreover, the criterion that the components of the imported product and the master product are manufactured by the same company is not appropriate.

The third question

81. If the answer to the first question is in the affirmative, the national court, by its third question, asks the Court to determine whether Article 9(2) of the directive permits a Member State to allow a plant protection product imported from non-EEA countries to be put

50 — See the second indent of point 35 of this Opinion.

51 — See, to that effect, in particular, Case 245/81 *Edeka* v *Germany* [1982] ECR 2745, Case 45/86 *Commission* v *Council* [1987] ECR 1493, and Case 263/87 *Denmark* v *Commission* [1989] ECR 1081.

on the market when the importer or person responsible for placing the product on the market is a person without a permanent office within the EEA.

82. Article 9(2) of the directive provides, as we have seen, that the person responsible for first placing a plant protection product on the market in a Member State must have a permanent office within the Community.

83. That requirement is demanded *only for first applications for marketing authorisations for plant protection products* in a Member State.

84. In so far as the factual situation in respect of which the national court poses its questions to the Court concern parallel imports of plant protection products, the reply must be that that provision is not applicable to the present case.

85. Nevertheless, as I said above, [52] I consider that, by this question, the national court is asking the Court to determine whether Community law would allow a Member State to require an importer, established in a third country and applying to place on the market in that Member State a product which is identical to a master product, to have a permanent office within the Community.

86. As we have seen, Article 110 and the first paragraph of Article 234 of the Treaty as well as the GATT Agreements preclude any unjustified barrier to world trade.

87. In accordance with what I said in relation to Question 1(ii), where the plant protection product imported from a third country is identical — according to the previously defined criteria — to a product authorised in the Member State of importation, the fact that authorisation to place the imported product on the market is granted only to the importer or to the person responsible for its placing on the market who can show that he has a permanent office or establishment within the Community or inside the EEA would constitute an unjustified barrier to world trade, prohibited by the Treaty.

52 — See points 59 and 60 of this Opinion.

Conclusion

88. In the light of the foregoing observations, I propose that the Court should reply as follows to the questions submitted to it by the High Court of Justice, Queen's Bench Division, for a preliminary ruling:

(1) (a) Articles 4 and 8 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market do not apply to applications for authorisation to place on the market plant protection products imported from another Member State, a European Economic Area (EEA) State or a third country and authorised in those States of origin, where the product is identical to a plant protection product already authorised in the Member State in which authorisation to place on the market is sought.

(b) (i) Such products are identical where they are alike in every respect and, in particular, where they:

— have the same composition, in particular not only as regards the active substances but also as regards the proportion of active substances to other substances;

— have the same effect on plants;

— are used in the same proper way — having regard to whether conditions as to agriculture, plant health and environment, in particular climatic conditions, relevant to the use of the products are comparable in the regions concerned in the State of origin and in the State of importation;

— have the same harmless side-effects, if any; and

— have likewise no harmful side-effects on humans, animals and the environment.

The products are also identical if the differences found in relation to those various aspects are negligible with regard to the therapeutic efficacy, the safety and the quality of the imported product under consideration.

(b) (ii) The criterion that the active substance or the components of the imported plant protection product and the master product are manufactured by the same company, by a company belonging to the same group or under licence is necessary but insufficient in order to characterise the two products as identical.

(b) (iii) Where, on the basis of those criteria, the competent authority of the Member State of importation finds that the two products are identical, it must grant, for the imported plant protection product, the authorisation to place on the market which it previously granted to the master product, unless considerations concerning the effective protection of the health and lives of humans and animals and of the environment preclude this, without being required to have the constituents of the imported product analysed beforehand.

(2) The competent authority of a Member State may permit the placing on the market of a plant protection product imported from a third country as being identical [according to the criteria set out in Question 1(b)] to the master product, even if the importer or the person responsible for placing it on the market does not have its permanent office in the Community or within the EEA.