JUDGMENT OF THE COURT (Sixth Chamber)
11 March 1999 *

In Case C-100/96,

REFERENCE to the Court under Article 177 of the EC Treaty by the High Court of Justice of England and Wales, Queen's Bench Division, for a preliminary ruling in the proceedings pending before that court between

The Queen

and

Ministry of Agriculture, Fisheries and Food,

ex parte **British Agrochemicals Association Ltd,**

on the interpretation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1),

* Language of the case: English.

THE COURT (Sixth Chamber),

composed of: P. J. G. Kapteyn, President of the Chamber, G. Hirsch, J. L. Murray (Rapporteur), H. Ragnemalm and R. Schintgen, Judges,

Advocate General: P. Léger,
Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

— British Agrochemicals Association Ltd, by David Pannick QC and Henry Carr, Barrister, instructed by Laurence Cohen and Caroline Ford, Solicitors,

— the United Kingdom Government, by Lindsey Nicoll, of the Treasury Solicitor's Department, acting as Agent, assisted by Kenneth Parker QC and Christopher Vajda, Barrister,

— the Greek Government, by Ioannis Chalkias, Legal Adviser in the State Legal Service, and by Chrysoula Vellopoulou, Adviser to the General Secretary for Community Matters, Ministry of Foreign Affairs, acting as Agents,

— the Commission of the European Communities, by Xavier Lewis and Gérard Berscheid, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of British Agrochemicals Association Ltd, represented by David Pannick and Thomas de la Mare, Barrister, the United Kingdom Government, represented by Lindsey Nicoll, assisted by Kenneth Parker, the Greek Government, represented by Ioannis Chalkias and Elli Mamouna, Secretary in the Special Department for Community Legal Affairs, Ministry of Foreign Affairs, acting as agent, and the Commission, represented by Xavier Lewis, at the hearing on 17 July 1997,

after hearing the Opinion of the Advocate General at the sitting on 2 October 1997,

gives the following

Judgment

1 By order of 3 November 1995, received at the Court on 25 March 1996, the High Court of Justice of England and Wales, Queen's Bench Division, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty 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 (OJ 1991 L 230, p. 1, hereinafter 'the Directive').

2 Those questions arose in a dispute between British Agrochemicals Association Limited (hereinafter 'British Agrochemicals') and the Ministry of Agriculture, Fisheries

and Food (hereinafter 'MAFF') concerning the legality of the 1994 Control Arrangements governing authorisation to place imported pesticides on the market.

3 The Directive, amended on several occasions, lays down uniform rules on the conditions and procedures for the grant of marketing authorisations for plant protection products.

4 According to Article 2(1) of the Directive, '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 intended for specific uses.

5 Under Article 2(10), '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' constitutes 'placing on the market'. Importation of a plant protection product into the territory of the Community is deemed to constitute placing on the market for the purposes of the Directive.

6 According to Article 3(1) of the Directive, '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, except where the intended use is covered by Article 22'. It is apparent from the order for reference that Article 22 is not relevant to the present case.

7 Article 4 of the Directive lays down 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. No active substance has yet been included in Annex I.

8 Article 8(1) of the Directive provides that the Member States may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, '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 ...', provided that the criteria mentioned in that provision are satisfied. Article 8(2) states, in particular, 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'.

9 The first subparagraph of Article 9(1) of the Directive provides, in particular, that 'application for 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'. According to Article 9(2), 'every applicant shall be required to have a permanent office within the Community'.

10 The 1994 Control Arrangements, which entered into force on 14 March 1994, were drawn up pursuant to the Control of Pesticides Regulations 1986 (S. I. 1986/1510).

11 The 1994 Control Arrangements prohibit the advertising, selling, supply, storage or use of a pesticide product in the United Kingdom unless the Minister for Agriculture, Fisheries and Food and the Secretary of State 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.

12 It is apparent from the case file that the 1994 Control Arrangements provide for the authorisation of pesticide products imported from third countries which are identical to products that have provisional or full approval under the Control of Pesticides Regulations ('the master product').

13 Under Paragraph 3(a) of the 1994 Control Arrangements, an imported product is deemed to be identical to a 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 United Kingdom 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 United Kingdom 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'.

14 According to Paragraph 3(b) of the 1994 Control Arrangements, 'where an imported product is manufactured under licence, information on the licensed source and the specification of the product may be required to prove identicality with the United Kingdom product'.

15 Paragraph 6 of the 1994 Control Arrangements provides that the application for approval must contain, first, a covering letter giving the name of both the master product and the imported product and the type of approval sought, secondly, three copies of the draft label and, finally, evidence that the product to be imported is identical, within the terms of these arrangements, to the 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.

16 Paragraph 9 of the 1994 Control Arrangements provides:

'The registration authority may require the provision of such additional information as it considers necessary in support of an application. Where the registration authority arranges for the chemical analysis of samples provided by the applicants, the results of analyses will be confidential to the registration authority.'

17 British Agrochemicals, a limited company which represents 39 members of the agrochemical manufacturing industry, is challenging, before the national court, the legality of the 1994 Control Arrangements. It claims that those arrangements are in breach of the Directive in that they allow an imported product on to 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 that of the imported product.

18 According to British Agrochemicals, the Directive does not provide for the grant of marketing authorisation following a speedy procedure on the ground that the formulation of the master product is identical to that of the imported product. British Agrochemicals takes the opposing view that the Directive puts in place a rigorous and binding system which presupposes that all marketing authorisations are issued after the safety, quality and efficacy of the plant protection product concerned have been checked by means of properly documented tests, analyses and trials.

19 MAFF, for its part, contends that the grant of marketing authorisations for plant protection products which have been the subject of a parallel import is not governed by the Directive which harmonises only the rules relating to applications for authorisation to place such products on the market for the first time. However, that elaborate procedure need not be followed where those products are already authorised. The 1994 Control Arrangements thus merely provide a simplified way of allowing on to the United Kingdom market imported products that are identical to master products already approved in the United Kingdom and marketed there. They do not call in question in any way the rigorous and binding system put in place by the Directive since the two instruments serve different purposes.

20 In those circumstances, the national court, taking the view that the dispute before it called for the interpretation of the relevant provisions of Community law, referred the following three 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:

(a) 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

(b) 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 on to 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 on to 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

21 By its first and second questions, which should be taken together, the national court seeks essentially to ascertain the conditions in which the competent authority of a Member State may authorise the placing on the market of a plant protection product which has been imported from a State belonging to the European Economic Area ('an EEA State') or a third country in whose territory marketing has already been authorised and which it deems to be identical to a product in respect of which marketing authorisation has already been granted in accordance with the provisions of the Directive.

22 It should be recalled at the outset that, according to the second recital in the preamble to the Directive, one of the most important ways of protecting plants and plant products and of improving agricultural production is to use plant protection products. According to the fourth recital, however, such use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised or if incorrectly used.

23 Furthermore, the Directive introduces a set of uniform rules concerning the conditions and procedures for the grant of marketing authorisations for plant protection products in order, first, to ensure a high standard of protection of human and animal health and of the environment and, secondly, to eliminate within the Community obstacles to trade in plant protection products and plant products arising from the existence of divergent national rules.

24 The Directive thus provides that a plant protection product may not be placed on the market of a Member State and used unless it has been duly approved in accordance with the Directive's provisions. Moreover, under the Directive, the importation of a plant protection product into the Community is tantamount to placing it on the market.

25 The United Kingdom Government claims that the Directive does not apply where a person is seeking to put on the market of a Member State a plant protection product imported from an EEA State or a third country which is identical to another plant protection product that is already authorised and marketed in that Member State. The Government takes the view that the Member States must adopt the definition of identicality laid down by the Court in Case 104/75 *De Peijper* [1976] ECR 613.

26 In that connection, it should be borne in mind that in *De Peijper* the Court held, at paragraphs 21 and 36, in the context of Articles 30 and 36 of the EEC Treaty, that, if the public health authorities of the importing Member State already have in their possession, as a result of a previous importation having led to the grant by those authorities of marketing authorisation, all the particulars for the purpose of checking that a medicinal preparation is effective and not harmful, it is clearly unnecessary, in order to protect the health and life of humans, for the said authorities to require a second trader who has imported a medicinal preparation which is in every respect the same or displays differences which have no therapeutic effect, to produce the abovementioned particulars to them again.

27 Furthermore, in Case C-201/94 *Smith & Nephew Pharmaceuticals and Primecrown* [1996] ECR I-5819, paragraph 21, concerning the interpretation of 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), as amended in particular by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36, hereinafter 'Directive 65/65'), the Court considered that that directive could not apply to a proprietary medicinal product covered by marketing authorisation in one Member State and imported into another Member State as a parallel import of a proprietary medicinal product already covered by marketing authorisation in the latter Member State, since that imported product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation.

28 It went on to explain, at paragraphs 25 and 26 of that judgment, that the competent authority in the Member State of importation must verify that the two proprietary medicinal products, which have a common origin by virtue of the fact that they are manufactured pursuant to agreements concluded with the same licensor, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and have the same therapeutic effects.

29 That reasoning may be applied, *mutatis mutandis*, to the placing of plant protection products on the market.

30 The Directive pursues in particular the objectives of protecting public health and eliminating barriers to trade within the Community, which are comparable to those of Directive 65/65, in addition to protecting animal health and the environment. With that in mind, it lays down a set of uniform rules concerning the conditions and procedures for the grant of marketing authorisation for plant protection products.

31 Accordingly, where a plant protection product covered by marketing authorisation granted in accordance with the provisions of the Directive in one Member State is imported into another Member State as a parallel import of a plant protection product already covered by marketing authorisation in the Member State of importation, the provisions of the Directive on the procedure for the grant of marketing authorisation do not apply.

32 Where two marketing authorisations are granted in accordance with the Directive, the objectives which it pursues as to protection of human and animal health and of the environment do not call for the same treatment. In such a situation, application of the Directive's provisions concerning the procedure for the grant of marketing authorisation would go beyond what is necessary to achieve those objectives and

could, without justification, run counter to the principle of the free movement of goods laid down in Article 30 of the Treaty.

33 It is important, however, that the competent authority should verify, apart from the existence of a common origin, that the two plant protection products, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and also have the same effect with due regard, in particular, to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product.

34 In order to verify that those conditions are met, the competent authority of the Member State of importation has available to it, as the Court pointed out in paragraph 27 of the judgment in *Smith & Nephew and Primecrown*, legislative and administrative means capable of compelling the manufacturer, his duly appointed representative or the licensee for the plant protection product already covered by marketing authorisation to supply information in their possession which the authority considers to be necessary. Moreover, the competent authority may consult the file submitted in connection with the application for marketing authorisation in respect of the plant protection product already authorised.

35 Finally, Article 12 of the Directive on the exchange of information is designed to enable the competent authority of the Member State of importation to obtain the documents necessary for verification.

36 If, on completion of the examination carried out by the competent authority of the Member State of importation, the latter finds that all the abovementioned criteria are fulfilled, the plant protection product to be imported must be considered to have already been placed on the market of the Member State of importation and, accordingly, must be able to benefit from the marketing authorisation granted in respect of the plant protection product already on the market, unless that is precluded by considerations concerning the effective protection of human and animal health and of the environment.

37 If the competent authority finds that the plant protection product to be imported from another Member State does not fulfil all the abovementioned criteria and the product cannot therefore be deemed to have already been placed on the market in the Member State of importation, that authority may grant the authorisation required for the marketing of the plant protection product to be imported only in compliance with the conditions laid down in the Directive.

38 As regards the importation of plant protection products from an EEA State, it should first of all be noted that Decision No 7/94 of the EEA Joint Committee of 21 March 1994, amending Protocol 47 and certain Annexes to the EEA Agreement (OJ 1994 L 160, p. 1), amended Annex II to the EEA Agreement, which deals with technical regulations, standards, testing and certification. That decision, which entered into force on 1 July 1994, extended the application of the Directive throughout the territory of the EEA.

39 Article 8(1) of the EEA Agreement, adopted by Decision 94/1/ECSC, EC of the Council and the Commission of 13 December 1993 (OJ 1994 L 1, p. 1), provides: 'The free movement of goods between the Contracting Parties shall be established in conformity with the provisions of this Agreement.' Article 11 of the Agreement prohibits quantitative restrictions on imports and all measures having equivalent effect between the Contracting Parties.

40 Accordingly, it must be held, on the same grounds as those mentioned at paragraph 33 above, that, where the competent authority of a Member State finds that a plant protection product imported from an EEA State in which it is already covered by marketing authorisation granted in accordance with the Directive, if not identical in all respects to a product already authorised within the Member State of importation, at least

— shares a common origin with that product in that it has been manufactured by the same company or by an associated undertaking or under licence according to the same formulation,

— was manufactured using the same active ingredient, and

— also has the same effect with due regard to differences which may exist in conditions relating to agriculture, plant health and the environment, in particular climatic conditions, relevant to the use of the product,

that product must be able to benefit from the marketing authorisation already granted in the Member State of importation, unless that is precluded by considerations concerning the protection of human and animal health and of the environment.

41 As regards the importation of a plant protection product from a third country, the conditions which led to the non-applicability of the provisions of the Directive concerning the procedure for the grant of marketing authorisation are not fulfilled in this case.

42 Such a product does not provide the same guarantees with regard to protection of human and animal health and of the environment as those afforded by a product imported from a Member State of the Community or from an EEA State in which it has already been granted marketing authorisation in accordance with the Directive.

43 In that connection, there is at present no harmonisation at international level of the conditions in which plant protection products may be placed on the market.

44 Nor does there exist, at international level, any general principle of the free movement of goods comparable to that prevailing within the Community and endorsed by the latter.

45 The United Kingdom Government claims, however, that it would be contrary to Article 5.1 of the Agreement on Technical Barriers to Trade which appears in Annex 1A to the Agreement establishing the World Trade Organisation, approved on behalf of the Community as regards matters within its competence 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, hereinafter 'the Technical Barriers Agreement'), to interpret the Directive as meaning that its provisions on the procedure for granting marketing authorisation apply to the placing on the market of a plant protection product imported from a third country which is deemed by the competent authority of the Member State of importation to be identical to a plant protection product already authorised within its own territory. Article 5.1.1 of the Technical Barriers Agreement lays down the principle of non-discrimination with regard to the preparation, adoption and application of procedures to assess conformity of products with technical regulations or standards, while Article 5.1.2 prohibits such procedures from having as their purpose the creation of unnecessary obstacles to international trade, taking account in particular of the risks non-conformity would create.

46 In that connection, it is sufficient to state that, on the grounds set out at paragraphs 43 and 44 above, to apply the conditions for the grant of marketing authorisation laid down by the Directive to a plant protection product imported from a third country but not already granted marketing authorisation in accordance therewith, cannot be considered to be discriminatory or to create an unnecessary barrier to international trade, even if the competent authority of the Member State of importation may regard that product as identical to a plant protection product already covered within its territory by a marketing authorisation granted in accordance with the Directive.

47 Thus, the Directive applies to the placing on the market in a Member State of a plant protection product imported from a third country, even if the competent authorities of the Member State of importation consider that product to be identical to a master plant protection product already authorised in accordance with the Directive.

48 It follows from the foregoing that the competent authority of one Member State may grant marketing authorisation for a plant protection product imported from a third country which is not already covered by marketing authorisation granted in accordance with the provisions of the Directive in another Member State, only under the conditions laid down by the Directive.

The third question

49 In view of the answer given to the first two questions, there is no need to answer the third.

Costs

50 The costs incurred by the United Kingdom and Greek Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the High Court of Justice of England and Wales, Queen's Bench Division, by order of 3 November 1995, hereby rules:

1. **Where the competent authority of a Member State finds that a plant protection product imported from an EEA State in which it is already covered by marketing authorisation granted in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, if not identical in all respects to a product already authorised within the Member State of importation, at least**

   — **shares a common origin with that product in that it has been manufactured by the same company or by an associated undertaking or under licence according to the same formulation,**

   — **was manufactured using the same active ingredient, and**

   — **also has the same effect with due regard to differences which may exist in conditions relating to agriculture, plant health and environment, and in particular climatic conditions, relevant to the use of the product,**

that product must be able to benefit from the marketing authorisation already granted in the Member State of importation, unless that is precluded by considerations concerning the protection of human and animal health and of the environment.

2. The competent authority of one Member State may grant marketing authorisation for a plant protection product imported from a third country which is not already covered by marketing authorisation granted in accordance with the provisions of Directive 91/414 in another Member State, only under the conditions laid down by that directive.

Kapteyn Hirsch Murray

Ragnemalm Schintgen

Delivered in open court in Luxembourg on 11 March 1999.

R. Grass

Registrar

P. J. G. Kapteyn

President of the Sixth Chamber