OPINION OF ADVOCATE GENERAL TRSTENJAK

delivered on 11 September 2007 [1]

I — Introduction

1. This action for failure to fulfil obligations relates to the compatibility of the French legislation on the conditions for authorisation of parallel imports of plant protection products with Article 28 EC. To be more exact, the Commission seeks a declaration that the French Republic, by requiring that a plant protection product which is a parallel import and the reference product have a common origin, has failed to fulfil its obligations under Article 28 EC.

1 — Original language: French.

II — Legal background

A — *Community law*

1. The EC Treaty

2. Under Article 28 EC, 'quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States'.

2. Secondary legislation

3. Under Article 3(1) of Council Directive 91/414/EEC of 15 July 1991 concerning

the placing of plant protection products on the market [2] ('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 …'.

4. Article 5 of the directive provides that 'in the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years …'.

5. The first subparagraph of Article 9(1) of Directive 91/414 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.' The first authorisation requires a complete assessment of the properties of the product.

6. However, the directive contains no provision governing the conditions for the grant of marketing authorisation for parallel imports, in other words when a trader seeks to import a product which is authorised in one Member State into another Member State in which a similar product has already been authorised.

B — *National law*

7. Under Article L-253-1 of the Code rural (French Rural Code), 'the placing on the market, use and possession by the end user of plant protection products are prohibited if those products lack marketing authorisation … '.

8. The conditions for the issue of marketing authorisations for plant protection products in France are set out in Decree No 94-359 of 5 May 1994, [3] which was adopted in order to transpose the directive.

2 — OJ 1991 L 230, p. 1.

3 — Official Journal of the French Republic, 7 May 1994, p. 6683.

9. Decree No 2001-317 of 4 April 2001 set up a simplified marketing authorisation procedure for plant protection products which come from the European Economic Area. [4]

10. Article 1 of Decree No 2001-317 provides:

'The introduction into the national territory of a plant protection product from a State of the European Economic Area in which it already has a marketing authorisation issued in accordance with Directive 91/414/EEC referred to above and identical to a product hereinafter called 'the reference product' shall be authorised on the following conditions:

The reference product must have a marketing authorisation issued by the minister responsible for agriculture ... .

The identity of the product introduced into the national territory with the reference product shall be assessed in the light of the following three criteria:

— common origin of the two products in the sense that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence;

— manufacture using the same active substance or substances;

— similar effects of the two products with due regard to differences which may exist in conditions relating to agriculture, plant health or the environment in particular climatic conditions, relevant to the use of the products.'

11. Under Article 4 of that Decree, 'the marketing authorisation of the product introduced into French territory may be refused or withdrawn ... on grounds of protection of human and animal health and also protection of the environment ... when there is no identity, within the meaning of Article 1, with the reference product ...'.

4 — Official Journal of the French Republic, 14 April 2001, p . 5811. Text consolidated in Articles R.253-52 to R.253-55 of the code rural.

12. That decree is supplemented by the order of 17 July 2001 establishing a simplified marketing authorisation procedure for parallel imports of plant protection products. [5]

III — Background to proceedings

13. On 29 February 2000, Endres-Merath, an undertaking based at Tettnang (Germany), applied to the French authorities for authorisation to place on the French market, under the name of Deltamex, the plant protection product Deltamethrin, originating in Austria, where it was marketed under the name of Mac-Deltamethrin. The corresponding product already authorised in France is called Decis.

14. According to the information provided by the French Government, Deltamex, just like Decis, is an insecticide which acts on contact and on ingestion, with a rapid and irreversible effect on insect nervous systems. It is used on, inter alia, cereals, rapeseeed, maize, vegetable crops, potatoes, peas, vines and tree cultivations.

15. On 17 April 2000, the French authorities granted Endres-Merath a marketing authorisation for Deltamex for a period of 10 years. However, by a decision of 31 July 2001, they withdrew that authorisation.

16. That withdrawal was raised in the course of a bilateral meeting of the French authorities and the Commission on 24 June 2004 in Paris, when the Commission inquired about the reasons for the withdrawal. The representatives of the Ministry of Agriculture indicated that the data relating to Deltamex lacked clarity and that impurities and labelling problems were causing difficulties.

17. The Commission was not persuaded by that explanation and sent to the French authorities a formal letter of notice on 18 October 2004, in which it states that the French Republic has failed to fulfil its obligations under Articles 28 EC and 30 EC:

— by depriving subsequent importers of a plant protection product which was the same, or different to a degree of no significance as to its efficiency and safety, of access to a simplified procedure for the authorisation of parallel imports,

5 — Official Journal of the French Republic, 27 July 2001, p. 12091.

when the French Republic has already, following marketing authorisation of a reference plant protection product, all information relevant to monitoring the efficiency and safety of the product;

— by requiring 'perfect identity' of the parallel import plant protection product and the reference product, inter alia with regard to the quantitative and qualitative composition of its excipients, and also the form of the product and its packaging, and by requiring that the parallel import plant protection product and the reference product have a common origin;

— by requiring evidence of that perfect identity, of common origin, and also of no possibility of different effects, by means of information to which the parallel importer can have no access.

18. The French authorities did not reply to that letter of formal notice.

19. By letter of 13 July 2005, the Commission sent to the French Republic a reasoned opinion in which it stated that, by requiring that the parallel import plant protection product and the reference product have a 'common origin' the French Republic has failed to fulfil its obligations under Article 28 EC. The other grounds of complaint specified in the letter of formal notice were not referred to in the reasoned opinion.

20. The French authorities replied, by a letter dated 15 September 2005, that the requirement imposed by Decree 2001-317 that the two products have a common origin, understood as meaning that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence, is no more than the repetition of the wording of the judgment in Case C-100/96 *British Agrochemicals Association*. [6]

21. The Commission was not satisfied with that reply and brought the present action on 4 May 2006, on the basis of Article 226 EC.

22. The Commission claims that the Court should:

— declare that, by requiring that the parallel import plant protection product and

6 — Case C-100/96 [1999] ECR I-1499.

the reference product have a common origin, the French Republic has failed to fulfil its obligations under Article 28 EC;

— order the French Republic to pay the costs.

23. The French Republic contends that the Court should:

— dismiss the present action;

— order the Commission to pay the costs.

24. The Kingdom of the Netherlands has intervened in support of the French Republic and requests that the Court dismiss the present action.

IV — Observations submitted to the Court

25. The Commission claims that to subject the issuing and continuation of authorisation for parallel imports of plant protection products to evidence of the common origin of the imported product and the reference product is a restriction on the free movement of goods, contrary to Article 28 EC. That condition exceeds, moreover, what may be considered necessary for the protection of public health, animal health and the environment.

26. The Court stated in Case C-112/02 *Kohlpharma* [7] that, as regards two medicinal products which are not significantly different, the absence of a common origin for the reference medicinal product and the imported medicinal product may not in itself constitute a ground for refusing a marketing authorisation to the second medicinal product. That approach, taken in relation to medicinal products, can be applied to plant protection products. The Commission refers to the statement in Case C-114/04 *Commission* v *Germany*, [8] in paragraph 24, that 'the marketing of medicinal products and plant protection products raise comparable issues' and, in paragraph 27, that 'the question of law at issue in these proceedings and in the case-law relating to parallel imports of medicinal products is the same'.

27. Lastly, the Commission argues that the grant of a marketing authorisation to a

7 — Case C-112/02 [2004] ECR I-3369, paragraph 18.

8 — Case C-114/04, not published in the ECR.

person who does not satisfy the condition of common origin does not, contrary to what is maintained by the Netherlands Government (see infra, point 32), infringe the data protection rights of the holder of the reference product marketing authorisation laid down in Article 13 of the directive, since that provision relates exclusively to initial marketing authorisations and does not apply to parallel imports.

28. The French Government denies the alleged failure to fulfil its obligations. The principles identified in *Kohlpharma*, cited above, pronounced in the context of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,[9] cannot be applied to the area of plant protection products. While the sole objective of Directive 2001/83 is the protection of human health, the directive aims not only to ensure that protection by avoiding the involuntary ingestion of chemical substances to be found on plants, but also to guarantee the protection of animal health and the environment from the consequences of the use of chemical substances designed for treating plants. Further, the current disparities among Member States as regards habits of consumption, professional practices and agricultural and environmental conditions, particularly climatic, are all specific factors to be taken into account, but are matters to which the regulation of pharmaceutical products has no regard.

29. The French legislation, by requiring that the imported product be identical to the reference product, does no more than meet the objectives of the directive while also ensuring that marketing authorisation procedure is transparent. Decree 2001-317 was, moreover, adopted to achieve conformity with *British Agrochemicals Association,* cited above.

30. That condition of common origin ensures that the active substances have the same origin, which provides the best safeguard that the substances are identical, particularly in their specification (degree of impurities, etc.). Quantitative or qualitative differences in composition of the active substance or substances might distort the action or even the effects of the product, inter alia by increasing its toxicity.

31. The French Government points out that, under the directive, the same active substance may currently be authorised with specifications which differ from State to State. Consequently, if the requirement was not made that the reference product and the imported product be manufactured by the same company or by associated undertakings

9 — OJ 2001 L 311, p. 67.

or under licence, assessment of the imported product would also have to focus on the active substances. The parallel imports procedure would then be more cumbersome.

32. The Netherlands Government agrees with the arguments advanced by the French Government and considers that the requirement of common origin is in accord with the principle of proportionality.

33. The Netherlands Government also submits that data protection will be not effective if common origin cannot be used as a criterion and argues that, if that requirement is not retained, the risks of trafficking in plant protection products, already significant, will be even greater.

V — Preliminary observations

34. Under Article 28 EC, quantitative restrictions on imports and all measures having equivalent effect are prohibited between Member States. Any measure which is capable of hindering, directly or indirectly, actually or potentially, intra-Community trade is a measure having equivalent effect. [10] None the less, Article 30 EC accepts that prohibitions or restrictions may be justified on grounds of 'the protection of health and life of humans, animals or plants'. The Court has also stated that protection of the environment is a mandatory requirement which may limit the scope of Article 28 EC. [11] However, the principle of proportionality, which underpins the last sentence of Article 30 EC, requires that the power of Member States to prohibit imports of products from other Member States be restricted to what is necessary for the attainment of legitimately pursued health protection objectives. [12]

35. While the directive provides that plant protection product marketing authorisations are issued by the Member States, the active substances must be authorised by the Commission and recorded on a list,

10 — Case 8/74 *Dassonville* [1974] ECR 837, and Case 120/78 *Rewe-Zentral* ('*Cassis de Dijon*'), [1979] ECR 649.

11 — Case 302/86 *Commission* v *Denmark* [1988] ECR 4607, paragraph 9. Thus, the obligation imposed by national legislation on manufacturers and importers, as part of a system under which the marketing of beer and soft drinks is authorised only in re-usable containers, to establish a deposit-and-return system for empty containers must be regarded as necessary to achieve the objectives pursued in relation to the protection of the environment so that the resulting restrictions on the free movement of goods cannot be regarded as disproportionate (paragraph 13).

12 — Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 18. National legislation or practice cannot benefit from the derogation laid down in Article 30 EC when the health and life of humans can be protected equally effectively by measures less restrictive of intra-Community trade (see, inter alia, Case C-172/00 *Ferring* [2002] ECR I-6891, paragraph 34, and Case C-15/01 *Paranova Läkemedel and Others* [2003] ECR I-4175, paragraph 24).

to be found in Annex I to the directive. [13] However, Member States may authorise, for a maximum period of 12 years, the distribution of plant protection products containing constituents not specified in Annex I to the directive, provided that they have already been on the market two years after the date of notification of the directive. [14] That period, which expired on 26 July 2003, has however been extended several times. The Commission has commenced a programme for the gradual examination, during this provisional phase, of the active substances in question [15] and, after the appropriate assessment, for decision on their inclusion in Annex I to the directive. [16]

36. As the Court has stated, it is apparent from the reasons underlying Directive 91/414 that it has the objective, firstly, of removing barriers to intra-Community trade in plant products and of improving plant production and, secondly, of protecting human and animal health and the environment. [17]

VI — Assessment

37. As has been stated in point 6 of this Opinion, the directive contains no provision governing the conditions for the grant of marketing authorisation for plant protection products [18] which are parallel imports.

13 — The use of plant protection products was regulated for the first time in 1979 by Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances (OJ 1979 L 33, p. 36). That directive determined at that time the list of products presenting, or likely to present, a risk to human or animal health and the use of which was prohibited on Community territory. Since then, the original list of those prohibited products has been amended several times to take account of technical and scientific progress. With the coming of the Single Market, Directive 79/117/EEC was replaced by Directive 91/414. The latter directive sets up an overall framework of harmonisation which allows the free movement of goods to be safeguarded while at the same time ensuring the safety of plant protection substances with regard to the need to protect the environment and public health. The directive provides for approval of active substances at European level in order to eliminate the diversity of the national procedures for the approval of plant protection products which were in force until then. Those active substances are to be recorded on a list, to be found in Annex I of the directive. A programme was launched to allow assessment of all the substances currently traded in the Member States and when appropriate to include them in the list of authorised substances (see Talbot-Rochdi, G. Politique agricole commune — Régime juridique des produits agroalimentaires' Jurisclasseur Europe, fascicule 1326, paragraph 143 et seq.).

14 — Article 8(2), first paragraph, of the directive.

15 — Second paragraph of Article 8(2).

16 — Fourth paragraph of Article 8(2).

17 — Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraph 30.

18 — On the issue of placing plant protection products on the market, see Kraus, V., *Die Zweitanmelderproblematik im Pflanzenschutzrecht*, Diss., Frankfurt am Main 1993, pp. 1-5; by the same author, Nationale Marktzugangsbeschränkungen für Pflanzenschutzmittelimporte, *Europäische Zeitschrift für Wirtschaftsrecht 1997*, Heft 11, pp. 331-334; Fluck, J., Konsequenzen der europäischen Wirkstoffzulassung für bestandkräftige deutsche Pflanzenschutzmittel-Zulassungen, *Europarecht 1999*, Heft 5, pp. 687-696; Fischer, K., Ursprungsidentität bei Arzneimittelzulassung, *Europäische Zeitschrift für Wirtschaftsrecht 2004*, Heft 17, pp. 530-533 and Die Erteilung einer Verkehrsfähigkeitsbscheinigung beim Parallelimport von Pflanzenschutzmitteln, Berlin 2006; Köpl, C., et Fredel, A., Parallelimport von Pflanzenschutzmitteln, *Neue Zeitschrift für Verwaltungsrecht 2004*, Heft 5, pp. 569-572; Koof, P., Welche gesetzlichen Rahmenbedingungen braucht der Pflanzenschutz- und Generikahandel in der Europäischen Union unter den Anforderungen des globalen Marktes?, *Agrar- und Umweltrecht 2005*, Heft 11, pp. 349-357; Bouveresse, A., Commentaire, Autorisation de mise sur le marché, *Revue mensuelle LexisNexis JurisClasseur*, 2005, pp. 19-20; Berr, C.-J., Retrait d'une autorisation de mise sur le marché, *Revue trimestrielle LexisNexis JurisClasseur*, 2006, pp. 678-679; Erlbacher, F., Neueste Rechtsprechung der Europäischen Gerichte in den Bereichen Landwirtschaft, Fischerei, Tiergesundheit und Pflanzenschutz (2. Halbjahr 2006), *Argrar- und Umweltrecht, 2007*, Heft 2, p. 46.

38. The Court, in *British Agrochemicals*, [19] cited above, has stated that, 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 28 of the Treaty. [20]

39. The Court then defined, in that judgment, the acceptable conditions of such a simplified authorisation procedure. In addition to the existence of a common origin in the sense that they have been manufactured by the same company or by an associated undertaking or under licence following the same formulation, the plant protection product for which parallel importation is sought and the reference product, without being in all respects identical, must, at the very least, have been manufactured following the same formulation while using the same active substance and have the same effects with due regard to differences which may exist in conditions relating to agriculture, plant protection and the environment, in particular climatic conditions, relevant to use of the product. [21]

40. The Commission considers the French legislation does not comply with the obligations imposed on France by Article 28 EC, by requiring that the parallel import plant protection product and the reference product have a common origin. However, as is submitted by the French Government, the French legislation, or to be exact Decree 2001-317 of 4 April 2001, by making the issue of a marketing authorisation subject, inter alia, to a condition that there be such common origin, does no more than repeat, almost in the same words, the first condition stated by the Court in *British Agrochemicals*, cited above. As stated in point 10 above, Article 1 of the Decree requires a 'common origin of the two products in the sense that they have been manufactured according to the same formulation by the same company or by an associated undertaking or under licence', whereas paragraph 40 of that judgment states that the product for which marketing authorisation is sought must have a 'common origin with that product [the reference product] in that it has been manufactured by the same company or by an associated undertaking or under licence according to the same formulation'.

41. The Commission maintains that it is appropriate to apply to plant protection products the approach taken by the Court on medicinal products for human use. The Commission refers to *Kohlpharma*, cited above, where it was held that the condition of common origin is not determinative but merely useful evidence of the essential

19 — Case C-100/96, cited above, paragraph 31.
20 — Case C-100/96, cited above, paragraph 32.
21 — Ibidem, paragraph 40.

identity of the product for which marketing authorisation is sought and the reference product.

42. For the reasons set out above, it does not appear to me that the approach taken in that judgment should be extended to the area of plant protection products, [22] and, consequently, it does not appear appropriate to review the usefulness of the condition of common origin clearly postulated in *British Agrochemicals* within the context of parallel imports of plant protection products.

43. First, the dangers of plant protection products and medicinal products are not the same. While a medicinal product is prescribed by a doctor, or at least is sold by a pharmacist, and ingested solely by a single patient, a plant protection product, such as the insecticide at issue in this action, which is used, according to the French Government, on, inter alia, vegetables, fruit trees, and vines, is likely to spread into the environment, [23] both through the air and through the ground. What is more, such products are designed to be used on plant products which are intended for sale and for human and animal consumption.

44. There is no doubt that plant protection products are dangerous. [24] To be persuaded of that, one need only read the Sixth environment action programme which aims inter alia to reduce the risks associated with the use of pesticides, strengthen the monitoring

22 — To that effect, see Ouart, P. E., EU-Parallelimporte von Pflanzenschutzmitteln, *Wettbewerb in Recht und Praxis*, 2005, Heft 3, pp. 323-330, arguing that the *Kohlpharma* cannot be transposed to plant protection products, given that the legislation in the latter field is significantly different from that affecting the field of medicinal products.

23 — The objective of environmental protection is, according to academic writing, likely to grow in importance. 'In the agricultural-food industry, action in favour of environmental protection has been slow to emerge. Given the absence of self-sufficiency when the CAP was established, the objective of performance and intensifying production by means of chemical and mechanical fertilisation was fundamental. Environmental questions were accordingly not raised. Those production-oriented methods very quickly revealed their harmful effects through the widespread pollution of the aquatic environment, the transformation of the countryside and even the impoverishment of the genetic heritage of fauna and flora (S. Leclerc, *Politique agricole commune et environment*, Apogée, Rennes 1993) … . In 1985, taking into account environmental data in production and marketing of agricultural food products will be presented as a "component" of the Common Agricultural Policy. … The Court of Justice had to recognise that environmental protection is a "mandatory public interest requirement" which may justify certain national restrictions on trade (the "Danish bottles" case, Case 302/86 *Commission* v *Denmark*, [1988] ECR 4607) … . The environmental objective of the agricultural-food legislation is likely to become more important. Not only is it a serious alternative to intensive production methods, but it also guarantees product quality, whether relating to health protection quality through the prohibition of intrusive chemicals, or organoleptic quality by so-called "natural" production of products.' Talbot-Rochdi, G., op. cit., paragraph 34 et seq., 1997).

24 — The Directive thus states in the 9th recital of its preamble 'the provisions governing authorisation must ensure a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, ground water and the environment [have not been properly investigated]; the protection of human and animal health and of the environment should take priority over the objective of improving plant production;'

of the use and distribution of pesticides and promote replacement of the more dangerous active substances by safer substances such as non-chemical substitutes, [25] or peruse the academic literature on the subject. [26] Moreover, there is no other method of preventing the spread of active substances into the environment which is as efficient but less restrictive. The requirement of a common origin for the imported product and the reference product cannot be considered to infringe the principle of proportionality.

45. In his Opinion delivered on 2 October 1997 in *British Agrochemicals*, Advocate General Léger, reasoning by analogy with the statement made by the Court in Case C-440/93 *Scotia Pharmaceuticals*, [27] was of the view 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'. [28] At point 75 of his Opinion he also stated that 'although it is necessary that the components of the imported product and of the reference product should be created by the same company, that criterion is not sufficient.' A fortiori, that first condition, necessary but not sufficient, cannot be removed.

46. The Court has moreover already underlined 'the paramount importance to be accorded to the protection of health' [29] and

25 — Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the sixth environment action programme of the European Community (OJ 2002 L 242, p. 1). The Communication of the Commission on that sixth programme (COM(2001), 31 final; page 47) states that 'one group of chemicals that requires particular attention is pesticides (i.e. plant protection products and biocides). They can affect human health via their contamination of groundwaters, soils, food and even the air. Gaps in the current data on the issue make it difficult to be precise about the scale and trends of the problem but there is sufficient evidence to suggest it is serious and growing. The contamination of groundwaters is of particular concern. On average, 65% of European drinking water is supplied from groundwaters and, even after remedial action has been taken to prevent further contamination, they often take a long time to recover to acceptable quality levels. Also of concern is the contamination of our foodstuffs and evidence of continuing accumulation of certain pesticides in plants and animals with associated impacts on their health and ability to reproduce'.

26 — Thus, in relation to French territory, we note that an article in the newspaper *Le Monde* (M. Auzanneau, 12 June 2007) provides the following information: according to F. Veillerette (co-author of *Pesticides*, Fayard, 2007): 'almost 900 pesticide molecules are used in France. They are to be found everywhere; everyone eats them on a daily basis. Because they are so ubiquitous, scientists have difficulty in identifying the precise sources of risk — as distinct from a restricted problem such as asbestos'; according to I. Baldi (Lecturer at the University of Bordeaux), who stresses the lack of scientific results in relation to the possible dangers linked to consumption of pesticides present within foods, 'there are some thirty studies in the world which all show an increased risk of cerebral tumours, and some tens of others which are evidence of an increased frequency of other pathologies'. Moreover, according to French research, farmers who are heavily exposed to pesticides, but also people who use pesticides on plants within the home, are statistically twice as likely to develop brain tumours (Occupational and Environmental Medicine, http://oem.bmj.com)[30 May 2007].

27 — Case C-440/93 [1995] ECR I-2851. What was at issue in that case was examination of the Community legislation relating to marketing authorisation for medicinal products for human use and the determination of the extent of the discretion allowed to the relevant competent national authorities. While the Court was able to find guidance in the case-law which it had developed in relation to medicinal products in order to set out principles governing plant protection products such as the need for a marketing authorisation for parallel imports, it does not at all follow that what may not be necessary for medicinal products, such as a common origin for the imported product and the reference product, is also not necessary for plant protection products.

28 — Point 70 of that Opinion.

29 — Order of 12 July 1996 in Case C-180/96 R *United Kingdom* v *Commission* [1996] ECR I-3903, paragraph 93, on the application by the United Kingdom of Great Britain and Northern Ireland for interim suspension of operation of Commission Decision 96/239/EC of 27 March 1996, on emergency measures to protect against bovine spongiform encephalopathy (BSE)(OJ 1996 L 78, p. 47).

held that the imperative requirements of protection of public health must prevail over other considerations, in particular over the principle of free movement of goods within the European Community.[30] The Court has also stated that 'more often than not, damage to the environment or to health cannot, by reason of its nature, be eliminated retroactively.'[31]

47. The Commission claims that the approach adopted in *Kohlpharma*, cited above, in relation to medicinal products, can be transposed to the area of plant protection products, in accordance with *Commission* v *Germany*, cited above, which states that the marketing of those two types of products 'raises comparable issues' (paragraph 24) and that 'the question of law at issue is the same' (paragraph 27) in both cases. Yet, in doing so, the Commission quite fails to state what the 'question of law at issue' was. In that case, the Commission asked the Court to find that, by not having allowed to parallel importers a reasonable period in which to dispose of their stocks when a marketing authorisation for a relevant plant protection product was withdrawn, the Federal Republic of Germany had failed to fulfil its obligations under Article 28 EC. The Court merely stated in that judgment that 'the effects of withdrawal of the relevant marketing authorisation are in the circumstances of this case the same for parallel importers as those which have been identified in the case-law relating to parallel imports of medicinal products (*Ferring*, cited above, paragraph 25). In both cases, the parallel importers lose the capacity to market the products in question'.[32] Paragraph 24 of the same judgment, which states that the issues raised by such marketing are comparable, intended to point out that the marketing of plant protection products merits no less attention that that given to medicinal products. The Court did not at all intend in that judgment to rule out that in some circumstances the marketing of plant protection products may require even greater attention than that of medicinal products. That was simply not the issue in that case. The judgment in *Commission* v *Germany*, delivered without hearing an opinion and not published in the European Court Reports, was in no way intended to alter the condition of common origin as defined and laid down in *British Agrochemicals*.

48. Secondly, the French Government correctly states that removal of the condition of common origin, far from making the issuing of a marketing authorisation easier, would only serves to make the parallel imports procedure more cumbersome and be a hindrance to trade that is much more significant that that to which the Commission objects. Indeed, the same active substance may have been authorised

30 — The Court held that, even if there was no absolute certainty that BSE was transmissible to humans, there was a serious risk, and refused to grant the application of the United Kingdom.

31 — Order of 2 October 2003 in Case C-320/03 R *Commission* v *Austria* [2003] ECR I-11665, paragraph 92, on the driving prohibition imposed on lorries transporting certain goods in a 'clean zone'.

32 — *Commission* v *Germany*, cited above, paragraph 26.

with specifications which differ from State to State, given that during the period in which the active substances are subject to the programme of assessment for the purposes of obtaining Commission approval, each Member State continues to authorise plant protection products in conformity with its national rules. If the imported product and the reference product have the same origin, in other words if they have been manufactured by the same company or by associated undertaking or under licence, it is unnecessary to carry out an assessment of the specifications of the imported product. On the other hand, if the imported product and the reference product have been manufactured by different undertakings, the removal of the condition of common origin means that there should be a systematic assessment of the active substances contained in the imported product. In fact, the identity of substances, as is argued by the French Government (see supra, point 31), is all the more certain when they have a common source of manufacture, since active substances comprise, in the wording of the directive, 'any impurity inevitabl[y] resulting from the manufacturing process.'[33]

49. Thirdly, the argument presented by the Netherlands Government on the subject of confidentiality of data must also be approved. The rule stated in Article 13 of the directive, to the effect that a Member State is not, when granting an authorisation, to make use of data provided by the first applicant for a marketing authorisation 'for the benefit of other applicants',[34] is also incompatible with removal of the requirement of common origin.[35] In fact, if that easily checked requirement was removed, the applicant for marketing authorisation for a parallel import product would have to prove that the product for which importation was sought is identical to the already authorised reference product. Since the file containing all the information relating to the reference product is confidential, evidence of that would, as a matter of logic, be difficult to obtain, unless the holder of the first marketing authorisation agrees to share such information.

50. Accordingly, it must be determined that the French Republic, by requiring that the parallel import plant protection product and the reference product have a common origin, has not failed to fulfil its obligations under Article 28 EC. Consequently, the action must be dismissed.

33 — Article 2(3) of the directive.

34 — Moreover, the directive obliges the Commission and the Member States, both in the procedure for authorisation of a plant protection product and in that for inclusion of a substance in Annex I to the directive, to treat industrial and commercial secrets as confidential, if a warranted request is made (Article 14, first paragraph of the directive).

35 — Only in the area of experiments on vertebrate animals does the directive provide that the holders of earlier authorisations and the new applicant must come to an agreement, in order to avoid the repetition of experiments on vertebrate animals. Failing such agreement, Member States are to impose terms, if the parties concerned are based on their territory, by determining both the procedure, and the reasonable balance of the interests of the parties concerned (Article 13(7), last three paragraphs).

VII — Costs

51. Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the French Republic applied for costs and the Commission has been unsuccessful, the latter should be ordered to pay the costs.

VIII — Conclusion

52. Having regard to all of the foregoing reflections, it is suggested that the Court should:

1. dismiss the action;

2. order the Commission to pay the costs.