OPINION OF ADVOCATE GENERAL LÉGER

delivered on 21 September 2000 [1]

1. The High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court), has referred to the Court four questions for a preliminary ruling on the interpretation of Directive 91/414 EEC [2] in the context of a dispute between Monsanto plc ('Monsanto') and the Minister of Agriculture, Fisheries and Food and the Secretary of State for the Environment (hereinafter 'the respondents').

2. Monsanto applied to the national court for judicial review. It claimed that the respondents had infringed the provisions of the directive by granting Clayton Plant Protection Ltd ('Clayton'), on 16 February 1998, marketing authorisation for a new glyphosate-based plant protection product ('the product') on the basis of the data on that active substance provided in 1974 by Monsanto. Monsanto claims that the marketing authorisation for such a generic product may only be granted on condition that the applicant is able to provide the competent national authority with data which takes account of current scientific and technical knowledge when the application is made.

3. The national court, uncertain as to whether the applicable national provisions are compatible with those of the directive, wishes to obtain clarification with regard to the documents which, according to the directive, must be provided by an applicant for marketing authorisation of a generic plant protection product in support of its application.

I — The Community legal framework

4. The purpose of the directive, adopted on the basis of Article 43 of the EC Treaty (now, after amendment, Article 37 EC), is to define the uniform rules on the conditions and procedures for the authorisation and use of plant protection products. [3]

1 — Original language: French.

2 — 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').

3 — Sixth and seventh recitals.

5. Its main objective is not only to improve agricultural production by the use of efficacious plant protection products, but also to protect humans, animals and the environment from risks and hazards arising from the unchecked use of those products. [4] For that reason, it is intended to ensure the marketing of safe products which will have no harmful effect on human or animal health or the environment, directly or indirectly. [5] Moreover, it aims at eliminating barriers to the free circulation of that type of goods. [6]

6. Article 2 of the directive defines the main expressions used.

7. Article 1(1) provides: 'This Directive concerns the authorisation, [7] placing on the market, [8] 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).'

8. Article 2(1) indicates that '*plant protection products*' must be understood to mean '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 purposes. [9]

9. Article 2(4) defines '*active substances*' as substances [10] or micro-organisms, including viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

10. Article 2(5) states 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'.

4 — Fourth, ninth and tenth recitals.

5 — See, in particular, Case C-303/94 *Parliament* v *Council* [1996] ECR I-2943, paragraph 27.

6 — Fifth and sixteenth recitals.

7 — According to Article 2(11), '*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 — Under Article 2(10), '*placing on the market*' refers 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'.

9 — Those are, in particular, to protect plants or plant products against all harmful organisms or prevent the action of such organisms (Article 2(1.1)), preserve plant products (Article 2(1.3)), and destroy undesired plants (Article 2(1.4)).

10 — 'Substance' is defined as 'chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitable[y] resulting from the manufacturing process' (Article 2(3)).

11. According to Article 3(1) of the directive, the Member States are to 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. [11] It is clear from the order for reference that Article 22 is not relevant to the present case.

12. Article 4 of the directive lays down the ordinary legal procedure concerning the granting (Article 4(1) to (4)), review (Article 4(5)) and withdrawal (Article 4(6)) of marketing authorisations in respect of plant protection products.

13. Under Article 4(1) of the directive, the granting of authorisation by a Member State is subject to several conditions being met. [12]

14. Article 4(1)(a) of the directive provides that only active substances which are listed in Annex I may be authorised. It is for the Commission to draw up that list in accordance with the procedure provided for by Articles 6 and 19. [13]

15. The conditions for including active substances in Annex I are laid down in Article 5. Article 5(1) thus provides that an active substance cannot be included in Annex I unless, in the light of current scientific and technical knowledge, it may be expected that plant protection products containing that active substance will fulfil certain conditions. [14]

16. To my knowledge, to date, only five active substances have been included in Annex I. However, the substance at issue in the main proceedings, glyphosate, does not appear in that annex.

17. Again under Article 4(1)(a) of the directive, the granting of marketing authorisations is furthermore subject to observance of the criteria laid down in Article 4(1)(b) to (e) of the directive. It is for the Member States to ensure that those requirements are met pursuant to the uniform principles provided for in Annex VI.

11 — That provision relates to the procedure which the Member States must follow for the purpose of authorising experiments and tests for research or development purposes involving the release into the environment of an unauthorised plant protection product.

12 — Article 4(2), (3) and (4) define some of the conditions set out in Article 4(1) relating, in particular, to the duration of such authorisation (Article 4(4)).

13 — Article 19 provides for the involvement of the Standing Committee on Plant Health, set up by Council Decision 76/894/EEC of 23 November 1976 establishing a Standing Committee on Plant Health (OJ 1976 L 340, p. 25).

14 — It is also provided in Article 5(1)(a) and (b) that the residues of such active substances as well as their use, consequent on application consistent with good plant protection practice, must not have any harmful effects on human or animal health or any unacceptable influence on the environment.

Those principles were laid down in Directive 94/43/EC, [15] amended by Directive 97/57/EC. [16]

18. Article 4(1) of the directive thus provides:

'1. Member States shall ensure that a plant protection product is not authorised unless:

(a) its active substances are listed in Annex I and any conditions laid down therein are fulfilled, and, with regard to the following points (b), (c), (d) and (e), pursuant to the uniform principles provided for in Annex VI, ...:

(b) it is established, in the light of current scientific and technical knowledge and shown from appraisal of the dossier provided for in Annex III, that when used in accordance with Article 3(3), and having regard to all normal conditions under which it may be used, and to the consequences of its use:

(i) it is sufficiently effective;

(ii) it has no unacceptable effect on plants or plant products;

(iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;

(iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;

(v) it has no unacceptable influence on the environment, having particular regard to the following considerations:

— its fate and distribution in the environment, particularly contamination of water including

15 — Council Directive 94/43/EC of 27 July 1994 establishing Annex VI to Directive 91/414/EEC (OJ 1994 L 227, p. 31), which entered into force on 1 September 1994 (Article 3 of that directive) and which was to be transposed at the latest by 1 September 1995 (Article 2).

16 — Council Directive 97/57/EC of 22 September 1997 (OJ 1997 L 265, p. 87), which entered into force on 27 September 1997 (Article 3) and which was to be transposed at the latest by 1 October 1997 (Article 2).

drinking water and groundwater,

— its impact on non-target species;

(c) the nature and quantity of its active substances and, where appropriate, any toxicologically or ecotoxicologically significant impurities and co-formulants can be determined by appropriate methods, harmonised according to the procedure provided in Article 21, or, if not, agreed by the authorities responsible for the authorisation;

(d) its residues, resulting from authorised uses, and which are of toxicological or environmental significance, can be determined by appropriate methods in general use;

(e) its physical and chemical properties have been determined and deemed acceptable for the purposes of the appropriate use and storage of the product;

(f) maximum residue levels in the agricultural products referred to in the authorisation have been provisionally established by the Member State and notified to the Commission in accordance with Article 12; within three months of the said notification, the Commission shall consider whether the provisional maximum levels established by the Member State are acceptable, and in accordance with the procedure laid down in Article 19 it shall establish provisional maximum levels throughout the Community and these shall remain in force until the corresponding maximum levels are adopted ...

In particular:

(i) Member States may not prohibit or impede the introduction into their territory of products containing pesticide residues provided the residue level does not exceed the provisional maximum levels set in accordance with the first subparagraph;

(ii) Member States must ensure that the conditions for approval are applied in such a way that the provisional maximum levels are not exceeded.'

19. By way of derogation from the ordinary legal procedure laid down in Article 4 of the directive and pending the adoption of the list of authorised active substances,

the Community legislature provided for transitional measures of two kinds.

20. According to Article 8 of the directive, the granting of marketing authorisation in respect of an active substance not listed in Annex I is governed by a different set of rules depending on whether the active substance in question is analogous to that contained in a product already on the market two years after notification of the directive (first subparagraph of Article 8(2)), or not[17] (first subparagraph of Article 8(1)).

21. Article 8(2) of the directive provides that: 'By way of derogation from Article 4 and without prejudice to paragraph 3 or to Directive 79/117/EEC,[18] 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.

After the adoption of this Directive, the Commission shall commence a programme of work for the gradual examination of these active substances within the 12-year period referred to in the foregoing subparagraph. This programme may require interested parties to submit all requisite data to the Commission and the Member States within a period provided for in the programme. A Regulation, adopted according to the procedure laid down in Article 19, will set out all the provisions necessary for the implementation of the programme.

Ten years following notification of this Directive the Commission shall present to the European Parliament and the Council a progress report on the programme. Depending upon the conclusions of the report, it may be decided, according to the procedure laid down in Article 19, whether, for certain substances, the 12-year period referred to in the first subparagraph is to be extended for a period to be determined.

During the 12-year period referred to in the first subparagraph it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I. The Member States shall ensure that the relevant authorisations are granted, withdrawn or varied, as appropriate, within a prescribed period.'

17 — That case, as will be seen below, is not relevant to the main proceedings.

18 — 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).

22. Article 8(3) of the directive states that: 'Where they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided.'

23. Article 13 of the directive provides for the data requirements, data protection and confidentiality of the data produced by applicants in support of their applications for marketing authorisation. In addition to the rules relating to the procedure according to which such data must be submitted, [19] that article requires the competent national authorities to respect the confidentiality of the data and to protect the rights of a holder of marketing authorisation over the data which it submitted in support of its application for marketing authorisation. [20]

24. Article 13(3) of the directive thus provides:

'In granting authorisations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants:

...

(c) for periods not exceeding 10 years from the date of the decision in each Member State and provided for in existing national rules, concerning an active substance on the market two years after the date of notification of this Directive ...'

25. In respect of 'active substances already on the market two years after notification of this Directive', Article 13(6), by way of derogation from the general arrangements relating to the production of data, provides that 'Member States may, with due regard for the provisions of the Treaty, continue to apply previous national rules concerning data requirements as long as such substances are not included in Annex I' to the directive.

26. The directive was notified to the Member States on 26 July 1991. It entered into force on that date. Pursuant to Article 23, the Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with the directive within two years following notification thereof.

19 — Article 13(1) of the directive.

20 — Article 13(3) and (4) of the directive.

II — National factual, legal and procedural framework

27. Glyphosate is an active substance used in the manufacture of herbicides. In 1974, Monsanto obtained the first commercial clearance for a glyphosate-based herbicide in the United Kingdom. In order to obtain it, Monsanto had to submit a data package for assessment. Authorisation was granted under two voluntary schemes operated pursuant to an agreement between the British Agrochemical Association ('BAA'), an industry representative body, and the Ministry of Agriculture, Fisheries and Food.

28. When the Control of Pesticides Regulations came into force on 6 October 1986, the two voluntary schemes lapsed, but statutory approvals were granted automatically to all products which had obtained clearance under the former scheme. This was also the case in respect of Monsanto's commercial clearance for its glyphosate-based products.

29. Under the system in force in the United Kingdom, the data relating to the active substance and the product submitted in support of an application for a first marketing authorisation of a plant protection product are protected for a period of 10 years.[21] For products registered prior to 6 October 1986 under the voluntary schemes, the 10-year period of protection began to run from the date when statutory approval was automatically granted under the Control of Pesticides Regulations.

30. The protection of data from which Monsanto benefits in respect of the information which it had provided in order to obtain the original commercial approval for its product expired on 6 October 1996. Since that date, the Pesticides Safety Directorate ('the PSD' or 'the competent national authorities'), an executive agency of the Ministry of Agriculture, Fisheries and Food, responsible for processing and assessing applications for authorisations of plant protection products, has been entitled to refer to the information contained in Monsanto's original data package when assessing applications by other manufacturers.

31. Under the scheme currently in force in the United Kingdom, any manufacturer wishing to obtain authorisation to place a new glyphosate-based herbicide on the market in the United Kingdom must submit a 'me-too' application to the PSD. That application is based on the principle that the generic manufacturer must provide data which is equivalent to that provided at the material time by the applicant for primary authorisation.

21 — See Article 13(3)(c) of the directive.

32. In the present case, the me-too applicants for glyphosate-based products may either provide data which is equivalent to that provided by Monsanto to obtain its primary authorisation or refer to the data in the package provided by Monsanto in respect of which protection has elapsed, or a mixture of both.

33. Whatever approach is adopted, the data which must be produced or cited when making a me-too application for a glyphosate-based product are based on the data provided at the time by Monsanto in order to obtain its original commercial approval in 1974.

34. Monsanto applied for judicial review to the High Court of Justice, Queen's Bench Division (Divisional Court), at a time when glyphosate was not listed in Annex I to the directive. In the context of those proceedings, Monsanto claimed that the respondents were failing to comply with Articles 4(1)(b) to (f), and 8(2) and (3) of the directive and sought, *inter alia*, a declaration to that effect.

35. Relying on the wording and purpose of the directive and on the case-law of the Court, Monsanto maintains, in essence, that the competent national authority must ascertain that the file submitted by an applicant for authorisation to market a generic plant protection product satisfies the criteria laid down in Article 4(1)(b) to (f) of the directive. Monsanto submits that that authority must make certain, furthermore, that the data provided is still relevant in the light of current scientific and technical knowledge.

36. On the other hand, principally on the basis of the wording of Article 8(2) and (3) of the directive, the respondents contend that the directive does not require compliance with the conditions set out in Article 4(1)(a) to (f) of the directive. They submit that, during the transitional period, the Member States enjoy a wide discretion as regards the documents which an applicant must provide to the competent national authority in support of its application for authorisation to market a generic product.

37. In those circumstances, the national court decided to stay proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'1. Whenever a Member State authorises the placing on the market in its territory of a plant protection product pursuant to Article 8(2) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, does

Article 8(3) of that Directive apply so as to require the Member State to evaluate the application for authorisation in accordance with the requirements laid down in Article 4(1)(b)(i) to (v) and (c) to (f)?

2. If the answer to Question 1 is in the affirmative, is the Member State under an obligation to apply the requirements of Article 4(1)(b)(i) to (v) to such applications "in the light of current scientific and technical knowledge"?

3. If the answer to Question 1 is in the affirmative, is the Member State also under an obligation to apply the requirements of Article 4(1)(c) to (f) to such applications "in the light of current scientific and technical knowledge"?

4. If the answers to Questions 1, 2 and/or 3 are in the affirmative, is the Member State under an obligation to ensure that its national provisions concerning the data to be provided (as referred to in Articles 8(3) and 13(6) of the directive) permit an evaluation to be carried out in accordance with the criteria laid down in Article 4(1)(b)(i) to (v) and (c) to (f) of the directive "in the light of current scientific and technical knowledge"?'

III — Assessment

Introductory remarks

38. First and foremost, it is undisputed that the factual context of the questions referred by the national court is that of the granting of a marketing authorisation in respect of a generic plant protection product during the transitional period.

39. The directive does not define 'generic product', but the Court had the opportunity to explain that concept in *Generics (UK) and Others.*[22] In that case, the Court was asked to interpret certain provisions of Directive 65/65/EEC,[23] as amended by Directive 87/21/EEC[24] and, in particular, to define the concept of 'generic medicinal product', also referred to as 'essentially

22 — Case C-368/96 [1998] ECR I-7967.

23 — Council Directive 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).

24 — Council Directive of 22 December 1986 (OJ 1987 L 15, p. 36).

similar medicinal product' or 'secondary medicinal product' in relation to an original medicinal product, otherwise known as a 'primary medicinal product'.

40. The Court took the view that 'generic medicinal product' was to be understood as a medicinal product which, despite being manufactured from the same active substance as that contained in a medicinal product which has been marketed for more than 10 years, has a chemical formulation or method of manufacture which differs from the primary product, provided that it is apparent that such differences are not significant, in the light of current scientific and technical knowledge when the application is being considered, by comparison with the original product as regards quality, safety and efficacy. [25] The Court added that the competent national authority could not disregard those three criteria when it was required to determine whether such a product was essentially analogous to a product authorised more than 10 years previously. [26]

41. I consider that that definition may be transposed to a case such as that in the main proceedings inasmuch as the wording of the main provisions of the harmonising directives relating to the issue of marketing authorisations for medicinal products for human use and for plant protection products is similar, [27] as are also their objectives. [28] Furthermore, during the hearing before the Court, the various interveners, when asked about the content of the concept of generic plant protection products, gave a definition which was substantially identical to that formulated by the Court in the *Generics* case, cited above.

42. Secondly, it is undisputed that a generic product is a new product and that it may not be marketed without a marketing authorisation having been obtained from the competent national authorities beforehand as required by the directive. [29]

43. As I have already stated, [30] marketing authorisation for a plant protection product must be granted in accordance with Article 4 of the directive provided that the active substance contained in that product is listed in Annex I. Otherwise, Article 8(2)

25 — *Generics (UK) and Others*, cited above, paragraph 36.

26 — Ibidem, paragraph 37.

27 — It is apparent from the provisions of the harmonising directives relating to the issue of marketing authorisations for medicinal products for human use and for plant protection products that both medicinal products and plant protection products must fulfil the three principal criteria of quality, efficacy and harmlessness before they can be marketed.

28 — Compare, in particular, paragraph 3 of the judgment in Case C-440/93 *Scotia Pharmaceuticals* [1995] ECR I-2851 and paragraph 27 in *Parliament* v *Council*, cited above.

29 — Which is not the case so far as concerns a parallel-import product which is covered by the marketing authorisation issued to the plant protection products already marketed in the importing country (Case C-100/96 *British Agrochemicals Association* [1999] ECR I-1499, paragraph 36). As regards the reasons for the difference in treatment between parallel-import products and generic products, see paragraph 32 of the judgment in Case C-100/96, cited above.

30 — See points 12 to 22 above.

of the directive applies where the active substance which is not listed in Annex I was on the market two years after notification of the directive.

44. It is common ground that glyphosate is an active substance which is not listed in Annex I and that it is contained in a product placed on the market by Monsanto in 1974 following marketing authorisation issued by the competent United Kingdom authority.

45. Nor is it disputed that, in the case in the main proceedings, the product in respect of which Clayton applied for marketing authorisation is manufactured from that active substance.

46. It appears from the foregoing that the active substance at issue was on the market on 26 July 1993, that is two years after notification of the directive.

47. In accordance with the analysis set out by the national court, the facts of the main proceedings fall within the scope of the procedure laid down in Article 8(2) of the directive.

The questions

48. The questions raised by the national court are closely linked. They seek, essentially, to ascertain the extent of the powers of the competent national authority when granting marketing authorisation in respect of a generic plant protection product containing an active substance not yet listed in Annex I by the Commission and contained in a product already on the market on 26 July 1993.

49. By its first question and by part of its fourth question (hereinafter 'the first question'), the national court wishes to know whether, during the transitional period, the issuing, by the competent national authority, of a marketing authorisation in respect of a plant protection product containing an active substance analogous to that contained in a product 'already on the market two years after the date of notification of this directive' is subject to compliance with the requirements laid down in Article 4(1)(b) to (f) of the directive. If so, the Court is asked to specify the manner in which the requirements relating to those data must be provided by an applicant for marketing authorisation of a plant protection product to the competent national authority in support of such an application.

50. By its second, third and, in part, its fourth question (hereinafter 'the second question'), the national court requests the Court to rule on whether the competent

national authority must take account of current scientific and technical knowledge when assessing compliance with the conditions laid down in Article 4(1)(b) to (f) of the directive. If so, the Court is asked to specify the manner in which this is to be carried out.

Answer to the first question

51. Let us recall that the first subparagraph of Article 8(2) of the directive provides:

'By way of derogation from Article 4 and without prejudice to paragraph 3 ... 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.'

52. Article 8(3) of the directive states, on the other hand, that:

'Where they review plant protection products containing an active substance in accordance with paragraph 2, and before such review has taken place, Member States shall apply the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f) in accordance with national provisions concerning the data to be provided.'

53. It is clear from those provisions that the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f) must be complied with only to the extent that the Member States carry out a 'review' and 'before such review has taken place'.

54. The answer to the first question must therefore clarify the term 'review' and the phrase 'before such review has taken place', as used in Article 8(3) of the directive.

55. In this respect, there are two conflicting possibilities.

56. According to Monsanto, the French Government, BAA and the Commission, the term 'review' used in Article 8(3) must be viewed in parallel with the term as used in Article 4(5). In both cases, what is therefore involved is a procedure for reviewing marketing authorisation granted by a Member State in respect of a plant protection product.

57. 'Review' as referred to in Article 8(3) must therefore be understood to mean the procedure for reviewing marketing authorisation granted in respect of a product containing a substance analogous to that contained in a product on the market two years after notification of the directive — 26 July 1993 — but which has not yet been included in Annex I. That term, it is claimed, refers also to the procedure involving the Commission under the programme of work provided for in the second to fourth subparagraphs of Article 8(2) of the directive. That procedure is designed to enable active substances placed on the market of the Member States to be listed in Annex I, in accordance with the procedure provided for by Article 8(3).

58. Moreover, the expression 'before such review has taken place' should be understood as referring to the case where, during the transitional period, an application for a marketing authorisation has been made to a Member State in respect of a new product containing an active substance analogous to that contained in a product on the market on 26 July 1993.

59. Monsanto, the French Government, BAA and the Commission argue that the Member State is obliged to comply with the requirements laid down in Article 4(1)(b) to (f) whenever an application is made to it for the granting or review of a marketing authorisation in respect of a product containing an active substance not listed in Annex I but analogous to that contained in a product on the market on 26 July 1993.

60. On the other hand, Clayton and the United Kingdom Government submit that 'review', within the meaning of Article 8(3) must not be understood as meaning review of a marketing authorisation granted in respect of a product, but only review of an active substance authorised before the directive was implemented. They thus claim that, where a Member State decides to review such an active substance, it must comply with the conditions laid down in Article 4(1)(b) to (f). By the expression 'and before such review has taken place', the Community legislature wished to make it clear that, at the end of that procedure, the Member States must defer to the decision taken by the Commission on the active substance under consideration. Thus, if the Commission decides not to list that active substance in Annex I, the Member States may no longer grant a marketing authorisation in respect of a product containing that active substance in accordance with national law, but must comply with the requirements of the directive. In other words, the expression 'before such review has taken place' means 'before the review procedure is completed'.

61. Clayton and the United Kingdom Government submit that Article 8(3) of the directive does not apply inasmuch as, in the present case, glyphosate has not yet been the subject of a review. Consequently, they submit that, during the transitional period,

in order to authorise the marketing of a plant protection product containing an active substance which is not included in Annex I but which was on the market on 26 July 1993, in accordance with Article 8(2) of the directive, the Member States are not obliged to apply Article 4(1)(b) to (f) of the directive, but rather the provisions of their domestic law. It must accordingly be considered that, during the transitional period, the Member States enjoy a very wide margin of discretion as regards the procedure and the conditions applicable to new applications for marketing authorisations in respect of a generic product containing an active substance not listed in Annex I.

62. I do not share the view of Clayton and the United Kingdom Government. As I see it, 'review' as provided for in Article 8(3) does indeed concern the procedure for review of marketing authorisations granted in respect of plant protection products containing active substances not listed in Annex I but analogous to those contained in products which were already on the market on 26 July 1993.

63. The wording of Article 8(3) is clear. It expressly states: '[W]here they review plant protection products containing an active substance ...'. Article 8(3) does therefore concern the procedure for review of marketing authorisations granted in respect of plant protection products and not only, as Clayton and the United Kingdom Government contend, the procedure put in motion by the Commission which consists in reviewing the active substances authorised by the competent national authorities in order to decide whether or not they are to be listed in Annex I.

64. The expression 'before such review has taken place' must therefore be read in conjunction with 'review plant protection products' and accordingly be interpreted in the light of the procedure for review of the authorisation granted to the product itself.

65. In my view, that expression means 'in all cases prior to the review provided for in the second to fourth subparagraphs of Article 8(2) of the directive'. Accordingly, I consider that that expression may be understood from the case provided for in the first subparagraph of Article 8(2) of the directive — namely the procedure for granting a marketing authorisation in respect of a new plant protection product containing the same active substance as that contained in a product already on the market on 26 July 1993. I therefore take the view that, during the transitional period, decisions to grant marketing authorisations in respect of plant protection products containing active substances analogous to those contained in products authorised since 26 July 1993 must comply with the requirements laid down in Article 4(1)(b) to (f).

66. Those requirements are, essentially, those relating to efficacy (Article 4(1)(b)(i)), harmlessness of the product both to humans and animals and to the environment (Article 4(1)(b)(ii), (iv)), and to its quality (Article 4(1)(c) to (f)).

67. However, in order to check whether those requirements have been complied with, the directive provides that, pending the adoption at Community level of harmonised test and analysis procedures, the Member States are allowed to comply with the relevant national requirements.

68. My conclusions are based on the wording of Article 8(2) and (3), the purpose of the directive and on the case-law of the Court of Justice.

69. It is apparent from the wording of Article 8(2) of the directive that it refers only to the scope of one of the systems which derogates from the ordinary legal procedure laid down in Article 4 of the directive.

70. Article 8(2) of the directive in fact does no more than point out that the Member States are authorised to grant marketing authorisation for a maximum period of 12 years, in a case such as that mentioned in the first subparagraph. As I have already said, what is involved is an application for a marketing authorisation in respect of a plant protection product containing an active substance analogous to that contained in a product on the market on 26 July 1993.

71. Because of the reference it makes to Article 8(2), Article 8(3) of the directive must be understood to be laying down procedural rules which must be followed by the Member States when granting marketing authorisation in respect of a product described in Article 8(2). That article thus makes clear that, as regards products containing active substances such as those referred to in Article 8(2), the Member States must ensure that the new product complies with the basic requirements of the directive.

72. Article 8(3) *in fine* and Article 13(6) of the directive, which derogates from the requirements concerning the procedures to be observed by the Member States with regard to the production of data, state, however, that national provisions relating to the production of such data are applicable as long as the harmonisation of the rules and procedures necessary for the full application of the directive has not been carried out by the Commission. In other words, those provisions express the rule according to which, during the transitional period and pending the adoption of har-

monised measures, the Member States may apply the national provisions in force when ensuring compliance of the product with the basic criteria laid down in Article 4(1)(b) to (f).

73. The measures awaiting harmonisation concern, in particular, provisions relating to the methods, tests and analyses enabling the quality of the product to be tested and determined. Article 4(1)(c) and (d) of the directive states that the quality of the product is to be determined 'by appropriate methods, harmonised according to the procedure... or, if not, agreed by the authorities responsible for the authorisation' ((c)) or 'by appropriate methods in general use' ((d)). Likewise, Article 4(3) provides that 'compliance with the requirements set out in paragraph 1(b) to (f) is established by official or officially recognised tests and analyses ... within the territory of the Member State concerned'.

74. It should moreover be borne in mind that, when the directive entered into force, the annexes relating to 'active substances authorised for incorporation in plant protection products' (Annex I), 'risk phrases' (Annex IV) and 'uniform principles for the evaluation of plant protection products' (Annex VI) had not been adopted and that all the provisions necessary for the full application of the directive have still not been adopted. [31]

75. The rule expressed in Article 8(3) *in fine* and in Article 13(6) of the directive must therefore be interpreted as a derogating and transitional rule postponing application of the harmonised provisions until such time as those rules are adopted. That rule is thus both logical and sensible.

76. The purpose of the directive endorses the interpretation of the disputed provisions that I would propose.

77. The aim of the directive is to allow free circulation of safe and healthy products within the Community. [32] In order to achieve that aim, the Community legislature proposes to adopt uniform rules on the conditions and procedures for the authorisation of plant protection products. [33]

31 — That is the case with Annex I. The programme of work referred to in Article 8(2) of the directive has still not been completed to date (see, in particular, Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414 (OJ 2000 L 55, p. 25)).

32 — See, in particular, the fourth, fifth, sixth, ninth and tenth recitals of the preamble to the directive.

33 — See, in particular, the seventh recital of the preamble to the directive.

78. The interpretation suggested by the United Kingdom Government and by Clayton considerably undermines that purpose. The effect of that interpretation is to defer the application of all the provisions of the directive until all the measures provided for by that directive have been adopted. That interpretation would therefore delay the application of the provisions of the directive which were to be implemented, pursuant to the first subparagraph of Article 23(1) of the directive, two years after its notification. The same is true of the basic principles laid down in Article 4(1)(b) to (f), namely those relating to efficacy, harmlessness and quality of the product. By allowing each Member State to continue to apply its national legislation beyond what is strictly necessary, such an interpretation compromises the objectives of safety and free movement of plant protection products and, consequently, undermines the effectiveness of the directive.

79. By contrast, the interpretation which I would suggest to the Court reconciles all the interests involved. Its effect is to require the Member States to observe and apply immediately the provisions of the directive where possible, while at the same time allowing them to continue to apply the national provisions in force so long as the Community has not adopted all the provisions necessary for the full implementation of the directive. I believe that my analysis makes it possible to approximate to the fullest extent possible legislation relating to marketing authorisation for plant protection products and thus to contribute to the aim of ensuring the safety and free circulation of those products. It makes it possible moreover to avoid delaying the placing on the market of new products that are needed in certain Member States in view of particular regional circumstances. [34]

80. Finally, the case-law of the Court appears to favour such an interpretation.

81. In Case C-137/97 *Commission* v *Germany*, [35] the Court was asked to declare that, by not adopting within the period prescribed all the laws, regulations and administrative provisions necessary for the transposition into domestic law of the directive, the Federal Republic of Germany had failed to fulfil its obligations under the directive and the EC Treaty.

82. In its defence, the German Government submitted in particular that the Commission's action could not be successful while not all the provisions necessary for the application of the directive had been adopted. The German Government referred, in particular, to the fact that no authorised active substances had been listed in Annex I and the difficulty in interpreting, and thus in applying, Article 13 of the directive.

34 — The need to allow products to be placed on the market in order to deal with problems specific to certain States or with emergencies is referred to in the 14th and 18th recitals of the preamble to the directive.

35 — Case C-137/96 *Commission* v *Germany* [1997] ECR I-6749.

83. To those submissions the Court replied that the fact that the Community had not adopted all the provisions necessary for the application of the abovementioned directive could not, 'in the absence of express provision to that effect, relieve Member States of their obligation to adopt within the period prescribed the measures necessary to comply with the Directive. That obligation remains, whether or not all the conditions for the implementation of the provisions of Community law have already been fulfilled. *As the Commission was right to observe, the point of transposing the relevant provisions is to ensure that the principle of the mutual recognition of authorisations is implemented as soon as the active substances are listed in Annex I to the directive*'. [36]

84. Accordingly, for the reasons set out above, I would propose that the Court rule that Article 8(3) of the directive must be interpreted as meaning that the procedure for which it provides is to be applied whenever a Member State authorises the placing on the market of a new plant protection product containing an active substance analogous to that contained in a plant protection product on the market two years after the date of notification of the directive. During the transitional period and pending the adoption of all the relevant Community provisions, the Member State is obliged to ensure that the requirements laid down in Article 4(1)(b) to (f) of the directive are fulfilled by the applicant for authorisation by applying, to that end, the national rules in force concerning the production of data.

Reply to the second question

85. The national court has asked the Court to rule on whether or not the competent national authority must assess whether the abovementioned conditions have been complied with in the light of current scientific and technical knowledge. If so, the Court is asked to specify the manner in which this is to be carried out.

86. Here, too, there are two conflicting possibilities.

87. Monsanto, BAA and the French Government argue, essentially on grounds of public health, that the national authorities competent to grant marketing authorisations are obliged to ascertain that the data provided by the applicant in support of its application for a marketing authorisation in respect of a generic product are still relevant in the light of current scientific and technical knowledge.

88. On the other hand, the United Kingdom Government and Clayton maintain

36 — Ibidem, paragraph 10, emphasis added.

that the applicant for a marketing authorisation in respect of a generic product may, where the data submitted by the applicant for a marketing authorisation in respect of the primary product is no longer protected, avail itself of those data in order to obtain marketing authorisation in respect of the secondary product. They rely essentially on the wording of Article 8(3) which does not refer to Article 4(1)(b) as a whole but only to the provisions of Article 4(1)(b)(i) to (v), and (c) to (f). However, the need to provide current data is mentioned in the first subparagraph of Article 4(1)(b). The United Kingdom Government and Clayton consider that, in omitting to refer to that subparagraph, the Community legislature intended expressly to exclude compliance with that requirement from the scope of Article 8(2) of the directive.

89. I do not share the view of the United Kingdom Government and Clayton.

90. It should first of all be borne in mind that the national court is dealing with an application for a marketing authorisation in respect of a generic product.

91. According to the case-law of the Court, in order to be able to describe a product as 'generic', the national authority must check that the product in question has been manufactured from an active substance which is substantially analogous to that contained in a product marketed for more than 10 years and that it also has a chemical formulation and method of manufacture essentially analogous to the original product. Those terms must be understood to mean that the differences which the secondary product might present with regard to the active substance, the chemical formulation or the method of manufacture must not prove, in the light of current scientific and technical knowledge when the application is being considered, significant by comparison with the original product. [37]

92. It follows from that definition that, in order to issue a marketing authorisation in respect of a generic product, the competent authority must first check whether the secondary product is essentially similar to the primary product. That exercise calls for a comparison between the two products to be carried out by the competent national authority in accordance with a method which takes into account the state of science and technology.

93. That approach is moreover approved of by the United Kingdom Government. At the hearing, it argued that, under the national rules in force, the competent

37 — See paragraph 40 above.

authority in the United Kingdom did carry out that type of check. According to the United Kingdom, in the case in the main proceedings, it proved to be the case, after such a check, that Clayton's product was basically identical to the product manufactured by Monsanto. Moreover, in the event of doubt as to the essentially identical nature of the secondary and primary products or where the national authority had the least concern that, in terms of the environment, animal or human health, that product could give rise to risk, the applicant for a marketing authorisation was requested to provide up-to-date data in order to clear up such doubts. Furthermore, where national authorities were aware of facts requiring a review of the original product, in particular because of new data, they could proceed to review the marketing authorisation granted earlier.

94. Monsanto contested the account given by the United Kingdom Government of both the applicable national law and the procedure followed by the competent authority with regard to the marketing authorisation issued in this case to Clayton. It added that if the statements made by the United Kingdom Government were in fact a reflection of the actual legal situation prevailing in the United Kingdom, then there would have been no need to bring the action in the main proceedings or make the reference for a preliminary ruling.

95. Without wishing to encroach upon the jurisdiction of the national court which has exclusive discretion to proceed to such verification, I would observe that the account given by the national court of the relevant national and legal framework does not seem to confirm the approach of the United Kingdom Government. [38] According to settled case-law, in the framework of the task with which the Court is charged under Article 177 of the EC Treaty (now Article 234 EC), it is for the national courts and the national courts alone to provide the Court with 'the factual or legal material necessary to give a useful answer to the questions submitted to it'. [39] I will consider the factual and legal material submitted by the national court in its order for reference as having been established.

96. None the less, for the sake of completeness, I would point out that, in so far as that material is contested, it is for the parties to the main proceedings, if they consider it useful, to ask the appropriate national court both to ascertain additional facts and to assess the scope of the national provisions and the manner in which they must be applied. [40]

38 — See, in particular, paragraph 18 of the order for reference which states: 'Applying these principles, the full and streamlined approaches to me-too approvals adopted by PSD in respect of glyphosate-based products are therefore based on the historic data package provided by the applicant in order to obtain its original commercial approval in 1974.'

39 — See, in particular, Case C-291/96 *Grado and Bashir* [1997] ECR I-5531, paragraph 12.

40 — Case C-412/96 *Kaunun Lukenne and Pohjolan Lukenne* [1998] ECR I-5141, paragraph 22.

97. Furthermore, the purpose of the directive endorses the approach put forward by Monsanto and BAA.

98. As we have seen, one of the objectives of the directive consists in allowing to be placed on the market of the Member States only those plant protection products which have been shown to be harmless to man, animals and the environment. In a field such as that dealt with by the directive, advances in science and technology are constant and sometimes rapid. It follows that the data relevant to obtaining a marketing authorisation in respect of a new product must in principle be assessed in the light of the scientific and technical knowledge available when the application for the grant of marketing authorisation is being considered.

99. It should be remembered that the product and the active substance are two discrete elements. [41] A generic product is by definition a new product, the method of manufacture and chemical formulation of which might be different from those of the primary product. It is necessary, in view of the public health objective pursued by the directive, for the competent national authority to check that modification of the method of manufacture of a generic product or of its chemical formulation cannot harm man, animals or the environment. [42]

100. The Court has consistently followed that approach so far as concerns the granting of marketing authorisation in respect of generic medicinal products for human use [43] or the issuing of marketing authorisation in respect of generic veterinary medicinal products. [44] In view of the similarity of the wording of the provisions of those different directives and of their objectives, I believe that the Court should also follow that approach in the framework of the present directive.

101. Likewise, it is apparent from the general scheme of the directive that the ordinary legal procedure for the granting, review and withdrawal of marketing authorisation for plant protection products

41 — See, to that end, the definitions of those concepts in points 8 to 10 of this Opinion.

42 — The Court pointed out in Case C-127/95 *Norbrook Laboratories* [1998] ECR I-1531, paragraphs 67 and 68, which concerned the provisions 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) and 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), that the requirements of public health could constrain Member States to require the applicant for a marketing authorisation to provide detailed and up-to-date information concerning the manufacturing process of a product. At that stage of manufacture of a product, the purity of that product could be compromised and the product could be revealed to be harmful. Those considerations also apply in the main proceedings.

43 — See the judgments in *Scotia Pharmaceuticals* and *Generics (UK) and Others*, cited above.

44 — See *Norbrook Laboratories*, cited above.

provides expressly that the Member States must take care to adjust the requirements relating to data in step with advances in technical and scientific knowledge. [45]

102. The Community legislature also uses occasionally the expression 'appropriate methods' to signify the need to constantly update the data provided in keeping with advances in science and technology. [46] It seems clear to me that a marketing authorisation issued on the basis of obsolete data would necessarily have been granted inappropriately.

103. Lastly, I consider that a derogating transitional procedure cannot have as its effect the relaxation of the conditions for granting marketing authorisations as regards product safety. [47] That would surely be the case were a State permitted to authorise a new product to be placed on the market on the basis of data provided in 1974 or were it not required to check whether information submitted in 1974 was still relevant in the light of current scientific and technical data.

45 — See Article Article 4(1)(b) regarding the authorisation procedure; Article 4(5) concerning the review procedure; Article 4(6)(a), first subparagraph, regarding cancellation; and finally Article 4(6)(c), first subparagraph, regarding modification of authorisation.

46 — See, in particular, Article 4(1)(c) and (d) of the directive.

47 — See, by analogy, *Scotia Pharmaceuticals*, cited above, paragraph 17.

104. I must therefore conclude that the competent national authority must assess whether the conditions laid down in Article 4(1)(b) to (f) of the directive have been complied with taking into account the state of science and technology at the time when the application is being considered.

105. The Court is asked to specify the manner in which compliance with those requirements must be ensured by the competent national authority.

106. I have set out ample reasons for considering that, in ascertaining whether those requirements have been complied with, it is for the Member State to apply the national provisions in force. [48] I would argue, for the same reasons, that, during the transitional period and pending the adoption of the relevant Community provisions, it is in applying the national rules in force that the Member State must ascertain that the conditions laid down in Article 4(1)(b) to (f) of the directive continue to be satisfied taking into account the state of science and technology at the time when the application is being considered.

48 — See paragraphs 67 to 83 of this Opinion.

Conclusion

107. In view of the foregoing observations, I would propose that the Court give the following answers to the questions referred by the High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court):

(1) Article 8(3) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market must be interpreted as meaning that the procedure which it lays down is to be applied whenever a Member State authorises the placing on the market on its territory of a new plant protection product containing an active substance analogous to that contained in a plant protection product on the market two years after the date of notification of the directive. During the transitional period and pending the adoption of the relevant Community provisions, Articles 8(3) and 13(6) of the directive must be interpreted as meaning that the Member State is obliged to ensure that the requirements laid down in Article 4(1)(b) to (f) of the directive are fulfilled by the applicant for authorisation. To that end, the Member State is to apply the national rules in force concerning the production of data.

(2) Article 8(3) of Directive 91/414 must be interpreted as meaning that the Member State must assess whether the conditions laid down in the abovementioned Article 4(1)(b) to (f) have been complied with taking into account the state of science and technology. During the transitional period and pending the adoption of the relevant Community provisions, Articles 8(3) and 13(6) of the directive must be interpreted as meaning that Member States are obliged to ensure that the requirements laid down in Article 4(1)(b) to (f) of the directive are fulfilled by the applicant for authorisation. To that end, the Member State is to apply the national rules in force concerning the production of data.