JUDGMENT OF THE COURT (Sixth Chamber)

3 May 2001 *

In Case C-306/98,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court) (United Kingdom) for a preliminary ruling in the proceedings pending before that court between

The Queen

and

Minister of Agriculture, Fisheries and Food,
Secretary of State for the Environment,

ex parte:

Monsanto plc,

intervener:

I Pi Ci SpA,

Clayton Plant Protection Ltd

and

* Language of the case: English.

British Agrochemicals Association Ltd (BAA),

on the interpretation of Articles 8(2) and (3) and 13(6) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1),

THE COURT (Sixth Chamber),

composed of: C. Gulmann (Rapporteur), President of the Chamber, J.-P. Puissochet and R. Schintgen, Judges,

Advocate General: P. Léger,
Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Monsanto plc, by M. Hoskins, Barrister, instructed by S. Kon and N. de Souza, Solicitors,

— Clayton Plant Protection Ltd, by M. Howe QC and L. Lane, Barrister, instructed by M. Stratford, Solicitor,

— the United Kingdom Government, by M. Ewing, acting as Agent, assisted by K. Parker QC, and P. Mantle, Barrister,

— the French Government, by K. Rispal-Bellanger and R. Loosli-Surrans, acting as Agents,

— the Commission of the European Communities, by X. Lewis acting as Agent,

having regard to the Report for the Hearing,

after hearing the oral observations of Monsanto plc, represented by M. Hoskins, Clayton Plant Protection Ltd, represented by M. Howe and L. Lane, British Agrochemicals Association Ltd (BAA), represented by T. de la Mare, Barrister, the United Kingdom Government, represented by G. Amodeo, acting as Agent, assisted by K. Parker, and the Commission, represented by X. Lewis at the hearing on 30 March 2000,

after hearing the Opinion of the Advocate General at the sitting on 21 September 2000,

gives the following

Judgment

1 By order of 14 July 1998, received at the Court on 4 August 1998, the High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court), referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) four questions on the interpretation of Articles 8(2) and (3) and 13(6) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

2 Those questions were raised in proceedings for judicial review brought by Monsanto plc ('Monsanto'), seeking a declaration that the Minister for Agriculture, Fisheries and Food and the Secretary of State for the Environment ('the ministers') were failing to comply with Articles 4(1)(b) to (f) and 8(2) and (3) of Directive 91/414.

The Community legal framework

3 Under Article 3(1) of Directive 91/414, plant protection products may not be placed on the market and used in a Member State unless its competent authorities have authorised the product in accordance with the directive.

4 Under the scheme introduced by Directive 91/414, a Member State may not authorise a plant protection product unless the active substances it contains are approved at Community level and listed in Annex I to that directive.

5 Article 4(1) 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 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 that 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 pursuant to the procedure provided for in the second subparagraph of Article 1(1) of Directive 90/[64]2/EEC and in Article 11 of Directive 86/362/EEC, as amended by Directive 88/298/EEC.

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.'

6 Article 8 of Directive 91/414, which provides for transitional measures and derogations for plant protection products containing active substances not listed in Annex I, provides, in Article 8(2):

'[B]y way of derogation from Article 4 and without prejudice to paragraph 3 or to Directive 79/117/EEC, 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.

...

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'.

7 Under Article 8(3) of Directive 91/414, '[w]here 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'.

8 According to Article 13(3)(c) of Directive 91/414, '[i]n granting authorisations, Member States shall not make use of the information referred to in Annex II for the benefit of other applicants... 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.' According to Article 13(4)(c) of the directive, '[i]n granting authorisations, Member States shall not make use of the information referred to in Annex III to the benefit of other applicants... for periods not exceeding 10 years and provided for in existing national rules after the first authorisation of the plant protection product in each Member State, where that authorisation precedes inclusion in Annex I of any active substance contained in the product.'

9 Article 13(6) of Directive 91/414, which provides for a derogation, for active substances already on the market two years after notification of the directive, from the general scheme concerning data to which the applicant for authorisation for a plant protection product is subject, 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].'

10 According to Article 23(1) of Directive 91/414, it was to be brought into force within two years of notification.

The national legal framework and the main proceedings

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

12 On the entry into force of the 1986 Control of Pesticides Regulations (SI 1986/1510) 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 system. This was also the case in respect of Monsanto's commercial clearance for its glyphosate-based products.

13 Under the legislation 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 commercial approval of a plant protection product are protected for a period of 10 years. 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 1986 Control of Pesticides Regulations.

14 The protection of data from which Monsanto benefited in respect of the information which it had provided in order to obtain in the United Kingdom the original commercial approval for its product expired on 6 October 1996. Since that date, the Pesticides Safety Directorate ('the PSD'), an executive agency of the

Ministry of Agriculture, Fisheries and Food responsible for processing and assessing applications for authorisations for plant protection products, has been entitled to refer to the information contained in Monsanto's original data package when assessing applications by other manufacturers.

15 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 procedure 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 in order to gain its primary authorisation. 'Me-too' applications are defined in the guidelines issued by the PSD as being applications that require a data package that matches the original requirements.

16 Under the United Kingdom rules, the ministers may, at any time, review a marketing authorisation. In such a case, the data relating to active ingredients submitted for the purpose of such a review is protected for a period of five years. Following the review, all holders of approvals for products containing the active ingredients in question must match the enhanced data package, either by generating their own data or by negotiating access to protected data owned by others. This applies equally to 'me-too' applicants who must provide data packages which reflect the data package submitted by the original applicant in order to obtain approval for their products.

17 To date, no review of glyphosate-based products has been carried out by the United Kingdom authorities. It follows that 'me-too' applicants for glyphosate-based products may either provide data which is equivalent to that provided by

Monsanto to obtain its original commercial approval or refer to the data in the package submitted by Monsanto for which protection has elapsed or a combination of both approaches.

18 Thus, 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.

19 At the time when Monsanto brought its proceedings for judicial review, glyphosate was not listed in Annex I to Directive 91/414.

20 In the main proceedings, Monsanto contended that, by not requiring 'me-too' applicants to submit up-to-date data concerning the active substances and the product before granting approval for it, the ministers were failing to comply with Articles 4(1)(b) to (f) and 8(2) and (3) of Directive 91/414, and it sought, *inter alia*, a declaration to that effect.

21 Monsanto contended that, under Article 8(2) and (3) of Directive 91/414, a Member State may not authorise the placing on the market in its territory of a new glyphosate-based plant protection product unless the applicant provides information establishing that, in the light of current scientific and technical knowledge, the product satisfies the criteria laid down by Article 4(1)(b) to (f) of that directive.

22 Such an interpretation would make it possible, according to Monsanto, to avoid the necessity of approval for plant protection products which present risks to human and animal health, groundwater and the environment, in accordance with the objective of reaching a high standard of protection, laid down in the ninth recital in the preamble to Directive 91/414.

23 Monsanto submits that even if the word 'review' as used in Article 8(3) of the abovementioned directive referred solely to the situation where a Member State initiates a 'review' of an existing authorisation, that article would still apply to the evaluation of an application under Article 8(2), since it also requires the Member States to comply with the requirements of Article 4(1)(b)(i) to (v) and (c) to (f) 'before such review has taken place'.

24 Monsanto accordingly claimed that the PSD should require all applicants for 'me-too' products to provide up-to-date data on the active substance and the product before granting approval for that product. To that end, it pointed out that a number of Member States, including the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, the Kingdom of the Netherlands, the Republic of Finland and the Kingdom of Sweden, were adopting that approach successfully.

25 In response, the ministers argued, first, that Article 8(3) of Directive 91/414 is inapplicable to the grant of 'me-too' approvals for glyphosate-based products under Article 8(2), so that, in granting such approvals, the PSD is not required to take Article 4(1)(b)(i) to (v) and (c) to (f) of the directive into account. According to the ministers, a clear distinction can be made between application for authorisation of a plant protection product, where Article 8(2) applies, and review of a plant protection product, where Article 8(3) applies. The latter provision applies only where a Member State initiates a review of an existing authorisation.

26 The ministers went on to argue, in the alternative, that, even if Article 8(3) were held to govern the grant of authorisation under Article 8(2), it does not refer to the opening words of subparagraph (b) of Article 4(1) so that those words are not in any event applicable to the grant of authorisations under Article 8(2). Consequently, the words 'in the light of current scientific and technical knowledge,' which appear there, do not apply in such circumstances.

27 Finally, the ministers submitted that the interpretation of the directive put forward by Monsanto would render application of Article 8(2) of Directive 91/414 unworkable in practice, as it would mean that all authorisations pursuant to transitional arrangements permitted under Article 8(2) would have to be processed as reviews. That would call for the updating of the data requirements before an application could be submitted followed by a full scientific evaluation of the new data by the registration authority. Such an interpretation would undermine the purpose of the transitional measures under Article 8(2) of Directive 91/414.

28 Taking the view that the outcome of the case before it required an interpretation of the relevant provisions of Directive 91/414, the High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court), decided to stay proceedings and to submit to the Court the following questions 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"?'

The first question

29 By its first question, the national court is asking essentially whether Article 8(3) of Directive 91/414 applies when, pursuant to Article 8(2) of the directive, an application is submitted to a Member State for first authorisation to place on the

market a generic plant protection product containing an active substance not listed in Annex I that is already on the domestic market two years after notification of that directive, with the consequence that that Member State is under an obligation to evaluate such an application in accordance with the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of that directive.

30 In that connection, it should be borne in mind that the first subparagraph of Article 8(1) of Directive 91/414 provides:

'[B]y way of derogation from Article 4, a Member State may, to enable a gradual assessment to be made of the properties of new active substances and to make it easier for new preparations to be made available for use in agriculture, authorise, for a provisional period not exceeding three years, the placing on the market of plant protection products containing an active substance not listed in Annex I and not yet available on the market two years after notification of this Directive, provided that:

(a) following application of Article 6(2) and (3) it is found that the dossier on the active substance satisfies the requirements of Annexes II and III in relation to the projected uses;

(b) the Member State establishes that the active substance can satisfy the requirements of Article 5(1) and that the plant protection product may be expected to satisfy the requirements of Article 4(1)(b) to (f)'.

31 The first subparagraph of Article 8(2) of Directive 91/414 provides, for its part, that, by way of derogation from Article 4 and without prejudice, in particular, to Article 8(3) of the directive, a Member State may, during a transitional period of 12 years, 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 that directive.

32 It is apparent therefore that, unlike the first subparagraph of Article 8(1) of Directive 91/414, the first subparagraph of Article 8(2) does not specify the requirements which must be satisfied in order to grant an authorisation to place on the market. However, it does state that such authorisation is to be issued without prejudice to Article 8(3) of Directive 91/414.

33 Under Article 8(3) of Directive 91/414, Member States are to apply the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of the directive where they 'review plant protection products' containing an active substance not listed in Annex I that is already on the market two years after the date of notification of the directive and before such review has taken place.

34 Such a review implies that the plant protection product has already been authorised to be placed on the market, as may be inferred, in particular, from Article 4(5) of Directive 91/414, according to which authorisations for plant protection products the active substances of which are listed in Annex I may be reviewed at any time if there are indications that any of the requirements for granting them are no longer satisfied.

35 However, a generic plant protection product in respect of which an application is submitted, pursuant to the first subparagraph of Article 8(2) of Directive 91/414, for a first authorisation to place on the market is not a plant protection product which has already been authorised to be placed on the market.

36 Accordingly, when such an application for authorisation to place on the market is submitted, there can be no question of reviewing the plant protection product concerned as provided for in Article 8(3) of Directive 91/414.

37 Monsanto and the Commission submit that, in any event, Article 8(3) of Directive 91/414 applies in the context of a procedure for the authorisation to place on the market a generic plant protection product because that provision provides that it also applies 'before the review has taken place'.

38 That argument cannot be upheld.

39 In reality, the expression 'before such review has taken place' which appears in Article 8(3) of Directive 91/414 must be understood, as the United Kingdom Government has, in substance, argued, as meaning that it is against the yardstick of the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of that directive that the Member States must decide whether to proceed to a review of plant protection products.

40 In that regard, it is important to point out that such an interpretation is compatible with all the language versions of Article 8(3) of Directive 91/414. In contrast, the interpretation advocated by Monsanto and the Commission, which rules out the existence of an essential functional link between the review phase and the phase preceding it, as referred to in Article 8(3) of Directive 91/414, cannot be reconciled, in particular, with the text in Danish ('Medlemsstater skal, når de tager plantebeskyttelsesmidler, som indeholder et aktivt stof, op til fornyet overvejelse i henhold til stk. 2, inden sådan fornyet overvejelse finder sted, påse, at de i artikel 4, stk. 1, litra b), nr. i) til v), og i litra c) til f), anførte krav er opfyldt i henhold til de nationale bestemmelser om dokumentation'), German ('Bei der Überprüfung von Pflanzenschutzmitteln, die einen Wirkstoff gemäß Absatz 2 enthalten, wenden die Mitgliedstaaten vor der Prüfung die Anforderungen gemäß Artikel 4 Absatz 1 Buchstabe b) Ziffern i) bis v) und Buchstaben c), d), e) und f) im Einklang mit den einzelstaatlichen Bestimmungen über die vorzulegenden Angaben an'), Italian ('Laddove autorizzino il riesame dei prodotti fitosanitari contenenti sostanze attive di cui al paragrafo 2, gli Stati membri, prima di procedere a tale esame, debbono applicare il disposto dell'articolo 4, paragrafo 1, lettera b), punti da i) a v), nonché lettere da c) a f), tenendo conto delle disposizioni nazionali relative ai dati da fornire') or Dutch ('Wanneer Lid-Staten een nieuw onderzoek instellen naar gewasbeschermingsmiddelen die een overeenkomstig lid 2 te onderzoeken werkzame stof bevatten, passen zij, voordat dit onderzoek heeft plaatsgevonden, de in artikel 4, lid 1, onder b), punten i) tot en met v), en onder c) tot en met f), genoemde voorwaarden toe, uit hoofde van de nationale bepalingen betreffende de te verstrekken gegevens').

41 It follows that Directive 91/414 does not require an application for a first authorisation to place on the market a generic plant protection product containing an active substance not listed in Annex I to that directive, which is already on the domestic market two years after notification of that directive, to be assessed in accordance with the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of that directive.

42 Such an application comes within the scope of Article 13(6) of Directive 91/414 which, in providing for a derogation, for active substances already on the market two years after notification of the directive, from the general scheme concerning

data to which an applicant for authorisation to place on the market a plant protection product is subject, 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.

43 Thus, during the transitional period mentioned in Article 8(2) of Directive 91/414, Member States are to continue to apply their scheme or their practice for placing on the market, in their territory, plant protection products containing an active substance not listed in Annex I to the directive that were already on the market two years after notification of that directive.

44 Moreover, such a solution corresponds to that adopted in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ 1998 L 123, p. 1), formerly known, as mentioned in the second recital in the preamble to that directive, as non-agricultural pesticides. Directive 98/8 contains, in relation to the placing of products on the market, provisions which bear a large number of similarities to those of Directive 91/414, in particular so far as concerns the principle of establishing a Community list of permitted active substances, a Community procedure for assessing whether an active substance can be entered in the Community list and the regular review of active substances on such a list. That directive provides, in Article 16, that a Member State may, for a transitional period of 10 years, continue to apply its current system or practice for placing biocidal products on the market. It may, in particular, authorise, in accordance with its current national rules, the placing on the market in its territory of a biocidal product containing active substances not listed in Annex I or I A to Directive 98/8 for that product type. Such active substances must be on the market within 24 months at most from the entry into force of Directive 98/8 as active substances of a biocidal product for purposes other than scientific research and development or process-orientated research and development.

45 In the light of the foregoing considerations, the answer to the first question must be that Article 8(3) of Directive 91/414 does not apply where, pursuant to Article 8(2) of the directive, an application is submitted to a Member State for first authorisation to place on the market a generic plant protection product containing an active substance not listed in Annex I to the directive, which is already on the domestic market two years after notification of that directive, with the consequence that that Member State is not under an obligation to assess such an application in accordance with the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of that directive.

The second, third and fourth questions

46 Having regard to the answer given to the first question, there is no need to answer the second, third or fourth questions.

Costs

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

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the High Court of Justice of England and Wales, Queen's Bench Division (Divisional Court), by order of 14 July 1998, hereby rules:

Article 8(3) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market does not apply where, pursuant to Article 8(2) of the directive, an application is submitted to a Member State for first authorisation to place on the market a generic plant protection product containing an active substance not listed in Annex I to the above-mentioned directive, which is already on the domestic market two years after notification of that directive, with the consequence that that Member State is not under an obligation to assess such an application in accordance with the requirements laid down in Article 4(1)(b)(i) to (v), and (c) to (f), of that directive.

Gulmann Puissochet Schintgen

Delivered in open court in Luxembourg on 3 May 2001.

R. Grass

Registrar

C. Gulmann

President of the Sixth Chamber