OPINION OF ADVOCATE GENERAL SHARPSTON

delivered on 29 November 2007 [1]

1. In the present case the College van Beroep voor het bedrijfsleven (Administrative Court for Trade and Industry) (Netherlands) has asked the Court to interpret Article 4(1) of Directive 2002/37. [2]

2. Directive 2002/37 amends Directive 91/414. [3] *Directive 91/414 requires* Member States to ensure that plant protection products (essentially herbicides, pesticides and fungicides to be applied to plants) are not placed on the market or used in their territory unless they have been authorised in accordance with the directive. A plant protection product may not be authorised unless its active substances are listed in Annex I to Directive 91/414. A Member State may, however, during a transitional period, authorise the placing on the market 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 the directive. I shall refer to such an authorisation as an existing authorisation.

3. Directive 2002/37 adds ethofumesate to Annex I to Directive 91/414, subject to certain conditions. Article 4(1) of Directive 2002/37 requires Member States to review existing authorisations for each plant protection product containing ethofumesate to ensure compliance with those conditions and, where necessary, to amend or withdraw the authorisation in accordance with Directive 91/414.

4. The issue before the Court in the present case is whether the holder of an existing authorisation for a plant protection product containing ethofumesate as an active substance can be required to provide a dossier satisfying Annex II to Direct-

1 — Original language: English.

2 — Commission Directive 2002/37/EC of 3 May 2002 amending Council Directive 91/414/EEC to include ethofumesate as an active substance (OJ 2002 L 117, p. 10).

3 — 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).

ive 91/414 (which contains the requirements for the dossier to be submitted for the inclusion of an active substance in Annex I) as a condition of retention of its authorisation.

plant protection products are authorised, to ensure that they have no unacceptable effect on plants or plant products, no unacceptable influence on the environment in general and, in particular, no harmful effect on human or animal health or on groundwater. [6]

Relevant Community legislation

Directive 91/414

6. Article 3(1) of Directive 91/414 requires Member States to prescribe that a plant protection product may not be placed on the market and used in their territory unless they have authorised the product in accordance with the directive.

5. The recitals in the preamble to Directive 91/414 refer to the importance of plant protection products; to the fact that their use may involve risks and hazards for humans, animals and the environment; to the barriers to trade flowing from different national rules governing their authorisation and to the desirability of eliminating such barriers by harmonising those rules. [4] Uniform rules should provide that plant protection products should not be put on the market or used unless authorised in accordance with provisions ensuring a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment have not been the subject of appropriate research. [5] It is necessary, when

7. Article 4(1) requires Member States to ensure that a plant protection product is not authorised unless, first, its active substances are listed in Annex I and any conditions laid down therein are fulfilled [7] and, second, a number of requirements laid down in Article 4(1)(b) to (f) are met. Article 4(1)(b) to (e) essentially concerns the safety and effectiveness of the product when used; and whether their requirements are met is

4 — Third to sixth recitals.
5 — Seventh to ninth recitals.
6 — Tenth recital.
7 — Article 4(1)(a).

to be assessed pursuant to the uniform principles provided for in Annex VI. Article 4(1)(f) requires maximum residue levels to have been established by the Member State and notified to and approved by the Commission.

8. Article 5 provides that an active substance is to be included in Annex I if it may be expected that plant protection products containing it will not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

9. Article 6(1) provides that the inclusion of an active substance in Annex I is to be decided in accordance with a prescribed procedure.

10. Article 6(2) requires a Member State receiving an application for the inclusion of an active substance in Annex I to ensure that a dossier which a Member State believes to satisfy the requirements of Annex II is forwarded 'by the applicant' to the other Member States and to the Commission together with a dossier complying with Annex III on at least one plant protection product containing that active substance.

11. Article 8 is headed 'Transitional measures and derogations'. Article 8(1), not relevant in the present case, deals with arrangements for new products containing active substances not yet approved and listed. Article 8(2) deals with existing products containing such active substances.

12. The first subparagraph of Article 8(2) provides that, by way of derogation from Article 4, 'a Member State may, during a period of 12 years following the notification of [the 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'. [8]

13. The second subparagraph of Article 8(2) requires the Commission to commence a programme of work for the gradual examination of those active substances within that 12-year period in accordance with a regulation [9] to be adopted in accordance with a procedure prescribed under Article 19 of the directive.

8 — It is common ground that the directive was notified on 26 July 1991.

9 — One such regulation was Regulation No 3600/92: see below, paragraph 21 et seq.

14. The fourth subparagraph of Article 8(2) provides:

'During the 12-year period referred to in the first subparagraph it may … be decided by [a prescribed procedure] 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.'

15. Article 13(1) provides that Member States are to require that 'applicants for authorisation of a plant protection product submit with their application' (a) a dossier satisfying Annex III and (b) for each active substance in the plant protection product a dossier satisfying Annex II.

16. Article 13(3)(d) prohibits Member States from making use of the information referred to in Annex II for the benefit of other applicants without consent for five years from the date of the decision following receipt of further information necessary to include the active substance in Annex I for the first time, to vary the conditions for inclusion in Annex I or to maintain such inclusion. [10]

17. Article 13(6) provides:

'By way of derogation from [Article 13(1)], for active substances already on the market two years after notification of this directive, 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.'

18. Annex II to Directive 91/414 contains requirements for the dossier to be submitted for the inclusion of an active substance in Annex I. Annex III contains requirements for the dossier to be submitted for the authorisation of a plant protection product. I shall henceforth refer to such dossiers as Annex II or Annex III dossiers.

10 — I have retranslated from the French text of Article 13(3)(d). The original version of the English text was plainly wrong. It was reformulated in a corrigendum (OJ 1992 L 170 p 40). Article 13(3)(c) also restricts the use of this information.

19. Annex VI [11] lays down uniform principles for the evaluation of plant protection products.

20. The period of 12 years referred to in Article 8(2) was extended until 31 December 2006 for active substances assessed in the framework of the first stage of the Commission's programme for examining such substances. [12]

Regulation No 3600/92

21. Regulation No 3600/92 [13] lays down the procedure for the inclusion in Annex I to Directive 91/414 of certain active substances contained in plant protection products covered by existing authorisations, referred to in Article 8(2) of that directive.

22. Those active substances include ethofumesate. [14]

23. Article 4(1) of Regulation No 3600/92 lays down the procedure to be followed by the producer [15] of an active substance referred to in Annex I thereto wishing to secure its inclusion in Annex I to Directive 91/414.

24. That procedure is initiated by the producer's notifying the Commission. I shall refer to a producer notifying the Commission in accordance with Article 4(1) of Regulation No 3600/92 as 'a notifier'.

25. Article 6 of Regulation No 3600/92 requires the notifiers, individually or collectively, to send to the designated authority, within a prescribed time-limit, for any given active substance (a) a summary dossier containing summary information for each point of Annexes II and III to Directive 91/414 and (b) a complete dossier containing complete information for each point of those Annexes.

11 — Inserted by Council Directive 94/43/EC of 27 July 1994 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ 1994 L 227, p. 31).

12 — Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances (OJ 2002 L 319, p. 3) as amended by Commission Regulation (EC) No 1335/2005 of 12 August 2005 (OJ 2005 L 211, p. 6).

13 — Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ 1992 L 366, p. 10).

14 — Listed in Annex I to Regulation No 3600/92.

15 — Defined as the manufacturer, his designated sole representative or the importer into the Community.

Directive 2002/37

26. Directive 2002/37, adopted on the basis of Article 6(1) of Directive 91/414, amends that directive so as to include ethofumesate in Annex I thereto, subject to certain conditions.

27. The preamble to Directive 2002/37 includes the following recitals:

'(5) It has appeared from the various examinations made that plant protection products containing ethofumesate may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include ethofumesate in Annex I to that Directive, in order to ensure that in all Member States authorisations of plant protection products containing ethofumesate can be granted in accordance with the provisions of Directive 91/414/EEC.

...

(8) After inclusion, Member States should be allowed a reasonable period within which to implement the provisions of Directive 91/414/EEC as regards plant protection products containing ethofumesate, and in particular, to review existing authorisations in accordance with the provisions of Directive 91/414/EEC to ensure that the conditions regarding ethofumesate set out in Annex I to Directive 91/414/EEC are satisfied. A longer period should be provided within which a complete dossier for each such plant protection product, satisfying the requirements of Annexes II and III to Directive 91/414/EEC, should be submitted and that product re-evaluated in accordance with the uniform principles laid down in Directive 91/414/EEC.'

28. Article 1 of Directive 2002/37 amends Annex I to Directive 91/414 so as to add ethofumesate thereto and include, under the heading 'Specific provisions':

'Only uses as herbicide may be authorised.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on ethofumesate, and in particular Appendices I and II thereof, as final-

ised in the Standing Committee on the Food Chain and Animal Health on 26 February 2002 shall be taken into account. In this overall assessment Member States may pay particular attention to the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and must apply risk mitigation measures, where appropriate.'

29. Article 4 of Directive 2002/37 provides:

'1. Member States shall review the authorisation for each plant protection product containing ethofumesate to ensure that the conditions relating to ethofumesate set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or withdraw the authorisation in accordance with Directive 91/414/EEC before 1 September 2003.

2. Member States shall, for each authorised plant protection product containing ethofumesate as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 1 March 2003, re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III thereto. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC. Where necessary and by 28 February 2007 at the latest, they shall amend or withdraw the authorisation for each such plant protection product.'

30. Directive 2002/37 entered into force on 1 March 2003. [16]

Directive 2005/53

31. Directive 91/414 has been amended by other directives, including Directive 2005/53. [17] The preamble to Directive 2005/53 includes the following recitals:

'(10) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed

16 — Article 5.

17 — Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ 2005 L 241, p. 51).

a period of six months after inclusion to review existing authorisations of plant protection products containing [certain chemicals, not including ethofumesate] to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

ectives which have been adopted until now amending Annex I.'

32. Article 3 of Directive 2005/53 provides:

'1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing [certain chemicals] as active substances by 31 August 2006.

(11) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the dir-

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to [certain chemicals] are met, with the exception of those identified in part B of the entries concerning those active substances, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By derogation from paragraph 1, for each authorised plant protection product

containing [certain chemicals] as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 28 February 2006 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entries in Annex I to that Directive concerning [certain chemicals]. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC …'

…

(c) that is necessary for the implementation of a Community measure.'

Relevant national law

34. The referring court has drawn the attention of the Court of Justice to Article 7(1)(c) of the 1962 Law on Pesticides, which reads as follows:

'1. The Board shall withdraw an authorisation or registration … if:

Background to the main proceedings and question referred

33. However, at the material time, Directive 2005/53 had not entered into force.

35. Feinchemie Schwebda GmbH and Bayer CropScience AG ('the applicants'), producers of plant protection products, notified the Commission in accordance with the procedure laid down by Regulation No 3600/92 with a view to the inclusion of ethofumesate in Annex I to Directive 91/414. In support of their application they submitted an Annex II dossier. As a result, ethofumesate was added, with effect from 1 March 2003, to the list of active substances authorised for incorporation in plant protection products in Annex I to Directive 91/414.

36. Agrichem BV ('Agrichem') held existing authorisations for seven products which contained ethofumesate as an active

substance. It did not act with the applicants as a co-notifier, nor did it submit an Annex II dossier.

37. Agrichem's authorisations were initially withdrawn by the College voor de toelating van bestrijdingsmiddelen (Netherlands Board for the authorisation of pesticides, 'the CTB'), by decisions of 23 January 2004, on the basis that no Annex II dossier had been submitted. Those withdrawals were subsequently revoked by a decision of 19 November 2004 ('the contested decision') in which the CTB took the view that an Annex II dossier could not be requested under Article 4(1) of Directive 2002/37.

38. The applicants have appealed against that decision to the College van Beroep voor het bedrijfsleven, which has referred the following question to the Court of Justice for a preliminary ruling:

'Must Article 4(1) of Directive 2002/37/EC be interpreted as meaning that that provision does not require Member States to terminate the authorisation of a plant protection product containing ethofumesate before September 2003 on the ground that the authorisation holder does not have, or have access to, a dossier satisfying the conditions set out in Annex II to Directive 91/414/EEC?'

Summary of the observations of the parties

39. Written observations have been submitted by the applicants, Agrichem, the Belgian and Netherlands Governments and the Commission, all of whom, apart from the Belgian Government, were present at the hearing on 19 September 2007.

40. With the exception of Agrichem, all those parties dispute the correctness of the contested decision. They argue, broadly, that Article 13(1) and (3) of Directive 91/414 creates a situation in which the holder of an existing authorisation who is not a notifier must either hold, or have access to, an Annex II or Annex III dossier before September 2003. If such a party does not have access to such a dossier, Article 13 precludes a Member State from using the information in an existing Annex II or Annex III dossier in its possession to the benefit of that party by continuing an existing authorisation. They contend that, as Directive 2002/37 should be interpreted in the light of Directive 91/414, the lack of express provision in Article 4(1) of Directive 2002/37 for the submission of a dossier during the re-examination process does not affect this preclusion.

41. Agrichem's argument focuses on the simple question of how best to interpret Directive 2002/37 and how that directive

fits with Directive 91/414. It is Agrichem's submission that the relevant provisions of those directives do not require it to be in possession of a full Annex II or Annex III dossier at the end of the period specified in Article 4(1) of Directive 2002/37. Agrichem also submits that those provisions do not oblige a Member State to withdraw an existing authorisation from a body which is not in possession of such a dossier at the end of that period.

44. The applicants and the Netherlands submit that the purpose of the legislation is to protect the intellectual property, the research and the investments of the companies which develop active substances and that, in the absence of such protection, the development of new active substances would cease.

45. Whilst the Commission took the view that the directives principally aim to protect plant protection products, it agrees with the applicants that the development of new active substances is essential for plant protection. Furthermore, it considers that the protection of information in Directive 91/414 operates to protect the investments of the developing companies.

Analysis

42. The main issue in the present case turns on the proper interpretation of Article 4 of Directive 2002/37 and Article 13 of Directive 91/414, and how the provisions of those two directives interact.

46. Agrichem agrees that the principal aim of Directive 91/414 is related to regulating the plant protection products available on the market, but disputes that that should produce an effect by which the holder of an existing authorisation should have that authorisation withdrawn.

The purpose of the directives

47. In my view it is clear from the recitals in the preamble to Directive 91/414[18] that the primary purpose of that directive is to ensure

43. The starting point must be to look at the purpose of the legislation at issue.

18 — Set out in point 5 above.

that the placement of plant protection products on the market is regulated, rather than to ensure the protection of intellectual property rights. That principal purpose should be borne in mind when addressing the specific provisions of Directives 91/414 and 2002/37.

Article 4 of Directive 2002/37

50. Article 4 of Directive 2002/37 concerns the information required of the holder of an existing authorisation and the time when the holder must have that information.

The main provisions

51. The CTB stated that authorisations for plant protection products containing ethofumesate as an active substance must in any event satisfy the conditions laid down by Directive 2002/37. Neither Directive 2002/37 nor Directive 91/414 lays down the condition that it must be demonstrated during the compliance check that an existing authorisation is supported by an Annex II dossier. The CTB concluded that it did not have the competence to request such a dossier.

48. In the order for reference, the referring court took the view that it did not appear from the wording of Article 4(1) of Directive 2002/37 that a Member State is required to terminate the authorisation of the plant protection product in question.

52. The referring court appears to be in agreement with the contested decision. That court stated that the scheme of a *review* of authorisations (to be completed by 1 September 2003) laid down by Article 4(1) of Directive 2002/37 is intended to ensure that the conditions relating to ethofumesate set out in Annex I are complied with. In contrast, the scheme of *re-evaluations* of existing authorisations (to be completed by 28 February 2007) laid down by Article 4(2) of that directive is intended to determine whether each plant protection product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414. The basis for that evaluation is an Annex III dossier.

49. In the contested decision, the CTB followed the recommendation of its Advisory Committee on Objections and held that it was not competent to request an Annex II dossier to support Agrichem's existing authorisations under Article 4(1) of Directive 2002/37.

53. The referring court also stated that it was not apparent from the wording of Article 4(1) of Directive 2002/37 that Member States are required to terminate the authorisation if the authorisation holder is unable to provide, before 1 September 2003, an Annex II dossier, as Article 4(1) does not require an Annex II dossier to be submitted by the authorisation holder for the review. Furthermore, that court assumes that the review can be carried out on the basis of data already known to the authority which previously granted the authorisation.

54. Agrichem is also in agreement with the contested decision. It submits that ethofumesate has been approved (on the basis of an Annex II dossier). That implies that there is no reason based on health concerns to withdraw an existing authorisation. It also argues that the staggered time-periods for review of existing authorisations under Article 4(1) of Directive 2002/37, and for the more substantial re-evaluation under Article 4(2) thereof, imply that a dossier is required for the latter but not the former. Requiring a dossier for a review under Article 4(1) would lead to there being little difference between the two types of evaluation.

55. In contrast, the Commission submits that Directive 2002/37 was enacted on the basis that Member States cannot authorise a body to place an ethofumesate product on the market unless that body possesses an appropriate dossier. Consequently, the effect of Article 4(1) is that the Member State concerned must withdraw authorisations unless a full dossier is provided by 1 September 2003.

56. The Commission's first contention appears to be correct from the plain wording of Article 4 of Directive 2002/37. However, it does not follow that a party that holds an existing authorisation should not be permitted to retain it.

57. Alternative meanings for Article 4 have been suggested by the Netherlands and by the Commission. The Netherlands suggests that although it is not apparent from the text of Article 4(1) that a dossier is needed, the requirement for a dossier is not in conflict with the wording of that article. The Commission has offered two possible interpretations of Articles 4(1) and 4(2). First, the Commission suggests that the first deadline (in Article 4(1)) requires the presentation of an Annex II dossier, whereas the second deadline (in Article 4(2)) requires the re-evaluation of an Annex III dossier (on the rationale that as multiple products will be

on the market, with multiple substances in them, checking each one will take longer). Alternatively, the Commission argues that Article 4(1) is superfluous and merely clarifies the general requirement to submit a dossier at the end of the first period.

58. In my view, the interpretations offered by the Netherlands and the Commission would involve interpreting Article 4 in a manner contrary to its plain wording, and in the case of the Commission's first argument, contrary to the plain wording of recital 8 of Directive 2002/37.

59. Taking the most straightforward interpretation of that provision, the review procedure for existing authorisations set out under Article 4(1) demands only basic information (as found in Annex I), and not a full Annex II or III dossier. It merely involves checking that 'the conditions relating to ethofumesate … are complied with'. It does *not* require a full re-evaluation of the plant protection product as such (that task is laid down by Article 4(2)). Therefore, Article 4(1) does not logically require withdrawal of an existing authorisation on the grounds that a company holding that authorisation does not have access to an Annex II (or III) dossier. On that basis, the question referred to this Court may be answered in the affirmative.

60. However, it is possible that the legislative framework in which Directive 2002/37 was enacted may provide a convincing explanation for a different interpretation of Article 4(1).

Relationship between the two directives

61. It is accepted by all parties that Article 6 of Directive 91/414 provides a framework which envisages the enactment of a series of directives, inter alia, Directive 2002/37. However, the question of the relationship between the two directives is a matter of some dispute.

62. The starting point of those parties who propose that the question referred be answered in the negative is that Directive 2002/37 should be interpreted in the light of Directive 91/414, rather than constituting *lex specialis*. That is because Directive 2002/37 is a Commission Directive, envisaged in Article 6 of Directive 91/414, which amends that directive only to the extent of including a further substance in Annex I. The applicants contend that Directive 2002/37 should therefore be interpreted in the light of Directive 91/414.

63. Agrichem accepts that argument but argues that when the plain meaning of the words in Directive 2002/37 is considered, Directive 91/414 does not have to modify the meaning of Directive 2002/37, as the two are complementary. Agrichem submits that Directive 91/414 would modify the meaning of Directive 2002/37 only in the event of a conflict, which is not the case.

64. Agrichem contends, in the alternative, that, although the enactment of Directive 2002/37 was envisaged by Directive 91/414, Directive 2002/37 nevertheless constitutes *lex specialis*, because it deals more specifically than Article 8 of Directive 91/414 with the transitional provisions.

Article 8 of Directive 91/414

65. Article 8 expressly creates a structure for dealing with the transitional period, during which it may be decided to include in Annex I an active substance contained in a plant protection product subject to an existing authorisation.

66. The Commission submits that the transitional regime in Article 8, under which a Member State may apply its own national provisions, will come to an end when the substance which is the subject of those provisions is entered in Annex I. The Commission contends that once an active substance is listed in Annex I, then all parties must have an Annex II or III dossier in accordance with Community legislation.

67. However, the argument is circular, because it takes one straight back to the question of whether Article 4(1) of Directive 2002/37 does or does not require a body holding an *existing* authorisation for a plant protection product to be in possession of Annex II dossier.

Directive 2005/53

68. The applicants, the Netherlands and the Commission submit that, in contrast to later amending directives, Directive 2002/37 is something of an anomaly, in that it provides for a longer period before the delivery of an Annex II dossier than that envisaged by Article 8 of Directive 91/414. These parties have referred to Directive 2005/53 as an example of a more typical amending directive.

69. These parties cite Article 3 of that directive, which states that for the active substances added by that directive, Member States must verify that the authorisation holder has access to an Annex II dossier. They point out that the 10th recital to Directive 2005/53 clearly states that Article 13 of Directive 91/414 is intended to apply to holders of existing authorisations, and that all authorisation holders should have access to an Annex II dossier.

70. The Commission therefore argues that Directive 2002/37 should have the same requirements read into it, on the basis that Directive 2005/53 simply rendered explicit an intention that was implicit in the earlier directives regarding the interaction between Directive 91/414 and the amending directives.

71. Agrichem submits that the interpretation proposed by the Commission would apply a prospective interpretation (found in the recitals) to a previous directive. Agrichem submits that as well as being contrary to the principle of legal certainty, such an interpretation is explicitly ruled out by the recitals themselves.

72. I do not accept the Commission's argument. Recital 11 to Directive 2005/53 states, quite explicitly, that Directive 2005/53 does not affect obligations which have arisen under previous amending directives. Yet that would be precisely the effect of the Commission's reading. I also recall that Directive 2005/53 does not concern ethofumesate; and that it had not entered into force at the material time.

73. I therefore agree with Agrichem that the interpretation found in the preamble to Directive 2005/53 should not be retrospectively applied to Directive 2002/37.

Article 13 of Directive 91/414

74. The relationship between Article 4(1) of Directive 2002/37 and the provisions of Directive 91/414 is defined by the second sentence of Article 4(1), which states that amendment or withdrawal of authorisations should be done in accordance with the provisions of Directive 91/414.

75. The only provision of Directive 91/414 which might lead to withdrawal of an author-

isation is Article 13. That article concerns the use of the information constituting an Annex II dossier which was submitted in order to add an active substance to the list of permitted substances found in Annex I to Directive 91/414.

76. I therefore turn to examine that provision.

The scope of Article 13(1)

77. The essential question to be answered is whether companies in Agrichem's position fall within the scope of Article 13. Agrichem argues that as a holder of existing authorisations, rather than a company which wishes to bring new plant protection products on to the market, it does not fall within the scope of Article 13. The provisions of that article are therefore irrelevant to it.

78. Agrichem points out that the wording of Article 13 refers to 'applicant'. A review under Article 4(1) of Directive 2002/37 is not based on an application. Therefore, the scope of Article 13 does not extend to holders of existing authorisations.

79. Furthermore, Agrichem recalls that in *Stichting Zuid-Hollandse Milieufederatie* [19] Article 13 was interpreted as applying to those bodies *making* applications for authorisation, rather than holders of existing authorisations. As existing authorisations for plant protection products containing ethofumesate have to be confirmed by re-examination under Article 4(1) of Directive 2002/37, the validity of such authorisations should remain unaffected by, and should not fall into, the sphere of operation of Article 13.

80. The applicants suggest that the definition of the term 'applicant' should apply to all bodies other than the notifying applicants. They argue that as the directives aim to protect the investments of companies which have researched and developed certain active substances, Articles 4 and 13 together operate to create a framework for authorisations in which the requirements which have to be met are set out in Article 13 if authorisation is to be sought or retained.

19 — Case C-138/05 [2006] ECR I-8339, inter alia at paragraph 46.

81. However, that contention relies upon implying an extra concept (namely, *retained*) into Article 13.

82. The Commission has also argued that the scope of Article 13 extends to holders of existing authorisations and that such holders should be treated differently from new applicants only during the transitional period, which is brought to an end by Article 13(6) when the product concerned is added to Annex I. Once a substance is entered into Annex I, Article 13(1) must be applied.

83. According to the Commission, Article 13 aims to protect the notifying authorisation holders by granting future authorisations on the basis of an Annex II dossier. For that reason, Article 13(1) should be construed as covering holders of existing authorisations. Otherwise, there is a difference in treatment between holders of existing authorisations (no dossier needed) and new applications for authorisation (dossier needed) which is unjust.

84. I do not find that a convincing explanation of why the holder of an existing authorisation should have to behave in the same way as a new applicant. Furthermore, Article 13(7) appears to differentiate between applicants and holders of existing authorisations.

85. The referring court suggests that the applicants' interpretation of the scope of Article 13(1) may give the notifying party an unjustified competitive advantage. I agree. In my view the reading proposed by the applicants amounts to a lock-out resulting from a complete prohibition on the use of active substances added to the list in Annex I to Directive 91/414, which applies to all parties other than the actual notifying bodies.

86. Although that lock-out would only last for a short period by virtue of Article 13(3)(c) and Article 13(3)(d), it is an anti-competitive measure. If the legislator intended to permit such a result, one would expect it to be stated explicitly in the legislation, rather than being left to be inferred indirectly.

87. Such a lock-out would also have the effect of prohibiting bodies which have already been granted authorisation to use specific plant protection products containing

such active substances from continuing to use them. It would in my view be both disproportionate and anti-competitive so to remove a previously-acquired right, validly granted under Article 8 of Directive 91/414.

88. I am not prepared to construe Article 13(1) in that way. I therefore conclude that a holder of an existing authorisation does not come within the scope of Article 13(1).

The effect of Article 13(3)

89. An alternative argument which has been proposed is that Article 13(3) prevents a Member State from making use of the contents of an Annex II or III dossier for the benefit of parties which do not have access to such a dossier.

90. The applicants submit that Article 13(3) of Directive 91/414 aims to protect the investments of notifying parties by way of a 'closed dossier' system. They argue that for a period of five years following notification, information contained in such dossiers must not be used by, or to the benefit of, any applicants for authorisation which do not themselves have, or have access to, an Annex II dossier.

91. In reply to that submission, Agrichem states that it has in fact already completed such a dossier, but was unable to do so before the deadline set out in Article 4(1) of Directive 2002/37. Agrichem argues that it has made no profit from the work of the applicants.

92. On the legal level, Agrichem argues that on a proper reading of Article 4(1) of Directive 2002/37, all a company must show in order to retain an existing authorisation is the information in Annex I, which is already in the public domain. This would therefore operate smoothly in conjunction with Article 13 of Directive 91/414, which would only restrict the use of information in the Annex II and III dossiers. Such a reading sits more naturally with the wording of the directives themselves.

93. I do not read Article 4(1) of Directive 2002/37 as requiring the holder of an existing authorisation to have access to an Annex II or Annex III dossier. It follows that Article 13(3) of Directive 91/414 cannot be relied upon by the applicants, as it does not apply in such a situation. Agrichem holds

existing authorisations for certain plant protection products containing ethofumesate as an active substance which it was granted in accordance with Article 8(2) of Directive 91/414. It is not a new applicant and therefore does not fall within the scope of Article 13(1) of Directive 91/414. Neither it, nor the Member State, needs to have access to, or make use of the information in, an Annex II or III dossier until there is a re-evaluation of its existing authorisations under Article 4(2) of Directive 2002/37.

The data protection issue

94. A subsidiary issue arises in relation to data protection, inasmuch as the data held by Agrichem were not sufficient to constitute a complete Annex II dossier. The question then arises whether Agrichem is entitled to refer to the data which were taken into account in the Community evaluation for ethofumesate which led to Directive 2002/37.

95. That issue is relevant only if, contrary to the view that I have expressed, Directives 91/414 and 2002/37 properly interpreted require Agrichem to submit a complete Annex II dossier, so that in order to do so it needs to seek access to the information submitted by the applicants. It seems to me that in such circumstances the usual data protection legislation [20] would apply, in the absence of any other, more specific, provisions. Those general provisions on data protection allow the need to preserve the confidentiality of business secrets to be taken into account.

96. Finally, I should mention that in reaching the contested decision, the CTB expressed the concern that if Article 4(1) of Directive 2002/37 is read literally (as in my view should be the case) that effectively renders the provisions of Directive 91/414 meaningless in particular as regards data protection.

97. I do not share that concern. Permitting Agrichem to continue to use those plant protection products containing ethofumesate as an active substance in respect of which it has existing authorisations does not entail granting it permission to access the data required to create an Annex II dossier. All that is required is the information in Annex I, which is in the public domain.

20 — Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ 1995 L 281, p. 31) or Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ 2001 L 145, p. 43) in the case of information submitted to and held by the Community institutions.

Conclusion

98. In the light of the above, I would answer the question referred by the College van Beroep voor het bedrijfsleven as follows:

'Article 4(1) of Commission Directive 2002/37/EC *does not require* Member States to terminate before 1 September 2003 an authorisation granted pursuant to the first subparagraph of Article 8(2) of Council Directive 91/414/EEC for a plant protection product containing ethofumesate as an active substance on the ground that the holder of that authorisation does not have, or have access to, a dossier satisfying the requirements of Annex II to Directive 91/414.'