JUDGMENT OF THE COURT OF FIRST INSTANCE (Fourth Chamber)

9 September 2008 *

In Case T-75/06,

Bayer CropScience AG, established in Monheim am Rhein (Germany),

Makhteshim-Agan Holding BV, established in Rotterdam (Netherlands),

Alfa Georgika Efodia AEVE, established in Athens (Greece),

Aragonesas Agro, SA, established in Madrid (Spain),

represented by C. Mereu and K. Van Maldegem, lawyers,

applicants,

supported by

European Crop Protection Association (ECPA), established in Brussels (Belgium), represented by D. Waelbroeck and N. Rampal, lawyers,

intervener,

* Language of the case: English.

Commission of the European Communities, represented by B. Doherty and L. Parpala, acting as Agents,

defendant,

supported by

Kingdom of Spain, represented by J. Rodríguez Cárcamo, abogado del Estado,

intervener,

APPLICATION for the annulment of Commission Decision 2005/864/EC of 2 December 2005 concerning the non-inclusion of Endosulfan in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that active substance (OJ 2005 L 317, p. 25),

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Fourth Chamber),

composed of O. Czúcz (Rapporteur), President, J.D. Cooke and I. Labucka, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 12 February 2008,

gives the following

Judgment

Legal context

Treaty provisions

1 Article 95(3) EC provides that, in its proposals to the Council for measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market and which concern health, safety, environmental protection and consumer protection, the Commission is to take as a base a high level of protection, taking account in particular of any new development based on scientific facts.

2 Article 152(1) EC states that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.

Directive 91/414/EEC

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) lays down the Community rules applicable to the granting of authorisation to place plant protection products on the market and to the withdrawal of such authorisation.

4 Article 4 of Directive 91/414 provides that 'Member States shall ensure that a plant protection product is not authorised unless … its active substances are listed in Annex I …'.

5 The conditions for the inclusion of active substances in Annex I are specified in Article 5 of Directive 91/414:

'1. In the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the following conditions:

(a) their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use;

(b) their use, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health or any unacceptable influence on the environment as provided for in Article 4(1)(b)(iv) and (v).

2. For inclusion of an active substance in Annex I, the following shall be taken into particular account:

(a) where relevant, an acceptable daily intake (ADI) for man;

(b) an acceptable operator exposure level if necessary;

(c) where relevant, an estimate of its fate and distribution in the environment as well as its impact on non-target species.

…'

6 Article 6 of Directive 91/414 provides:

'1. Inclusion of an active substance in Annex I shall be decided in accordance with the procedure laid down in Article 19.

…

2. A Member State receiving an application for the inclusion of an active substance in Annex I shall without undue delay ensure that a dossier which is believed 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 preparation containing that active substance. The Commission shall refer the dossier to the Standing Committee on Plant Health referred to in Article 19 for examination.

3. Without prejudice to the provisions of paragraph 4, at the request of a Member State, and within three to six months after the date of referral to the committee mentioned in Article 19, it shall be established by the procedure laid down in Article 20 whether the dossier has been submitted in accordance with the requirements of Annexes II and III.

4. If the assessment of the dossier referred to in paragraph 2 shows that further information is necessary, the Commission may ask the applicant to submit such information. The applicant or his authorised representative may be asked by the Commission to submit his remarks to it, in particular whenever an unfavourable decision is envisaged.

…'

7 Active substances which are not listed in Annex I to Directive 91/414 may, in certain circumstances, benefit from transitional arrangements permitting derogation. Thus, Article 8(2) of Directive 91/414 provides that 'a Member State may, during a period of 12 years following the notification of this directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this directive'. That 12-year period, which expired on 26 July 2003, was extended for certain substances by Commission Regulation (EC) No 2076/2002

of 20 November 2002 extending the time period referred to in Article 8(2) of Directive 91/414 and concerning the non-inclusion of certain active substances in Annex I to the 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 which also amended Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Council Directive 91/414 and the continued use of certain substances not included in its Annex I (OJ 2005 L 211, p. 6). Under Regulation No 1335/2005, the 12-year period was extended until 31 December 2006, 'unless a decision has been taken or is taken before the relevant date to include or not include the active substance concerned in Annex I to Directive 91/414/EEC'.

8 Article 8(2) of Directive 91/414 provides that, during that transitional period, each active substance concerned must undergo a programme for its examination (or 'review'), on conclusion of which it may be decided that the substance can be included in Annex I, or, if the substance does not satisfy the safety requirements laid down in Article 5 of Directive 91/414 or if the requisite information and data have not been submitted within the prescribed period, that the active substance will not be included. It is also stated that the examination of the active substance is to be carried out in accordance with the procedure referred to in Article 19 of Directive 91/414. That article, as amended by Council Regulation (EC) No 806/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (qualified majority) (OJ 2003 L 122, p. 1), provides that the Commission is to be assisted by a regulatory committee, the Standing Committee on the Food Chain and Animal Health ('the Committee').

Regulation (EEC) No 3600/92

9 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 Directive 92/414 (OJ 1992 L 366, p. 10) regulates the procedure for the assessment of a number of substances with a view to their possible inclusion in Annex I to Directive 91/414. One of those substances is endosulfan.

10 The procedure established by Regulation No 3600/92 begins with a notification of interest, as provided for in Article 4(1) of that regulation, under which '[a]ny producer wishing to secure the inclusion of an active substance referred to in Annex I hereto, or any salts, esters or amines thereof, in Annex I to [Directive 91/414], shall so notify the Commission within six months of the date of entry into force of this regulation'.

11 Article 5(2)(b) of Regulation No 3600/92 provides that, following the examination of the notifications of interest, a rapporteur Member State is to be designated for the assessment of each of the active substances concerned.

12 Once the rapporteur Member State has been designated, it is the responsibility of each notifier to send to that Member State, in accordance with Article 6(1) of Regulation No 3600/92, a 'summary dossier' and a 'complete dossier', as defined in paragraphs 2 and 3, respectively, of Article 6 of that regulation. The summary dossier must include, in particular, a copy of the notification; the recommended conditions for the use of the active substance; and summaries and results of trials for each point of Annex III to Directive 91/414 relevant to the assessment of the criteria referred to in Article 5 of that directive. That information must relate to one or more preparations which are representative for the recommended conditions of use in relation to the inclusion of the active substance in Annex I to the directive. The complete dossier must contain the protocols and the complete study reports concerning all that information. Under Article 6(2)(b) of Regulation No 3600/92, as supplemented by Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27), 'it has to be demonstrated by the notifier that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the requirements of [Directive 91/414] in relation to the criteria referred to in Article 5 thereof can be met'.

13 The summary dossier and the complete dossier are to be sent by notifiers to the rapporteur Member State by a deadline to be set by the Commission. In the case of endosulfan, the deadline for lodging those dossiers was set as 30 April 1995 by Commission Regulation (EC) No 933/94 of 27 April 1994 laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Regulation No 3600/92 (OJ 1994 L 107, p.8), and subsequently deferred until 31 October 1995 by Commission Regulation (EC) No 2230/95 of 21 September 1995 amending Regulation No 933/94 (OJ 1995 L 225, p. 1). It is also the responsibility of notifiers, under Article 6(1) of Regulation No 3600/92, to send the summary dossier and the complete dossier to the experts from other Member States who have been approved by the Commission, with a view to possible later consultation.

14 The rapporteur Member State is then required to examine the summary dossier and the complete dossier and, pursuant to Article 7(1)(b) of Regulation No 3600/92, must 'immediately after examining a dossier, ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission'. Article 7(2) of Regulation No 3600/92, as amended by Commission Regulation (EC) No 1199/97 of 27 June 1997 (OJ 1997 L 170, p. 19) provides that, from the start of its examination, 'the rapporteur Member State may request the notifiers to improve their dossiers, or add to them' and that it 'may consult with experts from other Member States, and may request additional technical or scientific information from other Member States in order to assist the evaluation'.

15 A report of its assessment of the dossiers lodged is then to be drawn up and forwarded to the Commission by the rapporteur Member State, at the latest 12 months after receipt of the dossiers, in accordance with Article 7(1)(c) of Regulation No 3600/92. The report must contain, inter alia, a recommendation as to whether it is appropriate to include the active substance concerned in Annex I to Directive 91/414.

16 Article 7(3) of Regulation No 3600/92, as amended by Regulation No 1199/97, provides that, after receiving the summary dossier and the report referred to in

Article 7(1), the Commission is to refer the dossier and the report to the Committee for examination. Before referring the dossier and the report to the Committee, the Commission is required to circulate the report of the rapporteur Member State to the other Member States for information. Moreover, before the dossier and the report are referred to the Committee, a consultation of experts of the Member States may be arranged and the Commission may also consult some or all of the notifiers concerned regarding the report or certain parts of the report on the relevant active substance.

17 Paragraph 3A of Article 7 of Regulation No 3600/92, as inserted by Regulation No 1199/97, provides that after the examination by the Committee, the Commission is to present to the Committee: (i) a draft directive to include the active substance in Annex I to Directive 91/414; or (ii) a draft decision addressed to the Member States to withdraw the authorisations of plant protection products containing the active substance; or (iii) a draft decision addressed to the Member States to suspend such products from the market, with the option of reconsidering the inclusion of the active substance in Annex I to the directive after submission of the results of additional trials or additional information; or (iv) a draft decision to postpone inclusion of the active substance in Annex I to that directive pending the submission of the results of additional trials or information.

18 However, under the first indent of the first subparagraph of Article 7(4) of Regulation No 3600/92, as supplemented by Regulation No 2266/2000, where it appears, following the Committee's examination, that the submission of the results of certain additional trials or of additional information is required, the Commission is to determine the time-limit within which the results or information concerned must be submitted. That provision states:

'[T]his time-limit will be 25 May 2002 unless an earlier time-limit is established by the Commission for a particular active substance except for the results of long-term studies, identified as being necessary by the rapporteur Member State and the Commission during the examination of the dossier and which are not expected to be fully completed by the deadline established, provided that the information submitted

contains evidence that such studies have been commissioned and that their results will be submitted at the latest on 25 May 2003. In exceptional cases, where it has not been possible for the rapporteur Member State and the Commission to identify such studies by 25 May 2001, an alternative date may be established for the completion of such studies, provided the notifier supplies the rapporteur Member State with evidence that such studies have been commissioned within three months of the request to undertake the studies, and with a protocol and progress report of the study by 25 May 2002.'

19 Article 7(4) of Regulation No 3600/92, as supplemented by Regulation No 2266/2000, also provides:

'[…S]ubmission of new studies will not be accepted. The rapporteur Member State, with the agreement of the Commission, may request the notifiers to submit further data necessary to clarify the dossier.

For active substances for which the results or information referred to in the first indent have not been submitted within the established time-limit the rapporteur Member State shall immediately inform the Commission. The Commission shall decide, as provided for in Article 8(2), last subparagraph, of [Directive 91/414], not to include in Annex I to … [Directive 91/414] such active substances mentioning the reasons for the non-inclusion.'

20 Under Article 7(5) of Regulation No 3600/92, 'the Commission shall submit to the Committee a draft decision for non-inclusion in Annex I to [Directive 91/414], in accordance with the final subparagraph of Article 8(2) thereof, where … the rapporteur Member State has informed the Commission that the results referred to in the first indent of paragraph 4 have not been submitted within the time-limit laid down'.

21 Article 8 of Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that, after receiving the results of additional trials or additional information, the rapporteur Member State must: (i) examine them; (ii) ensure that the results or additional information are sent by the notifier to the other Member States and to the Commission; and (iii) communicate to the Commission, within six months at the latest following receipt of the results or information, its assessment of the dossier (as an addendum to the assessment report already submitted to the Commission), together with a recommendation for the inclusion or the non-inclusion of the active substance in Annex I to Directive 91/414.

22 Under Article 8(3) of Regulation No 3600/92, as amended by Regulation No 2266/2000, once the Commission has received the report drawn up by the rapporteur Member State, it must refer it to the Committee for examination, and that '[b]efore referring the dossier and report to the Committee, the Commission shall circulate the rapporteur's report to the Member States for information and may organise a consultation of experts from one or several Member States'. In addition, '[t]he Commission may consult some or all of the notifiers of active substances on the report or parts of the report on the relevant active substance', and '[t]he rapporteur Member State shall provide the necessary technical and scientific assistance during these consultations'. On completion of the examination by the Committee, the Commission is to present a draft directive to the Committee for the inclusion of the substance in Annex I to Directive 91/414, or a draft decision for its non-inclusion.

Background to the dispute

The evaluation procedure

23 Endosulfan is an active substance used inter alia in the manufacture of pesticides. It acts as a contact poison on a wide variety of insects and mites on many crops, including cotton and many varieties of fruit and vegetables.

24 The applicants — Bayer CropScience AG, Makhteshim-Agan Holding BV, Alfa Georgika Efodia AEVE and Aragonesas Agro, SA — are companies whose business includes the production and marketing of endosulfan and endosulfan-based plant protection products.

25 Pursuant to Regulation No 933/94, the Kingdom of Spain was designated as the rapporteur Member State responsible for examination of endosulfan. As stated in Annex III to that regulation, the Kingdom of Spain designated as the competent authority for that task, in accordance with Article 3 of Regulation No 3660/92, the Spanish Ministry of Agriculture, Fisheries and Food ('MAPA'). MAPA assigned to the Instituto Nacional de Investigacíon y Tecnologia Agraria y Alimentaria (National Institute for Agricultural and Food Research and Technology) ('INIA') the task of drawing up assessment reports for active substances with a view to their inclusion in Annex I to Directive 91/414. Consequently, INIA was responsible for drawing up the draft assessment report for endosulfan and took part in the discussions between experts organised by the Commission.

26 By the submission deadline of 31 October 1995, only Makhteshim Agan International Coordination Center and AgrEvo GmbH (now called Bayer CropScience AG) had submitted to the Kingdom of Spain dossiers, within the meaning of Article 6 of Regulation No 3600/92, on endosulfan. They combined their efforts within a group called the 'Endosulfan task force' ('the task force').

27 During February 2000, the Kingdom of Spain sent the Commission a draft assessment report on endosulfan, which was then sent by the Commission to the Member States and to AgrEvo, as representative of the task force. The task force had been sent a preliminary draft of that report several months earlier. In the draft assessment report, the Kingdom of Spain concluded that the decision on the inclusion of endosulfan in Annex I to Directive 91/414 should be deferred pending receipt and examination of the additional information specified in that report.

28 From January to July 2001, a number of meetings were held between experts from several Member States to examine the draft assessment report and the comments to which it gave rise. Those meetings took place as part of the process of consulting experts from other Member States, as provided for in Article 7(2) of Regulation No 3600/92, pursuant to which the Commission, acting in cooperation with the competent national authorities, had established a framework for dialogue within which that kind of evaluation could be carried out, called European Commission Coordination (ECCO). The members of the task force took part in that dialogue.

29 On 27 June 2001, the report drawn up following that examination was circulated to the Member States and, on 25 August 2001, to the task force with a view to obtaining comments and additional clarifications.

30 On finding that certain additional information was needed for the examination of endosulfan, the Commission adopted — on 21 November 2001 — Decision 2001/810/EC concerning the decision on the possible inclusion of certain active substances into Annex I to Directive 91/414 (OJ 2001 L 305, p. 32), postponing to 25 May 2002 the deadline for submission of new data concerning endosulfan, and to 31 May 2003 the deadline for certain long-term studies. The deadlines coincided with those laid down in Article 7(4) of Regulation No 3600/92.

31 In May 2002, the task force produced new data in accordance with the timetable set by Decision 2001/810. In July 2002, the task force entered into discussions with the Kingdom of Spain concerning the possibility of notifying studies relating to a different formulation of endosulfan. The formulation originally notified was that of wettable powder ('WP') or emulsifiable concentrate ('EC'), whereas the new product took the form of a capsule suspension ('CS'). According to the task force, that new formulation could dispel some of the doubts already expressed by the Kingdom of Spain. At a meeting on 17 July 2002, the representatives of the Kingdom of Spain stated that they could not accept the new dossier, but suggested that the applicants try to obtain informal approval from the Commission on that matter. The applicants did not obtain such approval.

32 In May 2003, the applicants submitted the long-term studies referred to in Decision 2001/810, to which they had added certain new data, that is to say, they submitted a new dossier which was in conformity with Annex III to Directive 91/414 (see paragraph 6 above) concerning the CS formulation ('the CS dossier').

33 On 22 January 2004, a meeting took place between the task force and the Spanish authorities at which an expert in environmental matters and ecotoxicology expressed certain misgivings concerning endosulfan.

34 On 26 January 2004, the task force received from the Kingdom of Spain, by way of an addendum to the assessment report, the report on the evaluation of the data submitted by the task force in May 2002 and May 2003, together with an updated version of the evaluation tables.

35 On 17 May 2004, a tripartite meeting was held between the Commission, the Kingdom of Spain and the task force, pursuant to Article 6(4) of Directive 91/414. At that meeting, the Commission explained the problems raised by endosulfan and stated that it planned to propose to the Committee that endosulfan should not be included in Annex I to Directive 91/414. It also invited the task force to submit its comments before 21 June 2004, while making it clear that no new studies in support of the task force's arguments could be accepted, since the deadline of 31 May 2003 had already passed.

36 On 25 June 2004, the representatives of the task force sent a letter to the Commission objecting to the way in which the evaluation of endosulfan had been conducted and seeking authorisation to produce a number of additional technical explanations. With that letter, they submitted not only additional arguments, but also new studies.

37 By letter of 12 July 2004, the Commission asked the rapporteur Member State not to take into account the new studies submitted by the task force. A copy of that letter was sent to the task force.

38 On 24 September 2004, the task force wrote to the Commission asking it, in essence, to refer the examination of endosulfan back to the rapporteur Member State with instructions to examine all the relevant data, and giving the Commission formal notice to define its position within 60 days.

39 By letter of 26 November 2004, the Commission replied that it was preparing a draft decision for the non-inclusion of endosulfan in Annex I to Directive 91/414 and that it intended to present that draft to the Committee at its first meeting in 2005. The Commission also indicated that, in its letter of 12 July 2004, it had included a reminder of the procedure provided for under Regulation No 3600/92 and the deadlines for completing the examination of the substances covered by that regulation.

40 By application received at the Registry of the Court of First Instance on 31 January 2005, the applicants brought an action for failure to act (Case T-34/05 *Bayer CropScience and Others* v *Commission*).

41 By separate document, lodged at the Registry of the Court of First Instance on 31 January 2005, Makhteshim-Agan Holding, Aragonesas Agro and Alfa Georgika Efodia applied for certain interim measures concerning the evaluation of endosulfan with a view to its possible inclusion in Annex I to Directive 91/414.

42 By order of 27 April 2005, the President of the Court of First Instance dismissed the application for interim measures.

43 By order of 6 September 2006, the Third Chamber of the Court of First Instance decided that there was no need to give a decision on the application for failure to act, in view of the adoption by the Commission of Decision 2005/864/EC of 2 December 2005 concerning the non-inclusion of endosulfan in Annex I to Directive 91/414 and the withdrawal of authorisations for plant protection products containing this active substance (OJ 2005 L 317, p. 25; 'the contested decision').

The contested decision

44 In the contested decision the Commission concludes that the criteria for inclusion of endosulfan in Annex I to Directive 91/414 are not satisfied. Accordingly, it states in Article 1 of that decision that endosulfan is not to be included as an active substance in Annex I to Directive 91/414. In recital 8 of the contested decision, the Commission summarises the reasons for non-inclusion:

'During the evaluation of this active substance, a number of areas of concern have been identified. This was in particular the case concerning its environmental fate and behaviour as the route of degradation of the active substance is not completely clear and unknown metabolites were found in soil degradation, water/sediment degradation and mesocosm studies. In ecotoxicology many concerns remain since the long term risk, in particular, due to the presence of the abovementioned metabolites, cannot be sufficiently addressed with the available information. In addition exposure of operators under indoor conditions has not been considered to be sufficiently addressed with the available information. Moreover endosulfan is volatile, its main

metabolite is persistent and it has been found in monitoring results of regions where the substance was not used. Consequently, as these concerns remain unsolved, assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing endosulfan satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414…'

45 Article 2 of the contested decision states that the Member States are to ensure that authorisations for plant protection products containing endosulfan are withdrawn by 2 June 2006 and that, from 3 December 2005, no authorisations for plant protection products containing endosulfan are granted or renewed. It also lays down the conditions subject to which certain Member States may, for certain specific uses, maintain in force authorisations for plant protection products containing endosulfan until 30 June 2007.

46 Under Article 3 of the contested decision, any period of grace granted by a Member State to the holder of an authorisation must expire no later than 2 June 2007 in the case of uses for which authorisation is to be withdrawn on 2 June 2006, and no later than 31 December 2007 in the case of uses for which authorisation is to be withdrawn by 30 June 2007.

47 Recital 14 of the contested decision states that the decision does not prejudice 'the submission of an application for endosulfan according to the provisions of Article 6(2) of Directive 91/414… in view of a possible inclusion in its Annex I'.

48 Article 4 of the contested decision states that the decision is addressed to the Member States.

Procedure and forms of order sought

49 By application lodged at the Registry of the Court of First Instance on 27 February 2006, the applicants brought the present action.

50 By document lodged at the Registry of the Court of First Instance on 18 May 2006, the Kingdom of Spain sought leave to intervene in the present proceedings in support of the form of order sought by the Commission. By order of 30 June 2006, the President of the Third Chamber of the Court of First Instance granted leave to intervene.

51 By document lodged at the Registry on 12 June 2006, the European Crop Protection Association (ECPA) sought leave to intervene in the present proceedings in support of the form of order sought by the applicants. That application was allowed by order of 19 October 2006 of the President of the Third Chamber of the Court of First Instance. ECPA lodged its statement in intervention and the other parties lodged their observations on that statement within the period prescribed.

52 On 14 June 2006, the applicants applied for measures of organisation of procedure relating, in essence, to the appearance before the Court and oral testimony of certain persons who had been involved in the evaluation procedure on behalf of the rapporteur Member State and to the appointment of an expert to answer certain questions which the applicants had set out. The other parties lodged their observations on that application within the prescribed time-limits.

53 Upon hearing the report of the Judge-Rapporteur, the Court decided to open the oral procedure. By way of measures of organisation of procedure, the Court requested, on 24 October 2007, that the applicants, the Commission and the Kingdom of Spain answer written questions, which they did within the prescribed time-limit.

54 The parties presented oral argument at the hearing on 12 February 2008.

55 The applicants, supported by ECPA, claim that the Court of First Instance should:

— declare the application admissible and well founded or, in the alternative, reserve its decision on admissibility until the judgment in the main proceedings;

— annul the contested decision;

— order the Commission to pay the costs.

56 The Commission, supported by the Kingdom of Spain, contends that the Court of First Instance should:

— dismiss the application as inadmissible or unfounded;

— order the applicants to pay the costs.

Admissibility

57 Without raising an objection of inadmissibility, the Commission, supported by the Kingdom of Spain, expresses doubts as to the applicants' interest in bringing proceedings and also contests the *locus standi* of certain applicants.

Interest in bringing proceedings

Arguments of the parties

58 According to the Commission, annulment of the contested decision would not necessarily place the applicants in a more favourable position. The marketing authorisation for endosulfan had been maintained, under the transitional provisions laid down in Article 8(2) of Directive 91/414, pending its examination. That review period expired on 31 December 2006. In the event that the contested decision is annulled, the judgment will be delivered after that date. The Commission would have to take steps to comply with the judgment, in accordance with Article 233 EC, but the expiry of the transitional period means that there would be no obvious legal basis for allowing endosulfan to remain on the market pending a new assessment. The applicants' dossier would then have to be assessed under Article 6 of Directive 91/414 rather than under the review programme. Given that the applicants are free to notify endosulfan under Article 6 even while the present case is pending, the Commission maintains that annulment of the contested decision would not improve their situation except in so far as the judgment might provide guidance on the procedures and criteria for assessment.

59 The applicants dispute the Commission's arguments.

Findings of the Court

60 The Commission calls into question the applicants' interest in bringing proceedings. At the very least, it appears to be contending that the applicants' interest in bringing proceedings was lost in the course of the proceedings, specifically as of 31 December 2006, the date marking the end of the transitional period provided for under Article 8(2) of Directive 91/414, as amended. The Commission appears to be contending first that since that date, the applicants' products have no longer been covered by a marketing authorisation, although the applicants are free to notify their active substances on the basis of Article 6 of Directive 91/414, which lays down the procedure for the notification and inclusion of active substances not covered by the transitional arrangements under Article 8(2) of the directive for active substances contained in plant protection products which were already on the market two years after the date of notification of the directive. Secondly, it contends that there is no longer any obvious legal basis, other than Article 6, for assessing endosulfan because the review period under those transitional arrangements has expired. It is thus possible for the applicants to achieve the same final outcome — the examination of their additional data — both on the basis of Article 6 of Directive 91/414 and by means of their action for annulment.

61 The Court finds that, by providing that endosulfan is not to be included in Annex I to Directive 91/414 and by requiring the Member States to withdraw authorisations for plant protection products containing endosulfan, the contested decision is an act with adverse effects, the annulment of which would be to the advantage of the applicants, as well as to the producers and vendors of endosulfan-based plant protection products. The applicants' interest in bringing proceedings at the time when the action was brought was therefore vested and present.

62 Furthermore, contrary to what the Commission appears to be arguing, neither the expiry of the transitional review period nor the availability of the notification procedure provided for in Article 6 of Directive 91/414 affects the continued existence of that interest in bringing proceedings.

63 The applicants' interest in bringing proceedings is not diminished by the alleged impossibility for the Commission to take a new decision on the basis of Article 8(2) of Directive 91/414 in order to comply with a judgment annulling the contested decision. Under the first paragraph of Article 233 EC, the Commission is required to take the necessary measures to comply with an annulling judgment. In the event of an annulment, with its attendant retroactive effects, the Commission would have to take a fresh decision on the basis of the notified dossier concerned by that annulment and adjudicate by reference to the date of notification (see, to that effect and by analogy, Case T-328/03 *O2 (Germany)* v *Commission* [2006] ECR II-1231, paragraph 48). The fact that, since the adoption of the contested decision, there has been a change in the legislation on which it was based has no bearing, therefore, on the question whether it is appropriate for the applicants to challenge the procedure followed and the outcome obtained under the rules in force at the material time.

64 Consequently, the argument that, in the wake of a judgment of annulment, the Commission would have to evaluate endosulfan in accordance with the procedure under Article 6 of Directive 91/414 has no force. In any event, it cannot be denied that, for the applicants, the prospect of notifying endosulfan again on the basis of Article 6 of Directive 91/414 — a possibility to which the contested decision expressly refers in recital 14 — would be a less favourable outcome than the resumption, at the point where illegality possibly arose, of the evaluation procedure already underway. Thus, the fact that the applicants could have endosulfan examined under a new procedure on another legal basis does not undermine their interest in obtaining a decision from the Court on the lawfulness of the procedure initially followed.

65 The applicants have an interest, therefore, in obtaining a decision from the Court on the pleas in law put forward against the contested decision.

Locus standi

Arguments of the parties

66 The Commission acknowledges that Bayer CropScience is individually concerned by the contested decision, since it took part in the administrative procedure. However, it does not accept that the other applicants took part in that procedure and, consequently, denies that they may be regarded as individually concerned by the contested decision.

67 The applicants maintain that they are each individually concerned by the contested decision.

Findings of the Court

68 It should be borne in mind that, according to settled case-law, where admissibility must be established for one and the same application lodged by a number of applicants and the application is admissible in respect of one of them, there is no need to consider whether the other applicants are entitled to bring proceedings (see, to that effect, Case C-313/90 *CIRFS and Others* v *Commission* [1993] ECR I-1125, paragraph 31; Joined Cases T-127/99, T-129/99 and T-148/99 *Diputación Foral de Álava and Others* v *Commission* [2002] ECR II-1275, paragraph 52; and Case T-374/00 *Verband der freien Rohrwerke and Others* v *Commission* [2003] ECR II-2275, paragraph 57).

69 In view of the fact that the first applicant, Bayer CropScience, is — as the Commission itself concedes — directly and individually concerned by the contested decision, there is therefore no need to examine the *locus standi* of the other applicants in order to decide on the admissibility of the action.

70 It follows from all of the above that the action is admissible.

Substance

71 In support of their action, the applicants put forward three pleas in law. The first plea alleges procedural flaws, unfairness of the evaluation procedure and breach of the principle of the protection of legitimate expectations. The second plea alleges in a first branch infringement of Article 95(3) EC and in a second branch infringement of Article 5(1) of Directive 91/414. The third plea alleges breach of certain general principles of Community law. The Court considers it appropriate to examine together the first plea and the second branch of the second plea.

The first plea, alleging procedural flaws, unfairness of the evaluation procedure and breach of the principle of the protection of legitimate expectations, and the second branch of the second plea, alleging infringement of Article 5(1) of Directive 91/414

72 Under the first plea, the applicants put forward a number of objections concerning, inter alia: the fact that the contested decision is based on criteria other than those specified in Directive 91/414; the fact that the assessment of endosulfan is incomplete and based on selective use of the data submitted by the applicants; the retroactive application of new guidelines and new criteria, established by the Commission after the notification and submission of the data; the refusal by the Commission to advise and consult with the applicants in relation to the change in the evaluation criteria and policy; and the Commission's refusal, at the end of the evaluation

procedure, to examine new data provided in direct response to its application of new evaluation criteria and/or guidelines.

73 Those objections relate essentially to seven issues: (i) the unknown metabolite; (ii) the CS dossier; (iii) operator exposure under indoor conditions (iv) the revised good agricultural practices (GAP); (v) the classification of endosulfan as a persistent organic pollutant (POP) and a persistent, bioaccumulable and toxic substance (PBT); (vi) glasshouse use; and (vii) the impact of the delay brought about by the rapporteur Member State and the Commission in the progress of the evaluation procedure. Those issues will be examined in paragraphs 96 to 206 below.

74 Some of those issues, as well as the objections put forward under the second branch of the second plea, alleging infringement of Article 5(1) of Directive 91/414, relate to the question whether the Commission was entitled to refuse to examine certain data or studies allegedly submitted out of time. The Court considers that, since it relates to the general framework of assessment for the present case, it is appropriate to examine first the question whether the procedural time-limits for the submission of studies were applicable given that Article 5(1) of Directive 91/414 states that a decision as to the inclusion of an active substance in Annex I to that directive must be made 'in the light of current scientific and technical knowledge'.

The preliminary question concerning the application of the procedural time-limits and Article 5(1) of Directive 91/414

— Arguments of the parties

75 The applicants, supported by ECPA, complain in essence that the Commission took the decision not to include endosulfan in Annex I to Directive 91/414 because of

doubts concerning the safety of that substance which were based on the insufficient information available at a specific point in time before the end of the transitional period. The applicants submit that Article 5(1) of Directive 91/414, under which such decisions must take into account current scientific and technical knowledge, means that all the data they provided up to the end of the evaluation process must be taken into account. Failure to defer the deadlines for the submission of studies in the present case amounts to a manifest error of assessment, having regard to the fact that it was the behaviour of the Commission and the Kingdom of Spain that prevented the applicants from complying with the legislative deadlines. In support of their arguments, the applicants rely on the judgment of the Court of Justice in Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557 ('*IQV*').

76 The Commission, supported by the Kingdom of Spain, maintains that Article 5(1) of Directive 91/414 must be read in the light of the overall policy objective of placing plant protection products on the market and the system put in place to achieve that. The assessment of plant protection products serves to improve agricultural production but also to protect health and the environment. According to the Commission, the evaluation procedures must enable a very detailed examination to be made, while ensuring that decisions are reached within a reasonable length of time. Finally, those procedures must ensure the equal treatment of undertakings which have notified active substances, while taking account of the specific circumstances of individual substances. The applicants' extensive interpretation of Article 5(1) of Directive 91/414 would ultimately paralyse the whole system for placing plant protection products on the market, contrary to the objectives of Directive 91/414. Furthermore, *IQV*, cited in paragraph 75 above, related to a special case and is not relevant to the settlement of the dispute in the present case.

— Findings of the Court

77 The applicants claim that the Commission was under an obligation to take into account certain data and studies submitted out of time, which is tantamount to

maintaining that they should have been granted an extension of the procedural time-limits or that new deadlines should have been set for them.

78 It must be borne in mind that specific legislative provision has been made concerning the duration of the general evaluation procedure for active substances and the deadlines for submitting a complete dossier and additional information. Thus, Regulation No 3600/92, as amended by Regulation No 2266/2000, and Decision 2001/810 provided that, in the case of endosulfan, the deadline was 25 May 2002 for the submission of studies and additional data and 31 May 2003 for certain long-term studies. The lawfulness of those provisions has not been disputed in the present case.

79 Moreover, it is clear from Article 7(4) of Regulation No 3600/92 (see paragraph 18 above) that the Commission may postpone the deadline for long-term studies only in exceptional cases, that is to say, only where it has not been possible for the rapporteur Member State and the Commission to identify by 25 May 2001 the long-term studies necessary for the examination of the dossier. Furthermore, the notifier must provide the rapporteur Member State with evidence that such studies have been commissioned within three months of the request that they be undertaken, together with a protocol and progress report of the study by 25 May 2002. However, that was not the position in the present case because the data and studies at issue did not concern long-term studies requested by the evaluators.

80 Notwithstanding that clear legislative framework, it is necessary in the present case to examine the circumstances in which the Commission might have been under an obligation to postpone the deadline, especially in light of the fact that the transitional period for marketing authorisation for endosulfan should in principle have expired in July 2003, but had been extended in 2002 to 31 December 2005 and, finally, in 2005 to 31 December 2006 (see paragraph 7 above), provided that no decision had been taken before that date to include or not to include endosulfan in Annex I to Directive 91/414.

81 In that regard, it should be noted that, as is clear from recitals 5, 6 and 9 in the preamble thereto, Directive 91/414 aims to remove barriers to intra-Community trade in plant protection products, while maintaining a high level of protection of the environment and of human and animal health (Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-8339, paragraph 43).

82 In that context, if the Commission is to be able to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion (*IQV*, cited in paragraph 75 above, paragraph 75). The power to postpone deadlines is akin to a discretion, which depends on the circumstances of the case.

83 However, the exercise of that discretion is not excluded from judicial review. According to settled case-law, in the context of such a review the Community judicature must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of assessment or a misuse of powers (Case 98/78 *Racke* [1979] ECR 69, paragraph 5, and Case C-16/90 *Nölle* [1991] ECR I-5163, paragraph 12).

84 In particular, where a party claims that the institution competent in the matter has made a manifest error of assessment, the Community judicature must examine whether that institution has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14).

85 It must also be borne in mind that — as is clear from Article 6(2)(b) of Regulation No 3600/92, as supplemented by Regulation No 2266/2000 — it is the notifier who has to demonstrate that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the requirements of Directive 91/414 in relation to the criteria referred to in Article 5 thereof can be met. The burden of proof as regards the safety of the active substance thus lies with the notifier, something which is not, indeed, disputed by the applicants.

86 Furthermore, it is obvious that an indefinite postponement of the deadline for evaluating an active substance would be contrary to the aim pursued by Directive 91/414 of ensuring a high level of protection of the health of humans and animals.

87 As regards the applicants' reliance on *IQV*, cited in paragraph 75 above, it must be pointed out that that case concerned very specific facts, which differ from those in the present case, in so far as the decision refusing to include the active substance at issue in that case in Annex I to Directive 91/414 had been taken because of the total absence of any assessment, since a complete initial dossier had not been submitted. Accordingly, the point at issue in that dispute was the applicable deadline for submission of a complete notification dossier. In the present case, the non-inclusion decision was taken at the end of an evaluation process based, inter alia, on an initial notification accepted as complete, a draft assessment report, consultations with experts from the Member States and possibilities for the task force to submit arguments and additional studies in order to address doubts raised by the rapporteur Member State in the draft assessment report and in the course of those consultations.

88 Although the facts in the case which gave rise to the *IQV* judgment are very different from those in the present case, it should be noted that, after recognising that the Commission enjoys a broad discretion in the exercise of its powers under Directive 91/414, the Court of Justice held that the Commission had made a manifest error of assessment in refusing to grant Industrias Químicas del Vallés SA ('IQV') a deferral of the deadline for submission of a complete initial dossier because, first,

the impossibility on the part of IQV of complying with those deadlines was attributable, at least in part, to the contradictory behaviour of the competent authorities and, secondly, it was possible under the rules in question to defer the deadlines at issue (*IQV*, cited in paragraph 75 above, paragraphs 84 to 88).

89 It may be inferred from the case-law cited above that, in connection with a decision relating to the inclusion in Annex I to Directive 91/414 of a substance covered by the procedure set out in Article 8(2) of that directive, the deferral must be granted if it is not impossible to derogate from the procedural time-limits laid down in the rules in question, and if the parties who notified the active substance were in a situation of *force majeure* which prevented them from complying with the procedural time-limits, a situation which might obtain if the impossibility of complying with those time-limits was attributable, at least in part, to contradictory behaviour on the part of the competent authorities.

90 As regards the question whether it was impossible for the Commission to derogate from the procedural time-limits at issue in the present case, the Court considers that the Commission has not put forward any convincing arguments in that regard. It refers to practical and political constraints stemming from the fact that in 2001 it undertook to the Council and Parliament to take as many decisions as possible by July 2003, while emphasising that any extension would be limited and exceptional. The Commission also claims that all notifiers must comply with the procedural time-limits and that to allow special treatment for the applicants would raise questions of discrimination, specifically vis-à-vis undertakings which withdrew from the procedure on account of the expiry of the procedural deadlines, which they took to be mandatory. By the same token, according to the Commission, if the applicants were allowed to add new elements to their dossier at all times, resources devoted to endosulfan would have to be found at the expense of other substances, the assessment of which would therefore be delayed.

91 Clearly, political or practical considerations do not constitute a sufficient reason for refusing to postpone deadlines in a specific case, if such an extension is necessary to ensure a fair and equitable evaluation procedure. Furthermore, the Commission's argument relating to discrimination cannot be accepted where postponement is necessary on account of the specific circumstances of a particular evaluation procedure and its participants. It is settled law that the principle of equal treatment does not preclude all differences in treatment, but prohibits comparable situations from being treated differently, leading to a disadvantage for some operators as compared with others, unless such treatment is objectively justified (see Case T-351/02 *Deutsche Bahn* v *Commission* [2006] ECR II-1047, paragraph 137 and the case-law cited).

92 In any event, Decision 2001/810 itself sets different deadlines for the submission of data and studies in respect of certain substances. Thus, for example, the deadline for submission of studies, which is 25 May 2002 for most of the substances covered by that decision, is nevertheless set as 30 November 2002 for chlorotoluron, 31 December 2002 for dinocap and 31 January 2003 for benalaxyl. As regards the deadlines for the submission of long-term studies, the deadline for endosulfan is set as 31 May 2003. For most of the other substances covered by that decision, the deadline is 25 May 2003. However, the deadline for benomyl, chlorotoluron and dinocap is set as 31 December 2003. In Decision 2001/810, the Commission states that those substances are exceptional cases. Clearly, however, Article 7(4) of Regulation No 3600/92, as supplemented by Regulation No 2266/2000, provides for deadlines to be postponed only in 'exceptional cases' relating to long-term studies. Decision 2001/810 also grants derogations from the general deadline of 25 May 2002, in respect of which Regulation No 3600/92 allows no possibility of postponement (see paragraph 18 above). It follows that the Commission has failed to show that it would have been impossible to extend the procedural time-limits in the present case.

93 It is also important, however, to note that the reference in Article 5(1) of Directive 91/414 to 'current scientific and technical knowledge' cannot support the inference that undertakings which have notified an active substance and which are faced with the likelihood of a decision not to include that substance in Annex I to Directive 91/414 should have the possibility of submitting new data for as long as doubts

persist regarding the safety of that active substance. Such an interpretation of that provision would run counter to the objective of a high level of protection of the environment and of human and animal health which underlies Article 5(1) of Directive 91/414, in that it would be tantamount to granting to the notifier — on whom the burden of proof lies as regards the safety of the active substance and who has a better knowledge of that substance — a right of veto over a decision not to include the substance in Annex I to Directive 91/414.

94 Furthermore, the existence of such a right of veto is particularly inconceivable having regard to the fact that, as stated in recital 14 of the contested decision, it is possible to (re)notify the active substance on the basis of Article 6(2) of Directive 91/414, with a view to its inclusion in Annex I to that directive.

95 It is in the light of the above considerations that the claims put forward by the applicants must be examined in order to determine whether, in the present case, they were placed by the contradictory behaviour of the evaluators in a situation of *force majeure* which prevented them from complying with the legislative deadlines.

(i) the unknown metabolite

— Arguments of the parties

96 In essence, the applicants claim that the conclusion in recital 8 of the contested decision that the route of degradation of the active substance is not completely clear and

that unknown metabolites were found in soil degradation, water/sediment degradation and mesocosm studies, and the conclusion that in ecotoxicology many concerns remain — since the long-term risk due, in particular, to the presence of the abovementioned metabolites, cannot be sufficiently addressed with the available information — are based on manifest errors of assessment, that they infringe their rights of defence and frustrate their legitimate expectations, with the result that the evaluation procedure was inequitable.

97 First, the applicants maintain that they were informed belatedly — that is to say, not until January 2004 — of the problem concerning the unknown metabolite and, in particular, of the fact that it was crucial to the outcome of the evaluation procedure, so that it was impossible for them to address that concern on the part of the evaluators before the legislative deadlines. In May 2002, however, the applicants themselves had pointed out the presence of an unknown metabolite in endosulfan's route of degradation.

98 Secondly, they were confronted with guidelines which were constantly changing and included changing criteria for the relevance of metabolites, which had been retroactively applied. In particular, one of the criteria used by the evaluators — according to which metabolites accounting for less than 10% of the initial active substance are relevant — had been introduced by the 2002 guidelines, which were supposed to apply only to active substances notified during the third phase of the review programme but had been applied retroactively, given that endosulfan came under the first phase.

99 Thirdly, the presence of an unknown metabolite was pointed out in a study concerning the route of degradation rather than the rate of degradation, which the applicants were not even required to carry out because it related to tests based on the metabolite endosulfan sulfate and not on endosulfan itself. The evaluators thus took an inappropriate study into account in order to raise a problem which is not a problem.

100 Fourthly, the taking into account of a 10% threshold as a relevance criterion for 'metabolites of metabolites' (that is to say, for metabolites of endosulfan sulfate, itself a metabolite of endosulfan) is contrary to the guidelines, which do not provide for any analysis based on metabolites of active substances but only for studies based on the active substance itself. Furthermore, when assessing the various aspects of the applicants' active substance and related formulated products, the Commission aimed at 'zero risk', which amounts essentially to requiring the applicants to produce a *probatio diabolica*, which is considered illegal in all the Member States and in the case-law.

101 Fifthly, there was a constant lack of interaction with the rapporteur Member State on the issue of the unknown metabolite because there was no feedback on environmental issues, a problem which was most obvious in the period from 2001 to 2004.

102 Sixthly, the applicants have, in any event, provided scientific evidence that not even the 10% relevance threshold for metabolites of metabolites was met, with the result that the metabolite of endosulfan sulphate was not significant and could pose no risk to the environment. That is clear in particular from an extrapolation from the study of the routes of degradation in soil, which was submitted before the May 2002 deadline. Furthermore, the applicants submitted studies showing that the metabolite of the metabolite found in the soil was not relevant for the assessment of the ecotoxicology and environmental behaviour of endosulfan, because it was less toxic than the active substance itself.

103 Seventhly, the issue of the unknown metabolite could have been resolved by means of the revised GAP, the CS formulation and glasshouse use, all of which were covered by studies and arguments which the Commission refused to take into account because they were submitted out of time.

104 The Commission, supported by the Kingdom of Spain, disputes the applicants' arguments.

105 First, the Commission contends that it was already clear from the draft assessment report that endosulfan's route of degradation was problematic, and that the issue had also been raised during a meeting on 20 January 2000.

106 Secondly, the guidelines have no legal effects, so there is no positive rule of law stating that environmental concerns can be ignored below a certain threshold.

107 Thirdly, the rapporteur Member State and the Commission are entitled to base their findings on any type of study submitted by the applicants, irrespective of what type of issue the study in question is addressing.

108 Fourthly, as regards the issue of the relevance threshold for metabolites of metabolites, the Commission questions whether the applicants' arguments are admissible since they are not clear enough to comply with Article 44(1)(c) of the Rules of Procedure of the Court of First Instance. For the sake of completeness, the Commission nevertheless responds to those arguments by referring to an opinion of 30 November 2000 of the Scientific Committee on Pesticides, which supports the conclusion that a risk of ground water contamination cannot be ruled out where the level of metabolites generated is below the 10% threshold. Furthermore, it is clear from Annex II to Directive 91/414 that data relating to metabolites below the 10% level should also be submitted. In any event, the issue of the relevance threshold for metabolites comes under the broad discretion of the Commission.

109 Fifthly, as regards the alleged lack of interaction, the Commission and the Kingdom of Spain maintain, in essence, that the applicants had numerous opportunities during the evaluation process to make their point of view known and to submit additional data. Furthermore, the applicable legislation does not contain any information as regards the degree of interaction or feedback necessary.

110 Sixthly, the argument that the applicants submitted evidence that the metabolite of the metabolite did not meet the 10% relevance threshold, that it is not persistent and that, in any event, it is less toxic than endosulfan is inadmissible. The applicants did not call into question the scientific findings of the evaluation process until the reply; their application merely criticised the way in which the procedure had been carried out. In any event, the applicants' argument that the issue of the unknown metabolite can be disregarded is erroneous. For its part, the Kingdom of Spain also disputes the scientific findings of the studies submitted by the applicants in that regard.

111 Seventhly, as regards the question whether an answer to the metabolite problem is to be found in the approaches suggested by the applicants at the end of the procedure — relating, inter alia, to the revised GAP, the CS formulation and glasshouse use — the Commission and the rapporteur Member State were entitled to refuse to take those studies into account because they had been submitted out of time.

— Findings of the Court

112 A preliminary point to note is that the issue of the unknown metabolite relates in essence to the question whether the Commission could legitimately base the refusal to include endosulfan in Annex I to Directive 91/414 on the absence of sufficient data concerning certain substances deriving from the endosulfan degradation process, in particular, the metabolites or residue which appear only at the second stage of

degradation, that is to say, the degradation of the primary metabolite, endosulfan sulfate.

113 As regards, first, the question whether the applicants were informed in good time of the problem concerning the unknown metabolite, and the fact that it was crucial to the outcome of the analyses of the environmental risk posed by endosulfan and, in particular, whether they were so informed before the meeting of January 2004, during which — according to the applicants — the problem of the unknown metabolite was raised for the first time, it must be pointed out first of all that it is clear from the documents before the Court that various comments and requests for data made before 2004 refer to the evaluators' concern with understanding the degradation route of endosulfan and its metabolites, as well as the rate of degradation.

114 It is stated in the draft assessment report of December 1999 that 'a wider investigation of the degradation routes in soil and water must be done' and that 'correct degradation kinetics (route and rates) should be proposed'. It is also stated in that draft report that 'most of the degradation products of endosulfan are organochlorides that may be persistent and of environmental concern'.

115 Furthermore, in the findings of that draft assessment report reference is made to 'a high persistence of a soil residue constituted by a number of chlorinated metabolites, which may not account individually for more than 10% of applied dose but that all together may represent a high amount of it'. The following is also stated:

'Based on their chemical structure it may be expected that the physico chemical properties of these compounds will be similar and generally persistent and bio-

accumulable. Therefore, a wider investigation of the degradation routes of this compound must be done.'

116 Furthermore, the minutes of a visit to INIA in December 1999, drawn up by the applicants, states that 'it must be clearly shown that degradation of the chlorinated [ring] takes place with identification of the degradation products'.

117 Reference may also be made to the minutes of a meeting of 25 August 2001, which state as follows:

'The question on relevance of other metabolites in soil besides the endosulfan sulfate and their ecotoxicological impact was raised and becomes very important, in view of the clear message from Dr T., that the recently submitted ecotoxicological studies for the other metabolites clearly led to the conclusion that they are relevant from the toxicity point of view. Therefore, their relevance has finally to be based on the results of the running environmental chemistry studies in soil and sediment. If they show up only in minor quantities, their relevance will be denied. If opposite, major consequences for the ecotoxicological test program can be expected.'

118 It is apparent from the above examination of the documentary evidence that the applicants cannot deny that they were informed of the need to clarify the degradation routes of endosulfan at an early stage in the procedure, because requests to that effect had been made by the beginning of 2000 at the latest. It is also apparent from that examination that at that time, and by August 2001 at the latest, they had been informed of the evaluators' concern regarding the persistence of certain metabolites and that, if those metabolites were found to be relevant, the impact on the

toxicological analyses would be considerable. Consequently, the applicants had the opportunity to clarify the way in which endosulfan degraded, which was an issue of crucial importance for the environmental risk analysis. Nevertheless, on the basis of the studies submitted before May 2003, it was then found that the route of degradation was not sufficiently clear, a finding which the applicants dispute and with regard to which they have, moreover, been able to submit additional arguments. However, such a disagreement as to substance cannot be confused with the question whether the applicants had a genuine opportunity during the evaluation process to clarify the degradation route of endosulfan, or whether the evaluators disclosed the significance of that issue for the risk analysis.

119 Secondly, as regards the question whether the applicants were confronted during the evaluation process with guidelines which had undergone a number of amendments, making it impossible to comply with the procedural deadlines of May 2002 and May 2003, it must first of all be stated that the Commission is permitted to lay down for itself guidelines for the exercise of its discretionary power in the form of measures not provided for in Article 249 EC, provided that those measures contain directions as to the approach to be followed and do not depart from the rules of the Treaty. The Community judicature determines whether the disputed measure is consistent with those guidelines. However, documents which are no more than drafts cannot entail any self-imposed limitation on the Commission's discretion (see, to that effect, Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraphs 140 to 142). Consequently, the lawfulness of the contested decision must be assessed in the light of the provisions of Directive 91/414, not of the abovementioned guidelines (see, to that effect and by analogy, *Alpharma* v *Council*, paragraph 146).

120 Furthermore, the examination of that objection, which was framed in very broad terms in the application, must be confined to specific examples — given by the applicants in the application — of cases in which they were confronted by rules deriving from guidelines which had undergone a number of amendments. The need for such precision arises because, under the first paragraph of Article 21 of the Statute of the Court of Justice, which applies to the procedure before the Court of First Instance pursuant to the first paragraph of Article 53 of that Statute, and under Article 44(1)(c) of the Rules of Procedure of the Court of First Instance, the application is required to contain, inter alia, a summary of the pleas in law on which it is based. It must

accordingly specify the nature of the grounds on which the action is based and, in consequence, a mere abstract statement of the grounds does not satisfy the requirements of the Statute of the Court of Justice or the Rules of Procedure of the Court of First Instance (Case T-102/92 *Viho* v *Commission* [1995] ECR II-17, paragraph 68).

121 The objection that the applicants were confronted with guidelines which had undergone a number of amendments, as specified in the application, relates, first, to a set of draft guidelines on the relevance of metabolites in groundwater of regulated substances, the November 2001 version of which had introduced a new relevance criterion: an upper cut-off value of 10 µg/l in groundwater for all metabolites, regardless of their toxicity. Those guidelines were not completed until February 2003. In that regard, it must be noted that the applicants do not explain why, in November 2001, it was too late to submit further studies in accordance with that criterion. In any event, it should also be noted that, according to the applicants, they submitted studies which took that criterion into account before the May 2003 deadline. Furthermore, as the Commission points out, an opinion of November 2000 of the Scientific Committee on Pesticides, which was accessible via the Internet, stated that every effort possible should be made to identify metabolites. In addition, it is stated in Annex II to Directive 91/414, as amended in 1995 by Commission Directive 95/36/EC of 14 July 1995 (OJ 1995 L 172, p. 8), that undertakings notifying an active substance with a view to its inclusion in Annex I to Directive 91/414 must 'identify where possible … individual components present which account for less than 10% of the amount of active substance'. The applicants cannot therefore claim that that criterion was 'new' in 2001 or that it was applied retroactively.

122 Secondly, the objection that the applicants were confronted with guidelines which had undergone a number of amendments relates to guidelines on aquatic and terrestrial ecotoxicology issued in October 2002, which — according to the applicants — required for the first time that a distinction be made between 'minor' (<10%) metabolites in soil and 'major' (>10%) metabolites in soil, for the purposes of assessing their relevance for the evaluation of the harmful effects of the active substance. However, it is clear from the above that that criterion was not new, as it had appeared in Annex II to Directive 91/414 since 1995.

123 In any event, the evaluators' approach of taking into account metabolites which did not individually exceed the 10% threshold but could exceed it when taken together with other metabolites had already been pointed out in the conclusions of the draft assessment report (see paragraph 115 above).

124 Lastly, it should also be pointed out that what the applicants are actually disputing is the relevance of that threshold for metabolites of metabolites. The objection contesting that threshold and its application in the present case will be examined below (see paragraph 133 et seq. below).

125 Thirdly, as regards whether the evaluators could legitimately raise the issue of the metabolite of the metabolite and the risk of its persistence in soil, given that that issue emerged from a study carried out by the applicants for a different purpose, it should be pointed out that, manifestly, it is not relevant to know, for the purposes of the inclusion of endosulfan in Annex I to Directive 91/414, in which study a potential problem for the environment was raised provided that it was in a document on which the applicants were able to adopt a position. In the present case, it is clear from the documents before the Court that it was a study by the applicants themselves that confirmed for the evaluators that there was indeed a problem concerning a metabolite of a metabolite. The Court finds that the applicants have failed to submit any cogent argument to substantiate the view that the Commission may not take into account the results of such a study.

126 Fourthly, as regards whether the taking into account of the 10% relevance threshold for metabolites of metabolites is contrary to the guidelines, hence based on a criterion foreign to the applicable regulatory framework, it must be stated that the wording of that objection — according to which 'there are no EU requirements or guidelines for assessing the metabolite of a metabolite when the starting material is anything but the parent substance' — is very abstract. That objection is linked to the applicants' refutation of a statement in the draft assessment report to the effect that the studies concerning the degradation of endosulfan suggest 'a high persistence of a residue in soil composed of a number of chlorinated metabolites which, while individually they

may not exceed the level of 10% of the dose applied, together … may comprise a large quantity of residue'. In order to appraise that objection, it is necessary to determine whether the concepts used in Directive 91/414 and the Annexes thereto have been defined broadly enough to allow the evaluators to take into account the potentially harmful effects of metabolites of metabolites.

127 In the context of that examination, the Court would point out that Article 5(1)(a) of Directive 91/414 provides that an active substance is to be included in Annex I if it may be expected that plant protection products containing that active substance will fulfil, inter alia, the following condition: that 'their residues … do not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, and the said residues, in so far as they are of toxicological or environmental significance, can be measured by methods in general use'. Article 2(2) of the directive defines the terms 'residues of plant protection products' broadly, as 'one or more substances present in or on plants or products of plant origin, edible animal products or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites and products resulting from their degradation or reaction'. Furthermore, Annexes II and III to Directive 91/414, concerning the dossiers for evaluation, contain a number of references to requests for data relating to the breakdown products of active substances in the broad sense. It follows that it is Directive 91/414 itself which authorises the evaluators to examine the behaviour of the products derived from the active substance. In those circumstances and in the absence of actual evidence to the contrary, it cannot be accepted that the evaluators made a manifest error of assessment by wanting to clarify the route of degradation of the metabolite of endosulfan sulfate and by applying the relevance threshold at issue to its breakdown products. The claim that such an examination is contrary to the guidelines is thus unfounded. It follows that the applicants have failed to establish that the Commission made a manifest error of assessment or infringed their rights of defence by taking the view, in the present case, that breakdown products of endosulfan which individually represented less than 10% of the active substance endosulfan, but more than 10% of the metabolite endosulfan sulphate, were relevant.

128 Lastly, it is also necessary to reject the argument that the evaluators wished thus to achieve 'zero risk' and required the applicants to produce a *probatio diabolica*, by basing the decision not to include endosulfan in Annex I to Directive 91/414 on a lack of information rather than on identified risks, because it is clear from the above analysis that the Commission wished to have evidence of a safe use, but that meant that it had to understand the behaviour of the metabolite of endosulfan sulfate. That position has not been shown to be manifestly incorrect. In any event, the applicants claim that they established a safe use and that they demonstrated an acceptable level of persistence and toxicity in respect of that metabolite. Accordingly, it must be held that there is no force in the argument that the Commission required them to submit evidence which was scientifically impossible to establish.

129 Fifthly, as regards the objection alleging lack of interaction with the rapporteur Member State on the issue of the unknown metabolite and, in particular, the alleged absence of feedback on environmental issues during the period from 2001 to 2004, it must be borne in mind that, as pointed out by the Commission and the Kingdom of Spain, the applicable rules do not impose any obligation of communication or feedback in the light of which the numerous meetings and exchanges of information between the rapporteur Member State and the applicants could have been considered insufficient. As for the comment in ECCO report 106, relied on by the applicants — according to which they were requested to 'work very closely with the rapporteur Spain in order not to run into any misunderstandings on the data to be provided or the deadlines to be observed' — it is difficult to gauge, by reference to a requirement framed in such general terms, whether the interaction with the rapporteur Member State was sufficient.

130 However, it should be borne in mind that respect for the rights of the defence is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests be placed in a position in which they may effectively make known their views (see, to that effect, Case C-28/05 *Dokter and Others* [2006] ECR I-5431, paragraph 74 and the case-law cited).

131 As regards whether, in the light of that case-law and with regard to the disputed period from August 2001 to January 2004 during which the applicants did not receive feedback on environmental fate and behaviour or on ecotoxicology and received insufficient feedback from one person in particular — Dr T., a contract expert who was specialised in those areas — those circumstances could have led the applicants' rights of defence to be infringed, their reasoning is clearly contradictory as they claim to have submitted studies in May 2002 which resolved the problem of the unknown metabolite. It is therefore difficult to understand how more meetings could have led to a different final outcome in the contested decision. An irregularity can bring about the annulment of the contested decision only to the extent that it is such as to actually affect the applicant's rights of defence and therefore the content of that decision (see, to that effect, Case 30/78 *Distillers Company* v *Commission* [1980] ECR 2229, paragraph 26). The objection is therefore of no consequence.

132 In any event, the objection relates, at least in part, to the question already examined above of whether the problem of the unknown metabolite and, in particular, the fact that it was crucial to the analyses of the environmental risk posed by endosulfan, was not raised until the meeting in January 2004. As has been pointed out above, the applicants were informed well before that meeting of the need to identify endosulfan's route of degradation and of the significance of that issue for the risk analysis. They thus had the opportunity to submit studies clarifying the route of degradation, but disagree with the evaluators as regards the results of those studies, in particular as regards the relevance of the metabolite of endosulfan sulfate, and its persistence and toxicity. The existence of a disagreement on substance as regards the inferences to be drawn from a particular study does not amount to evidence of a lack of opportunity to make their views known and cannot be classed as an infringement of the applicants' rights of defence.

133 Sixthly, as regards the applicants' objection that they provided scientific evidence showing, first, that the metabolite of endosulfan sulfate did not meet the more stringent relevance criterion for metabolites of metabolites and, secondly, that that metabolite of the metabolite found in soil was not relevant for the assessment of endosulfan's ecotoxicology and environmental behaviour because it was not persistent and was less toxic than the active substance itself, it must be pointed out

that the applicants claim, in essence, that endosulfan should have been included in Annex I to Directive 91/414 because the evaluators' findings regarding the relevance of the metabolite of the metabolite of endosulfan were incorrect. However, clearly that objection was put forward for the first time in the reply.

134 It follows from Article 44(1)(c), read in conjunction with Article 48(2) of the Rules of Procedure, that the application initiating proceedings must contain, inter alia, a summary of the pleas in law relied on, and that new pleas in law may not be introduced in the course of proceedings unless they are based on matters of law or of fact which came to light in the course of the procedure. A plea which may be regarded as amplifying a plea put forward previously — whether directly or by implication — in the originating application and which is closely connected therewith, must be held admissible. By contrast, a plea which cannot be regarded as based on matters of law or of fact which came to light in the course of the proceedings has to be held inadmissible. In the circumstances of the present case, there was nothing to prevent the applicants from raising the plea at the stage of the application (see, to that effect, Case C-430/00 P *Dürbeck* v *Commission* [2001] ECR I-8547, paragraphs 17 to 19).

135 In response to a written question from the Court asking them to respond to the Commission's argument that the challenge to the scientific assessment underpinning the contested decision is a new line of argument which is not found in the application and should therefore be held inadmissible, the applicants submit that the legal grounds set out in the application — inter alia, infringement of Article 95(3) EC, Article 5(1) of Directive 91/414 and breach of the principle of the excellence and independence of scientific advice — clearly include the submission that they regarded the scientific assessment underpinning the contested decision as incorrect, especially because that assessment did not take into account all the available data that they had submitted. Moreover, the applicants maintain that, by addressing the scientific issues at stake in closer detail in the reply, they are merely rebutting the factual arguments put forward by the Commission and are not introducing new legal grounds for annulment.

136 In that respect, it must be pointed out — as regards the reliance in the application on Article 95(3) EC, Article 5(1) of Directive 91/414 and the principle of the excellence and independence of scientific advice — that it is absolutely clear from the arguments put forward in support of the pleas relied on in the application that those pleas concern the question whether the Commission was under an obligation to take into account in its analysis studies submitted by the applicants after a particular deadline, which is a question relating to the way in which the Commission carried out the evaluation procedure but not a challenge directed at the substantive content of its findings, even though the taking into account of the documents which were refused could conceivably have led to a different final decision on the substance. The argument that the applicants' objection merely seeks to rebut the factual arguments put forward in the course of the proceedings cannot succeed either, because it is clear from the reply that, by that objection, the applicants are maintaining that the Commission's finding that endosulfan's route of degradation is not completely clear and that unknown metabolites have been discovered in the course of certain studies (soil degradation, water or sediment degradation and mesocosm studies) is based on a premiss which is factually and scientifically incorrect. However, as was pointed out above, the clear aim of the pleas relied on in the application is to challenge, not the content of the Commission's findings, but the way in which the Commission had arrived at those findings and, in particular, its refusal to take certain evidence into account.

137 Accordingly, it cannot be accepted that that objection merely amplifies a plea put forward previously. Furthermore, it has not been shown that it was impossible for the applicants to raise that plea at the stage of the application. The objection that the findings in the contested decision concerning the relevance of metabolites of metabolites are incorrect is therefore inadmissible.

138 In any event, there is obvious disagreement between the parties as regards the scientific findings in the applicants' studies.

139 As regards whether the metabolite of endosulfan sulfate meets the relevance threshold, the applicants submit that the unknown secondary metabolite represents

17% of the primary metabolite endosulfan sulfate, which in turn represents 13.4% of the parent endosulfan, and that the secondary metabolite therefore represents only 2.3% of the parent endosulfan. The Commission and the Kingdom of Spain do not dispute those calculations but maintain that they are entitled, as was explained above, to treat as relevant metabolites below the 10% threshold in relation to the parent substance endosulfan.

140 As regards the persistence of the metabolite of endosulfan sulphate, this is measured mainly by reference to its capacity to change into CO^2 (mineralisation) and by establishing the rate of degradation for 50% and for 90%. According to the applicants, it is apparent from a study submitted in May 2002 that endosulfan sulfate degrades up to 35% after the first year, which corresponds to a degradation rate of 9.5% after 100 days. The applicants argue that the relevant Commission guidelines require the mineralisation rate to be above 5% over a period of 100 days and that that criterion has thus clearly been met. The Kingdom of Spain maintains, on the other hand, that it is apparent from the study in question that the mineralisation of endosulfan in soil is probably less than 5%. The average lifespan of endosulfan sulfate (degradation rate of 50%) is in the range of 123 to 391 days and the mineralisation at 120 days ranges between 1.01% and 13.08%. The average mineralisation of endosulfan sulfate is in line with that of endosulfan. It may therefore be concluded that endosulfan breaks down into endosulfan sulfate and that the mineralisation of endosulfan sulfate ranges between 1.01% and 13.08% at 120 days and between 5% and 35% at 365 days, depending on the type of soil. None of the metabolites detected and identified in earlier assays were detected in that study. Nevertheless, there is a metabolite which appeared at levels in excess of 10% of the applied radioactivity. All attempts to identify that metabolite failed but the suspicion is that its structure is similar to that of the metabolites dicarboxylic acid and dihidrodiol. The identification of that metabolite is essential for the purposes of establishing endosulfan's route of degradation and the residue definition which must be used in the field dissipation studies.

141 As was pointed out above, it is settled case-law that in matters concerning the common agricultural policy the Community institutions enjoy a broad discretion as regards the definition of the objectives to be pursued and the choice of the appropriate means of action. Accordingly, review by the Community judicature of the substance must be confined to determining whether the exercise of such discretion is

vitiated by manifest error or by misuse of powers, or whether the Community institutions clearly exceeded the bounds of their discretion. Furthermore, it is settled case-law that where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action. It follows that where the Community institutions were required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts, judicial review of the way in which they did so must be limited. In such cases, the Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the Community institutions of their discretion in that regard is vitiated by manifest error or by misuse of powers, or whether the Community institutions clearly exceeded the bounds of their discretion (see *Alpharma* v *Council*, paragraph 119 above, paragraphs 177 to 180 and the case-law cited).

142 In the light of that case-law, it must be concluded that the applicants have failed to show that the Commission made a manifest error of assessment, or misused its powers, or clearly exceeded the bounds of its discretion by considering the metabolite of the metabolite in question to be relevant and by deciding, in view of its persistence in soil, that the lack of exact knowledge concerning the behaviour of that metabolite made it impossible to carry out an appropriate environmental risk assessment for endosulfan.

143 Seventhly, as regards whether the CS formulation, the revised GAP or glasshouse use would actually have made it possible to resolve the doubts raised regarding the presence of an unknown metabolite, it must be concluded that, besides the fact that the pleas relied on in the application relate only to the question whether the Commission could refuse to take that data into account, the Court cannot, in any event, rule on the impact of the CS formulation, the revised GAP or the glasshouse use approach inasmuch as the Commission refused, on the ground that they were submitted out

of time, to take them into consideration, and it is not for the Court to substitute its analysis in that regard for that of the Commission. The question whether the Commission was entitled to refuse to take the studies concerning those issues into account will be dealt with below.

144 It follows from all of the above that the applicants' submissions relating to the problem of the unknown metabolite must be rejected in their entirety.

(ii) the CS dossier

— Arguments of the parties

145 The applicants maintain that the examination of endosulfan was incomplete as the CS dossier, which had been submitted by the deadline, was not taken into account. However, even if were to be conceded that the CS dossier had been submitted out of time, the Commission should have taken it into account as the applicants could not have submitted it any earlier. Furthermore, contrary to the contention of the Commission and the Kingdom of Spain, as the CS dossier supplemented the dossier initially notified concerning the EC formulation, an examination of the CS dossier would have taken only a very short time (three months at the most), above all in view of the fact that the rapporteur Member State was already familiar with the CS formulation through its notification at national level. The taking into account of the CS dossier would have made it possible to identify a safe use in outdoor conditions and would therefore have made it possible to include endosulfan in Annex I to Directive 91/414, because the evaluators had already led the applicants to believe that a safe indoor use had been identified with the EC formulation.

146 According to the Commission, supported by the Kingdom of Spain, the CS dossier was submitted out of time and the Commission was therefore entitled to refuse to take it into account. Furthermore, a review of the CS dossier would have meant that the Rapporteur would have had to revise the entire assessment of endosulfan.

— Findings of the Court

147 It is clear from the documents before the Court that the applicants submitted the CS formulation to the rapporteur Member State for the first time at the meeting on 17 July 2002 after announcing it as a subject for discussion in an e-mail of 31 May 2002. It emerges from the minutes of that meeting that, rather than replacing the EC formulation for endosulfan initially notified, the applicants wanted to add the CS technology to the dossier in order to show a safe outdoor use for endosulfan. It is also apparent from those minutes that INIA and MAPA stated at the meeting that the submission of a second dossier on the basis of Annex III to Directive 91/414 was unreasonable because of the additional workload and the difficulty of obtaining the Commission's agreement to that procedure. Nevertheless, the applicants submitted a CS dossier under Annex III to Directive 91/414 in May 2003.

148 First, the applicants maintain, in essence, that the CS dossier was submitted by the deadline. That assertion is not correct. The deadline for the submission of data, as laid down in Regulation No 2266/2000, amending Article 7(4) of Regulation No 3600/92, was 25 May 2002 except for the results of long-term studies which had been commissioned, which had been identified as necessary by the rapporteur Member State and the Commission during the examination of the dossier, and which would not be fully completed by that date. Such studies had to be identified by 25 May 2001 at the latest and could then be submitted up until 25 May 2003. In exceptional cases, such as those where it had not been possible for the rapporteur Member State and the Commission to identify such studies by 25 May 2001, an alter-

native date could be established for the completion of such studies, provided that the notifier supplied the rapporteur Member State with evidence that they had been commissioned within three months of the request to undertake them, and sent it a protocol and progress report of the study by 25 May 2002. The applicants maintain that they could still submit that dossier in May 2003, but it is clear that the applicable legislation provided for that possibility in well-defined cases which are different from that of the present case.

149 Secondly, in answer to a written question from the Court, the applicants stated that they had submitted the CS dossier in response to a specific concern on the part of the evaluators of which they had been informed in October 2001 and which related to the aquatic toxicity of endosulfan.

150 Clearly, however, the applicants provide no explanation which makes it possible to understand why they did not submit the CS dossier before the deadline of 25 May 2002 or, at least, approach the Commission in order to secure a formal acknowledgement that the CS dossier could be submitted as a long-term study as late as 31 May 2003 in accordance with Decision 2001/810. Instead, they merely make vague claims that the preparation of such a dossier takes time and that the scientific studies necessary to address the issue of aquatic ecotoxicology were not available in October 2001 on account of alleged changes in the guidelines on aquatic ecotoxicology, which they do not, however, identify.

151 Thirdly, it is apparent from the documents before the Court that the applicants had been working on that formulation for many years. Accordingly, it is difficult to understand why they waited until the end of the procedure before submitting the CS dossier as the final way of proving a safe use for endosulfan. Lastly, the fact that the possibility of limiting evidence to a safe use was not introduced until 2000 (by Regulation No 2266/2000) is not a credible argument either because there was still ample time to prepare a dossier for submission within the procedural time-limits.

152 It follows from the above that the Commission's refusal to take the CS dossier into account is not vitiated by a manifest error of assessment because the applicants have not proved that it was impossible for them to submit the CS dossier by 25 May 2002. The answer to the question whether a reassessment of the CS dossier would have taken some months or more is thus not relevant for the purposes of deciding the present dispute and it is therefore not necessary to grant the applicants' application for the appointment of experts or to question INIA in that regard.

153 Furthermore, as regards the fact that the rapporteur Member State suggested during the meeting of July 2002 that the applicants should apply for national registration in certain Member States, in order to obtain support there for the CS formulation, and the fact that MAPA's representatives led the applicants to believe that MAPA was going to evaluate the CS dossier on the basis of the dossier for national registration — a fact, moreover, for which the only evidence is an internal e-mail of the applicants — it is clear that, notwithstanding possible differences in the views expressed by MAPA and INIA in that regard, it cannot be inferred from those factual circumstances that the applicants could have had a legitimate expectation that the CS dossier would be taken into account in the evaluation procedure. It emerges from the minutes of a meeting of 24 September 2002 between the applicants and MAPA that, according to MAPA, an 'Annex III' dossier in respect of a second formulation was to be submitted in May 2003 at the latest, but subject to approval from the Commission. The applicants do not dispute that they failed to obtain that informal approval. There was therefore no infringement of legitimate expectations entertained by the applicants, because it has not been established that they had precise, unconditional and consistent assurances from authorised, reliable sources which could have created a legitimate expectation on their part as regards the taking into account of the CS dossier and thus as regards the inclusion of endosulfan in Annex I to Directive 91/414 (see, to that effect, Case T-162/04 *Branco* v *Commission*, not published in the ECR, paragraph 119 and the case-law cited).

154 Lastly, as regards the substantive question whether the CS formulation would have made it possible to identify a safe outdoor use for endosulfan — which the Commission and the Kingdom of Spain dispute — it must be concluded, given that the CS dossier was not taken into account in the evaluation process which led to the contested decision, that that question falls outside the ambit of the dispute as submitted to the Court.

155 The applicants' submissions relating to the issue of the CS dossier must therefore be rejected in their entirety.

(iii) operator exposure under indoor conditions

— Arguments of the parties

156 In essence, the applicants maintain that the issue of operator exposure was raised in the draft assessment report but was subsequently resolved. In that regard, they refer inter alia to the addendum to the assessment report of November 2003, in which it is stated by the rapporteur Member State that the study which they submitted regarding operator protection was 'well characterised' and that the proposed scenario for the application of endosulfan, involving the use of protective equipment such as gloves, protective clothing and a mask, was 'acceptable'. The applicants also refer to the ECCO evaluation tables of March 2004 and the minutes of the tripartite meeting from which it is apparent that the rapporteur Member State had identified a safe use for operators. The re-emergence of the operator exposure issue after the tripartite meeting in 2004 and its being taken into account as a decisive ground for the non-inclusion of endosulfan in Annex I to Directive 91/414 thus infringes the applicants' legitimate expectations and rights of defence. Furthermore, the applicants request that the Court adopt measures of organisation of procedure requiring the Commission to produce the Member States' comments which gave rise to that change of opinion.

157 In any event, the problem had been resolved by the reduced GAP proposed after the expiry of the procedural time-limits, which the Commission did not take into account, and by new studies relating to the glasshouse use of endosulfan, which were not taken into account either.

158 The Commission, supported by the Kingdom of Spain, maintains that the Evaluation Working Group attached to the Committee discussed the issue of operator exposure on 11 March 2004, well before the tripartite meeting, and that the applicants had an opportunity to comment. The initially positive reaction of the rapporteur Member State was based on an extrapolation from field data in orchards. On further discussion, doubts arose about the reliability of that extrapolation. For that reason, it was ultimately concluded in the Evaluation Working Group that the problem of operator exposure had not been resolved.

— Findings of the Court

159 It should be noted at the outset that the applicants' submissions with regard to this issue relate to the finding in recital 8 of the contested decision that 'exposure of operators under indoor conditions has not been considered to be sufficiently addressed with the available information'.

160 It should be pointed out, first, that the applicants do not dispute that the insufficiency of the data they initially submitted regarding that issue was raised at the beginning of 2000 in the draft assessment report, which stated inter alia that, as the toxicity studies submitted did not allow a correct No Observed Adverse Effect Level (NOAEL) for use in the Acceptable Operator Exposure Level (AOEL) calculation to be established, the dermal and inhalation short-term toxicity studies were not considered acceptable. The applicants therefore had the opportunity to submit additional studies to establish that endosulfan was safe in that respect after the doubts expressed in that regard in the draft assessment report.

161 Secondly, it should be pointed out that the applicants' letter to the Commission of 24 September 2004 shows that they were aware of the fact that additional data

on operator exposure was necessary after the meeting of the Evaluation Working Group of 11 March 2004. As regards the tripartite meeting of 17 May 2004, it is clear from the minutes that even though the rapporteur Member State referred in those minutes to an identified safe use, additional data still had to be submitted, in particular concerning glasshouse workers and bystanders. The applicants then submitted new calculations but the information submitted was ultimately considered insufficient by the Evaluation Working Group.

162 However, it should also be pointed out that the Commission and the Kingdom of Spain do not dispute that, at a certain point in the evaluation procedure, the Kingdom of Spain identified a use which was safe in terms of operator exposure. According to the Commission and the Kingdom of Spain, what was involved was an extrapolation from a study under outdoor conditions on the basis of which the rapporteur Member State accepted the fact that protective clothing also provided sufficient protection for operators under indoor conditions, but experts from the other Member States did not agree.

163 In view of the above considerations, it is necessary to determine whether the applicants should have been permitted to submit new studies after the tripartite meeting and not just arguments, as had been expressly permitted, in view of the fact that the rapporteur Member State had led them to believe at a certain stage of the procedure that a safe use had been identified. The question is linked to that of the refusal to examine the revised GAP (see below) which, according to the applicants, would have made it possible to resolve the operator protection problem, but which were not taken into account because they were submitted out of time.

164 First, it is clear from the legislative framework that the view of the rapporteur Member State in the evaluation process is not decisive. The rapporteur Member State gathers the data and suggests a decision but it is the Commission which ultimately decides, on the basis of the Committee's opinion. The mere expression of a view by the rapporteur Member State at a particular stage of the evaluation procedure on the identification of a safe use in respect of operator exposure cannot therefore be regarded as sufficient to give rise to certainty on the part of the applicants that that problem had been completely resolved, particularly in light of the fact that, even at the stage of the tripartite meeting, the adoption of a final position was deferred until additional data had been received.

165 Furthermore, it cannot be accepted that the applicants' rights of defence and, more specifically, their right to a fair hearing, were infringed as regards the issue of the operator in general and of his protection under indoor conditions in particular, because it is clear from the above summary of the facts that they had a number of opportunities to submit studies and that they could still have submitted arguments after the tripartite meeting, which means that they had an opportunity to make known their views effectively (see, to that effect, *Dokter and Others*, cited in paragraph 130 above, paragraph 74 and the case-law cited). However, according to the applicants, their studies showed that there was no risk for operators under indoor conditions but the Committee and the Commission disagreed. The fact nevertheless remains that a disagreement as to substance in that regard cannot be equated with an infringement of the applicants' right to a fair hearing. It was open to the applicants to dispute before this Court the conclusions drawn by the Commission in the contested decision from the studies at issue, but they have not done so because they focused their application on the Commission's alleged obligation to grant them new deadlines and, more specifically, to agree to a reassessment of the issue on the basis of the reduced GAP. In any event, as pointed out by the Commission and the Kingdom of Spain, it is clear from recital 8 of the contested decision that the decision not to include endosulfan in Annex I to Directive 91/414 is based primarily on doubts relating to the non-identification of its route of degradation and to the presence of an unknown metabolite. In those circumstances, it is therefore inconceivable that a possibility for the applicants to clarify subsequently the issue of operators under outdoor conditions could have led to a different final outcome in the contested decision and thus any irregularity in that regard cannot on its own bring about the annulment of that decision (see, to that effect, *Distillers Company* v *Commission*, cited in paragraph 131 above, paragraph 26).

166 It follows from the above that the fact that one of the grounds for the contested decision is that of the insufficiency of the study on operator exposure under indoor conditions, as regards which the applicants may have been led to believe that a safe use had already been identified by the rapporteur Member State, is not a sufficient basis for finding that their rights of defence were infringed; nor does it constitute a manifest error of assessment in the context of applying Article 5(1) of Directive 91/414.

167 Lastly, as regards the request for the production of documents made by the applicants in the reply, whereby the Court is asked to call upon the Commission to produce the

observations of the Member States following the tripartite meeting of 17 May 2004 in which doubts were raised as regards the protection of operators under indoor conditions, the Commission stated in its rejoinder and at the hearing that it does not have such written documents. In any event, it follows from the above that the Court considers that there is sufficient information in the documents before it, and thus it is not necessary to grant that request.

168 It is clear from all of the above that the applicants' submissions relating to the issue of operator exposure under indoor conditions must be rejected in their entirety.

(iv) the revised GAP

— Arguments of the parties

169 The applicants maintain that, even though the Commission accepted at the tripartite meeting that new GAP could be submitted, the contested decision does not take into account their arguments concerning the revised GAP, which relate to a proposal that endosulfan should be examined in a more dilute form than the form in which it underwent evaluation and on the basis of a single application per season.

170 The Commission, supported by the Kingdom of Spain, maintains that the revised GAP were submitted out of time and that, in consequence, it did not have to take account of them, especially in view of the fact that taking them into account would have meant that an entire section of the evaluation would have been called into question.

— Findings of the Court

171 It should be noted at the outset that, generally, GAP are rules which should be complied with in planting and the manner of cultivation so as to optimise agricultural production, while reducing the risks to human beings and the environment. As regards plant protection products, such rules are also called 'good plant protection practice'. It is clear from the legislative framework and from the documents before the Court that, for the purposes of evaluation procedures under Directive 91/414, an active substance falls to be examined in accordance with certain rules relating to application, inter alia in terms of the dosage of the plant protection products containing that substance and the frequency with which they are applied.

172 In the present case, the issue of the reduced GAP relates to the applicants' proposal — submitted after the tripartite meeting and, in particular, in the letter of 25 June 2004 — that endosulfan should be examined in a more dilute form than the form in which it had undergone evaluation, and on the basis of a single application per season. The Commission contends that, at that stage in the procedure, it still accepted new arguments, but that the submission of new GAP would have meant that an entire section of the evaluation would have been called into question.

173 It should be noted, first, that the applicants' reasoning concerning that aspect of the evaluation procedure is scant, as they merely refer in the application to the fact that the Commission did not examine the reduced GAP, even though it had agreed to do so at the tripartite meeting. However, it is not apparent from the minutes of the tripartite meeting that the Commission accepted that new GAP could be submitted. Furthermore, the Commission's statement that the taking into account of the reduced GAP would have meant that an entire section of the evaluation would have been called into question is consistent with the comments made by the applicants themselves in the letter of 25 June 2004 by which they submitted the new GAP to the evaluators, because they stated in that letter that the revised GAP would facilitate the risk analysis, in particular as regards ecotoxicology and the evaluation of endosulfan's fate, which clearly implies that significant aspects of the evaluation process would be

called into question and does not merely concern new arguments in relation to the existing evaluation. In addition, the applicants have not established that the revised GAP could not have been submitted earlier in the procedure, because it is apparent from the documents before the Court that a revision of the GAP had already taken place in the early stages of the procedure, inter alia in 2001 in order to meet the requirement introduced by Regulation No 2266/2000 for submission of a safe use.

174 The Court therefore holds that the applicants have failed to demonstrate that there was any situation of *force majeure* such that the evaluators' refusal to take the revised GAP into account in July 2004 was vitiated by a manifest error of assessment.

175 Lastly, as regards the applicants' claim that the revised GAP were submitted in order to reduce the risk of operator exposure — besides the fact that the applicants' arguments are contradictory in that they claim to have understood at the tripartite meeting that the issue of operator exposure had been resolved in its entirety — it must be borne in mind that, as was pointed out above, since the issue of operator exposure was of secondary importance in relation to the doubts raised by the evaluators concerning the existence of an unknown metabolite, a possible irregularity on that point cannot bring about the annulment of the contested decision, because even if the problem of operator exposure had been resolved, the problem of the unknown metabolite would still have brought about the decision not to include endosulfan in Annex I to Directive 91/414.

176 It follows from all of the above that the applicants' submissions concerning the revised GAP must be rejected.

(v) the alleged classification of endosulfan as a POP and a PBT

— Arguments of the parties

177 In essence, the applicants maintain that the contested decision and the evaluation underpinning it are based on two scientific criteria, which are not specified in Directive 91/414: the classification of a substance as a POP or as a PBT, which is relevant in the context of Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ 2000 L 327, p. 1), but not in the context of Directive 91/414. Thus, the Commission explains in recital 8 of the contested decision that endosulfan raises concerns because of its persistence and its volatile characteristics as shown by transboundary monitoring results, a finding which reflects application of the POP criterion. Moreover, the term 'POP' is expressly used in the minutes of the tripartite meeting, which devote an entire section to that issue, and the conclusions of a meeting of the Evaluation Working Group dated 11 March 2004 state very clearly that the remaining concerns over that molecule are based in particular on the fact that 'the substance could also be a POP'. The contested decision therefore infringes Article 5(1) of Directive 91/414, and the legitimate expectation on the part of the applicants that the evaluation would be based only on scientific criteria covered by that directive.

178 In any event, the problem would have been resolved if the Commission had taken into account the data on glasshouse use.

179 Furthermore, contrary to Article 5 of Directive 91/414, the POP and PBT criteria, as well as Directive 2000/60, are based on the notion of hazard and not of risk.

180 The Commission, supported by the Kingdom of Spain, disputes the argument that the contested decision is based on criteria other than those under Article 5(1) of Directive 91/414.

— Findings of the Court

181 The issue of the alleged classification of endosulfan as a POP and a PBT relates to the finding in recital 8 of the contested decision that endosulfan is volatile, that its main metabolite is persistent and has been found in the monitoring results for regions where the substance was not used.

182 As a preliminary point, it should be pointed out that, in the context of this objection, the applicants are in essence maintaining that that finding is based on an analysis which was not made under Directive 91/414 but under Directive 2000/60. Directive 2000/60 seeks to improve the quality of water through the progressive identification and elimination in the waters of the European Union of a series of substances which are deemed to be hazardous and of certain pollutants. The definitions of hazardous substances and pollutants in Directive 2000/60 include a reference to the notions of POP and PBT. According to the applicants, Directive 2000/60 is based on an evaluation of hazard to the aquatic environment whereas Directive 91/414 requires the application of the more restrictive criterion of risk to the environment.

183 First, it should be noted that, as the applicants point out, the POP and PBT criteria were the subject of discussions during the evaluation period and the classification of endosulfan as a POP or as a PBT was taken into account in the course of the

evaluation procedure. The minutes drawn up by the Commission of the tripartite meeting of 17 May 2004 devote an entire section to that issue, in which mention is made of the presentation of the rapporteur Member State's conclusions as to the classification of endosulfan as a POP and a PBT and as to the classification of endosulfan as a hazardous substance for the purposes of Directive 2000/60. It is also stated in the minutes that, under that directive, full mineralisation of the substance must be proved. The minutes also mention the applicants' objections as regards the use of the POP and PBT criteria in the context of Directive 91/414 and their argument that full mineralisation of a substance is not an objective under Directive 91/414. The Commission's contention that it adopted the contested decision independently of any discussion about whether endosulfan is a POP or a PBT or of any classification of endosulfan under Directive 2000/60 must therefore be rejected.

184 However, it cannot be inferred from the fact that endosulfan's classification as a POP or a PBT or its classification under Directive 2000/60 were examined in the course of the evaluation procedure that the contested decision infringes Article 5(1) of Directive 91/414. On the contrary, the finding at issue in the contested decision (see paragraph 44 above) does not appear at first sight to be incompatible with the criteria under Article 5(1), which are framed in broad terms and based on an analysis of the risk of harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment (see paragraph 5 above).

185 It must also be borne in mind that, irrespective of whether endosulfan may be classified as a POP or a PBT under Directive 2000/60, it was for the applicants to establish in the course of the evaluation procedure that the conditions laid down in Article 5(1) of Directive 91/414 had been met. However, the applicants do not explain how the classification of a substance as a POP or a PBT precludes its having the harmful effects referred to in Article 5(1) of Directive 91/414. The mere fact that endosulfan's classification as a POP or a PBT or its classification under Directive 2000/60 was examined in the course of the evaluation procedure cannot, therefore, in the absence of persuasive arguments showing that the findings of the contested decision are contrary to Article 5(1) of Directive 91/414, constitute a sufficient reason for the annulment of that decision. The objection is therefore unfounded.

186 Furthermore, it follows from the above that the arguments inferred from the fact that Directive 2000/60 is based on hazard analysis and Directive 91/414 is based on risk analysis, as well as the argument relating to an infringement of the applicants' legitimate expectation that only the criteria covered by Directive 91/414 would be applied, are irrelevant.

187 Accordingly, the submissions relating to the alleged classification of endosulfan as a POP or a PBT must be rejected in their entirety.

188 The question whether the glasshouse use solution proposed by the applicants at the end of the evaluation procedure would, in any event, have dispelled the doubts related to a possible classification of endosulfan as a POP or a PBT is addressed in the analysis of the issue of glasshouse use, set out below.

(vi) glasshouse use

— Arguments of the parties

189 The applicants submit that, in failing to take account of the solution they ultimately proposed of restricting endosulfan to glasshouse use with reduced GAP, the contested decision infringes Article 5(1) of Directive 91/414 and their rights of defence. Glasshouse use would solve the problem of the unknown metabolite, because the endosulfan would not be able to enter either the soil or water.

190 In the reply, the applicants add that the non-inclusion of endosulfan in Annex I to Directive 91/414, even for glasshouse use only, infringes the principles of proportionality and of equal treatment.

191 The Commission, supported by the Kingdom of Spain, maintains that it was entitled to refuse to examine the glasshouse use solution because it had been submitted out of time. In any event, that solution does not dispel the doubts raised by the unknown metabolite, as a glasshouse is not a completely closed environment.

— Findings of the Court

192 The issue of glasshouse use relates to a proposal that the applicants submitted after the tripartite meeting in a letter of 25 June 2004 to the Commission in which they stated that they were ready to support the use of endosulfan for tomatoes in glasshouses as a 'worst case reserve'.

193 In answer to a written question from the Court asking them the reasons for that late submission, the applicants replied that they had not been able to submit it beforehand because the concern relating to operator exposure had not been mentioned until the tripartite meeting, before which they had been led to believe that that problem had been solved. In that regard, it should be noted, however, that the letter of 25 June 2004 and the applicants' arguments in the reply reveal that the solution of using endosulfan in glasshouses for the cultivation of tomatoes had been proposed as a way of meeting the evaluators' remaining concerns, in particular that of the unknown metabolite which, as was found above, the applicants could have identified by 2000 at the latest.

194 The applicants also maintain that the Commission cannot base the refusal to examine that last-resort solution on the alleged incompleteness of the analysis in respect of glasshouse tomatoes, because that use was part of the initial notification. Furthermore, they maintain that, from 2001 to 2004, they were even led to believe that the application of endosulfan to glasshouse tomatoes would warrant the inclusion of endosulfan in Annex I to Directive 91/414. That objection must also be rejected because — as the Kingdom of Spain explained at the hearing, without being contradicted by the applicants — endosulfan had been notified in respect of 10 field uses and one glasshouse use. The examination of endosulfan had therefore clearly been focused on the environmental effects of the potentially most problematic use, that is to say, the outdoor use of endosulfan. It cannot therefore be inferred from the fact that the findings of the evaluation procedure concerned, in essence, the risk of harmful effects from endosulfan outdoors that glasshouse use must be regarded as compatible with Article 5(1) of Directive 91/414. Moreover, up until the end of the evaluation procedure, the applicants continued to request authorisation for all the applications notified.

195 It follows from the above that the applicants have failed to put forward any valid arguments as to why they could not have submitted that solution earlier in the evaluation procedure. Furthermore, by submitting that solution so late and by continuing to seek endosulfan's inclusion in Annex I to Directive 91/414 for as wide a use as possible, the applicants knowingly ran the risk of not being able to prove, within the procedural time-limits, that endosulfan met the criteria under Article 5(1) of Directive 91/414. Lastly, as regards the arguments relating to the alleged infringement of the principles of proportionality and equal treatment, they will be dealt with below in the examination of the third plea in law.

196 In any event, it must also be pointed out that there is obvious disagreement between the parties as regards whether a glasshouse constitutes a closed environment. The applicants maintain that the Commission's objections in that regard relating to toxicity in respect of birds are irrelevant, because there are no birds in glasshouses. However, it is clear from the documents before the Court and from the comments of the Kingdom of Spain at the hearing that there are also other concerns, regarding, for example, the possibility that endosulfan could enter the groundwater. Thus,

the Commission and the Kingdom of Spain clearly do not accept the applicants' argument that the glasshouse use solution would make it possible to overlook the problem of the unknown metabolite. Besides the fact, pointed out above, that the Commission must be recognised as enjoying a broad discretion as regards that type of complex scientific assessment, that debate also shows that even if the Court were to hold that failure to take into account the glasshouse use solution, submitted out of time, constituted a procedural flaw which infringed the applicants' rights of defence, it would by no means be established that its taking into account could have resulted in a different decision. That irregularity cannot therefore render the contested decision unlawful or, in consequence, lead to its annulment.

197 It follows that the submissions concerning the issue of glasshouse use must be rejected.

(vii) the impact of the delay in the evaluation procedure brought about by the rapporteur Member State and the Commission

— Arguments of the parties

198 According to the applicants, supported by ECPA, the rapporteur Member State did not submit its draft assessment report until February 2000, thereby infringing Article 7(1)(c) of Regulation No 3600/92 under which its deadline for that purpose falls 12 months after receipt of the complete dossier. In the present case, the updated version of the applicants' dossier had been submitted at the end of 1996. It is not possible, therefore, to raise against the applicants the defence of deadlines for the submission of data at the end of the evaluation procedure, because the rapporteur Member State was at least partly responsible for the delay. Furthermore, the applicants reject the argument of the Commission and the rapporteur Member State that the applicants share responsibility for the delay incurred during the evaluation procedure.

199 According to the Commission, the applicants themselves contributed to the delay which they now criticise. The Commission acknowledges that the procedures carried out under Directive 91/414, especially for the first phase of the review programme, did not go as quickly as expected, but that is true of all substances and all notifiers. However, it is unfair of the applicants to blame the rapporteur Member State and/or the Commission for all the delays. Moreover, not every delay in the procedure had negative consequences for the applicants, since endosulfan was thus able to stay on the market longer. Furthermore, even if the procedure had been less lengthy, there is no reason to suppose that the outcome would have been any different.

200 The Kingdom of Spain supports the Commission's arguments and also contends that most of the procedural delays were caused by the applicants themselves, a clear sign that they had no desire for the procedure to come to an end.

— Findings of the Court

201 It should be noted as a preliminary point that this issue concerns, in essence, the potential impact on the applicants' ability to meet the procedural deadlines of May 2002 and May 2003 of the initial delay in the evaluation procedure while the draft assessment report was being prepared.

202 First, it should be noted that the rapporteur Member State submitted the draft assessment report much later than provided for in the timetable laid down in Article 7(1)(c) of Regulation No 3600/92, as amended, which required the report to be sent to the Commission within 12 months of receipt of the dossiers. In the present case,

however, the complete dossier had been submitted in April 1995 and an updated version one year later, but the assessment report was not submitted to the Commission until 22 February 2000. In their written pleadings, neither the Commission nor the Kingdom of Spain provides an explanation for the considerable disparity between the date of actual submission and the timetable set by the legislation. Instead, they merely rely on certain delays at a later stage of the review procedure allegedly brought about by the applicants, a point which the applicants dispute. In reply to a written question from the Court, the Kingdom of Spain drew attention to the organisational difficulties encountered at the beginning of the evaluation procedure in view of the novelty of the procedure and the number of substances for which Spain had been designated as the rapporteur Member State. The Kingdom of Spain states that before 10 May 1996 there was no accredited entity to carry out assessments and that, from 1996 to 1998, the accredited entity carried out the assessment of the active substance endosulfan and kept the applicants informed of its conclusions as it progressed. The Kingdom of Spain also states that, as from July 1998, the applicants provided additional documents which changed even the GAP, thus delaying the submission of the draft assessment report even further.

203 It is clear that the arguments of the Commission and the Kingdom of Spain only partly explain the considerable delay in submitting the draft assessment report. However, it must be borne in mind that a procedural irregularity will entail the annulment of a decision in whole or in part only if it is shown that in the absence of such irregularity the contested decision might have been substantively different (Case 150/84 *Bernardi* v *Parliament* [1986] ECR 1375, paragraph 28; Case T-62/98 *Volkswagen* v *Commission* [2000] ECR II-2707, paragraph 283; Case T-279/02 *Degussa* v *Commission* [2006] ECR II-897, paragraph 416; see also, to that effect, Joined Cases 209/78 to 215/78 and 218/78 *van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 47).

204 In the light of that case-law, the applicants' line of argument is contradictory. First, they cannot credibly maintain that the delay in the submission of the draft assessment report made it impossible for them to submit data by a particular deadline when their reasoning is entirely predicated on the fact that the data which was not taken into account meets concerns which were expressed late in the evaluation procedure. Only if the draft assessment report had revealed the need to submit a supplementary

study could its late submission have prevented the applicants from meeting those deadlines and thus had an actual impact on the contested decision. Secondly, the applicants complain that there was a lack of interaction with the rapporteur Member State prior to 2000. Obviously, however, if the interaction between the applicants and the rapporteur Member State had been even more intense than that revealed by the evidence of their correspondence — submitted with the procedural documents and pointed out in the rapporteur Member State's answer to the written question from the Court — that would inevitably have delayed the submission of the draft assessment report. Furthermore, that documentary evidence shows that the applicants were closely involved in the preparation of the draft assessment report and that should have made it possible for them to improve the assessment. Thirdly, it emerges from the documents before the Court that the applicants sometimes contributed to the delay themselves by submitting new data or parameters, or, during the second stage of the review, by not always complying with the dates agreed upon for the submission of studies: accordingly, it would be difficult to say to what extent submission of the draft assessment report at an earlier date would have made it possible to identify some of the evaluators' concerns earlier.

205 The objection relating to the impact of the delay brought about by the rapporteur Member State and the Commission must therefore be rejected.

206 It follows from all of the above that the separate examination of each of the seven issues has not brought to light any manifest error of assessment on the part of the Commission in the application of Article 5(1) of Directive 91/414, or an infringement of the rights of the defence or the frustration of any legitimate expectation entertained by the applicants. Accordingly, it cannot be accepted either that the combined effect of the various aspects of the evaluation procedure which were called into question in connection with those issues constitutes a sufficient basis for the annulment of the contested decision, because it does not follow that the applicants were in a situation of *force majeure* which prevented them from complying with the procedural deadlines. The first plea in its entirety and the second branch of the second plea must therefore be rejected.

The first branch of the second plea, alleging infringement of Article 95(3) EC

Arguments of the parties

207 The applicants, supported by ECPA, claim that, by failing to review all the data submitted, including those submitted before the May 2002 and May 2003 deadlines, and by basing the evaluation of endosulfan on a narrow and incomplete set of data, the Commission infringed Article 95(3) EC. Whilst Directive 91/414 is formally based on Article 43 of the EC Treaty (now, after amendment, Article 37 EC), establishing a common agricultural policy, it is clear from the recitals in its preamble that it pursues objectives related to the internal market, which means that Article 95 EC is applicable. Thus, Article 4 of Directive 91/414 guarantees free movement of plant protection products by prohibiting the Member States from impeding, on grounds relating to the matters harmonised by the directive, the import, sale or authorisation of plant protection products which comply with the harmonised provisions. Moreover, the question of the legal basis for Directive 91/414 is immaterial.

208 Under Article 95(3) EC, when adopting measures to protect public health or the environment, the Commission is required to take into account the most recent data, including new developments based on scientific facts. Moreover, the first subparagraph of Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities. The combined effect of those provisions is that any decision adopted under Directive 91/414 must achieve a high level of protection assessed by reference to the most recent data.

209 The Commission, supported by the Kingdom of Spain, maintains that Article 95(3) EC is not applicable because it serves only as the legal basis for acts, adopted by the Council under the co-decision procedure laid down in Article 251 EC, the object of which is the establishment and the functioning of the internal market. Directive 91/414, which is the legal basis for the contested decision and the underlying evaluation procedures, was adopted on the basis of Article 43 of the EC Treaty, which does not involve co-decision.

210 Furthermore, agricultural legislation like Directive 91/414 may harmonise provisions of national law without being founded on Article 100 of the EC Treaty (now Article 94 EC), because Article 38(2) of the EC Treaty (now, after amendment, Article 32(2) EC) gives precedence to specific provisions in the agricultural field over general provisions relating to the establishment of the common market. The fact that an agricultural measure may also take account of environmental or health issues does not bring it within the scope of the environmental rules of the Treaty. For similar reasons, Article 152 EC is not relevant, either.

211 The Commission also states that it enjoys a broad margin of discretion in the agricultural field and that the Court of First Instance and the Court of Justice have explicitly held that that principle applies to procedures under Directive 91/414.

212 Lastly, the Commission states that it fails to understand why the duty to take into account the most current scientific information available would be different for rules underlying internal market legislation.

Findings of the Court

213 Article 95(3) EC — the applicability of which the Commission disputes in the present case — provides that, in its proposals to the Council for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market concerning health, safety, environmental protection and consumer protection, the Commission is to take as a base a high level of protection, taking account in particular of any new development based on scientific facts.

214 In that regard, it should be noted that the applicants confirm in their written pleadings that they are not challenging the legality of Directive 91/414 in relation to Article 95(3) EC, but that of the measures adopted by the Commission on the basis of that directive. They admit that Directive 91/414 does not itself run counter to the conditions laid down in Article 95(3) EC; rather, it reinforces these conditions since Article 5 of Directive 91/414 reflects the wording of Article 95(3) EC by requiring decisions to be taken 'in the light of current scientific and technical knowledge'. Clearly, therefore, the arguments put forward by the applicants in support of that branch of the plea overlap with the arguments in support of the first plea in law and the second branch of the second plea in law, which have been held to be unfounded. The grounds of challenge relating to the alleged infringement of Article 95(3) EC must therefore also be rejected without there being any need for the Court to rule on the applicability of that provision.

215 As regards Article 152(1) EC, on which the applicants rely in the alternative and under which a high level of protection of human health is to be ensured in the definition and implementation of all Community policies and activities, it is clear that no independent line of reasoning has been put forward and that the applicants merely repeat the reference to the Commission's alleged obligation to take into account the most recent data. In consequence, that objection must also be rejected.

216 It follows from the above that the first branch of the second plea must be rejected.

The third plea, alleging breach of certain general principles of Community law

217 By their third plea, the applicants allege, more specifically, breach of: the principle of proportionality (first branch); the principle of the protection of legitimate expectations and the principle of legal certainty (second branch); the prohibition against acting *ultra vires* (lack of competence) (third branch); the duty to undertake a diligent and impartial assessment (fourth branch); the prohibition against a misuse of powers (fifth branch); the rights of the defence and the right to be heard (sixth branch); the principle of the excellence and independence of scientific opinions (seventh branch); the principle of equal treatment (eighth part); the principle of *lex specialis* (ninth branch); and the principle of estoppel or *nemini licet venire contra factum proprium* (tenth branch). It is appropriate first to examine separately the first branch and the eighth branch, alleging respectively breach of the principle of proportionality and breach of the principle of equal treatment, before examining the other branches of the third plea together.

The first branch, alleging breach of the principle of proportionality

— Arguments of the parties

218 According to the applicants, it is clear from the case-law that, in order to establish whether a decision of a Community institution complies with the principle of

proportionality, it must be determined whether the means which it employs are suitable for the purpose of achieving the desired objective and whether they do not go beyond what is necessary to achieve that objective. In the present case, the decision not to review all the data submitted by the applicants runs counter to the aim of Directive 91/414, which is to assess the safety of plant protection products and their active ingredients by reference to the criteria specified in that directive and 'in light of the current scientific and technical knowledge', and it does not constitute the least restrictive means of achieving that objective since the resulting decision of non-inclusion in Annex I to that directive would cause endosulfan to be withdrawn from the European Union market, with irreparable commercial consequences for the applicants. Such a result is wholly disproportionate, particularly when driven merely by the need to meet artificially set time-limits, as in the present case.

219 The applicants refer to the order of the President of the Court of Justice in the *IQV* case (order of 21 October 2003 in Case C-365/03 P(R) *Industrias Químicas del Vallés* v *Commission* [2003] ECR I-12389), and the order of the President of the Court of First Instance of 5 August 2003 in Case T-158/03 R *Industrias Químicas del Vallés* v *Commission* [2003] ECR II-3041), which make it clear that the Commission cannot rely on time-limits as the sole ground for refusing to consider the new data submitted by the applicants. The slight delay that the review of such data would have entailed is well below the additional time allowed to IQV for the submission of new metalaxyl data, and certainly negligible as compared with the overall assessment period for endosulfan, which was delayed by the rapporteur Member State's own belated assessment, and which, in any event, was open until 31 December 2005 and further extended to 31 December 2006.

220 In their reply, the applicants add that endosulfan should have been included in Annex I to Directive 91/414 at least for use in glasshouses and that such an outcome would have been proportionate to the aims of the directive and would also have ensured that endosulfan was treated in the same way as other active substances. The Commission accepted the inclusion of beta-cyfluthrine in Annex I to Directive 91/414 on the ground that 'uses other than ornamentals in greenhouses and seed treatment are currently not adequately supported and have not shown to be acceptable under the criteria required by Annex VI' and that '[t]o support authorisation of such uses, data

and information to prove their acceptability to human consumers and the environment will have to be generated in the Member States.' The same approach was taken for the active substance cyfluthrine and could have been taken for endosulfan.

221 ECPA supports the applicants' arguments and adds that the Commission's refusal to take into account all the data available is particularly disproportionate in the present case, because endosulfan and the products containing it do not present any imminent or identified hazard or risk. ECPA also argues that there were at the very least less restrictive means of achieving the aim pursued than that of simply refusing the inclusion of endosulfan in Annex I to Directive 91/414. In that regard, the options available for removing any remaining uncertainty were a reduced period of inclusion in Annex I to Directive 91/414, enhanced safety factors, further data requirements and the mandatory commitment of the notifier to carry out further tests.

222 The Commission, supported by the Kingdom of Spain, contests the applicants' arguments. Furthermore, it disputes the admissibility of the objection that it was disproportionate not to include endosulfan in Annex I to Directive 91/414 for glasshouse use alone because, in its opinion, the application refers to the principle of proportionality only in relation to the issue concerning time-limits.

— Findings of the Court

223 It should be borne in mind that the general principle of proportionality requires that measures adopted by Community institutions must not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by

the legislation in question; that, where there is a choice between several appropriate measures, recourse must be had to the least onerous; and that the disadvantages caused must not be disproportionate to the aims pursued (see Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraph 28 and the case-law cited).

224 It follows that, within the context of judicial review of the application of that principle, in view of the broad discretion which the Commission enjoys in adopting decisions relating to the inclusion of active substances in Annex I to Directive 91/414, the lawfulness of a measure can be affected only if the measure is manifestly inappropriate in relation to the objective which it is intended to attain (see, to that effect, *Zuid-Hollandse Milieufederatie and Natuur en Milieu*, cited in paragraph 223 above, paragraph 29).

225 Furthermore, as was pointed out in paragraph 81 above, it is apparent from the recitals in the preamble to Directive 91/414 that its aims are, first, to remove barriers to intra-Community trade in plant protection products and to improve plant production and, second, to protect human and animal health and the environment.

226 As regards the application of the principle of proportionality to the Commission's decision not to take into account data submitted after the procedural deadlines, it should be borne in mind that the examination of the legislative framework together with the *IQV* judgment, carried out by the Court in the course of examining the first plea and the second branch of the second plea, reveals that, under the procedure leading to the adoption of a decision relating to the inclusion in Annex I to Directive 91/414 of a substance covered by the procedure laid down in Article 8(2) of that directive, a deferral must be granted if the notifiers of the active substance were in a situation of *force majeure* which prevented them from complying with the procedural time-limits for the submission of additional information to prove that there is a safe use for the active substance in question.

227 It is apparent from the above examination of the various issues that the applicants have failed to prove that they were in a situation of *force majeure* which prevented them from submitting, within the procedural time-limits, the data which the Commission refused to take into account. In consequence, the Commission's decision not to take into account the data and studies at issue cannot be held to be in breach of the principle of proportionality.

228 Furthermore, in those circumstances, the decision not to include endosulfan in Annex I to Directive 91/414 is not disproportionate either, inasmuch as it is based on the absence of sufficient information to show that there were no risks, such as those referred to in Article 5(1) of Directive 91/414, in view of the fact that the objectives pursued by Directive 91/414 of protecting human and animal health and the environment militate against a deferral of the decision to include or not to include the active substance at issue in Annex I to Directive 91/414 being left to the discretion of the producers of the active substance in question, and the fact that, in any event, it is possible for those producers to have the active substance re-examined by means of the procedure provided for in Article 6(2) of Directive 91/414.

229 Lastly, as regards the applicants' claim that, in the contested decision, the Commission should have provided for the inclusion of endosulfan in Annex I to Directive 91/414 for glasshouse use, it should be pointed out that submissions put forward in the application in support of that branch of the plea relate to the Commission's decision not to grant them a deferral of the legislative time-limits for the submission of data. Accordingly, those submissions do not concern the alleged proportionality of the contested decision in requiring endosulfan to be withdrawn from the market even though a less restrictive approach could have been chosen. In consequence, the applicants' claim that the Commission should have provided for the inclusion of endosulfan in Annex I to Directive 91/414 for glasshouse use, which was put forward for the first time in the reply, must be held inadmissible on the basis of the case-law referred to in paragraph 134 above. Furthermore, the fact that ECPA mentioned that submission in its statement in intervention does not call into question the finding that it is really a new plea which the applicants could have raised at the stage of the

application (see, to that effect, Case T-114/02 *BaByliss* v *Commission* [2003] ECR II-1279, paragraph 417). In any event, it is clear from the above examination of the first plea and the second branch of the second plea that the Commission did not make a manifest error of assessment in refusing to take into account the glasshouse use solution that the applicants had submitted after the expiry of the procedural time-limits. Accordingly, a complaint finding fault with the Commission for not permitting the inclusion of endosulfan in Annex I to Directive 91/414 for glasshouse use cannot be sustained.

230 It follows from all the above that the first branch of the third plea is unfounded.

The eighth branch, alleging breach of the principle of equal treatment

— Arguments of the parties

231 The applicants, supported by ECPA, allege that the assessment of endosulfan was dealt with less favourably than that of other compounds subject to the same review requirements, such as metalaxyl and chlorpyrifos, in respect of which additional periods of time were granted for the submission and evaluation of relevant new data.

232 Furthermore, in the case of eight active substances, the Commission decided to postpone the deadline for inclusion in Annex I to Directive 91/414 until 31 December 2006. On account of that postponement, eight substances belonging to the first stage of the review, including fenarimol and vinclozolin, were given longer marketing

periods and notifiers had the opportunity to submit additional data. Thus, the deadline for vinclozolin was deferred from 1998 to 2006 and that for fenarimol from 1997 to 2006, whilst the 2001 deadline for endosulfan was deferred only to 2005. The applicants have produced a table illustrating the effect of the rapporteur Member State's late submission of the initial assessment on the number of meetings for data evaluation and on feedback between notifiers and evaluating authorities. Fenarimol and vinclozolin thus benefited from more frequent meetings and from several additional years for the development of new data in response to the evaluation and in the light of technical progress, in accordance with Directive 91/414. That means that, in a few cases at least, the Commission has treated similar situations in a different fashion, contrary to the principle of equal treatment and Article 40(3) EC.

233 Moreover, the unequal treatment relates not only to the longer evaluation period granted for other substances belonging to the same list as endosulfan, but also to a difference in the overall evaluation criteria and the final result of the endosulfan assessment.

234 The Commission, supported by the Kingdom of Spain, contests the applicants' arguments.

— Findings of the Court

235 First, it should be pointed out that Article 40 EC concerns the scope of the Council's powers in the field of freedom of movement for workers and therefore has no link

with the submissions put forward in the context of this branch of the plea. Furthermore, the applicants have not submitted any clarification as to its relevance. The claim alleging infringement of that provision must therefore be held inadmissible on the basis of the case-law cited in paragraph 120 above.

236 Secondly, the principle of equal treatment is breached only where comparable situations are treated differently or different situations are treated in the same way, unless such treatment is objectively justified (see Case T-52/02 *SNCZ* v *Commission* [2005] ECR II-5005, paragraph 109 and the case-law cited).

237 In that regard, it should first be noted that — as the Commission has stated — in their arguments regarding the approach adopted in the case of other active substances, the applicants are merely listing examples of other substances for which a different approach was adopted, without explaining why endosulfan should have been treated in the same way. Those submissions must therefore be held inadmissible on the basis of the case-law cited in paragraph 120 above. Furthermore and in any event, the main issue raised in connection with that branch of the plea relates once again to the refusal to take into account the data submitted out of time, because, for the Commission to have been able to choose a course of action other than that of not including endosulfan, in any of its applications, in Annex I to Directive 91/414, it would have had to agree to examine the arguments concerning the reduced GAP, the CS formulation or glasshouse use.

238 Next, as regards the applicants' arguments based on a comparison between the way in which the evaluation procedure was conducted for endosulfan and the way in which other substances were treated in the context of the same procedure, it must be concluded that the applicants have submitted specific factors for comparison only in respect of fenarimol and vinclozolin. They have submitted inter alia in the application a comparative table which has come from the Commission and from which it is apparent — according to the applicants — that, in the case of those other active substances, meetings were held more often and the evaluation process was longer,

thus offering additional opportunities for the submission of new data. They claim that, in the case of endosulfan, there were fewer evaluation meetings and opportunities for subsequent discussion on account of the initial delay in the evaluation procedure. Moreover, the Commission did not set a deadline for the submission of new data on fenarimol or vinclozolin. Furthermore, the decision as to whether to include those two substances in Annex I to Directive 91/414 had not yet been made when the application was lodged in April 2006.

239 In reply to a written question from the Court, the Commission stated that the number of discussions was higher in the case of substances for which the risk assessment and risk management decisions were difficult. Furthermore, as regards the fact that the deadlines for the submission of data were different for those substances, the Commission disputes the assertion that the undertakings which notified those substances could submit new data until December 2003 or April 2004. Those undertakings were also faced with legislative deadlines and could not keep lodging new data. Nor is it correct to assume that a later delivery of the draft assessment report has negative consequences for the substance in question because, for example, the draft assessment report for MCPB was not delivered until December 2001, but MCPB was included in Annex I to Directive 91/414 by Commission Directive 2005/57/EC of 21 September 2005 amending Council Directive 91/414/EEC to include MCPA and MCPB as active substances (OJ 2005 L 246, p. 14).

240 As regards fenarimol, the Commission has explained that this is a controversial substance on which it was difficult to decide. The Committee did not deliver an opinion on a draft directive approving the substance and the Commission proposed two separate acts in June and September 2006. Fenarimol was ultimately included in Annex I to Directive 91/414 in 2006 subject to compliance with strict conditions, including a review after 18 months, whereas endosulfan was granted a phase-out period of almost two years.

241 As regards vinclozolin, again the Committee delivered no opinion, and the Commission proposed a directive in June 2006 with a view to its inclusion in Annex I to Directive 91/414. The Commission states that the Council opposed that proposal and that the Commission did not present any alternative text. It states that, in consequence, from 1 January 2007 vinclozolin was no longer covered by the transitional provisions laid down in Article 8(2) of Directive 91/414 and had to be withdrawn from the market.

242 It is clear from those explanations — which, moreover, the applicants did not seek to challenge at the hearing — that it has not been established that fenarimol and vinclozolin were treated more favourably than endosulfan. The Court therefore holds that, having regard in particular to the specific nature of each review procedure, which makes comparisons extremely difficult, and also to the Commission's discretion as to the way in which it conducts investigations of such a technical and complex nature, which has been referred to several times above, the applicants have failed to establish that the differences in the way in which the evaluation procedures subject to comparison were conducted were not objectively justified.

243 It follows from the above that the eighth branch of the third plea is unfounded.

The other branches of the third plea

244 As was pointed out above, by the second, third, fourth, fifth, sixth, seventh, ninth and tenth branches, the applicants allege, respectively, breach of: the principle of the protection of legitimate expectations and the principle of legal certainty; the prohib-

ition against acting *ultra vires*; the duty to undertake a diligent and impartial assessment; the prohibition against a misuse of powers; the rights of the defence and right to be heard; the principle of the excellence and independence of scientific opinions; the principle of *lex specialis*; and the principle of estoppel or *nemini licet venire contra factum proprium*.

— Arguments of the parties

245 First, as regards the alleged breach of the principle of the protection of legitimate expectations and the principle of legal certainty, the applicants, supported by ECPA, claim that the Commission's decision to assess endosulfan by reference to criteria extraneous to Directive 91/414, such as the PBT and POP criteria, or rules that were modified in the course of the assessment, such as the guidelines on metabolites, is in breach of their legitimate expectation that the assessment of their active substance would be carried out under that directive alone, as well as of the principle of legal certainty. The Court of Justice has consistently endorsed the principles of legal certainty and the protection of legitimate expectations, by virtue of which the effect of Community legislation must be clear and predictable for those who are subject to it (Joined Cases 212/80 to 217/80 *Meridionale Industria Salumi and Others* [1981] ECR 2735, paragraph 10). As the Commission changed the evaluation criteria several times, it should at the very least have given the applicants sufficient time and opportunities to adapt their notification to the new criteria. Moreover, it is for the Community legislature to include any new evaluation criteria in Directive 91/414, acting upon a proposal from the Commission and in accordance with the appropriate legislative procedures, not for the Commission to make new law on its own initiative. Using evaluation criteria which are not expressly provided for in Directive 91/414 invalidates decisions based on such new criteria, as in the case of endosulfan.

246 Secondly, as regards the prohibition against acting *ultra vires*, the applicants, supported by ECPA, submit that the Commission does not have the authority to assess endosulfan by reference to the PBT and POP criteria or the rules on metabolites, which are not expressly mentioned in Directive 91/414. It is settled case-law that an implementing act, which is adopted in accordance with the provisions of a basic directive, must be annulled if it has 'modified the scope of the obligations imposed … by the basic directive, without following the legislative procedure prescribed by the Treaty' (Case C-303/94 *Parliament* v *Council* [1996] ECR I-2943). In any event, the POP and PBT evaluation carried out by the Commission was superficial and handled without technical or legal competence.

247 Thirdly, as regards the alleged infringement of the duty to undertake a diligent and impartial assessment, the applicants, supported by ECPA, maintain that the Commission cannot assess the safety of endosulfan on the basis of data results which relate to another substance — endosulfan sulphate and/or other unknown metabolites — and which derive from a hazard-based PBT assessment performed at working group level only and without conclusion under Directive 2000/60. The Commission is obliged to assess endosulfan with reference to its own properties, on the basis of a complete risk assessment, and not by reference to the allegedly hazardous properties of chemically distinct substances, such as metabolites, using an incomplete set of data. Furthermore, according to the applicants, it emerges from the minutes of the tripartite meeting of 17 May 2004 that the rapporteur Member State and the Commission appear to have arbitrarily selected certain data results on endosulfan which support a particular conclusion and to have deliberately ignored other results and adjustments made by the applicants in order to alleviate any remaining concerns on the part of the evaluators relating to a safe use in connection with the CS formulation. By so doing, the Commission failed to undertake a diligent and impartial assessment of endosulfan.

248 Fourthly, as regards the alleged misuse of powers, the applicants, supported by ECPA, submit that the Commission misused its powers by pursuing the non-inclusion of endosulfan in Annex I to Directive 91/414 by reference to criteria extraneous to that directive and on the basis of an arbitrarily selected set of data that does not include the most recent data submitted by the applicants. The Commission's conclusions

concerning endosulfan are based on incomplete and narrow results, or on results deriving from hazard-based methodology applied under the principles of Directive 2000/60, but not under the evaluation process provided for in Directive 91/414, thus giving the impression of an arbitrary decision adopted with the sole purpose of substantiating PBT and/or POP findings to support a decision not to include endosulfan in Annex I to Directive 91/414. Moreover, the Commission and the rapporteur Member State requested the submission of certain studies that are neither part of Directive 91/414 nor linked to real use conditions. In any event, endosulfan and its metabolites must be assessed separately. Alleged PBT properties or other concerns over endosulfan's metabolites cannot, according to the applicants, negatively affect the assessment of endosulfan itself under Directive 91/414 and require an evaluation in their own right, which the rapporteur Member State has chosen not to undertake. By using the results of endosulfan metabolites (or lack of results) to achieve the non-inclusion of endosulfan in Annex I to Directive 91/414, the Commission has misused the powers conferred on it by that directive.

249 Fifthly, as regards the alleged infringement of the rights of the defence and the right to a fair hearing, the applicants, supported by ECPA, claim that, by failing to review the new data and supporting arguments submitted by the applicants, by changing the assessment criteria several times without giving the applicants enough time to adjust to the new criteria, and by applying criteria extraneous to Directive 91/414, the Commission denied the applicants the opportunity to present an effective defence. The rapporteur Member State did not evaluate endosulfan in accordance with the Directive 91/414 criteria, failed to communicate with the notifiers, requested the submission of studies that were either irrelevant or beyond the Directive 91/414 framework and refused to review certain data submitted by the applicants which, however, were critical for the correct assessment of endosulfan. Confronted with such manifest errors and infringements, the Commission should have intervened by virtue of its duty to ensure due process to make sure, first, that the assessment was made in a scientifically and legally sound fashion and, second, that the applicants were given sufficient time and opportunities effectively to defend their position and adjust to rules which had been amended a number of times.

250 Sixthly, as regards the breach of the principle of the excellence and independence of scientific advice, the applicants, supported by ECPA, rely on the Commission Communication of 30 April 1997 on consumer health and food safety, in which it is stated that high-quality scientific advice for the drafting and amendment of Community rules regarding consumer protection in general and consumer health in particular is of the utmost importance. Moreover, under Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety (OJ 1997 L 237, p. 18), scientific advice on matters relating to consumer health must, in the interest of consumers and industry, be based on the principles of excellence and independence. Moreover, the Court of First Instance has held that 'a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures' (Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 172). In the case of endosulfan, the rapporteur Member State recommended non-inclusion of the compound in Annex I to Directive 91/414 largely on the basis of concerns relating to metabolites and alleged PBT and POP properties not provided for in Directive 91/414 and not used for the evaluation of other compounds. Moreover, the continually changing guidelines rendered the assessment of the applicants' dossier totally unpredictable. The assessment is therefore wholly subjective and fails to provide the requisite high-level objective scientific advice.

251 Seventhly, as regards the alleged breach of the principle of *lex specialis*, the applicants, supported by ECPA, claim that the Commission is not entitled to reach a decision not to include endosulfan in Annex I to Directive 91/414 using criteria like the PBT and POP criteria, which are hazard-based and do not belong to the Directive 91/414 assessment but derive from a Directive 2000/60 assessment. Directive 91/414 is more specific and is thus the legislation which prevails (the *lex specialis*). Consequently, in the case of conflicts between Directive 2000/60 and Directive 91/414, the latter has primacy over the former.

252 Lastly, according to the applicants, supported by ECPA, by application of the principle of estoppel or *nemini licet venire contra factum proprium*, it is not possible to rely on a fact or an irregularity which may have been the consequence of one's own behaviour. In the present case, the applicants maintain that the application of that principle precludes the Commission from refusing to review the new data that they submitted on the ground that certain artificially set deadlines must be met, when such a decision is clearly and solely driven by an overall delay in the assessment of plant protection products in general, and of endosulfan in particular, owing to the Commission's own failure to raise its concerns on endosulfan promptly, to give the applicants sufficient time to address those concerns and to review their submissions before the deadline. Similarly, where a deadline cannot be met owing to the creation of unforeseen new evaluation criteria during the evaluation process, any deadline for decision-making is invalidated under the principle of estoppel. In the present case, the Commission established the new criteria and guidelines during the evaluation process, thereby itself creating the impediment for meeting the deadline in question.

253 The Commission, supported by the Kingdom of Spain, disputes the applicants' arguments.

— Findings of the Court

254 First, as regards the alleged misuse of powers, it must be borne in mind that, according to settled case-law, the concept of misuse of powers has a precisely defined scope in Community law and relates to cases where an administrative authority exercises its powers for a purpose other than that for which they were conferred. A decision amounts to a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken to achieve an end other than that stated (Case C-285/94 *Italy* v *Commission* [1997] ECR I-3519, paragraph 52; Case T-254/97

Fruchthandelsgesellschaft Chemnitz v *Commission* [1999] ECR II-2743, paragraph 76; and Case T-612/97 *Cordis* v *Commission* [1999] ECR II-2771, paragraph 41).

255 Clearly, the applicants have failed to provide, in order to establish the misuse of powers, objective, relevant and consistent factors which could support the conclusion that the decision to request some study or other in the course of the evaluation procedure, or the contested decision itself, was taken to achieve ends other than those stated, such as the attainment of the objectives of Directive 91/414, that is to say, the removal of barriers to intra-Community trade in plant protection products and the improvement of plant production, and the protection of human and animal health and the environment.

256 Next, as regards the principle of the excellence and independence of scientific advice, paragraphs 170 to 172 of *Pfizer Animal Health* v *Council* — cited in paragraph 250 above and relied upon by the applicants — state:

'Under the precautionary principle the Community institutions are entitled in the interests of human health to adopt, on the basis of as yet incomplete scientific knowledge, protective measures which may seriously harm legally protected positions, and they enjoy a broad discretion in that regard. However, according to the settled case-law of the Court of Justice and the Court of First Instance, in such circumstances, the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case … It follows that a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures.'

257 On the basis of that case-law and contrary to the view of the Commission, the applicants' reliance on the need to base the contested decision on excellent and independent scientific advice is not irrelevant. However, it should be pointed out that certain specific features of the evaluation procedure, such as the consultation with experts from the Member States and the possibility for notifiers to submit additional data and studies on the basis of meetings and discussions with the various parties involved in the evaluation procedure, are clearly a response to the concern regarding compliance with the procedural guarantees referred to in *Pfizer Animal Health* v *Council*, cited in paragraph 250 above. As it is, it was held above that there was no irregularity on the part of the Commission in the course of the procedure capable of entailing the annulment of the contested decision. Furthermore, it should be pointed out that the applicants confuse compliance with procedural guarantees with the possibility of differing views on the substance.

258 As to the remainder, it must be held that the applicants have failed to present arguments which are different from those put forward in support of the first and second pleas, both of which were rejected. The arguments put forward in support of the other branches of this plea must therefore be rejected.

259 In view of all of the above, this plea must be rejected and, in consequence, the action must be dismissed in its entirety.

The measures of organisation of procedure and of inquiry

260 In addition to the requests refused in paragraphs 152 and 167 above, the applicants also asked the Court to order certain experts to appear before it; or to question them in writing about specific issues relating to the relevance of data which had been

submitted by the applicants, but not taken into account by the Commission, and to the time necessary to examine those data; and to commission an expert's report on the technical issues raised in the present case. The Court holds that those measures would serve no useful purpose, in view, inter alia, of the findings made in the examination of the first plea and the second branch of the second plea, and that those requests must therefore be refused.

Costs

261 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicants have been unsuccessful and the Commission has applied for costs, the applicants must be ordered to bear their own costs and to pay those of the Commission.

262 Under the first subparagraph of Article 87(4) of the Rules of Procedure, Member States which intervene in the proceedings are to bear their own costs. Consequently, the Kingdom of Spain must bear its own costs.

263 Under the third subparagraph of Article 87(4) of the Rules of Procedure, EPCA, as intervener, must also bear its own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fourth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Bayer CropScience AG, Makhteshim-Agan Holding BV, Alfa Georgika Efodia AEVE and Aragonesas Agro, SA to bear their own costs and to pay those incurred by the Commission;**

3. **Orders the Kingdom of Spain and the European Crop Protection Association (ECPA) to bear their own costs.**

Czúcz Cooke Labucka

Delivered in open court in Luxembourg on 9 September 2008.

Registrar President

E. Coulon O. Czúcz

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