JUDGMENT OF THE COURT OF FIRST INSTANCE (Sixth Chamber)

7 October 2009 *

In Case T-420/05,

Vischim Srl, established in Cesano Maderno (Italy), represented by C. Mereu and K. Van Maldegem, lawyers,

applicant,

v

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

defendant,

APPLICATION for annulment, with regard to the inclusion of the active substance chlorothalonil, of Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ 2005 L 241, p. 51), for

* Language of the case: English.

annulment of the review report for chlorothalonil (document SANCO/4343/2000 final of 14 February 2005), for a declaration of failure to act and for damages,

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

composed of A.W.H. Meij, President, F. Dehousse and V. Vadapalas (Rapporteur), Judges,

Registrar: C. Kantza, Administrator,

having regard to the written procedure and further to the hearing on 25 September 2008,

gives the following

Judgment

Legal context

1. *Directive 91/414/EEC*

1 As provided in Article 4(1)(a) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1), 'Member States shall ensure that a plant protection product is not authorised unless its active substances are listed in Annex I and any conditions laid down therein are fulfilled'.

2 Article 5(1) of Directive 91/414 states that, 'in the light of current scientific and technical knowledge, an active substance shall be included in Annex I for an initial period not exceeding 10 years, if it may be expected that plant protection products containing the active substance will fulfil the … conditions' which are then set out and relate to the products not being harmful for human or animal health or the environment.

3 By virtue of the first and second indents of Article 5(4) of Directive 91/414, an active substance's inclusion may be subject to requirements relating to 'the minimum degree of purity of the active substance' and to 'the nature and maximum content of certain impurities'.

4 Article 8(2) of Directive 91/414 provides:

'By way of derogation from Article 4 …, a Member State may, during a period of 12 years following the notification of this Directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive.

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

…

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

5 Article 19 of Directive 91/414, as amended by Council Regulation (EC) No 806/2003 of 14 April 2003 (OJ 2003 L 122, p. 1), provides that the Commission of the European

Communities is to be assisted by a regulatory committee, the Standing Committee on the Food Chain and Animal Health ('the Committee').

6 As regards the active substance chlorothalonil, the period referred to in Article 8(2) of Directive 91/414, which was to expire on 26 July 2003, was extended, initially until 31 December 2005, by Commission Regulation (EC) No 2076/2002 of 20 November 2002 (OJ 2002 L 319, p. 3), then until 31 December 2006, by Commission Regulation (EC) No 1335/2005 of 12 August 2005 (OJ 2005 L 211, p. 6), unless a decision on its inclusion in Annex I to Directive 91/414 was taken before that date.

2. *Regulation (EEC) No 3600/92*

7 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 91/414 (OJ 1992 L 366, p. 10) sets out 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 chlorothalonil.

8 Article 4(1) of Regulation No 3600/92 states that 'any producer wishing to secure the inclusion of an active substance … 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'.

9 According to Article 5 of Regulation No 3600/92, the Commission, after examining the notifications, is to draw up, in the form of a regulation, the list of active substances adopted for assessment, designate a rapporteur Member State for each of those active substances and indicate, for each of them, the names of the producers who have

presented a notification and the deadline for the submission to the rapporteur Member State of the dossiers referred to in Article 6 of the regulation.

10 Article 6 of Regulation No 3600/92, as supplemented by Commission Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27), provides that the notifiers are, individually or collectively, to send the summary dossier and the complete dossier to the rapporteur Member State, and it specifies the content of those dossiers.

11 Article 7(1) and (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:

'1. For each active substance for which it has been designated rapporteur, the Member State shall:

(a) examine the dossiers referred to in Article 6(2) and (3), in the order in which they are received …;

(b) immediately after examining a dossier, ensure that notifiers submit the updated summary dossier to the other Member States and to the Commission;

(c) send the Commission … a report of its assessment of the dossier, including a recommendation:

— to include the active substance in Annex I to Directive [91/414], stating the conditions for its inclusion, or

— to remove the active substance from the market, or

— …

(d) in particular, include in the report a reference to each test and study report, for each point of Annex II to … Directive [91/414], relied on for the assessment in the form of a list of test and study reports including the title, the author(s), the date of the study or test and the date of publication, the standard to which the test or study was conducted, the holder's name and, if any, the claim made by the holder or notifier for data protection.

2. From the start of the examination referred to in paragraph 1, the rapporteur Member State may request the notifiers to improve their dossiers, or add to them. …'

12 Article 7(3) of Regulation No 3600/92, as amended by Regulation No 1199/97, provides:

'After receiving the summary dossier and the report referred to in paragraph 1, the Commission shall refer the dossier and the report to the Committee for examination.

…

Before the dossier and report are referred to the Committee, a consultation of experts from the Member States may be organised and the Commission may consult some or all of the notifiers … on the report or parts of the report on the relevant active substance.'

13 Article 7(3A) of Regulation No 3600/92, as added by Regulation No 1199/97, states:

'After the examination referred to in paragraph 3, the Commission shall … present to the Committee:

(a) a draft directive to include the active substance in Annex I to Directive [91/414], setting out where appropriate the conditions, including the time-limit, for such inclusion;

….'

14 Under Article 7(6) of Regulation No 3600/92, as added by Regulation No 1199/97, 'where the Commission presents a draft directive or a draft decision in accordance with paragraph 3A or a draft in accordance with paragraph 5, it shall at the same time present the conclusions of the Committee's examination in the format of an updated review report to be noted in the summary record of the meeting'.

Background to the dispute

15 On 8 July 1993 the applicant, Vischim Srl, an Italian company producing chlorothalonil, informed the Commission of its wish to secure the inclusion of that active substance in Annex I to Directive 91/414.

16 By 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), the Commission issued a list of the active substances to be assessed in the first stage of the programme of work referred to in Article 8(2) of Directive 91/414. In the case of chlorothalonil, the list indicates 16 notifiers, including the applicant. The deadline for the submission of the dossiers to the rapporteur Member State was set in Article 2 of that regulation, as amended by Commission Regulation (EC) No 2230/95 of 21 September 1995 (OJ 1995 L 225, p. 1).

17 Only two notifiers in respect of chlorothalonil submitted their dossiers within the deadline, namely ISK Biotech Europe (which was replaced in the course of the assessment procedure by Zeneca Agrochemicals, which in turn became Syngenta) and the applicant.

18 On 31 January 2000, the rapporteur Member State submitted its report on the assessment of the dossiers to the Commission.

19 Between March and September 2001, the report was the subject of consultation by experts from the Member States ('the peer review'), under the auspices of the body called European Community Co-Ordination (ECCO).

20 The dossiers were referred to the Committee for examination, in accordance with Article 7(3) of Regulation No 3600/92, and that examination went on from July 2001 to September 2004.

21 Following that examination, the Commission drew up a draft review report for chlorothalonil (document SANCO/4343/2000, rev 3.1 of 20 January 2005; 'the draft review report'). So far as concerns the specification for chlorothalonil, Appendix I to the draft review report refers to the specification adopted by the FAO (Food and Agriculture Organisation of the United Nations) in 1998, setting the maximum hexachlorobenzene (HCB) content at 0.3 g/kg. This appendix nevertheless contains a note to the effect that the FAO specification had been under re-evaluation since 2003. Appendix IIIA to the same draft, dated 19 January 2005, sets out the 'list of studies for which the main submitter has claimed data protection and which … were considered as essential for the evaluation', including references to the data submitted by Syngenta and by the applicant.

22 The authorities of the rapporteur Member State emailed the draft review report to the applicant on 8 February 2005.

23 In February 2005, the FAO adopted, on the basis of the data submitted by Syngenta, a new specification for chlorothalonil setting the maximum HCB content at 0.01g/kg.

24 On 15 February 2005, the Committee issued a favourable opinion on the draft directive, referred to it by the Commission, relating to the inclusion of chlorothalonil in Annex I to Directive 91/414 and finalised the review report for chlorothalonil (document SANCO/4343/2000 final of 14 February 2005; 'the review report'). So far as concerns the specification for chlorothalonil, Appendix I to the review report refers to the FAO specification of February 2005, indicating a maximum HCB content of 0.01 g/kg. Appendix IIIA to the review report, dated 15 March 2005, refers only to the data submitted by Syngenta.

25 By letter of 19 February 2005, the applicant submitted to the authorities of the rapporteur Member State its observations on the draft review report annexed to the email of 8 February 2005.

26 By email of 15 March 2005, the authorities of the rapporteur Member State replied to the applicant's observations, stating inter alia that it had been decided to pursue the assessment of chlorothalonil on the basis of Syngenta's dossier.

27 By letter of 14 April 2005, the applicant requested the Commission to refrain from adopting the directive unless the specification for chlorothalonil was modified to take account of the specification for its product.

28 The Commission replied to the applicant on 19 May 2005, stating that its staff '[were] collecting the necessary information to examine in depth the concerns expressed in [its] request and [would] not fail to inform [the applicant] of their views'.

29 The applicant repeated that request in two further letters to the Commission, dated 9 June and 14 July 2005, to which the Commission did not reply.

30 On 16 September 2005, the Commission adopted Directive 2005/53/EC amending Directive 91/414 to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ 2005 L 241, p. 51; 'the contested directive').

31 By virtue of Article 1 of the contested directive and the annex thereto, chlorothalonil was included under No 102 in the table in Annex I to Directive 91/414. The fourth column of that table, headed 'Purity', states: 'Hexachlorobenzene: not more than 0.01g/kg'.

32 Under Article 3(1) of the contested directive, the Member States were obliged, where necessary, to amend or withdraw existing authorisations for plant protection products containing chlorothalonil by 31 August 2006, verifying whether the conditions in Annex I to Directive 91/414 were met and whether the holder of the authorisation had, or had access to, a dossier satisfying the requirements of Annex II to Directive 91/414 in accordance with the conditions of Article 13 of that directive.

33 The contested directive entered into force on 1 March 2006. Under the first and second paragraphs of Article 2, the Member States had to adopt and publish the provisions necessary in order to comply with the contested directive by 31 August 2006 at the latest, and to apply them from 1 September 2006.

34 In December 2005, the FAO published, on the basis of the information submitted by the applicant, a new specification for chlorothalonil increasing the maximum HCB content to 0.04 g/kg.

35 On 22 September 2006, the Commission adopted Directive 2006/76/EC amending Directive 91/414 as regards the specification of the active substance chlorothalonil (OJ 2006 L 263, p. 9).

36 Pursuant to Article 1 of Directive 2006/76, the specification laid down for chlorothalonil in the context of its inclusion in Annex I to Directive 91/414 was

replaced by the annexed table. The fourth column of that table, headed 'Purity', states: 'Hexachlorobenzene: not more than 0.04 g/kg'.

37 Directive 2006/76 entered into force on 23 September 2006. Under Article 2, the Member States had to adopt the provisions necessary in order to comply with Directive 2006/76 by 31 August 2006 at the latest, and to apply them from 1 September 2006.

Procedure and forms of order sought

38 By application lodged at the Registry of the Court of First Instance on 25 November 2005, the applicant brought the present action.

39 In the context of its action, the applicant made two successive applications for interim measures, which were dismissed by orders of the President of the Court of First Instance of 4 April 2006 in Case T-420/05 R *Vischim* v *Commission*, not published in the ECR, and of 13 October 2006 in Case T-420/05 R II *Vischim* v *Commission* [2006] ECR II-4085, the latter order being upheld by order of the President of the Court of Justice of 3 April 2007 in Case C-459/06 P(R) *Vischim* v *Commission*, not published in the ECR.

40 In the context of measures of organisation of procedure, the Commission, by letter of 18 October 2006, first, corrected an error in a table annexed to its rejoinder and, second, set out its observations concerning the adoption of Directive 2006/76.

41 By letters of 14 December 2006 and 2 March 2007, the applicant requested permission to submit supplementary claims and pleas in law in the light of the adoption of Directive 2006/76. In its observations of 3 April 2007 the Commission opposed the applicant's request.

42 In the context of the measures of organisation of procedure, on 20 July 2007 the applicant lodged its claims and pleas in law as amended in the light of the adoption of Directive 2006/76. The Commission submitted its observations on 28 September 2007.

43 Upon a change in the composition of the Chambers of the Court, the Judge-Rapporteur was assigned to the Sixth Chamber, to which the present case was consequently allocated.

44 As a member of the Chamber was unable to sit, the President of the Court of First Instance designated another Judge to complete the Chamber, pursuant to Article 32(3) of the Rules of Procedure of the Court of First Instance.

45 After the parties had been heard, the present case and Case T-380/06 were joined for the purposes of the oral procedure.

46 Upon hearing the report of the Judge-Rapporteur, the Court decided to open the oral procedure and, by way of measures of organisation of procedure, put certain questions in writing to the parties, which replied to them by letters of 16 June and 7 and 14 July 2008.

47 The parties presented oral argument and replied to the questions put by the Court at the hearing on 25 September 2008.

48 In its application, the applicant claims that the Court should:

— partially annul the contested directive as regards the inclusion of chlorothalonil under No 102 in the table in Annex I to Directive 91/414 or, in the alternative, modify the specification for chlorothalonil in order to reflect the specification adopted by the FAO in November 2005;

— partially annul the review report in so far as it does not accord the applicant the status of 'main data submitter' and does not refer to its data in Appendix IIIA thereto;

— order the Commission, under Article 232 EC, to act on the applicant's request contained in the letter of 14 April 2005;

— order the Commission, under Article 288 EC, to compensate the applicant for damage suffered as a result of the adoption of the contested directive or, in the alternative, as a result of its failure to act;

— order the Commission to pay the costs.

49 The Commission contends that the Court should:

— dismiss the action as inadmissible or, in the alternative, as unfounded;

— order the applicant to pay the costs.

Law

1. *The claim for annulment of the contested directive, so far as concerns the specification for chlorothalonil*

Adaptation of the claim for annulment

50 By its document of 20 July 2007, the applicant seeks to replace its first head of claim set out in the application with a claim for annulment of the second paragraph of Article 2 and of Article 3(1) of the contested directive or, in the alternative, for annulment of the contested directive in its entirety. It also indicates that, if the Court decides to dismiss the new claim as inadmissible, it will maintain the claim set out in its application.

51 The Commission argues that the claim of 20 July 2007 amounts to new pleas in law which are inadmissible under Article 48(2) of the Rules of Procedure.

52 It is to be recalled that the specification for chlorothalonil referred to in the contested directive was replaced by the amended specification introduced by Directive 2006/76.

53 In accordance with settled case-law, where a contested measure is, during the proceedings, replaced by a measure with the same subject-matter, this must be considered a new factor allowing the applicant to adapt his claims and pleas in law, that is to say to extend his original claims and pleas to the later measure or to put forward supplementary claims and pleas against that measure (Case 14/81 *Alpha Steel* v *Commission* [1982] ECR 749, paragraph 8, and Joined Cases T-46/98 and T-151/98 *CEMR* v *Commission* [2000] ECR II-167, paragraph 33).

54 Here, however, the new claim put forward by the applicant is not directed against the later measure, namely Directive 2006/76, which indeed is the subject of a separate action (Case T-380/06). The new claim seeks, from another angle, the partial or entire annulment of the contested directive, which is already the subject of the claim set out in the application. Since new pleas in law which are not based on matters of law or of fact that have come to light in the course of the procedure are therefore involved, the claim must be considered inadmissible pursuant to Article 48(2) of the Rules of Procedure.

55 Accordingly, it is necessary to dismiss the applicant's new claim of 20 July 2007 and to rule on the claim set out in the application.

Admissibility

Legal interest in bringing proceedings

56 The Commission submits that the amendment of the specification for chlorothalonil resulting from the adoption of Directive 2006/76 eliminated the applicant's interest in bringing proceedings for annulment of the contested directive.

57 The applicant confirms that its product conforms to the specification for chlorothalonil introduced by Directive 2006/76, but contends that the specification established by the contested directive produced legal effects, which subsist despite the alteration of the specification and justify retention of its interest in bringing proceedings. It states, in this regard, that the authorisations for its plant protection products containing chlorothalonil were withdrawn in several Member States.

58 It is to be recalled that, in accordance with settled case-law, an interest in the annulment of a measure exists only if its annulment is of itself capable of having legal consequences (Case 53/85 *AKZO Chemie* v *Commission* [1986] ECR 1965, paragraph 21, and Case T-102/96 *Gencor* v *Commission* [1999] ECR II-753, paragraph 40).

59 In the present case, the contested directive, which was adopted on 16 September 2005 and entered into force on 1 March 2006, obliged the Member States to review existing authorisations for plant protection products containing chlorothalonil by 31 August 2006. Under the second subparagraph of Article 3(1) of the contested directive, this review entailed, first, verifying whether the conditions upon which that substance was included in Annex I to Directive 91/414 were met and, second, checking compliance with the obligation to have, or to have access to, a dossier satisfying the requirements of Annex II to Directive 91/414.

60 The specification envisaged by the contested directive was replaced by the amended specification prescribed by Directive 2006/76. The latter, by virtue of the first paragraph of Article 2 thereof, had to be transposed by the Member States retroactively by 31 August 2006, namely the date laid down by the first subparagraph of Article 3(1) of the contested directive for the withdrawal or amendment of the existing national authorisations which did not accord with the conditions upon which chlorothalonil was included in Annex I to Directive 91/414 that were laid down by the contested directive. On the other hand, that retroactive effect of Directive 2006/76 does not extend to the date upon which the contested directive entered into force and, accordingly, is not capable of eliminating the legal consequences produced by the contested directive until 31 August 2006.

61 It follows that the contested directive was liable to affect the applicant's legal position inasmuch as it was not entitled to rely on the fact that its products complied with the conditions upon which chlorothalonil was included in Annex I to Directive 91/414 during the period, laid down by the contested directive, intended to enable the persons concerned to prepare for the review of national authorisations.

62 Finally, it is to be noted that the present claim for annulment retains at the very least an interest as the basis for claims for damages made by the applicant (see, to this effect, Joined Cases C-68/94 and C-30/95 *France and Others* v *Commission* [1998] ECR I-1375, paragraph 74, and the case-law cited).

63 Accordingly, it must be held that the applicant has retained a legal interest in bringing the present claim for annulment.

The applicant's standing to bring proceedings

64 In defence, the Commission contests the admissibility of the present claim by pleading that the contested directive is legislative in nature and that the applicant is not directly and individually concerned.

65 The applicant contends that it has standing, inter alia in view of its participation in the assessment procedure for chlorothalonil.

66 It is to be observed that the contested directive is a measure of general application which is addressed to the Member States.

67 Although the fourth paragraph of Article 230 EC makes no express provision regarding the admissibility of actions brought by natural or legal persons for annulment of a directive, it is clear from the case-law that that fact in itself is not sufficient to render such actions inadmissible. The Community institutions cannot, merely by means of their choice of legal instrument, deprive individuals of the judicial protection which they are afforded by that provision of the Treaty (Case T-135/96 *UEAPME* v *Council* [1998] ECR II-2335, paragraph 63, and order in Case T-223/01 *Japan Tobacco and JT International* v *Parliament and Council* [2002] ECR II-3259, paragraph 28).

68 Furthermore, the fact that the contested measure is of general application does not preclude it from being of direct and individual concern to certain natural and legal persons. In those circumstances, a Community measure can be of a general nature and, at the same time, vis-à-vis some traders, in the nature of a decision (see Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 84, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 76, and the case-law cited).

69 It must therefore be examined whether the contested directive affects the applicant's legal position in an individual and direct manner.

70 As regards, first, individual concern, the fact that a person is involved in the procedure leading to the adoption of a Community measure is capable of distinguishing that person individually in relation to the measure in question only if the applicable Community legislation grants him certain procedural safeguards (see *Pfizer Animal Health* v *Council*, paragraph 101, and *Alpharma* v *Council*, paragraph 93, and the case-law cited).

71 The assessment procedure envisaged by Article 8(2) of Directive 91/414, concerning active substances already on the market two years after the date of notification of that directive, is, in accordance with the detailed rules laid down in Article 4(1) of Regulation No 3600/92, initiated by notification made by an interested producer. Under Article 6(1) of that regulation, the notifier is required to submit the dossier containing the data for the assessment of the active substance concerned. It is also apparent from Article 7(2) and (3) of the regulation that the notifier is associated with the various stages of examination of his dossier and enjoys procedural safeguards on that basis.

72 Accordingly, it must be held that a notifier, having submitted the dossier and participated in the assessment procedure, is individually concerned by the Commission measure bringing the procedure to an end. He is just as concerned by a directive authorising the active substance subject to conditions as he would be by a decision to refuse authorisation (see, to this effect, Joined Cases T-125/96 and T-152/96 *Boehringer* v *Council and Commission* [1999] ECR II-3427, paragraph 168).

73 In the present case, it is not in dispute that the applicant is one of the two notifiers which submitted dossiers and participated in the assessment of chlorothalonil. It is therefore individually concerned by the contested directive so far as concerns chlorothalonil.

74 Next, as regards direct concern, that notion requires the contested measure, first, to affect the applicant's legal situation directly and, second, to leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from Community rules alone without the application of other intermediate rules (Case C-386/96 P *Dreyfus* v *Commission* [1998] ECR I-2309, paragraph 43).

75 In the present case, through adoption of the contested directive the Commission brought the assessment of chlorothalonil to an end, deciding to include that active substance in Annex I to Directive 91/414, subject to certain conditions relating in particular to the maximum HCB content.

76 By virtue of Article 3(1) of the contested directive, the Member States were obliged to review authorisations for plant protection products containing chlorothalonil, verifying within the prescribed period that they complied with the conditions upon which that substance was included in Annex I to Directive 91/414.

77 In laying down the conditions for placing chlorothalonil on the Community market, the contested directive directly affects the legal situation of the applicant, as a company manufacturing that active substance. Furthermore, so far as concerns those conditions laid down by the contested directive, the action which the Member States had to take was purely automatic. In particular, as the Commission accepts in its rejoinder, the Member States had no discretion as to the maximum HCB content.

78 It must therefore be held that, so far as concerns this condition of chlorothalonil's inclusion, the contested directive directly affects the applicant's legal situation and leaves the Member States no discretion.

79 It follows from the foregoing that the applicant is entitled to seek the annulment of the contested directive so far as concerns chlorothalonil.

The request that the contested specification be varied

80 With regard to the request set out by the applicant in the alternative, that the Court amend the specification referred to in the contested directive, it is to be recalled that, when reviewing legality on the basis of Article 230 EC, the Community judicature is not entitled to issue directions to the institutions or to assume the role assigned to them (Case T-155/04 *SELEX Sistemi Integrati* v *Commission* [2006] ECR II-4797, paragraph 28). Consequently, the request put in the alternative is inadmissible.

Substance

81 In support of the present claim for annulment of the contested directive, the applicant puts forward, first, three pleas relating to the procedure, alleging (i) the exclusion of its dossier from the assessment procedure (ii) irregularities in tne procedure before the Committee and (iii) breach of procedural safeguards and of the right to be heard, and second, three substantive pleas, respectively alleging breach of Article 5 of Directive 91/414, breach of Article 13 of Directive 91/414 and breach of certain general principles of Community law.

The first plea: the alleged exclusion of the applicant's dossier from the assessment procedure

— Arguments of the parties

82 The applicant submits, first of all, that the Commission unlawfully excluded it from the assessment procedure for chlorothalonil by not according it the status of 'main data submitter' and by excluding its data and the specification for its product.

83 At the start of the assessment procedure, the applicant and Syngenta were regarded by the rapporteur Member State as 'main data submitters'. This fact is stated in the review report. However, the applicant learnt from that document that in the course of the assessment it had been decided to regard only Syngenta as a 'main data submitter'. The applicant was never informed of that decision or of the reasons for its exclusion.

84 The specification submitted by the applicant was assessed in the course of the procedure and therefore should have been taken into account when adopting the contested directive.

85 It is apparent from the rapporteur Member State's assessment report of 31 January 2000 that Syngenta's and the applicant's products were studied in accordance with the Community requirements and that the reported results fulfilled those requirements. The applicant's product was also examined in the peer review. Additional information was requested, which the applicant submitted in May 2002. It was concluded on 2 December 2003 that the applicant had fulfilled this data requirement. This fact is confirmed by the evaluation table for chlorothalonil of 28 January 2004 (Commission working document SANCO/4342/2000 rev. 1-3).

86 Furthermore, in the course of the procedure the applicant submitted a number of studies, listed in Appendix IIIA to the draft review report. In the final version of Appendix IIIA dated 15 March 2005 these studies relating to its dossier are no longer included.

87 The applicant contends in this connection that its dossier was essential for the assessment. It is apparent from the evaluation table of 28 January 2004 that only the applicant had submitted all the data concerning the specification for chlorothalonil, because Syngenta still had to address 'the difference between the two values for quantum yield' and it fulfilled that requirement only 'after recalculation of the results for Vischim'. Therefore, with regard to the identity of the active substance, Syngenta's dossier is complete only by reference to the applicant's dossier. Furthermore, some of the applicant's studies are cited, in support of the scientific assessment, in Appendix II (page 17) to the review report.

88 Thus, contrary to the Commission's contention, the examination of chlorothalonil could not have been completed on the basis of Syngenta's dossier alone. As is apparent from point 4.9 of the document drawn up by the rapporteur Member State in April 2004, Syngenta's dossier contained a gap so far as concerns ecotoxicology, relating to the earthworm study. Next, the 'NOAEL' (No-Observed-Adverse-Effect Level) value for 'long-term toxicity and carcinogenicity', indicated in Appendix II to the review report, was calculated on the basis of the study on rats provided by the applicant.

89 Moreover, the inclusion of an active substance in Annex I to Directive 91/414 can be based on a 'compilation' of data submitted by various notifiers, irrespective of whether their individual dossiers were complete. According to a Commission working document (document SANCO/10435/2004 of 15 April 2005), 'acceptable studies which, alone, do not address fully a particular requirement or concern identified in the context of inclusion in Annex I but together contribute to a weight of evidence approach … should all be included [in the review report]'.

90 Finally, the applicant contests the Commission's view that, as from May 2004, the assessment continued solely on the basis of Syngenta's dossier, submitting that, by that date, the assessment had already been completed.

91 The Commission contests the applicant's arguments.

— Findings of the Court

92 In this plea, the applicant criticises its alleged exclusion from the assessment procedure as a 'main data submitter' and the fact that the assessment was completed solely on the basis of Syngenta's dossier, to the exclusion of the data and the specification for chlorothalonil contained within its dossier.

93 It should be recalled, as regards the detailed rules of the procedure concerned, that under Article 6(1) of Regulation No 3600/92 the notifiers must, individually or collectively, send to the rapporteur Member State the dossiers containing the data required for the assessment of the active substance notified. Pursuant to Article 7(2) of that regulation, the rapporteur Member State may request the notifiers to improve their dossiers or add to them.

94 It is apparent from those provisions that, under the procedure concerned, a notifier who has submitted an individual dossier is obliged to supply all the data necessary for the assessment of the notified active substance.

95 In the present case, it is to be noted first of all that the assessment procedure at issue concerned, at the outset, the dossiers submitted, individually, by the applicant and by Syngenta.

96 According to point 1 of the review report, those notifiers alone had submitted in time dossiers which did not contain substantial gaps, and were considered to be the 'main data submitters'. It is apparent from the report that it was decided in the course of the assessment to consider Syngenta alone to be the 'main data submitter'.

97 So far as concerns the classification of Syngenta and the applicant as 'main data submitters', that term is not referred to in the applicable legislation but results from the Commission's practice. Thus, since classification as a 'main data submitter' during the assessment is not capable of conferring a particular legal status on the notifier concerned, the applicant's argument regarding the alleged refusal to accord it that status for the entire assessment procedure is ineffective.

98 As regards, next, the applicant's argument concerning the alleged exclusion of its dossier, the Commission submits that it turned out in the course of the assessment that the applicant's dossier contained significant gaps and accordingly, from May 2004, it was decided to continue the assessment on the basis of Syngenta's dossier alone. Consequently, according to the Commission, the assessment of chlorothalonil which preceded the adoption of the contested directive was founded solely on Syngenta's dossier.

99 It is apparent from a document drawn up by the rapporteur Member State in April 2004 entitled 'Level 4 — Demand for further information', which the Commission annexed to its defence, that, at that advanced stage of the assessment, the applicant's dossier still contained significant gaps.

100 As the Commission stated at the hearing, without dispute on the part of the applicant, that document identifies a total of 42 studies missing from the applicant's dossier. For example, under the heading 'Toxicology and metabolism' the document indicates that the applicant's dossier did not contain information enabling a 'NOAEL for systemic effects' to be established, 'information on the subacute oral toxicity', 'information on the toxicity of metabolites', 'data on comparative dermal absorption' or an 'in vitro [study] using rat and human skin'. In addition, the rapporteur Member State requested the carrying out of field studies for the different uses of chlorothalonil and the submission of information 'on dislodgeable residues in soil', 'on the acute dermal toxicity of Chlorothalonil 500g/l' and 'on the exact composition of Chlorothalonil 75 WG'.

101 Moreover, in its written response of 16 June 2008 to the question asked by the Court, the applicant acknowledged that it did not submit the data identified in that document to the rapporteur Member State until between July 2006 and August 2007, that is to say after the contested directive was adopted.

102 It follows that the applicant did not submit in the assessment procedure a dossier containing all the data required for the assessment of chlorothalonil.

103 This finding is not invalidated by the fact that at the beginning of the procedure the applicant's dossier had been regarded as not containing substantial gaps and that it was examined in the rapporteur Member State's assessment report of 31 January 2000 and within the framework of the peer review between March and September 2001.

104 The relevant procedural rules do not require a definitive finding as to the completeness of the dossier to be made at the beginning of the assessment. Accordingly, in the present

case, the initial finding that the applicant's dossier did not contain 'substantial gaps' did not signify, as the words chosen also indicate, that the dossier was complete in all respects.

105 Nor can the applicant rely on the argument that the references to the data submitted by it during the assessment were included in Appendix IIIA to the draft review report. According to recital 4 in the preamble to the contested directive and entry No 102 in the table annexed to that directive, the review report was finalised on 15 February 2005. Thus, contrary to the applicant's submissions, the assessment in question continued until that date and could not be regarded as concluded at the stage of the draft review report. The mere fact that the references to the applicant's data had been included in that draft, but were removed in the final version of the report, is not sufficient to demonstrate that its dossier was complete.

106 Next, the applicant has not shown that the dossier of the other notifier was incomplete and therefore would necessarily have had to be completed by the data derived from its dossier.

107 First, the applicant's argument that its dossier was needed in order to establish that Syngenta's dossier was compliant with regard to 'values for quantum yield' is refuted by the information submitted by the Commission in its written response of 16 June 2008 to the questions asked by the Court, according to which the Syngenta study concerned was accepted by the rapporteur Member State upon the receipt of further information.

108 Second, while the review report does refer to certain data derived from the applicant's dossier, namely to the NOAEL value calculated on the basis of its study on rats and to its study on earthworm reproduction and growth which is cited in Appendix II to that report, this incidental reference to the data submitted by the applicant does not demonstrate that the dossier of the other notifier did not contain sufficient information.

109 In its written response of 16 June 2008 to the questions asked by the Court the Commission explained — and the applicant has not established the contrary — that Syngenta's dossier contained equivalent information and that the references to a value resulting from the studies carried out by the applicant were included only because the rapporteur Member State considered that this value was more appropriate scientifically. The submission of additional studies was, moreover, required at Member State level (point 7 of the review report).

110 Finally, it is also necessary to reject the applicant's argument that it was not obliged to supply information equivalent to that submitted by Syngenta since, in a procedure involving a number of notifiers, the Commission could take account of the totality of the data derived from the various dossiers. Even if such an option is open to the Commission, the fact remains that, as has been pointed out in paragraph 94 above, in so far as the notifiers do not submit a joint dossier, each notifier has the task of making sure that his individual dossier is complete.

111 In this connection, the applicant submitted at the hearing that in 1998 Zeneca Agrochemicals and it had agreed that the data submitted during the assessment by each of them would be regarded as representing their joint efforts.

112 In support of this argument, the applicant refers first of all to a letter, annexed to its application, of 16 April 1998 from Zeneca Agrochemicals to the rapporteur Member State, which makes reference to a meeting on 24 February 1998 between Zeneca Agrochemicals, itself and the rapporteur Member State, in the course of which the latter had requested them to provide comments jointly.

113 In the letter, Zeneca Agrochemicals requested the rapporteur Member State to provide confirmation in writing that only it and the applicant were considered to be 'main data holders', stating that, following that confirmation, 'it [would] make contact with [the applicant] to determine how [they] should best proceed with this matter [relating to the

possibility of providing joint comments]'. While it appears from this that Zeneca Agrochemicals and the applicant initiated negotiations regarding the possibility of submitting joint comments, the letter alone does not demonstrate that they in fact decided to provide data jointly.

114 The applicant also refers to two agreements concluded between it and Zeneca Agrochemicals on 18 June 1998 and 8 July 1999, concerning the exchange of data relating to chlorothalonil. According to the applicant, under those agreements any comment submitted by Syngenta in the course of the assessment had to be considered a joint comment on their part.

115 However, without there being any need to rule on the consequences of those agreements, which were adduced for the first time at the hearing and whose validity, according to the applicant's own explanations, has not been acknowledged by Syngenta, it must be pointed out that — as the Commission stated at the hearing without being contradicted by the applicant — the agreements were not submitted for the attention of the rapporteur Member State or the Committee.

116 This fact is borne out by the absence of any reference to a collective submission of data in the assessment documents which have been adduced by the parties in connection with their pleadings, and in which the data submitted by Syngenta and by the applicant are the subject of separate assessments.

117 Therefore, the applicant has not demonstrated that the data which it and Syngenta submitted should have been assessed as a joint dossier representing their collective efforts. Consequently, the applicant is wrong in contending that it was not obliged, under the applicable legislation, to supply the information required for the assessment in so far as equivalent information would have been submitted by Syngenta.

118 In light of the foregoing, it must be held that the Commission did not commit a procedural irregularity in assessing chlorothalonil on the basis of Syngenta's dossier, to the exclusion of the data and the specification for chlorothalonil in the dossier submitted by the applicant, which did not contain sufficient data.

119 Consequently, this plea cannot succeed.

The second plea: the alleged irregularities in the procedure before the Committee

— Arguments of the parties

120 The applicant contends that the Committee finalised the review report on 15 February 2005 and, thus, could not have approved the subsequent modifications to the report, concerning the specification for chlorothalonil and the removal of the references to the studies submitted by it. The draft Committee agenda for 15 April 2005 makes no reference to the review report. In its reply, the applicant maintains that the draft review report was not submitted to the Committee three weeks before the meeting of 15 February 2005, in breach of the Committee's rules.

121 The Commission contests the applicant's arguments.

— Findings of the Court

122 The applicant asserts, in essence, that the review report was not duly finalised by the Committee, because the version finalised at its meeting of 15 February 2005 was modified subsequently.

123 Under Article 7(6) of Regulation No 3600/92, as added by Regulation No 1199/97, 'where the Commission presents a draft directive … it shall at the same time present the conclusions of the Committee's examination in the format of an updated review report to be noted in the summary record of the meeting'. As is, moreover, stated in the fourth recital in the preamble to Regulation No 1199/97, 'it is necessary that any draft directive or draft decision referred to the … Committee … should be directly linked to the report and recommendation made by the rapporteur Member State, including any modifications made following consultations'.

124 It must therefore be examined whether, in this instance, the Commission met its obligation to present to the Committee, at the same time as the draft directive, the updated review report, setting out the conclusions of the substantive assessment of the proposed measure.

125 It is apparent from the arguments of the parties that the text of the review report presented to the Committee at its meeting on 15 February 2005 was modified following that meeting so far as concerns, first, the conditions for chlorothalonil's inclusion in Annex I to Directive 91/414 that were related to its purity and, second, the removal of the references to the studies submitted by the applicant. Although Appendix I to that report, which sets out the specification for chlorothalonil, is dated 20 January 2005, it refers to the FAO specification adopted in February 2005. Also, Appendix IIIA, containing the list of studies, is dated 15 March 2005.

126 The Commission states that the two modifications in question, proposed by the rapporteur Member State on 10 February 2005, were presented to the Committee at its meeting on 15 February 2005 and adopted by it, but were not incorporated into the review report until after that meeting.

127 It is apparent from these explanations, which the applicant does not call into question, that the modifications concerned to the review report were presented to the Committee, which therefore had all the relevant information on 15 February 2005.

128 This finding is not affected by the fact that the review report was updated only subsequently in order to take account of the modifications adopted by the Committee and that, accordingly, certain appendices to the review report bear a date later than 15 February 2005.

129 Moreover, as is apparent from the minutes of the meeting of the Committee of 15 April 2005, adduced by the applicant, at that meeting the Committee 'took note' of the 'amended review report' concerning chlorothalonil.

130 The applicant's contentions concerning the period in respect of submission of the documents to the committee, which was allegedly too short, must be dismissed as inadmissible since the applicant cannot plead breach of the procedural rules established to protect the interests of the Member States meeting in the Committee (see, to this effect and by analogy, Case C-443/05 P *Common Market Fertilizers* v *Commission* [2007] ECR I-7209, paragraphs 144 and 145).

131 In any event, it is apparent from the rules of procedure adopted by the Committee pursuant to Article 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission

(OJ 1999 L 184, p. 23) that, while documents must in general be available 14 days before the meeting of the Committee, modifications may be proposed at shorter notice and even during the meeting.

132 It follows from the foregoing that the applicant has not established a defect in the procedure before the Committee.

133 This plea cannot therefore be upheld.

The third plea: breach of procedural safeguards and of the right to be heard

— Arguments of the parties

134 The applicant contends that the rapporteur Member State and the Commission acted in breach of the procedural safeguards which it enjoyed, by excluding it from certain meetings and fundamental exchanges and by not providing it with feedback and support as required by Regulation No 3600/92, which were provided to Syngenta.

135 The rapporteur Member State and the Commission failed to ensure that the applicant submitted its summary dossier to the other Member States, did not consult it regarding the assessment report, did not forward the results of the peer review to it and did not invite it to the meeting on 12 December 2002 with Syngenta.

136 The applicant maintains, referring to fundamental principles of Community law and the case-law concerning anti-dumping measures, that in the procedure here it enjoyed rights of defence and the right to be heard, which were infringed by the Commission.

137 In this connection, the applicant criticises the Commission, first, for excluding it from the discussions relating to the specification for chlorothalonil, in particular to the taking into account of the FAO specification adopted in February 2005, and second, for failing to provide it with reasons for its exclusion from the procedure or the removal of its studies from the review report.

138 Finally, the irregularities vitiating the assessment procedure for chlorothalonil amount to a breach of the principle of sound administration.

139 The Commission contests the applicant's arguments. It submits in particular that the legislation applicable to the procedure in question does not provide for procedural safeguards in favour of notifiers.

— Findings of the Court

140 It is to be pointed out, first of all, that in the context of a procedure involving a reassessment of an existing product on the market on the basis of a dossier submitted by the manufacturer concerned, the latter must be closely associated with the assessment and may invoke the right to be informed of the main gaps in its dossier which stand in the way of authorisation of its product, compliance with such procedural safeguards being subject to judicial review. In the light of the principles of legal certainty and of sound administration, except in urgent cases the Commission cannot refuse authorisation for an existing product on the market without having allowed the

person concerned to provide the information appropriate for filling those gaps (see, to this effect, Case T-392/02 *Solvay Pharmaceuticals* v *Council* [2003] ECR II-4555, paragraphs 186 to 188).

141 These considerations apply in the context of the procedure at issue, which was initiated by the notification submitted by the applicant and the detailed rules for which provide that the notifier is associated with the assessment of his dossier. Under Article 7(2) and (3) of Regulation No 3600/92, the rapporteur Member State may request the notifiers to improve their dossiers or add to them and the Commission may, before forwarding the summary dossier and the assessment report drawn up by the rapporteur Member State to the Committee, consult the notifiers on that report.

142 It follows that, in the procedure at issue, a notifier who has submitted a dossier for assessment by the rapporteur Member State and the Commission can invoke the right to be informed of any gaps in his dossier which stand in the way of authorisation of the active substance concerned.

143 On the other hand, in the absence of any express procedural provision to such effect, the Commission cannot be required to inform notifiers of the content of the measure proposed to the Committee.

144 The arguments relied upon by the applicant in the present plea should be examined in the light of those observations.

145 First, the applicant maintains that it was not associated with the various stages of the assessment in an appropriate manner consistent with the guidance contained in the Commission's working documents or, in any event, in the same manner as the other notifier.

146 It is to be noted that the review report does not mention the applicant's participation at certain stages of the procedure. Point 1 of the report, relating to the procedure followed for the assessment, refers only to the submission of Syngenta's summary dossier on 31 July 2000, the dispatch of the assessment report to Syngenta on 20 April 2000, the dispatch of the results of the peer review to the 'main data submitter' on 16 November 2001 and the meeting on 12 December 2002 with Syngenta.

147 However, the case-file shows that in actual fact the applicant was associated with the assessment in an appropriate manner.

148 As regards submission of the summary dossier to the other Member States, it is clear from the applicant's letter of 27 July 2000 annexed by the Commission to its defence that the applicant submitted that dossier at the request of the rapporteur Member State.

149 As to consultation of the notifiers on the rapporteur Member State's assessment report of 31 January 2000, Article 7(3) of Regulation No 3600/92, relied upon by the applicant, does not require the notifiers to be consulted before this document is drawn up, but merely empowers the Commission to consult some or all of the notifiers on the document after it has been drawn up. In any event, the applicant states in its application that it received the report in question, as Syngenta did, on 20 April 2000.

150 As regards communication of the results of the peer review, the Commission has stated that according to the rapporteur Member State the applicant received the results and was requested to supplement its dossier. This fact is confirmed by the applicant itself, which states in its application that it was requested to provide additional information following the peer review and did so in May 2002.

151 So far as concerns the meeting on 12 December 2002, the Commission states, without being contradicted by the applicant, that this meeting addressed only the issues relating to Syngenta's dossier.

152 In view of all these factors, it must be found with regard to the stages of the assessment at issue that the applicant was associated with the procedure in the same manner as the other notifier, and therefore without breach of the principle of equal treatment.

153 Second, the applicant complains that the Commission failed to inform it of the decision to proceed with the assessment on the basis of the other notifier's dossier alone and of the reasons for the removal of the references to its studies from the review report.

154 Under the detailed rules of the procedure at issue, noted in paragraphs 93 and 94 above, the applicant had to submit a complete dossier, including all the data necessary for the assessment.

155 It is clear from the case-file that on 5 February 2004 the authorities of the rapporteur Member State sent the applicant the latest additions to the assessment report, including the document entitled 'Level 4 — Demand for further information', corresponding to the document bearing the same title drawn up by the rapporteur Member State in April 2004 (see paragraph 99 above), which indicated the main gaps remaining in the applicant's dossier. Moreover, the applicant confirmed receipt of those documents by its email of 5 March 2004 annexed to the Commission's defence.

156 While the applicant argues for the first time in its written response of 16 June 2008 to the question asked by the Court that some of the data in question were not identified in good time by the rapporteur Member State, it does not provide any reason at all for the

belated reliance upon this argument. Since the applicant did not rely in its application — or indeed in its reply — on the line of argument relating to the alleged failure of the rapporteur Member State to inform it in good time of the data necessary for the assessment, this line of argument must be considered to be a new plea, inadmissible under Article 48(2) of the Rules of Procedure. In any event, the line of argument concerns only one of the gaps identified in the document referred to in the preceding paragraph, namely a 'lysimeter study', and therefore is also ineffective.

157 Accordingly, the applicant was informed of the fact that its dossier did not contain sufficient data, in particular in the context of the documents sent on 5 February 2004. Being so informed, it had to expect, having regard to the detailed rules of the procedure concerned, that its dossier would not constitute the basis for the assessment and that the assessment would proceed on the basis of the complete dossier of the other notifier. It is, moreover, apparent from the Commission's written response of 16 June 2008 to the questions asked by the Court that it was stated in Addendum 13 to the assessment report which was among the documents sent to the applicant on 5 February 2004 that 'Syngenta [was] considered to be the main notifier and a full assessment [would] be made for the data of this notifier only'.

158 The fact that the references to the studies submitted by the applicant were still included in the list appended to the draft review report of 20 January 2005 of studies considered essential for the assessment (see paragraph 21 above), although indicative of a certain inconsistency, was nevertheless not capable in itself of giving rise to serious doubt as to the correctness of the earlier indications, referred to in the previous paragraph, that the applicant's dossier was incomplete and would not constitute the basis for the assessment.

159 Furthermore, as regards the removal of the references to the applicant's studies from the final version of the review report, the document in question purely provides information and is not capable of producing binding legal consequences. The objection alleging that information was not given as to the reasons for the removal of those references is therefore misplaced (see paragraphs 214 to 217 and 243 to 249 below). In

any event, the removal of the references was solely a consequence of the fact that the applicant's dossier, being incomplete, could not constitute the basis for the assessment.

160 Accordingly, it is necessary to reject the applicant's complaint alleging a lack of information in respect of the fact that the assessment was proceeding on the basis of Syngenta's dossier alone and in respect of the reasons for the removal of the applicant's studies from the list appended to the review report.

161 Third, the applicant contends that the Commission excluded it from the discussions concerning the specification for chlorothalonil which led to the specification published by the FAO in February 2005 being taken into account.

162 As is apparent from the arguments of the parties, the successive reports adopted in the course of the assessment referred to the specification adopted by the FAO in 1998, which was applicable until the new specification was published in February 2005.

163 Nevertheless, the applicant states in its application that it knew, at least from May 2004, that that FAO specification was about to be re-examined on the basis of information submitted by Syngenta. The applicant also acknowledged at the hearing that it had been informed of this FAO re-examination in the course of 2004, while making clear that it was unaware of the precise content of the discussions conducted at FAO level.

164 Furthermore, while the draft review report sent to the applicant on 8 February 2005 still referred to the 1998 FAO specification, it indicated that that specification had been under re-evaluation by the FAO since 2003.

165 Since these matters had been made known to the applicant, it could not expect that the specification as revised by the FAO would not be taken into account in the assessment at issue.

166 Accordingly, the applicant cannot criticise the Commission for not having kept it informed of the considerations which led to the inclusion of chlorothalonil with reference to the specification adopted by the FAO in February 2005.

167 Finally, as regards the applicant's reliance on breach of its right to be heard, it is to be recalled that the principle of observance of the rights of the defence, which is applicable in any procedings initiated against a person that are liable to culminate in a measure adversely affecting that person, requires that the addressees of decisions significantly affecting their interests be placed in a position in which they may effectively make known their views (Case C-32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I-5373, paragraph 21).

168 As has already been found (see paragraphs 155 to 157 above), the applicant was informed of the gaps in its dossier which resulted in the dossier not being able to constitute the basis for the assessment of chlorothalonil. Having received that information, contained in particular in the documents sent on 5 February 2004, the applicant had the possibility of making its views known during the assessment, so far as concerns the determination that its dossier was incomplete.

169 In those circumstances, the Commission was not under an obligation to invite the applicant to submit its observations on the content of the measure proposed to the Committee on 15 February 2005. The Commission could rightly consider that such

consultation was inappropriate, given that the applicant's dossier remained incomplete and, accordingly, could not constitute the basis for the substantive assessment of the proposed measure.

170 In any event, it is settled case-law that a procedural irregularity will lead to annulment of a decision only if it is established that the content of that decision could have differed if that irregularity had not occurred (Case T-279/02 *Degussa* v *Commission* [2006] ECR II-897, paragraph 416; see also, to this effect, Joined Cases 209/78 to 215/78 and 218/78 *Van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 47).

171 In the present case, since the applicant did not meet its obligation to submit a complete dossier, the fact that it was not consulted at the final stage of the procedure, namely when the draft directive and the draft review report were forwarded to the Committee, could not affect the content of the contested specification, which was adopted on the basis of the dossier of the other notifier and took account of the specification published by the FAO in February 2005.

172 It follows from all of the foregoing that the applicant has not demonstrated that the procedure in question was vitiated by a breach of the procedural safeguards enjoyed by it, or of its right to be heard, capable of resulting in annulment of the contested directive.

173 Finally, the applicant's complaint alleging breach of the principle of sound administration must also be rejected. In this submission, the applicant merely alleges that the procedure followed for the assessment of chlorothalonil was flawed. However, it is apparent from the foregoing that the procedure was not vitiated by any defect.

174 In light of all these considerations, the present plea must be dismissed.

The fourth plea: breach of Article 5 of Directive 91/414

— Arguments of the parties

175 The applicant contends that the Commission infringed Article 5(1) of Directive 91/414 because it did not include the specification for the applicant's product when chlorothalonil was included in Annex I to that directive, although, according to the rapporteur Member State's assessment report of 31 January 2000, that product fulfilled the conditions for inclusion.

176 The Commission's decision to exclude the applicant's specification was based solely on the new FAO specification and not on the results of its assessment. The conditions for inclusion laid down in Article 5 of Directive 91/414 make no reference to FAO specifications.

177 Furthermore, the Commission infringed Article 5(1) of Directive 91/414 by acting on the basis of the FAO specification, which did not correspond to the active substances notified by the applicant and Syngenta and assessed by the rapporteur Member State.

178 The substances notified at the beginning of the procedure took account of the 1998 FAO specification, indicating a maximum HCB content of 0.3 g/kg. The fact that Syngenta was the source of the review which led to the publication of the new specification by the FAO, setting the HCB limit at 0.01 g/kg, could not prevail over the Community assessment, which had already been completed at the time of the new

specification's publication in February 2005. The Commission was unable to take account of the new specification without undertaking a new assessment of the product corresponding to that specification.

179 In its reply, the applicant notes that the product notified by ISK Biotech Europe in 1995 contained more than 0.01 g/kg of HCB, a fact confirmed by a letter from Zeneca Agrochemicals of 11 June 1998. Thus, at the beginning of the procedure neither of the notifiers notified a product with the HCB limit of 0.01 g/kg set by the contested directive.

180 It adds that the specification adopted by the FAO in February 2005 was not assessed by the rapporteur Member State and could not serve as the basis for setting the HCB level in the contested directive. The FAO assessment criteria differ from those of Directive 91/414. The applicant was under no obligation to demonstrate, in the Community procedure, that its product corresponded to the new FAO specification.

181 Moreover, the maximum HCB content set by the contested directive was not scientifically necessary and was disproportionate. The applicant states that, shortly after the adoption of the contested directive, it succeeded in obtaining a modification of the FAO specification, raising the HCB limit to 0.04 g/kg. The assessment carried out by the rapporteur Member State after the contested directive was adopted indeed showed that chlorothalonil containing 0.04 g/kg of HCB was as safe as chlorothalonil containing 0.01 g/kg of HCB.

182 Finally, by excluding the studies provided by the applicant from the examination, the Commission infringed its obligation under Article 95 EC and Article 5(1) of Directive 91/414 to take account of all available data reflecting current technical and scientific knowledge.

183 The Commission contests the applicant's arguments.

— Findings of the Court

184 It should be noted that the contested specification for chlorothalonil was adopted on the basis of Syngenta's dossier and also was accompanied by conditions relating to purity, in particular the maximum HCB content.

185 In the first place, the applicant maintains that the Commission infringed Article 5 of Directive 91/414 because it failed to take account of the specification for its product when adopting the contested directive.

186 It is to be observed that the authorisation of active substances as envisaged in Article 5(1) of Directive 91/414 is conditional upon their assessment by the Commission under the procedure provided for by that directive.

187 As stated in paragraph 118 above, the Commission did not infringe that procedure by not basing its decision relating to the inclusion of chlorothalonil in Annex I to Directive 91/414 on the applicant's dossier, which did not contain sufficient information.

188 Furthermore, having regard to the grounds set out in paragraphs 103 and 104 above, that finding is not affected by the fact that the specification for the applicant's product

was examined in the context of the rapporteur Member State's assessment report of 31 January 2000, since the conclusions reached in that preliminary document were liable to be revised in the course of the assessment.

189 The applicant cannot therefore maintain that the Commission infringed Article 5 of Directive 91/414 because it did not take account of the specification for the applicant's product.

190 In the second place, the applicant contends that the Commission infringed Article 5 of Directive 91/414 and the principle of proportionality by establishing the specification for chlorothalonil by reference to the FAO specification adopted in February 2005, which set the HCB limit at 0.01 g/kg.

191 According to the applicant, the Commission acted unlawfully in authorising chlorothalonil subject to a condition which, first, was established solely by reference to the FAO specification, second, did not flow from the dossiers assessed in the procedure and, third, was neither scientifically necessary nor proportionate.

192 First, it is to be recalled that, under Article 5(4) of Directive 91/414, inclusion of an active substance in Annex I to that directive may be subject to requirements relating, inter alia, to 'the minimum degree of purity of the active substance' and to 'the nature and maximum content of certain impurities'.

193 Contrary to the applicant's submissions, Article 5 of Directive 91/414 does not limit the Commission's appraisal so far as concerns the taking into account, in order to determine those requirements, of specifications recommended at international level.

194 Moreover, given the complex technical assessments undertaken in the context of the procedure at issue, the Commission enjoys a broad discretion (see, to this effect, Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, paragraph 75, and the case-law cited).

195 In view of this broad discretion as to the matters to be taken into consideration when assessing the criteria laid down in Article 5 of Directive 91/414, the Commission was fully entitled to establish the conditions of chlorothalonil's inclusion by taking account of the FAO specification.

196 Second, as regards the applicant's argument that the HCB limit referred to in the contested directive did not correspond to the notifications made at the beginning of the procedure concerned, it is to be pointed out that the condition in question was lawfully established by reference to the FAO specification applicable when the assessment was finalised.

197 The applicant's argument derived from the content of the specifications notified by the persons concerned therefore does not affect the legality of that determination.

198 In any event, it is apparent from the arguments of the parties that the specification contained in the dossier which was submitted by Syngenta, and which was assessed with a view to the inclusion of chlorothalonil in Annex I to Directive 91/414, accorded with the HCB limit referred to in the contested directive.

199 While the Commission has acknowledged that, at the beginning of the procedure, the specification notified by Syngenta did not take account of that limit, it is nevertheless apparent from its observations of 18 October 2006 and its written response of 16 June 2008 to the questions asked by the Court that, at the time when the assessment was finalised, the data supplied by Syngenta concerned a Syngenta product corresponding

to the FAO specification adopted in February 2005. This is, moreover, borne out by the fact, upon which the parties agree, that that FAO specification was established on the basis of Syngenta's data.

200 In light of these factors, it is also necessary to reject the applicant's argument that taking account of the FAO specification adopted in February 2005 was not justified without a new assessment of the dossiers. The applicant does not explain in what way taking account of that specification, which corresponded to the product in Syngenta's dossier at the time when the assessment was finalised, could have necessitated a new assessment of that dossier.

201 Finally, the applicant is wrong in its contention that the assessment in question had already been completed when the FAO specification was adopted in February 2005. The assessment was not terminated until the review report was finalised by the Committee, on 15 February 2005.

202 Accordingly, the applicant has not established that taking account of the specification adopted by the FAO in February 2005 resulted in a breach of Article 5 of Directive 91/414.

203 Third, as regards the assertion that the measure at issue lacks proportionality, it is to be recalled that the principle of proportionality requires that acts adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question. Within the context of judicial review of the application of that principle in fields where the institutions enjoy a broad discretion, the legality of a measure can be affected only if it is manifestly inappropriate having regard to the objective which it seeks to pursue (see, to this effect, Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraphs 28 and 29, and the case-law cited).

204 In the present case, it must be found that taking account of the minimum standards recommended at international level, such as FAO specifications, cannot in itself be regarded as manifestly inappropriate in the field concerned.

205 The fact, relied upon by the applicant, that the FAO re-examined the specification in question after the contested directive was adopted, increasing the HCB limit to 0.04 g/kg, and that this limit was accepted in the report drawn up by the rapporteur Member State in April 2006 does not demonstrate that it was manifestly inappropriate to take account of the FAO specification adopted in February 2005. In any event, the facts relied upon are subsequent to the contested directive's adoption and incapable of calling its legality into question in light of the principle of proportionality.

206 In view of these considerations, the applicant has not established that the Commission infringed Article 5 of Directive 91/414 or the principle of proportionality, so far as concerns the HCB limit laid down under the contested directive.

207 In the third place, the applicant contends that the Commission infringed its obligation pursuant to Article 5(1) of Directive 91/414 to take all the relevant data into account, since it did not rely on the data which the applicant submitted.

208 The applicant, putting forward evidence and arguments identical to those examined in the context of the first plea, submits that its dossier was necessary for the assessment, in light of the alleged gaps in the other notifier's dossier. However, that submission must be rejected for the same reasons as those set out in paragraphs 107 to 109 above.

209 Finally, as regards the applicant's reliance upon Article 95 EC, it is to be noted that, while Directive 91/414 is based upon Article 43 of the EC Treaty (now, after amendment, Article 37 EC), Article 5 of Directive 91/414 nevertheless partly reflects the wording of Article 95(3) EC by requiring decisions to be taken 'in the light of current scientific and technical knowledge'.

210 In the present case, the complaint alleging a breach of Article 95 EC is not based on any argument distinct from those relating to the alleged breach of Article 5 of Directive 91/414, which have been rejected in the preceding paragraphs. Accordingly, the complaint regarding a breach of Article 95 EC must also be rejected and there is no need to rule on that provision's applicability in the present case.

211 In light of all the foregoing, the present plea cannot be upheld.

The fifth plea: breach of Article 13 of Directive 91/414

— Arguments of the parties

212 The applicant contends that it requested protection for the data submitted for the assessment of chlorothalonil, under Article 13 of Directive 91/414. The fact that the Commission did not include the references to those data in the review report resulted in breach of the applicant's rights arising from Article 13.

213 The Commission contests the applicant's arguments.

— Findings of the Court

214 According to the applicant, the fact that the references to its data were not included in the list set out in Appendix IIIA to the review report resulted in a breach of Article 13 of Directive 91/414.

215 It is to be noted in this regard that the data protection provided for in Article 13(3) of Directive 91/414 is not in any way dependent upon the data's inclusion in a list drawn up by the Commission when the measures relating to the inclusion of an active substance are adopted (see paragraphs 243 to 249 below).

216 Nor does the contested directive contain any reference to the list concerned, set out in Appendix IIIA to the review report.

217 Accordingly, this plea cannot result in annulment of the contested directive and must therefore be dismissed as ineffective.

The sixth plea: breach of the principles of subsidiarity, the protection of legitimate expectations, legal certainty and equal treatment, of the applicant's right freely to conduct business activities and its right to property, and of Article 2 EC

— Arguments of the parties

218 The applicant maintains, referring to the purpose of Directive 91/414 and in particular Article 13(5) thereof, that the Commission should have fixed a minimum purity standard for chlorothalonil, whilst at the same time allowing the Member States to assess the equivalence of products from different sources. However, the Commission relied solely on the Syngenta specification, imposing on the Member States a maximum purity standard for chlorothalonil, in breach of the principle of subsidiarity.

219 Moreover, by including chlorothalonil on the basis solely of the specification notified by Syngenta, to the exclusion of that notified by the applicant and assessed in the procedure concerned, the Commission infringed the principles of the protection of legitimate expectations, legal certainty and equal treatment, breached the applicant's right freely to conduct business activities and its right to property, and gave Syngenta a monopoly in the Community chlorothalonil market in breach of Article 2 EC.

220 The Commission contests the applicant's arguments.

— Findings of the Court

221 As regards, first of all, the principle of subsidiarity, this principle is set out in the second paragraph of Article 5 EC, according to which, in areas which do not fall within its exclusive competence, the Community is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

222 Article 5 of Directive 91/414 prescribes a Community procedure for authorisation of active substances contained in plant protection products. Also, under Article 5(4) of Directive 91/414, authorisation of an active substance may be accompanied by conditions relating to purity and the level of impurities.

223 Since those provisions confer exclusive competence upon the Community institutions to determine the active substances authorised at Community level and to prescribe the conditions relating to their purity, the measure adopted in the exercise of that competence is not covered by application of the principle of subsidiarity. Therefore, the submission alleging breach of this principle must be dismissed as unfounded.

224 As regards, next, the principle of the protection of legitimate expectations, it is settled case-law that the right to rely on this principle extends to any individual in a situation where the Community administration has caused him to entertain legitimate expectations (see Joined Cases T-213/01 and T-214/01 *Österreichische Postsparkasse and Bank für Arbeit und Wirtschaft* v *Commission* [2006] ECR II-1601, paragraph 210, and the case-law cited).

225 In the present case, first, the applicant contends that the specification for its product had been examined in the context of the rapporteur Member State's assessment report of 31 January 2000 and that it could therefore legitimately expect that that specification would be taken into account when chlorothalonil was authorised.

226 However, the fact that, at first, the applicant's dossier was considered not to contain fundamental data gaps and was examined at an initial stage of the assessment cannot have caused the applicant to entertain any legitimate expectation that the specification contained in its dossier would constitute the basis for the inclusion of chlorothalonil in Annex I to Directive 91/414. Given the manner, noted in paragraph 104 above, in which the procedure at issue operates, the fact that, at an initial stage of the assessment, the applicant's dossier was regarded as not containing substantial gaps did not in any way imply that the dossier contained all the data necessary to conclude that the product in question met the conditions under Article 5(1) of Directive 91/414.

227 Second, the applicant maintains that the Commission infringed the principle of the protection of legitimate expectations because it took account of the FAO specification adopted in February 2005. However, as set out in paragraphs 163 to 165 above, since the applicant had been informed of the fact that the FAO specification was in the process of being re-examined, it could not expect the new specification not to be taken into account when the measure concerned was adopted.

228 So far as concerns the principle of legal certainty, which requires that legal rules be clear and precise and aims to ensure that situations and legal relationships governed by Community law remain foreseeable (Case C-63/93 *Duff and Others* [1996] ECR I-569, paragraph 20), it is to be observed that, although Article 5 of Directive 91/414 does not refer to the FAO's specifications, it is evident from the purpose of that provision that they can be taken into account when assessing active substances.

229 Furthermore, it is clear from the rules relating to the content of the dossiers submitted in support of applications for the inclusion of active substances, in particular from paragraph 2(iii) of Part A of Annex II to Directive 91/414, that FAO specifications are matters that can be taken into account when assessing active substances. This fact is borne out by the Commission's practice, noted by it in its defence, regarding the adoption of directives providing for the inclusion of substances in Annex I to Directive 91/414, under which the specification for the substance concerned is defined by reference to the FAO specification when one exists.

230 As regards the principle of equal treatment, the applicant submits that it was not associated with the procedure in the same manner as the other notifier, and in particular that it did not enjoy the same opportunities to defend its position during the procedure. In this regard, however, the applicant does not put forward any argument distinct from those relied upon in the context of the third plea, which have been examined and rejected in paragraphs 147 to 152 above. These arguments must therefore be discounted.

231 Finally, the applicant complains that the Commission adopted the specification for chlorothalonil, preventing it from obtaining the national authorisations necessary in order to be able to continue its activities and to exercise the intellectual property rights relating to the scientific studies carried out with a view to the Community assessment. It further contends that the Commission installed a Syngenta monopoly in the market concerned, contrary to the principle of free competition and to the objectives of the Community laid down by Article 2 EC.

232 As to those submissions, in so far as the contested directive makes the authorisation of chlorothalonil subject, in a general and abstract manner, to defined conditions reproducing the FAO specification in force at the time when the assessment was finalised, it cannot in any way be regarded as seeking to restrict the right to manufacture chlorothalonil to some producer or other, to the detriment of the applicant.

233 Nor can the specification for chlorothalonil which the contested directive laid down, and which was adopted lawfully from the point of view of Article 5 of Directive 91/414 and the principle of proportionality, be regarded as involving an undue or disproportionate limitation of the applicant's intellectual property rights or of the right freely to pursue a trade or profession. Furthermore, as pointed out in paragraphs 214 to 217 above, the applicant has not established that the contested directive could have affected its rights relating to protection of the studies carried out with a view to the assessment of chlorothalonil.

234 In light of the foregoing, this plea must be dismissed.

235 Consequently, the claim for annulment of the contested directive must be dismissed.

2. *The claim for annulment of the review report*

236 The Commission contests the admissibility of the claim for annulment of the review report, stating that it is a technical document which produces no legal effect independent of the contested directive.

237 According to settled case-law, measures which produce binding legal effects such as to affect the interests of an applicant by bringing about a distinct change in his legal position may be the subject of an action for annulment under Article 230 EC. In principle, an intermediate measure intended to pave the way for the final decision is not therefore a challengeable act. However, according to case-law, acts adopted in the course of the preparatory procedure which were themselves the culmination of a special procedure distinct from that intended to permit the Commission to take a decision on the substance of the case and which produce binding legal effects such as to

affect the interests of an applicant, by bringing about a distinct change in his legal position, constitute challengeable acts (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraphs 9 to 11, and *Österreichische Postsparkasse and Bank für Arbeit und Wirtschaft* v *Commission*, paragraph 65).

238 In the present case, it is clear from Article 7(6) of Regulation No 3600/92 that the review report is an intermediate measure drawn up by the Commission containing the conclusions of the Committee's examination, and intended to pave the way for the decision relating to the inclusion of the active substance concerned in Annex I to Directive 91/414.

239 It must accordingly be examined whether, despite being intermediate in nature, the review report, as the applicant asserts, produces binding legal effects such as to affect its interests.

240 The applicant asserts that the review report adversely affects it in that the report does not mention it as a 'main data submitter' and does not contain the references to its data submitted for the purpose of the assessment of chlorothalonil, an omission which affects its right to the protection of those data under Article 13(3) of Directive 91/414.

241 First, as regards the refusal to classify the applicant as a 'main data submitter', it is to be recalled that that term is not referred to in the applicable legislation and accordingly is not capable of conferring a particular legal status on the notifier concerned. Therefore, this alleged refusal cannot adversely affect the applicant.

242 Second, as to the fact that the references to its data were not included in Appendix IIIA to the review report, Article 13(1)(b) of Directive 91/414 provides that Member States are to require that applicants for authorisation of a plant protection product submit

with their application a 'dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex II' to that directive. Also, Article 13(3) of Directive 91/414 prohibits the Member States from making use of the information referred to in Annex II for the benefit of other applicants, during the periods laid down by that provision, unless the first applicant has given agreement to its use.

243 Contrary to the applicant's submissions, it does not appear from those provisions that the prohibition on making use for the benefit of another applicant of information submitted in the context of an application for authorisation of a plant protection product is conditional upon the information's inclusion in a document drawn up by the Commission at the time of the assessment of the active substance concerned, such as the review report at issue.

244 Accordingly, in the absence of a legislative provision empowering the Commission to adopt a measure identifying the data subject to protection under Article 13(3) of Directive 91/414, the list in Appendix IIIA to the review report can only be regarded as having informative value.

245 This finding is not affected by the fact, relied upon by the applicant, that the Member States refer to the list concerned when implementing Article 13(3) of Directive 91/414, since that fact is no more than the consequence of the cooperation between the Commission and the national bodies responsible for the application of Community legislation (see, to this effect, Case T-160/98 *Van Parys and Pacific Fruit Company* v *Commission* [2002] ECR II-233, paragraph 65).

246 The fact that that list simply provides information is apparent, moreover, from point 8 of the review report, according to which the information concerned 'does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 13 of … Directive 91/414'.

247 In any event, even if it is accepted that, as the applicant submits, the list concerned constitutes a reference document for the Member States, in the sense that it sets out the further information which was necessary for the first inclusion of chlorothalonil in Annex I to Directive 91/414, and which is subject to protection under Article 13(3)(d) of that directive, it does not follow that the list would have a legal effect excluding from protection data which do not appear on it.

248 This finding is in no way affected by the letter of 30 January 2006 from the United Kingdom authorities, adduced by the applicant, in which they informed the applicant that they would grant its data submitted in support of the national authorisations protection equivalent to that applied to Syngenta's data, which were protected under Article 13(3)(d) of Directive 91/414.

249 Consequently, the lack of reference to the applicant's data in Appendix IIIA to the review report is not capable of producing binding legal consequences, so far as concerns application of the measures adopted by the Member States in implementing Article 13(3) of Directive 91/414.

250 In the light of these considerations, the review report can only be regarded as an intermediate act, as it does not produce independent legal effects such as to affect the applicant's interests.

251 Consequently, the present claim must be dismissed as inadmissible.

3. *The claim for a declaration of failure to act*

252 The applicant asks the Court to declare, under Article 232 EC, that the Commission failed to define its position on the letter of 14 April 2005 requesting it to refrain from adopting the proposal approved by the Committee on 15 February 2005 unless the specification for chlorothalonil was modified to take account of the specification for the applicant's product.

253 It is clear from the case-law that the conditions, laid down by Article 232 EC, governing the admissibility of an action for a declaration of failure to act are not satisfied where the defendant institution, after being called upon to act, defined its position on that request before the action was brought (see, to this effect, Case C-25/91 *Pesqueras Echebastar* v *Commission* [1993] ECR I-1719, paragraph 11).

254 Here, the Commission defined its position on the content of the applicant's letter of 14 April 2005 by adopting the contested directive on 16 September 2005, before the present action was brought.

255 The fact that the position adopted does not satisfy the applicant is immaterial. Article 232 EC refers to failure to act in the sense of failure to take a decision or to define a position, not the adoption of a measure different from that desired or considered necessary by the persons concerned (Joined Cases C-15/91 and C-108/91 *Buckl and Others* v *Commission* [1992] ECR I-6061, paragraphs 16 and 17).

256 Accordingly, this claim for a declaration of failure to act must be dismissed as inadmissible.

4. *The claim for damages*

257 By its application for damages, the applicant requests compensation for the damage suffered as a result of the adoption of the contested directive.

258 In its document of 20 July 2007, submitted in the context of the measures of organisation of procedure following the adoption of Directive 2006/76, the applicant seeks to adapt this request, claiming that the Commission should be ordered to pay the provisional amount of EUR 170 940 000 in compensation for the damage suffered as a result of the adoption of the contested directive, in the light of Directive 2006/76.

259 In so far as, by that request, the applicant seeks to put forward a new claim for compensation in respect of the damage suffered as a result of the adoption of Directive 2006/76, that claim and the pleas in law put forward in support of it are inadmissible, by virtue of Article 48(2) of the Rules of Procedure.

260 As regards the merits of the application for damages, it is settled case-law that a claim for compensation for damage must be dismissed where there is a close connection between it and a claim for annulment which has itself been dismissed (see Case T-340/99 *Arne Mathisen* v *Council* [2002] ECR II-2905, paragraph 134, and the case-law cited).

261 In the present case, there is a close connection between the claim for annulment and the claim for damages, which is based on the arguments, set out in the context of the claim for annulment of the contested directive, to the effect that the contested directive is unlawful for breach of Directive 91/414 and Regulation No 3600/92 and of the principles of sound administration and the protection of legitimate expectations. However, examination of those arguments has revealed no unlawfulness on the Commission's part such as to render the Community liable.

262 Accordingly, the claim for damages must be dismissed as a result of the dismissal of the claim for annulment to which it is closely connected.

263 In addition, in so far as the applicant refers, in the alternative, to the damage allegedly caused by the Commission's failure to define its position in response to the applicant's letter of 14 April 2005, it is to be recalled that the Commission defined its position in this regard by adopting the contested directive. The applicant does not plead any damage that occurred before the adoption of the contested directive, which brought the failure to act alleged to an end.

264 Consequently, the claim for damages must also be dismissed as regards the Commission's alleged failure to act.

265 In the light of all the foregoing, the present action must be dismissed in its entirety.

Costs

266 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 applicant has been unsuccessful, it must be ordered to pay the costs, including those relating to the proceedings for interim measures, in accordance with the form of order sought by the Commission.

On those grounds,

THE COURT OF FIRST INSTANCE (Sixth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Vischim Srl to pay the costs, including those relating to the proceedings for interim measures.**

Meij Dehousse Vadapalas

Delivered in open court in Luxembourg on 7 October 2009.

[Signatures]

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