JUDGMENT OF THE COURT OF FIRST INSTANCE (Second Chamber)

19 November 2009 *

In Case T-334/07,

Denka International BV, established in Barneveld (Netherlands), 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 of Commission Decision 2007/387/EC of 6 June 2007 concerning the non-inclusion of dichlorvos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ 2007 L 145, p. 16),

* Language of the case: English.

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

composed of I. Pelikánová, President, K. Jürimäe (Rapporteur) and S. Soldevila Fragoso, Judges,

Registrar: C. Kantza, Administrator,

having regard to the written procedure and further to the hearing on 3 March 2009,

gives the following

Judgment

Legal context

Directive 91/414/EEC

1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) lays down the Community rules applicable to the granting of authorisation to place plant protection products on the market and to the withdrawal of such authorisation.

2 Article 4(1) of Directive 91/414 provides that 'Member States shall ensure that a plant protection product is not authorised unless … its active substances are listed in Annex I …'.

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

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

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

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

…'

4 Article 6(1) of Directive 91/414 provides:

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

The following shall also be decided in accordance with that procedure:

— any conditions for inclusion,

…’

5 Active substances which are not listed in Annex I to Directive 91/414 may, in certain circumstances, benefit from transitional arrangements permitting derogation. Under Article 8(2) of Directive 91/414 a Member State could, during a period of 12 years following the notification of Directive 91/414, authorise the placing on its domestic market of plant protection products containing active substances not listed in Annex I that were already on the market two years after the date of notification of Directive 91/414, namely 25 July 1993. The Commission of the European Communities was to commence a programme of work for the gradual examination of those active substances. Subsequently, it could be decided whether or not the substance would be included in Annex I to the directive. The Member States were to ensure that the relevant authorisations would be granted, withdrawn or varied, as appropriate.

6 That 12-year period was extended by Article 1 of Commission Regulation (EC) No 1335/2005 of 12 August 2005 amending Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Directive 91/414 and the continued use of certain substances not included in its Annex I (OJ 2005 L 211, p. 6) until 30 September 2007 for the active substances which are assessed in the framework of the second stage under Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Directive 91/414 (OJ 2000 L 55, p. 25).

Regulation No 451/2000

7 Regulation No 451/2000, as amended by Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414 and amending Regulation No 451/2000 (OJ 2002 L 224, p. 23), organises the procedure for evaluation of various substances with a view to their possible inclusion in Annex I to Directive 91/414. Dichlorvos is one of those substances.

8 The procedure introduced by Regulation No 451/2000 begins with a notification of interest, provided for under Article 4(1) of the regulation, which, as regards dichlorvos, was to be sent by 31 August 2000, at the latest, to the rapporteur Member State ('the RMS') designated in Annex I to the regulation, namely the Italian Republic, by any producer who wished to secure its inclusion in Annex I to Directive 91/414.

9 Pursuant to Article 6(1) of Regulation No 451/2000, each notifier has the task of sending to the RMS a summary dossier and a complete dossier, as defined in Article 6(2) and (3) of the regulation.

10 The time-limit for the submission of those dossiers and of relevant information which could contribute to the evaluation of the active substances was set at 30 April 2002, by virtue of Article 5(4)(c) and (d) of Regulation No 451/2000, in conjunction with Article 2 of Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Directive 91/414 and revising the list of Member States designated as rapporteurs for those substances (OJ 2001 L 98, p. 6).

11 As set out in Article 7(1) of Regulation No 451/2000, the RMS is required to report to the Commission on the completeness of the dossiers, at the latest six months after the receipt of all dossiers for an active substance. In the case of active substances for which a dossier is considered to be complete, the RMS then evaluates the dossier.

12 The evaluation proper of the active substances is governed by Article 8 of Regulation No 451/2000, as amended by Article 20 of Regulation No 1490/2002.

13 Article 8(1) of Regulation No 451/2000 provides:

'The [RMS] shall evaluate and report only on those active substances for which at least one dossier has been determined to be complete … It shall send a draft report of its assessment of the dossier to the European Food Safety Authority … as quickly as possible, and at the latest 12 months after the dossier was determined to be complete…

At the same time, the [RMS] shall make a recommendation to the Commission either:

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

— not to include the active substance in Annex I to … Directive [91/414], stating the reasons for the non-inclusion.

…'

14 At that stage of the evaluation, Article 8(2) of Regulation No 451/2000, as amended, provides that 'submission of new studies shall not [as a rule] be accepted', but that '[the RMS] may request the notifiers to submit further data which are necessary to clarify the dossier' and that it 'shall set a time-limit within which [that] information should be provided'.

15 Under the first subparagraph of Article 8(5) of Regulation No 451/2000, as amended, 'the [European Food Safety Authority] shall circulate the rapporteur's draft assessment report to the Member States and may organise a consultation of experts including [the RMS]'. At that stage of the procedure, the second subparagraph of Article 8(5) of Regulation No 451/2000, as amended, provides:

'Without prejudice to Article 7 of Directive [91/414], submission of new studies shall not be accepted. The [RMS], with the agreement of the [European Food Safety Authority], may request the notifiers to submit within specified periods further data considered by the [RMS] or the [European Food Safety Authority] necessary to clarify the dossier.'

16 Article 8(7) of Regulation No 451/2000 provides:

'The [European Food Safety Authority] shall evaluate the rapporteur's draft assessment report and deliver its opinion on whether the active substance can be expected to meet the safety requirements of … Directive [91/414] to the Commission at the latest one year after receipt of the [RMS's] draft assessment report. Where appropriate, the [European Food Safety Authority] shall give its opinion on the available options claimed to meet the safety requirements …'

17 Article 8(8) of Regulation No 451/2000 provides:

'At the latest six months after receipt of the [European Food Safety Authority] opinion referred to in paragraph 7, the Commission shall submit the draft review report… [I]t shall submit 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, or

(b) a draft decision addressed to the Member States to withdraw the authorisations of plant-protection products containing the active substance, pursuant to the fourth subparagraph of Article 8(2) of … Directive [91/414], whereby that active substance is not included in Annex I to … Directive [91/414], mentioning the reasons for the non-inclusion.

…'

Regulation (EC) No 178/2002

18 Article 28(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) provides:

'The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the [European Food Safety Authority], each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.'

Background to the dispute

19 The applicant, Denka International BV, is a company which markets dichlorvos and plant protection products based on dichlorvos.

20 Dichlorvos is an active substance used as an organophosphate insecticide in greenhouses and post-harvest applications in stores.

21 On 20 April 2000, the applicant notified the Commission of its wish to obtain the inclusion of dichlorvos in Annex I to Directive 91/414.

22 On 17 April 2002, the applicant submitted its dossier to the RMS. After requesting some clarifications concerning the dossier, the RMS decided, on 17 October 2002, that the dossier was complete and proceeded with the evaluation, pursuant to Article 8 of Regulation No 451/2000.

23 On 20 October 2003, the RMS submitted its draft assessment report ('the DAR') to the European Food Safety Authority (EFSA). The DAR recommended the non-inclusion of dichlorvos in Annex I to Directive 91/414 on the ground, primarily, that much essential information was missing.

24 On 21 June 2004, the DAR was communicated by the EFSA to the Member States and the applicant. Following that communication, the applicant submitted, on 16 August 2004, an expert report on chronic toxicity and its comments on the DAR. The communication of the DAR marked the beginning of the procedure known as 'peer review', as envisaged by Article 8(5) of Regulation No 451/2000.

25 In this context, an evaluation meeting was held, on 9 February 2005, bringing together the Member States' representatives, the EFSA and the applicant.

26 In May 2005, the RMS published an addendum to the DAR taking into account, as had been decided at the meeting of 9 February 2005, the expert report on chronic toxicity and the comments from the Member States and the applicant. In that addendum, the RMS indicated that, despite the data submitted by the applicant, questions remained concerning, in particular, the long-term toxicity and mutagenicity of dichlorvos. In that addendum, the RMS maintained its recommendation that dichlorvos should not be included in Annex I to Directive 91/414.

27 From 27 June until 1 July 2005, a meeting of the EFSA Pesticides Peer review Co-Ordination ('the EPCO') was held, during which the toxicity of dichlorvos was discussed. At that meeting, the EPCO was not able to reach a definitive finding, in particular concerning the mutagenicity and carcinogenicity of dichlorvos. Consequently, it was decided to forward two questions to one of the EFSA's scientific panels, the Scientific Panel on Plant health, Plant protection products and their Residues ('the PPR Panel'). Thus, the EPCO asked the PPR Panel, on the one hand, if it was possible to identify a mechanism by which dichlorvos causes tumours and to set a threshold for the exposures needed before they appear and, on the other hand, whether the tumours observed in rats and mice were relevant to the evaluation of the effect of dichlorvos on human health.

28 On 1 April 2006, the PPR Panel adopted an opinion which was discussed on 5 April 2006 at the final evaluation meeting for dichlorvos between the Member States' representatives and the EFSA.

29 On 12 May 2006, the EFSA finalised its report entitled 'Conclusion regarding the peer review of the pesticide risk assessment of the active substance dichlorvos' ('the EFSA report') and then sent it to the Commission, pursuant to Article 8(7) of Regulation No 451/2000.

30 On 22 June 2006, the applicant submitted its comments on the EFSA report.

31 The EFSA report and the PPR Panel's opinion were examined by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. A first meeting of that committee took place on 14 July 2006. At a second meeting, on 28 and 29 September 2006, the Commission drew up its review report for dichlorvos, in which it proposed not to include that substance in Annex I to the Directive.

32 On 6 June 2007, the Commission adopted Decision 2007/387/EC concerning the non-inclusion of dichlorvos in Annex I to Directive 91/414 and the withdrawal of authorisations for plant protection products containing that substance (OJ 2007 L 145, p. 16, 'the contested decision').

33 Article 1 of the contested decision provides that dichlorvos is not to be included in Annex I to Directive 91/414. Therefore, Article 2 requires the withdrawal of the authorisations granted for plant protection products containing dichlorvos by 6 December 2007 and that authorisations for such products are neither granted nor renewed from 7 June 2007. Under Article 4, the contested decision is addressed to the Member States.

34 The reasons for the non-inclusion of dichlorvos in Annex I to Directive 91/414 are stated in recital 5 of the contested decision:

'During the evaluation of this active substance, a number of concerns were identified. In particular, based on the available toxicological data and taking into account the uncertainties of the genotoxic and carcinogenic properties of the substance [and] also considering the overall poor quality of the dossier, it has not been demonstrated that the estimated operator, worker and bystander exposure, is acceptable.'

Procedure and forms of order sought

35 By application lodged at the Registry of the Court of First Instance on 31 August 2007, the applicant brought the present action.

36 The applicant claims that the Court should:

— declare the action admissible and well founded;

— annul the contested decision;

— order the Commission to pay the costs as well as compensatory and moratory interests of 8%.

37 The Commission contends that the Court should:

— dismiss the action;

— order the applicant to pay the costs.

Law

38 In support of its action, the applicant raises one plea of illegality and nine pleas for annulment. The plea of illegality is based on the illegality of Article 20 of Regulation

No 1490/2002. The pleas allege, first, infringement of Article 8(7) of Regulation No 451/2000, infringement of Article 28(1) of Regulation No 178/2002 and infringement of Article 8 of Regulation No 451/2000; second, that the contested decision lacks objective scientific justification; third, infringement of Article 5 of Directive 91/414; fourth, infringement of the principle of proportionality, of the right to a fair hearing and of the rights of the defence; fifth, infringement of the principle of the protection of legitimate expectations; sixth, infringement of the principle of sound administration and of the duty of excellence and independence of scientific opinions; seventh, infringement of the 'principle of non-discrimination'; eighth, infringement of Article 95 EC, of Article 4(1) and of Article 5(1) of Directive 91/414 and, ninth, infringement of the principle of subsidiarity and of Article 5 EC.

The plea of illegality relating to Article 20 of Regulation No 1490/2002

Arguments of the parties

39 The applicant pleads the illegality of Article 20 of Regulation No 1490/2002, which it claims substantially prejudiced its rights and legitimate expectations by providing for the EFSA's involvement in the evaluation procedure for active substances referred to in the second stage of the work programme, such as dichlorvos, which constitutes an additional obligatory step in the evaluation procedure for active substances, whereas, under the previous legislation, that step was optional. Article 20 of Regulation No 1490/2002 should be declared illegal and inapplicable to the applicant as that provision was applied retroactively to the ongoing dichlorvos review procedure.

40 The applicant submits that the Community law principle of non-retroactivity requires that the law applicable to the dichlorvos evaluation procedure under Directive 91/414 is the law in force at the time the review started. This principle requires that this law cannot be fundamentally altered thereafter. The retroactive application of legal acts

can only be accepted exceptionally, if properly reasoned and if the legitimate expectations of economic operators are not frustrated.

41 The applicant submits that neither Directive 91/414, Regulation No 451/2000 nor Article 20 of Regulation No 1490/2002 provide an explanation as to why the EFSA should retroactively intervene in ongoing assessments. Moreover, the applicant's legitimate expectations were frustrated as it could not envisage the intervention of a separate body, such as the EFSA, in the evaluation procedure, nor the late peer review of its DAR.

42 The Commission maintains that the plea of illegality raised by the applicant should be rejected as unfounded.

Findings of the Court

43 The provisions of Article 8 of Regulation No 451/2000 were amended by Article 20 of Regulation No 1490/2002. Prior to the entry into force of Regulation No 1490/2002, active substances were evaluated by the RMS and the Commission, which, under the second subparagraph of Article 8(3) of Regulation No 451/2000 '[could] organise a consultation of experts from one or several Member States', whereas Regulation No 1490/2002 granted the EFSA a role in the evaluation of active substances. Therefore, under Article 8(1) of Regulation No 451/2000, as amended, the RMS is to send to the EFSA the DAR for active substances in respect of which a dossier is regarded as complete, and the EFSA, under Article 8(7) of that regulation, is to evaluate that report and deliver its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414 to the Commission.

44 Moreover, as regards, in the first place, the head of claim relating to the retroactive application of Article 20 of Regulation No 1490/2002, it must be stated that Regulation No 1490/2002 does not provide for any retroactive application of its provisions, in particular of Article 20. Article 21 of Regulation No 1490/2002 provides that the regulation entered into force on the seventh day following its publication in the Official Journal, that is to say on 28 August 2002, and its provisions were directly applicable as from that date.

45 In that regard, it must be borne in mind that, unlike substantive rules of Community law, which must be interpreted as not applying, in principle, to situations existing before their entry into force, procedural rules are of immediate application (see Joined Cases T-27/03, T-46/03, T-58/03, T-79/03, T-80/03, T-97/03 and T-98/03 *SP and Others* v *Commission* [2007] ECR II-4331, paragraph 116 and the case-law cited).

46 The provisions of Regulation No 1490/2002 which provide for the EFSA's involvement in the evaluation procedure for active substances constitute procedural rules which, in accordance with the case-law cited in paragraph 45 above, are of immediate application.

47 Consequently, the applicant cannot claim that the immediate application of the new provisions of Article 8 of Regulation No 451/2000 to ongoing evaluation procedures for active substances was illegal. Furthermore, in the light of the immediate application of procedural rules, there was no requirement for any specific statement of reasons on that point in Regulation No 1490/2002.

48 As regards, in the second place, the head of claim alleging infringement of the principle of the protection of legitimate expectations, it is apparent from settled case-law

that the scope of that principle cannot be extended to the point of generally preventing new rules from applying to the future effects of situations which arose under the earlier rules (Case 203/86 *Spain* v *Council* [1988] ECR 4563, paragraph 19; Case C-60/98 *Butterfly Music* [1999] ECR I-3939, paragraph 25; and Case C-162/00 *Pokrzeptowicz-Meyer* [2002] ECR I-1049, paragraph 55).

49 Moreover, first, in practice, Regulation No 1490/2002 did not insert an additional step into the evaluation procedure for active substances. As was pointed out in paragraph 43 above, the second subparagraph of Article 8(3) of Regulation No 451/2000 provided, prior to its amendment by Regulation No 1490/2002, that the Commission '[could] organise a consultation of experts from one or several Member States'. Consequently, on that basis, at the time when it notified its dossier to the RMS the applicant could expect a peer review to be carried out.

50 Secondly, as Regulation No 178/2002 was published on 1 February 2002, the applicant could expect, in particular on the basis of recitals 34 and 36 in the preamble to that regulation and of Article 22 thereof, that the EFSA would be asked to issue a scientific opinion in the evaluation procedure of active substances contained in plant-protection products. The applicant could not therefore have had the legitimate expectation that the EFSA would not take part in the evaluation.

51 The plea of illegality must therefore be rejected.

The first plea, alleging infringement of Article 8(7) of Regulation No 451/2000, Article 28(1) of Regulation No 178/2002 and Article 8 of Regulation No 451/2000

The first part of the first plea

— Arguments of the parties

52 In the first part of the first plea, the applicant submits that, pursuant to Article 8(7) of Regulation No 451/2000, the EFSA should have sent its report to the Commission in October 2004. However, it did this only in May 2006. Therefore, according to the applicant, the EFSA carried out its evaluation during a period in which it was not legally entitled to do so and for which it had not been granted special authority by the Commission or another Community institution. The EFSA therefore exceeded its powers.

53 As the EFSA report was, in accordance with Article 8(8) of Regulation No 451/2000, the basis of the contested decision, the procedural irregularity affecting the report justifies the annulment of the contested decision. If the EFSA had respected the time-limit laid down by Article 8(7) of Regulation No 451/2000, the contested decision would have been different because the Commission would have had to re-refer the DAR to the EFSA or another independent scientific body for peer review at a later date. The RMS would therefore have been able to indicate any concerns it had to the applicant which would have had more time to assess the DAR and produce additional studies or evidence-based data.

54 The Commission disputes the applicant's arguments and submits that the first part of this plea should be rejected.

— Findings of the Court

55 Under Article 8(7) of Regulation No 451/2000, the EFSA must evaluate the DAR and deliver its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414 to the Commission at the latest one year after receipt of the DAR. In the present case, the EFSA did not comply with that time-limit. Although the EFSA received the DAR on 20 October 2003, it delivered its opinion to the Commission only on 12 May 2006.

56 However, even if the time-limit in Article 8(7) of Regulation No 451/2000 were mandatory, failure to comply with that time-limit could affect the legality of the contested decision only if it were established that the content of the contested decision could have differed if that irregularity had not occurred (see, to that effect, Case 150/84 *Bernardi* v *Parliament* [1986] ECR 1375, paragraph 28, and Case T-279/02 *Degussa* v *Commission* [2006] ECR II-897, paragraph 416).

57 The applicant claims that that is the case in so far as, if the EFSA had respected the time-limit laid down by Article 8(7) of Regulation No 451/2000, the Commission would have had to re-refer the DAR to the EFSA or another independent scientific body for another peer review. The RMS would therefore have been able to indicate any concerns it had to the applicant which would have had more time to assess the DAR and produce additional studies or evidence-based data.

58 It must be noted, however, that the DAR, the addendum to it and the EFSA report showed that the dossier, as notified by the applicant, did not contain all the particulars necessary to permit a satisfactory evaluation of the harmful effects of dichlorvos. If, on 12 May 2006, after exchanges of views and information which had taken place within the EFSA over many months, that body ultimately did not reach the conclusion that dichlorvos was harmless, it could not, a fortiori, in the light of the inadequate nature of the dossier notified, have reached a different conclusion if it had adopted its

report within one year after receipt of the DAR. On the contrary, it would have been impossible for the RMS to submit an addendum to the DAR, as it did in May 2005.

59 Moreover, contrary to what the applicant maintains as regards the possibility of the Commission's re-referring the DAR to the EFSA or another independent scientific body for another peer review, Regulation No 451/2000 does not provide for such a possibility. First, it is apparent from Article 8(1) of that regulation that the Commission has no power to submit a DAR. That falls solely to the Member State which must send the DAR to the EFSA at the latest 12 months after the dossier has been considered to be complete. Secondly, under Article 8(4) of Regulation No 451/2000, the resubmission of an amended report is possible only in exceptional cases where that document clearly does not fulfil the requirements concerning the format recommended by the Commission. In those circumstances, the Commission is to agree with the EFSA and the RMS on a period for resubmission of an amended report, which must not, under Article 4 of Regulation No 451/2000 exceed four months. Clearly, therefore, the applicant is incorrect in arguing that, if the EFSA report had been adopted within the time-limit, the Commission would have had to re-refer the DAR to the EFSA or another independent scientific body, as a result of which it would in particular have had more time to produce additional studies.

60 The first part of the first plea must therefore be rejected as unfounded.

The second part of the first plea

— Arguments of the parties

61 In the second part of the first plea, the applicant observes that, in accordance with Article 28(1) of Regulation No 178/2002, the EPCO, during its review of dichlorvos

under Directive 91/414, submitted questions concerning the carcinogenicity and genotoxicity of dichlorvos to the PPR Panel. According to the applicant, pursuant to Article 28(1) of Regulation No 178/2002, the PPR Panel's opinion represents the scientific opinion of the EFSA as a whole. That opinion ought therefore to have been taken into account, without modification, in the EFSA report. As that report contradicts the PPR Panel's opinion, Article 28(1) of Regulation No 178/2002 was infringed. Moreover, as the EFSA report constitutes the scientific basis of the contested decision, that decision lacks any scientific and procedural basis and should therefore be annulled.

62 The Commission disputes the applicant's arguments and maintains that this part of the plea should be rejected.

— Findings of the Court

63 In essence, the applicant's contentions give rise to two questions. The first relates to the legal status of the PPR Panel's opinion. More specifically, it must be established whether that opinion is binding on the EFSA. The second question, which only arises if the answer to the first question is in the affirmative, concerns the alleged contradiction between the PPR Panel's opinion and the EFSA report. Those two questions must be examined in turn.

64 First, as regards the legal status of the PPR Panel's opinion, it is necessary, first of all, to clarify the role assigned to the PPR Panel in evaluation procedures for dossiers notified by producers who wish to secure the inclusion of an active substance in Annex I to Directive 91/414, as provided for in Article 8 of Regulation No 451/2000.

65 In that regard, it is important to note that the PPR Panel is not explicitly mentioned in that article. Thus, under Article 8(1) of Regulation No 451/2000, the RMS is to draw up a DAR which it sends to the EFSA. Under Article 8(5) of that regulation, the EFSA is to circulate the DAR to the Member States and may organise a consultation of experts. Lastly, under Article 8(7) of that regulation, the EFSA is to evaluate the DAR and deliver its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414 to the Commission.

66 Nevertheless, it is under Article 8(5) of Regulation No 451/2000 that a role may be allotted to the PPR Panel. Under that article, the EFSA is required to organise a peer review, that is to say by the Member States and, if necessary, by national experts, in order to evaluate the DAR. The EFSA has elaborated specific procedures with the aim of rationalising that examination. Those procedures are described in the document entitled 'Procedure of the peer review of active substances used in plant protection products evaluated in the second stage of the review programme'. In that document, the EFSA sets out four types of procedure from which it may choose, depending on the difficulties presented by the dossier. Those procedures are managed, within the EFSA, by a unit for the coordination of the peer review of pesticides, also known as PRAPeR (EFSA's Pesticide Risk Assessment Peer Review), a unit which took on the functions previously assumed by EPCO. It is in the context of the procedure specifically drawn up by the EFSA to evaluate active substances whose harmlessness is problematic — which is one of the four types of procedure mentioned above — that the EFSA has provided for a role for the PPR Panel, which was created pursuant to Article 28(4) of Regulation No 178/2002. In respect of those substances, the EFSA provided for the convening of meetings of national experts and the possibility of consulting the PPR Panel on problematic issues.

67 Secondly, it must be established whether the PPR Panel's opinion is binding on the EFSA in respect of the drawing up of its report. The applicant maintains that that is the case and refers to Article 28(1) of Regulation No 178/2002.

68 Under that article, '[t]he … permanent Scientific Panels shall be responsible for providing the scientific opinions of the [EFSA], each within their own spheres of competence'. It is important to note that, as the applicant submits, the wording of that article implies that the EFSA must, if it decides to request a scientific opinion from such a panel, comply with that opinion. That interpretation is borne out by the rules which the EFSA has established for itself: if the PPR Panel is consulted, it is laid down that the report of the meetings of national experts mentioned in paragraph 66 above must take account of its opinion. An exception to that rule is conceivable only where the EFSA has available to it scientific information justifying the setting aside of that opinion.

69 Nevertheless, it must be stated that, contrary to what the applicant submits, in the evaluation procedure for dossiers notified by producers wishing to have an active substance included in Annex I to Directive 91/414, the opinion of the PPR Panel cannot be confused with the opinion of the EFSA, drawn up pursuant to Article 8(7) of Regulation No 451/2000, on whether the active substance can be expected to meet the safety requirements of Directive 91/414. It has already been pointed out that, in the course of the above procedure, the PPR Panel may be consulted by PRAPeR on certain specific difficulties in the dossiers the evaluation of which the latter coordinates. However, the PPR Panel may not under any circumstances assume the role assigned to the EFSA in the preparation of the opinion referred to in Article 8(7) of Regulation No 451/2000.

70 It follows from the above that, in the procedure provided for in Article 8 of Regulation No 451/2000, the opinion of the PPR Panel is binding on the EFSA as regards the issues on which it has been consulted, but that is subject always to the general assessment of the risk posed by the active substance at issue.

71 Secondly, it must be established whether the PPR Panel's opinion was distorted or contradicted in the EFSA report. In that regard, it should be borne in mind that the PPR Panel's scientific opinion was provided at the request of the EPCO. The PPR Panel was asked two questions. First, it was asked whether it could identify the mechanisms by which dichlorvos causes tumours and, in the affirmative, whether it could ascertain if a threshold for exposure could be set. Secondly, it was asked whether the tumours observed in animals could be relevant to the evaluation of the effect of dichlorvos on human health.

72 As regards the first question, the PPR Panel drew a distinction, in its answer, between genotoxicity and carcinogenicity. As regards the possible mechanisms by which dichlorvos might be genotoxic, the PPR Panel's opinion concluded, first, that dichlorvos was an *in vitro* mutagen and, secondly, that there was some limited evidence that dichlorvos is a site-of-contact *in vivo* mutagen but that the mechanism of that effect is unclear. As regards the carcinogenicity of dichlorvos, the PPR Panel stated that the only carcinogenic effect found was that of forestomach tumours in mice. According to the PPR Panel, such tumours appear to be a consequence of high sustained local concentrations of dichlorvos (caused by the gavage of the animals). In that regard, the PPR Panel stated that it was possible, but far from certain, that those tumours were caused by a modification of the DNA in cells at the site of contact, which implied, in principle, that tumours could be produced at other sites. However, according to the PPR Panel, the doses necessary to produce the tumours were so high that the appearance of such tumours at other sites was unlikely. That therefore means that, according to the PPR Panel, there is a threshold for the carcinogenic response.

73 As regards the second question, the PPR Panel concluded that, as there is no equivalent to the forestomach of mice in humans, there was considerable scientific uncertainty as to the mode of action and relevance for humans of the forestomach tumours induced by dichlorvos in the mouse. The PPR Panel reiterated that, whilst it was not possible to exclude DNA interaction as a critical step in the production of those tumours, their appearance appeared to be a consequence of high and sustained local concentrations of dichlorvos. According to the PPR Panel, the evidence available appeared to suggest that those tumours would not occur at the levels of exposure that would be encountered in the proposed use of the active substance, in so far as severe systemic toxicity would occur before the tumours developed.

74 The EFSA report contains a faithful summary of those answers. At the end of that summary, the EFSA concedes that, in accordance with the PPR Panel's opinion, a threshold value, below which the use of the active substance dichlorvos is safe, may theoretically be set. However, according to the EFSA report, since the dossier contains no robust long-term study on carcinogenicity, it is not possible either to fix the 'no observed adverse effect level' (NOAEL) or to have a full picture of the toxicological properties of the active substance. Consequently, the EFSA report states that such a threshold value cannot be established in the present case.

75 In the light of the above, it must be held that the EFSA report neither distorts nor fails to comply with the PPR Panel's opinion. In that regard, it is important to point out that the fact that, in its report, the EFSA found that the assessment of the risks dichlorvos poses to human health was inconclusive, owing to the uncertainties connected with the genotoxic and carcinogenic properties of that substance, whereas the PPR Panel stated that the evidence available appeared to suggest that the risk of genotoxicity and carcinogenicity was minimal, is directly connected with the Court's finding in paragraph 69 above that the PPR Panel may be consulted by PRAPeR on certain specific difficulties in the dossiers to be evaluated, but may not under any circumstances assume the role assigned to the EFSA in the preparation of the opinion referred to in Article 8(7) of Regulation No 451/2000. The PPR Panel carries out a risk assessment of a theoretical nature, whereas it is the task of the EFSA, when it carries out the same assessment, to take into account the practical contingencies connected with the management of those risks. In the present case, although the PPR Panel was of the opinion that, in theory, the risks of genotoxicity and carcinogenicity were minimal, the EFSA report stated that the risk assessment was inconclusive because of the gaps in the data submitted by the applicant, which made it impossible to set a threshold value.

76 Consequently, the second part of the first plea must be rejected as unfounded.

The third part of the first plea

— Arguments of the parties

77 In the third part of the first plea, the applicant submits that, according to case-law, the Commission is obliged to submit to the Member States any information that is relevant to its decision on inclusion or non-inclusion of an active substance, before the vote in the Standing Committee on the Food Chain and Animal Health. Failure to do so constitutes an infringement of the procedural requirements of Article 8 of Regulation No 451/2000.

78 The applicant observes in this respect that it is apparent from recital 6 of the contested decision that the Commission carefully examined all of the applicant's comments. Among those are its comments on the EFSA report, dated 22 June 2006. As these comments were not sent to the Member States, the Commission infringed its obligations under Article 8 of Regulation No 451/2000, which justifies the annulment of the contested decision.

79 The applicant submits, moreover, in the reply, that although those comments were in fact sent to the Member States on 11 September 2006, as the Commission claims, the Commission proposed the non-inclusion of dichlorvos for the first time at the meeting of the Standing Committee on the Food Chain and Animal Health on 14 July 2006. The Member States' representatives would therefore not have had access to those documents when they first examined the Commission's proposal. Moreover, they would only have had access to them 17 days before the meeting of the Standing Committee on the Food Chain and Animal Health of 28 September 2006, during which the contested decision was adopted.

80 The Commission disputes the applicant's arguments and maintains that this part of the plea should be rejected.

— Findings of the Court

81 The court notes, first of all, that, under Article 8(8) of Regulation No 451/2000, at the latest six months after receipt of the EFSA report, the Commission must submit the draft review report and a draft directive to include the active substance in Annex I or a draft decision addressed to the Member States to withdraw the authorisations of plant-protection products containing the active substance in question and, consequently, not to include that substance in Annex I of Directive 91/414.

82 In the present case, it must be pointed out that, irrespective of whether the Commission is obliged to communicate the applicant's comments on the EFSA report, it is apparent from the material in the dossier that the applicant's comments dated 22 June 2006 were sent to the Member States on 11 September 2006 for the purposes of the meeting of the Standing Committee on the Food Chain and Animal Health on 28 and 29 September 2006. Even if, as the applicant states, an initial meeting of that committee took place on 14 July 2006, a meeting at the end of which no decision relating to the inclusion of dichlorvos in Annex I to Directive 91/414 was taken, the vote relating to the non-inclusion of dichlorvos in Annex I to Directive 91/414 took place, within that committee, only at the meeting of 28 and 29 September 2006. It is therefore clear that the applicant's comments were communicated to the Member States in sufficient time for them to be able to take them into account during their vote.

83 Consequently, the third part of the first plea must be rejected as unfounded.

The second plea, alleging that the contested decision lacks scientific justification

Arguments of the parties

84 The applicant submits, first, that the Commission did not have available sufficient scientific indications to conclude, on an objective basis, that it was necessary to ban dichlorvos.

85 Therefore, the applicant submits that the contested decision is based on the key scientific finding that the genotoxicity and carcinogenicity of dichlorvos cannot be excluded. That finding is contradicted by the PPR Panel's opinion that dichlorvos does

not pose a carcinogenic or genotoxic risk. Thus, the statement in the opinion that, '[a]fter considering all of the available data, the PPR Panel concluded that with the exception of tumours of the forestomach in mice, there was no convincing evidence for a compound related increase in tumour incidence' contradicts the findings set out in the EFSA report and the contested decision.

86 The applicant maintains that the PPR Panel's opinion should legally be understood as that of the EFSA as a whole.

87 Moreover, the Commission, like the EFSA, could only choose between following the PPR Panel's opinion or departing from it, subject, in the latter case, to referring to a new opinion of the PPR Panel or a scientific body of the same stature or level. In that respect, the EFSA report is particularly questionable, as it was finalised only five days after the release of the PPR Panel's opinion which, itself, required a year of methodical evaluation. Moreover, the Commission did not base itself on the clear scientific findings concerning the non-genotoxicity and non-carcinogenicity of dichlorvos, as set out in the PPR Panel's opinion, and there was no valid contrary scientific research. Finally, the PPR Panel's opinion is not mentioned in the contested decision and the Commission does not provide any justification for disregarding it in that decision.

88 Secondly, the applicant submits that even if the EFSA report is considered to be a valid basis for the contested decision, this report is itself flawed because it was not drafted by the EFSA in its capacity as an independent body providing scientific advice, but as a coordinator of expert meetings. This is apparent from recital 4 to the contested decision and the EFSA report itself.

89 Thirdly, the applicant submits that the effects of dichlorvos on the general population and the environment are irrelevant in view of the proposed use of dichlorvos, namely

indoors on flower bulbs. It is clear from both a logical and a scientific point of view that there is no risk to the general population or the environment if dichlorvos is used only indoors on flower bulbs. Consequently, there is no scientific justification for the restriction in the contested decision based on hypothetical concerns.

90 Fourthly, concerning the Commission's claim that it was impossible to complete the risk assessment because of gaps in the dossier, the applicant submits, in the reply, that the RMS itself declared that the dossier was complete. Such a declaration necessarily implies that the RMS considered that the dossier included all of the data required pursuant to Directive 91/414 to carry out the evaluation of the active substance. The fact that the competent authorities judged the dossier complete and proceeded with the evaluation of the dossier gave rise to a legitimate expectation on the part of the applicant that all of the data required had been provided.

91 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

92 It should be noted that, as is clear from recitals 5, 6 and 9 in the preamble thereto, Directive 91/414 aims to remove barriers to intra-Community trade in plant protection products, while maintaining a high level of protection of the environment and of human and animal health (Case C-138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I-8339, paragraph 43, and Case T-75/06 *Bayer CropScience and Others* v *Commission* [2008] ECR II-2081, paragraph 81).

93 In that context, if the Commission is to be able to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake, it must be recognised as enjoying a broad discretion (Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557 ('*IQV*'), paragraph 75, and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 82).

94 However, the exercise of that discretion is not excluded from judicial review. In that regard, according to settled case-law, in the course of such a review the Community judicature must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of assessment or a misuse of powers (Case 98/78 *Racke* [1979] ECR 69, paragraph 5; Case C-16/90 *Nölle* [1991] ECR I-5163, paragraph 12; and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 83).

95 It must also be borne in mind that — as is clear from Article 6(2)(b) of Regulation No 451/2000 — it is the notifier who has to demonstrate that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the requirements of Directive 91/414 in relation to the criteria referred to in Article 5 are met. The burden of proof as regards the safety of the active substance thus lies with the notifier (see, by analogy, *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 85).

96 The question whether, as the applicant claims, the scientific findings set out in the contested decision lack an objective and valid scientific basis must be examined in the light of the foregoing considerations.

97 In the first place, as regards the applicant's argument that the contested decision is based on the key scientific finding that the genotoxicity and carcinogenicity of dichlorvos cannot be excluded, a finding which is contradicted by the PPR Panel's opinion, it must be pointed out, first, that it is apparent from recital 5 of the contested decision

that, although the fundamental concern relates to the uncertainties of the genotoxic and carcinogenic properties of dichlorvos, reference is also made to the overall poor quality of the dossier as an obstacle to demonstrating that the estimated operator, worker and bystander exposure, was acceptable.

98 Although the Commission gives no further particulars in the contested decision as regards the gaps in the dossier, the EFSA report, which it is not disputed constitutes the scientific basis for the contested decision, provides such particulars. Consequently, the EFSA report mentions the following problems in addition to the uncertainties related to the genotoxic and carcinogenic properties of dichlorvos:

— no definitive reference value has been confirmed;

— as definitive reference values were not agreed on, the risk assessment to operators, workers and bystanders is inconclusive;

— it is not possible to define a technical specification for dichlorvos;

— no analytical methods for ascertaining the residues of dichlorvos in soil, water, air, blood and animal tissues are available.

99 Consequently, the applicant wrongly overlooks the problems identified in the contested decision, other than the uncertainties of the genotoxic and carcinogenic properties of dichlorvos.

100 Secondly, it must be stated that, contrary to what the applicant claims, the contested decision does not contradict the PPR Panel's opinion. As has already been explained in paragraphs 71 to 75 above, the EFSA report, which constitutes the scientific basis for the contested decision, faithfully reports the terms in which that opinion is couched. Although the EFSA report states that the assessment of the risks is inconclusive, whereas the PPR Panel suggests that the risk of genotoxicity and carcinogenicity is minimal, the EFSA explains in that report, as was pointed out in paragraph 74 above, the reason why risks which may appear to be acceptable in theory are not acceptable in the present case. Furthermore, as was shown in paragraph 98 above, the EFSA report refers to problems other than the uncertainties of the genotoxic and carcinogenic properties of dichlorvos, in relation to which the PPR Panel had not been consulted.

101 In the light of the foregoing, it is necessary to reject the applicant's argument that the contested decision is based on the key scientific finding - allegedly contradicted by the PPR Panel's opinion - that the genotoxicity and carcinogenicity of dichlorvos cannot be excluded.

102 In the second place, as regards the argument that the EFSA report was not drafted by the EFSA in its capacity as an independent body, but as a coordinator of expert meetings, it must be pointed out that that assertion shows that the applicant is unaware of the evaluation procedure for dossiers notified by producers who wish to secure the inclusion of an active substance in Annex I to Directive 91/414, as provided for in Article 8 of Regulation No 451/2000.

103 As has already been pointed out in paragraph 65 above, under Article 8(1) of Regulation No 451/2000, the RMS is to draw up a DAR which it sends to the EFSA. Under Article 8(5) of that regulation, the EFSA is to circulate the DAR to the Member States and may organise a consultation of experts. Lastly, under Article 8(7) of that regulation, the EFSA is to evaluate the DAR and deliver its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414 to the Commission.

104 That evaluation procedure must be interpreted in the light of the preamble to Regulation No 1490/2002, in so far as that regulation amended Article 8 of Regulation No 451/2000. It is apparent, in particular, from recital 12 in the preamble to Regulation No 1490/2002 that DARs are 'reviewed by the EFSA before they are submitted to the Standing Committee on the Food Chain and Animal Health'. Under Article 8(5) of Regulation No 451/2000, this takes the form of a peer review. It is on the basis of that peer review that the EFSA circulates the DAR and its own report to the Commission pursuant to Article 8(7) of Regulation No 451/2000.

105 Consequently, the Commission is right to state, in recital 4 of the contested decision, that the DAR was 'peer reviewed' by the Member States and the EFSA and presented to the Commission in the format of the EFSA report. Therefore, that report cannot be regarded as flawed inasmuch as it was allegedly not drafted by the EFSA in its capacity as an independent body.

106 In the third place, as regards the applicant's argument that the effects of dichlorvos on the general population and the environment are irrelevant in so far as dichlorvos is intended for use only indoors on flower bulbs, it must be pointed out that, even if there were no risk to the general population or the environment, the applicant would be required to prove, in accordance with Article 6(2)(b) of Regulation No 451/2000, that the risk for operators who handle the active substance meets the requirements of Directive 91/414 and in particular the criteria referred to in Article 5 of that directive. It has already been stated in paragraphs 97 to 99 above that the gaps in the dossier did not make a conclusive risk assessment possible.

107 In the fourth place, the applicant's argument that, as the RMS had declared that the dossier was complete, the Commission could no longer complain that it had omitted information, is inadmissible under Article 48(2) of the Rules of Procedure of the Court of First Instance, in so far as it was raised for the first time in the reply.

108 In any event, that argument is unfounded. In that regard it must be pointed out that, under Article 6(1) of Regulation No 451/2000, the notifiers must 'submit to the designated authority of the [RMS] for any given active substance the complete dossier referred to in paragraph 3'. Under Article 6(3) of Regulation No 451/2000, the complete dossier is to contain 'physically the individual test and study reports'.

109 However, the fact that a dossier has been declared to be complete by the RMS for the purposes of Article 6(1) of Regulation No 451/2000 does not necessarily guarantee that it contains all the information to enable the RMS, the EFSA and the Commission to adopt a position on the harmful effects, within the meaning of Article 5(1) of Directive 91/414, of the active substance concerned. It must be pointed out in that regard that a dossier which contains the studies and reports provided for in Article 6(3) of Regulation No 451/2000 will be regarded as complete by the RMS but that does not constitute a decision on the quality of the dossier and does not preclude the possibility of a request for further data to enable the RMS and/or the EFSA to carry out their scientific evaluation of the active substance.

110 It is apparent from all of the foregoing that the second plea must be rejected.

The third plea, alleging infringement of Article 5 of Directive 91/414

Arguments of the parties

111 The applicant submits that, according to the case-law, danger must be distinguished from risk. According to the applicant, the evaluation criteria set out in Article 5 of Directive 91/414 are based on risk assessment. The contested decision infringes that article in that it is not based on a risk assessment but only on the inherent hazard properties of dichlorvos.

112 Thus, according to the applicant, the Commission refers, in recital 5 of the contested decision, to uncertainties related to the genotoxic and carcinogenic properties of that substance to justify its non-inclusion in Annex I to Directive 91/414. The genotoxicity and carcinogenicity of dichlorvos relate to its inherent hazard properties. A finding of genotoxicity and carcinogenicity does not in itself justify a conclusion that dichlorvos poses an unacceptable risk to the environment and human health. In that respect, the contested decision merely states that the available data are not sufficient, without coming to a clear conclusion as to whether or not they demonstrate an unacceptable risk to human health and the environment.

113 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

114 It is apparent from the ninth recital in the preamble to Directive 91/414 that the provisions governing the authorisation of plant protection products must ensure a high standard of protection, which, in particular, must prevent the authorisation of plant protection products whose risks to health, groundwater and the environment have not been the subject of appropriate research.

115 In that context, it must be pointed out that the criteria set out in Article 5(1) of Directive 91/414 for a substance to be capable of being included in Annex I are framed in broad terms and based on an analysis of the risk of harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment (*Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 184).

116 Furthermore, that provision must be interpreted in conjunction with the precautionary principle. In accordance with that principle, where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 99, and Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 139). Moreover, in a situation in which the precautionary principle is applied, which by definition coincides with a situation in which there is scientific uncertainty, a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality (*Pfizer Animal Health* v *Council*, paragraph 142).

117 In view of the foregoing and of the case-law cited in paragraphs 92 to 95 above, the Court notes that it is apparent from recital 5 of the contested decision that that decision is based not only on the available toxicological data and on the uncertainties of the genotoxic and carcinogenic properties of dichlorvos, but also, more generally, on the overall poor quality of the dossier. In that regard, it has already been stated, in paragraph 98 above, that there were gaps in the dossier submitted by the applicant and thus no reliable conclusion could be drawn as regards the genotoxic and carcinogenic properties of dichlorvos and, more generally, as regards the safety of dichlorvos. Accordingly, the EFSA report states that certain uncertainties can be dispelled only if the missing data and studies are provided.

118 It must therefore be held, in view of the precautionary principle, that the Commission, in the light of the available toxicological data, the uncertainties of the genotoxic and carcinogenic properties of dichlorvos and the gaps in the dossier which make it impossible to carry out a conclusive risk assessment, did not make a manifest error of assessment in adopting the contested decision or infringe Article 5 of Directive 91/414.

119 The third plea must therefore be rejected as unfounded.

The fourth plea, alleging infringement of the rights of the defence, the right to a fair hearing and the principle of proportionality

The first part of the fourth plea

— Arguments of the parties

120 The applicant submits that the Commission infringed its rights of defence and its right to a fair hearing by failing (i) to give it sufficient opportunity and time to make comments and to submit studies addressing the objections raised during the evaluation of dichlorvos concerning the absence of long-term studies allowing genotoxic and carcinogenic risk to be excluded, and (ii) in its obligation to examine carefully the applicant's comments.

121 First, concerning the failure to give the applicant sufficient opportunity and time to make comments and to submit studies, the applicant takes the view that it is necessary to assess whether the lack of long-term studies was raised by the Commission or the EFSA early enough in the evaluation procedure and whether it had sufficient time to submit the missing data.

122 As regards the time at which the lack of long-term studies was raised by the Commission and the EFSA, the applicant submits as follows: (i) neither the RMS nor the PPR Panel raised the issue of long-term studies as a critical part of the scientific evaluation; (ii) this issue became a formal data requirement, on the EFSA's part, only at a very late stage in the procedure when the EFSA had completed its report; (iii) the applicant could not have anticipated this requirement as the PPR Panel regarded it as unnecessary. In the reply, the applicant submits (iv) that the Commission's claim that it did not have to inform the applicant of the gaps in the dossier and give it time to

remedy them because a notifier can always re-apply must be considered a disproportionate and inappropriate answer to an unforeseeable data gap which arises during the review process.

123 Concerning the issue of the time available to prepare the long-term studies, the applicant submits that the Commission did not give it the opportunity and time to address that issue as it took the view that the deadlines to do so had lapsed. The Commission should have extended or suspended its own administrative deadlines to give the applicant a fair chance to defend its position. This is particularly so in the light of the fact that the applicant had received specific assurances, at the EPCO meeting of 27 June to 1 July 2005 and from the PPR Panel, that no long-term studies were needed. The applicant's situation is therefore comparable to that of the applicant in the case which gave rise to the judgment in *IQV*, paragraph 93 above. Moreover, the Commission's negligence in respect of the applicant's right to a fair hearing is accentuated by the fact that the applicant did its utmost throughout the evaluation to fulfil any requests from the competent authorities. Finally, as the competent authorities did not respect the legislative deadlines, they cannot legitimately seek to enforce to the letter the deadlines which apply to the applicant.

124 Secondly, concerning the failure to examine carefully the applicant's comments, the applicant observes that, in recital 6 of the contested decision, the Commission states that all of the comments which it submitted were carefully examined. However, this is not the case.

125 Thus, the applicant submits that the Commission made a manifest error of assessment by not allowing it to submit new long-term studies, after having rejected its arguments and the PPR Panel's opinion that those studies were unnecessary.

126 The Commission disputes the applicant's arguments and maintains that this part of the plea should be rejected.

— Findings of the Court

127 It should be borne in mind that, according to settled case-law, respect for the rights of the defence is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests be placed in a position in which they may effectively make known their views (see, to that effect, Case C-28/05 *Dokter and Others* [2006] ECR I-5431, paragraph 74, and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 130).

128 In the present case, the first point to note is that the contested decision adversely affects the applicant since it refuses to grant its request to have dichlorvos included in Annex I to Directive 91/414.

129 Next, in the first place, as regards the applicant's argument that its rights of defence were infringed in so far as it was not granted either sufficient opportunity or time to submit studies addressing the objections concerning the absence of long-term studies raised in the EFSA report, it must be pointed out, first, that the applicable legislative provisions do not impose any requirement that a notifier be given the opportunity to submit studies during the evaluation procedure.

130 Thus, Article 8(2) and (5) of Regulation No 451/2000 provides that 'new studies' are not, in principle, to be accepted, once the RMS and EFSA respectively have

commenced the evaluation of the active substance. Even though, under those provisions, the RMS, if necessary with the agreement of the EFSA, where the DAR has already been sent to the latter, may request the notifier to submit within specified periods further data considered by the RMS or the EFSA necessary to clarify the dossier, those provisions do not provide for such an exception in respect of the submission of new studies. A fortiori, there is no possibility of providing further data or studies after the EFSA has finalised its report.

131 Secondly, contrary to what the applicant claims, the Commission is not required to extend or suspend the legislative deadlines to give the applicant a fair chance to defend its position. According to the applicant, that obligation stems, on the one hand, from the specific assurances that no long-term studies were needed which were received at the EPCO meeting of 27 June to 1 July 2005 and from the PPR Panel and, on the other hand, from the judgment in *IQV*, paragraph 93 above.

132 However, irrespective of whether the applicant actually received specific assurances that no long-term studies were needed, such assurances could not have founded a legitimate expectation on the applicant's part, since Article 8(5) of Regulation No 451/2000 provides expressly that new studies are not, in principle, to be accepted once the EFSA has commenced its evaluation of the active substance. The case-law is clear that only assurances which comply with the applicable rules may give rise to legitimate expectations (Case T-347/03 *Branco* v *Commission* [2005] ECR II-2555, paragraph 102, and Case T-282/02 *Cementbouw Handel & Industrie* v *Commission* [2006] ECR II-319, paragraph 77).

133 Moreover, the judgment in *IQV*, paragraph 93 above, is of no assistance in the present case. It is apparent from that judgment that a deferral of the deadline for the evaluation of an active substance must be granted if it is not impossible to derogate from the procedural time-limits laid down in the rules in question, and if the parties who

notified the active substance were in a situation of force majeure which prevented them from complying with the procedural time-limits, a situation which might obtain if the impossibility of complying with those time-limits was attributable, at least in part, to contradictory behaviour on the part of the competent authorities (*IQV*, paragraph 93 above, paragraphs 84 to 88, and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 89). In the present case, the fact remains that the applicant has not adduced any evidence to show that it was in a situation of force majeure which prevented it from complying with those time-limits and it is not necessary to examine whether it would have been possible to derogate from the procedural time-limits laid down in the rules in question. On the contrary, as has already been stated in paragraph 58 above, the DAR, which was communicated to the applicant in June 2004, already showed that the dossier, as notified by the applicant, did not contain all the particulars necessary to permit the EFSA to carry out a satisfactory evaluation of the harmful effects of dichlorvos. In particular, point 4.6 of the DAR states that the submission of a study relating to the long-term toxicity of dichlorvos is required.

134 In the second place, as regards the alleged infringement of the obligation to give the applicant sufficient opportunity and time to make comments and of the obligation to examine carefully the comments made, it should be pointed out that it is apparent from recital 6 of the contested decision that the applicant was invited to make such comments on the EFSA report, an invitation to which it responded with the submission of its comments on 22 June 2006. That recital confirms that the applicant's comments 'have been carefully examined', but that 'the … concerns remained unsolved'. It follows that not only was the applicant invited to make comments but that they were also carefully examined.

135 Accordingly, it must be held that the applicant's right to a fair hearing during the procedure preceding the adoption of the contested decision was respected. The first part of the fourth plea must therefore be rejected as unfounded.

The second part of the fourth plea

— Arguments of the parties

136 The applicant submits that by summarily rejecting the PPR Panel's opinion and the applicant's comments of 22 June 2006, without considering other ways of resolving the conflict of opinions between experts, for example by seeking another opinion or giving the applicant more time to collect the necessary information, the Commission infringed the principle of proportionality.

137 The Commission disputes the applicant's arguments and maintains that this part of the plea should be rejected.

— Findings of the Court

138 According to settled case-law, the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (Case 137/85 *Maizena and Others* [1987] ECR 4587, paragraph 15; *Pfizer Animal Health* v *Council*, paragraph 116 above, paragraph 411; and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 223).

139 None the less, in agricultural matters, judicial review of compliance with the principle of proportionality is special in so far as the Court of Justice and the Court of

First Instance recognise that the Community legislature has a discretionary power which corresponds to the political responsibilities given to it by Articles 34 EC to 37 EC (Case C-157/96 *National Farmers Union and Others* [1998] ECR I-2211, paragraph 61). Consequently, the legality of such a measure can be affected only if the measure is manifestly inappropriate in terms of the objective which the competent institution is seeking to pursue (Case C-189/01 *Jippes and Others* [2001] ECR I-5689, paragraph 82; *Pfizer Animal Health* v *Council*, paragraph 116 above, paragraph 412; and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraphs 177 to 180).

140 The applicant claims, in essence, that the Commission should not have rejected the PPR Panel's opinion and the applicant's comments of 22 June 2006, without considering other ways of resolving the conflict of opinions between experts, for example by seeking another opinion or giving the applicant more time to collect the necessary information.

141 In that regard, it must be stated that the argument that the Commission could have sought another opinion or extended the legislative deadlines has no basis in the applicable legal framework. At the time the Commission intervenes in the evaluation of an active substance, the EFSA has already, pursuant to Article 8(7) of Regulation No 451/2000, given an opinion on whether that substance can be expected to meet the safety requirements of Directive 91/414. At that stage of the procedure, neither Directive 91/414 nor Regulation No 451/2000 provides for the possibility of seeking another opinion. Furthermore, it was established, in paragraphs 129 to 133 above, that it is not possible to extend the legislative deadlines save in a case of force majeure and that the applicant has not adduced any evidence to show that it was in a situation of force majeure.

142 Accordingly, it must be held that the applicant has not established that the Commission had a choice between several appropriate measures, which required it to have recourse to the least onerous measure in accordance with the principle of proportionality.

143 In any event, it must be pointed out that the assertion that the Commission summarily rejected the PPR Panel's opinion and the applicant's comments is factually incorrect. It was established, in paragraphs 74 and 134 above respectively, that the wording of the PPR Panel's opinion was faithfully reproduced in the EFSA report and that the applicant's comments on that report were carefully examined. Consequently, the applicant's contention must be held to be unfounded.

144 The second part of the fourth plea cannot therefore be upheld and thus that plea must be rejected as unfounded.

The fifth plea, alleging infringement of the principle of the protection of legitimate expectations

Arguments of the parties

145 The applicant claims that the principle of the protection of legitimate expectations was infringed on two occasions. First, it received assurances that the new data which it submitted, in the context of the review of dichlorvos, would be studied and peer reviewed. Those assurances were from two bodies acting on behalf of or under the Commission's authority, the RMS and the EFSA. By failing to peer review the data submitted by the applicant, the Commission frustrated its legitimate expectations.

146 Secondly, the applicant submits that it was led to believe that there was no need to produce a long-term carcinogenicity study because the time-limits applicable to the review process did not permit this, and that the issue had been referred to the PPR Panel for a final conclusion. The fact that the PPR Panel issued an opinion which assuaged any concerns concerning carcinogenicity and genotoxicity reinforced the

applicant's legitimate expectations that the EFSA would produce a report consistent with that opinion.

147 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

148 According to settled case-law, the right to rely on the principle of the protection of legitimate expectations extends to any individual who is in a situation in which it is clear that the Community authorities have, by giving him precise assurances, led him to entertain legitimate expectations (Joined Cases C-37/02 and C-38/02 *Di Lenardo and Dilexport* [2004] ECR I-6911, paragraph 70, and Case T-203/96 *Embassy Limousines & Services* v *Parliament* [1998] ECR II-4239, paragraph 74; see also, to that effect, *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 153). Regardless of the form in which it is communicated, precise, unconditional and consistent information which comes from an authorised and reliable source constitutes such assurance (see, to that effect, Case C-82/98 P *Kögler* v *Court of Justice* [2000] ECR I-3855, paragraph 33). However, a person may not plead infringement of the principle unless he has been given precise assurances by the authorities (judgment of 24 November 2005 in Case C-506/03 *Germany* v *Commission*, not published in the ECR, paragraph 58, and Joined Cases C-182/03 and C-217/03 *Belgium and Forum 187* v *Commission* [2006] ECR I-5479, paragraph 147).

149 In that regard, first, as part of the procedure for evaluating an active substance for the purposes of its inclusion in Annex I to Directive 91/414, which is provided for in Article 8 of Regulation No 451/2000, the EFSA is to evaluate the harmful effects of the substance concerned and deliver a scientific opinion on that point to the Commission. That scientific opinion is drawn up on the basis of the DAR, as evaluated during a peer review by the Member States and, if necessary, by national experts. A meeting between the notifier or notifiers of the active substance in question and

the EFSA generally takes place before the peer review commences. It is then for the Commission, and if appropriate the Council, to adopt a definitive decision on the active substance concerned. In the light of the role thus conferred on the EFSA in the procedure for evaluating an active substance, it must be held that, contrary to what the Commission claims, both precise assurances made by the Commission and those made by EFSA in the course of the procedure for evaluating an active substance are capable of giving rise to a legitimate expectation on the part of the notifier.

150 Secondly, as regards the assurances allegedly received by the applicant that the new data which it submitted, in the course of the review of dichlorvos, would be studied and peer reviewed, it should be noted that the applicant does not specify which data was submitted but not evaluated. Under the first paragraph of Article 21 of the Statute of the Court of Justice, which applies to the procedure before the Court of First Instance pursuant to the first paragraph of Article 53 of that Statute, and under Article 44(1)(c) of the Rules of Procedure of the Court of First Instance, the application is required to contain, inter alia, a summary of the pleas in law on which it is based. It must accordingly specify the nature of the grounds on which the action is based and, in consequence, a mere abstract statement of the grounds does not satisfy the requirements of the Statute of the Court of Justice or the Rules of Procedure of the Court of First Instance (*Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 120). Therefore, in view of the fact that the applicant's claim regarding the data allegedly submitted but not evaluated is not sufficiently specific, that head of claim must be rejected as inadmissible.

151 Thirdly, as regards the argument that the applicant was led to believe that there was no need to produce a long-term carcinogenicity study in respect of dichlorvos because (i) the time-limits applicable to the review process did not permit this, (ii) the issue had been referred to the PPR Panel for a final conclusion and (iii) the PPR Panel had issued an opinion which assuaged any concerns concerning the carcinogenicity and genotoxicity of dichlorvos, the fact remains that the applicant does not claim to have received precise assurances that there was no need to produce such a study. It merely claims that it deduced from certain facts that it did not have to submit a long-term study. It follows that, in the absence of precise assurances given by the EFSA or the Commission in that regard, it cannot be claimed that there has been infringement of the principle of the protection of legitimate expectations.

152 In the light of the foregoing, the fifth plea must be rejected.

The sixth plea, alleging infringement of the principle of sound administration and of the duty of excellence and independence of scientific opinions

Arguments of the parties

153 The applicant submits that the Commission infringed the principle of sound administration, as laid down by Article 211 EC, in not basing the contested decision, first, on independent scientific advice, secondly, on conclusive evidence, thirdly, on a timely scientific review, and fourthly, on a diligent and careful evaluation of all the data, and in not warning the applicant that the quality of its dossier was inadequate.

154 First, according to the applicant, the EFSA report and the contested decision do not meet the requirement of independence. In fact, as is apparent from that report, which mentions that 'it was agreed at the meeting with Member States' representatives in April 2006 that the risk assessment is still inconclusive', and from recital 4 of the contested decision, when the EFSA adopted its report it made its own expert opinion on the carcinogenicity and genotoxicity of dichlorvos subject to assessment and discussion by the Member States' representatives on 5 April 2006. It is the involvement of the Member States' representatives in the adoption of the EFSA's scientific opinion, as required by Article 8(7) of Regulation No 451/000, which undermines the independence of that opinion.

155 Secondly, the applicant observes that the national experts merely stated that the data on carcinogenicity and genotoxicity were inconclusive, that a new long-term study was not appropriate at that stage and that it was for the PPR Panel to reach a final

conclusion on this point. According to the applicant, the experts in fact took the view that a new long-term study was inappropriate in the light of the expiry of the overall administrative time-limits. However, it is apparent from the judgment in *IQV*, paragraph 93 above, that the need to respect strict time-limits cannot prevail over the requirement to conduct a comprehensive and state-of-the-art risk assessment. Moreover, if the data were inconclusive and only the PPR Panel was able to reach a conclusion on this point, it is unclear why the experts did not follow the PPR Panel's opinion. Accordingly, by disregarding the PPR Panel's opinion, the Commission made a manifest error of assessment and infringed its obligation of sound administration.

156 Thirdly, according to the applicant, the Commission failed in the present case to respect the time-limits laid down by Directive 91/414 and its Annexes for the evaluation of plant protection products, as the EFSA submitted its report to the Commission after the time-limit laid down in Regulation No 451/2000.

157 Fourthly, the applicant submits that the Commission also infringed its obligation of sound administration, and its obligation to examine each case diligently and impartially, by not submitting to the Member States and the EFSA the comments lodged by the applicant on 22 June 2006, although according to case-law it was obliged to submit studies or data relevant to the evaluation of dichlorvos to the same review as all of the studies relied on during the assessment process.

158 Fifthly, the applicant submits, in the reply, that if the Commission considered that the dossier was of such poor quality that it was impossible to undertake a risk assessment, it was obliged, pursuant to the principle of sound administration, to warn it of that in the period between the submission of its dossier, in April 2002, and the publication of the contested decision in June 2007.

159 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

160 First, as regards the applicant's head of claim alleging that the contested decision is not based on independent scientific advice, it must be pointed out that the line of argument which the applicant develops in this plea is identical to that developed in the second plea. That line of argument has been held to be unfounded. This head of claim must therefore be rejected.

161 Secondly, as regards the applicant's head of claim alleging that the contested decision is not based on conclusive evidence, it must be pointed out that the applicant claims, in essence, that the application of strict time-limits cannot prevail over the requirement to conduct a comprehensive and state-of-the-art risk assessment and that the Commission made a manifest error of assessment by disregarding the PPR Panel's opinion. It should be noted that, in essence, that line of argument is identical to that developed in the first part of the fourth plea and the second part of the first plea respectively. That line of argument has been held to be unfounded. This head of claim must therefore be rejected.

162 Thirdly, as regards the applicant's head of claim alleging that the contested decision is not based on a timely scientific review, it must be noted that that line of argument is identical to that developed in the first part of the first plea. That line of argument has been held to be unfounded. This head of claim must therefore be rejected.

163 Fourthly, as regards the applicant's head of claim alleging that the contested decision is not based on a diligent and careful evaluation of all the data, it must be pointed out that the applicant bases its head of claim on the fact that the Commission did not communicate to the Member States and the EFSA the comments it had submitted on 22 June 2006. That line of argument is identical, in essence, to that developed in the third part of the first plea. That line of argument has been held to be unfounded. This head of claim must therefore also be rejected.

164 Fifthly, as regards the applicant's head of claim alleging that the Commission was obliged, pursuant to the principle of sound administration, to warn it of the poor quality of its dossier in the period between the submission thereof, in April 2002, and the date of publication of the contested decision, it has already been pointed out, in paragraph 58 above, that the DAR, the addendum to it and the EFSA report, which were sent to the applicant in the period 2004 to 2006, showed that the dossier, as notified by the applicant, did not contain all the particulars necessary to permit the EFSA to carry out a satisfactory evaluation of the harmful effects of dichlorvos. Furthermore, it is apparent from the material in the dossier that the applicant was informed of gaps in its dossier in 2003, even before the DAR had been finalised. Consequently, the applicant cannot claim that it was not warned about the poor quality of its dossier.

165 In the light of the foregoing, the sixth plea must be rejected as unfounded.

The seventh plea, alleging infringement of the principle of equal treatment

Arguments of the parties

166 The applicant submits that active substances, which are subject to risk assessment in the context of the transitional work programme carried out by the Commission under Article 8(2) of Directive 91/414, are in an identical situation. It observes that several substances like maneb, mancozeb and oxamyl have been included in Annex I to Directive 91/414 although they showed risks of toxicity on the basis of the data provided, on the condition however that the substances in question were subject to further tests in accordance with Article 6(1) of Directive 91/414.

167 Therefore, the contested decision infringes the 'principle of non-discrimination', as there is no reason which objectively justifies the distinction made, for the purposes of the application of Article 6(1) of Directive 91/414, between oxamyl, mancozeb and maneb, on the one hand, and dichlorvos, on the other.

168 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

169 The principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way, unless such treatment is objectively justified (Case T-38/02 *Groupe Danone* v *Commission* [2005] ECR II-4407, paragraph 453, and *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 236).

170 In the present case, the applicant considers dichlorvos to be comparable to the active substances covered by Commission Directive 2005/72/EC of 21 October 2005 amending Directive 91/414 to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ 2005 L 279, p. 63), Commission Directive 2006/16/EC of 7 February 2006 amending Directive 91/414 to include oxamyl as active substance (OJ 2006 L 36, p. 37) and Commission Directive 2007/25/EC of 23 April 2007 amending Directive 91/414 to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances (OJ 2007 L 106, p. 34). In those directives, the Commission agreed to include the active substances in question in Annex I to Directive 91/414 subject to further studies being carried out.

171 The Court points out that it is apparent from recital 5 in the preamble to Directive 2005/72, recital 4 in the preamble to Directive 2006/16 and recital 4 in the preamble to Directive 2007/25 that the Commission found that it had appeared from the various examinations made, that plant protection products containing the active substances covered by those directives could be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414. It therefore included those active substances in Annex I to that directive, on the condition, however, that further testing would be carried out for confirmation of the risk assessment on certain points.

172 By contrast, with regard to dichlorvos, the Commission did not find that the plant protection products containing that active substance satisfied the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414. On the contrary, it stated, in recital 6 of the contested decision, that 'assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings [had] not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing dichlorvos satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414'.

173 Since the evaluation of dichlorvos, on the one hand, and the active substances covered by Directives 2005/72, 2006/16 and 2007/25, on the other hand, culminated in different outcomes, the Commission could treat dichlorvos differently and could therefore decide, without infringing the principle of equal treatment, not to include that active substance in Annex I to Directive 91/414.

174 Accordingly, the seventh plea must be rejected as unfounded.

The eighth plea, alleging infringement of Article 95 EC, of Article 4(1) and of Article 5(1) of Directive 91/414

Arguments of the parties

175 The applicant submits that the Commission did not adopt the contested decision in the light of the scientific and technical knowledge available as at 6 June 2007, the date of adoption of that decision. It therefore infringed Article 95 EC and Articles 4(1) and 5(1) of Directive 91/414.

176 In that respect, the applicant states that Article 95(3) EC provides that, when adopting measures to protect public heath and the environment, the Community institutions are required to take into account all available scientific evidence. Moreover, Article 5 of Directive 91/414 does not give the Commission the discretion to derogate from the obligation to adopt relevant decisions in the light of current scientific and technical knowledge. That point of view is supported by the case-law of the Court of Justice and the Court of First Instance. Finally, Article 4 of Directive 91/414 contains a reference to the need for Member States to adopt relevant decisions concerning active substances in the light of scientific and technical knowledge.

177 The applicant observes, first, that the Commission did not review all of the data available to it. The applicant submitted several studies to the Commission, in August 2005, in which it evaluated (i) operator exposure levels of dichlorvos, (ii) the risk to bystanders, (iii) the physical and chemical properties of dichlorvos and (iv) the analytical method in water. Moreover, in March 2006 it also submitted the requested study concerning the analytical method in air. Those studies were never assessed, despite an explicit assurance that they would be. The applicant observes, secondly, that the Commission did not allow it to submit more conclusive data as it took the view that the time-limit to do so had lapsed.

178 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

— The head of claim alleging infringement of Article 5(1) of Directive 91/414

179 Article 5(1)(b) of Directive 91/414 provides that, for a substance to be included in Annex I to that directive, it must be expected, in the light of current scientific and technical knowledge, that the use of plant protection products containing the active substance in question, consequent on application consistent with good plant protection practice, does not have any harmful effects on human or animal health and that it does not have any unacceptable influence on the environment as provided for in Article 4(1)(b)(iv) and (v) of that directive.

180 It follows from that provision, interpreted in combination with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justifies, in principle, the refusal to include that substance in Annex I to Directive 91/414. The precautionary principle is designed to prevent potential risks (Case T-229/04 *Sweden* v *Commission* [2007] ECR II-2437, paragraph 161).

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

safety of that active substance. Such an interpretation would run counter to the objective of a high level of protection of the environment and of human and animal health which underlies Article 5(1) of Directive 91/414, in that it would be tantamount to granting to the notifier — on whom the burden of proof lies as regards the safety of the active substance and who has a better knowledge of that substance — a right of veto over a decision not to include the substance in Annex I to Directive 91/414 (*Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 93).

182 Moreover, such an interpretation of that provision is particularly inconceivable having regard to the fact that, as stated in recital 10 of the contested decision, it is possible to (re)notify the active substance on the basis of Article 6(2) of Directive 91/414, with a view to its inclusion in Annex I to that directive (see, to that effect, *Bayer CropScience and Others* v *Commission*, paragraph 92 above, paragraph 94).

183 Furthermore, as has already been stated in paragraph 130 above, there are specific legislative provisions regarding the periods which notifiers must comply with in submitting studies and data under the general procedure for the evaluation of active substances in Directive 91/414, in particular in Article 8(5) of Regulation No 451/2000. Since the applicant does not claim to have submitted the further data requested by the EFSA, in agreement with the RMS, at the evaluation meeting of 9 February 2005, it must be held that the studies which were not taken into account by the Commission were not submitted in accordance with that article.

184 Although, as the applicant points out, Article 8(5) of Regulation No 451/2000 does not give the Commission the authority to derogate from the obligation to adopt decisions under Directive 91/414 in the light of current scientific and technical knowledge, that provision must be interpreted in accordance with the spirit and the purpose of Article 5 of Directive 91/414, for which it sets out practical detailed rules of application.

185 It has already been pointed out, in paragraph 133 above, that a deferral of the deadline for the evaluation of an active substance — and, as the case may be, for the submission of new data — must be granted only if, first, it is not impossible to derogate from the procedural time-limits laid down in the rules in question, and, secondly, if the parties who notified the active substance were in a situation of force majeure which prevented them from complying with the procedural time-limits. Besides the situation, referred to in paragraph 133 above, in which the impossibility of complying with those time-limits is attributable to contradictory behaviour on the part of the competent authorities, such a situation is conceivable where current scientific and technical knowledge has changed, unforeseeably, since the dossier was notified to the RMS.

186 In the present case, the fact remains that the applicant has not adduced any evidence to show that it was in a situation of force majeure which prevented it from complying with the time-limits. In particular, it has not been shown that there has been any new development in the scientific and technical knowledge relating to dichlorvos, since the dossier was notified to the RMS, of such a kind as to call in question the reliability of the information contained in that dossier.

187 Accordingly, the head of claim alleging infringement of Article 5(1) of Directive 91/414 must be rejected.

— The head of claim alleging infringement of Article 95(3) EC

188 Article 95(3) EC provides that, in its proposals to the Council for measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market and which concern health, safety, environmental protection and consumer protection, the Commission is to take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Article 152(1) EC states that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.

189 Furthermore, it should be noted that the applicant maintains, in its written pleadings, that Article 5 of Directive 91/414 substantiates and reflects those provisions of the EC Treaty. Clearly, therefore, the line of argument which the applicant develops as regards Article 95(3) EC is indissociable from that developed in support of Article 5 of Directive 91/414. That line of argument has been held to be unfounded. The head of claim alleging infringement of Article 95(3) EC must therefore also be rejected without there being any need to rule on the question whether Article 95(3) EC is applicable, which is disputed by the Commission.

— The head of claim alleging infringement of Article 4(1) of Directive 91/414

190 Article 4(1) of Directive 91/414 provides that Member States are to ensure that a plant protection product is not authorised unless it has been established, in the light of current scientific and technical knowledge, that it is harmless. In so far as that article, which relates to the granting by the Member States of authorisations of plant protection products ('APPPs'), is drafted in terms which are, in essence, similar to those of Article 5(1) of Directive 91/414, those articles must be interpreted in the same way.

191 Therefore, irrespective of the fact that that article is addressed to the Member States and not to the Commission, it must be held that, as with the head of claim alleging infringement of Article 95(3) EC, the line of argument relating to the infringement of Article 4(1) of Directive 91/414 is indissociable from that relating to Article 5(1) of that directive. That line of argument has been held to be unfounded. The head of claim alleging infringement of Article 4(1) of Directive 91/414 must therefore be rejected.

192 It follows from the foregoing that the applicant's argument alleging that the Commission is under an obligation to take account of 'current scientific and technical knowledge' cannot be upheld. The eighth plea must therefore be rejected in its entirety as unfounded.

The ninth plea, alleging infringement of the principle of subsidiarity and of Article 5 EC

Arguments of the parties

193 The applicant submits that if the Commission decides to ban an active substance without examining whether that decision could be better taken at the Member State level, it infringes the principle of subsidiarity on which, on its own admission, Directive 91/414 is based.

194 In fact, according to the applicant, the Commission's practice is to examine whether an active substance can be included in Annex I to Directive 91/414, subject to the condition that additional or confirmatory data is submitted to the Member State's authorities when holders of APPPs attempt to justify keeping their APPPs. This practice in effect gives the Member State from which an APPP is requested the task of carrying out the ultimate scientific evaluation of the active substance contained in a plant protection product. Member States therefore decide whether the data submitted at national level are sufficient to allay any concerns. This is a logical aspect of the system given that evaluation of an active substance based on objective risk assessment criteria cannot, for example, take into full consideration the variations in the geographical and agricultural conditions specific to each Member State.

195 Although the Commission was legally obliged to consider the extent to which it was better placed than the Member States to deal with the issues of concern which, according to the contested decision, continued to exist, it failed to reflect in this manner.

196 The Commission disputes the applicant's arguments and maintains that this plea should be rejected.

Findings of the Court

197 The Court observes that the principle of subsidiarity is set out in the second paragraph of Article 5 EC, which states that, 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 at Community level.

198 Furthermore, the Court notes that the contested decision was adopted in accordance with the procedures set out in Directive 91/414 and in Regulation No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of that directive. However, the applicant does not claim that that directive and that regulation are unlawful in the light of the principle of subsidiarity.

199 In that regard, it should be noted that Directive 91/414 divides the responsibilities between the Community and the Member States on the basis of the objectives of the proposed action. Thus, under Articles 3 and 4 of Directive 91/414, the authorisation of plant protection products is the responsibility of the Member States. However, under Article 4(1) of that directive Member States may not, as a rule, authorise a plant protection product unless its active substances are listed in Annex I. Furthermore, it is apparent from Article 8(8) of Regulation No 451/2000 that only the Commission or, as the case may be, only the Council has the competence to decide whether an active substance covered by the second stage of the work programme should be included in Annex I to Directive 91/414. That provision does not in any event permit Member States to take a final decision on whether the active substance in question complies with the conditions of Article 5(1) of Directive 91/414.

200 Since the legal framework governing the adoption of the contested decision did not provide, in that regard, for intervention on the part of the Member States, it cannot be complained that the Commission infringed the principle of subsidiarity.

201 Consequently, the ninth plea must be rejected as ineffective.

202 It follows from all of the foregoing that the action must be rejected in its entirety.

Costs

203 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 and the Commission has applied for costs, the applicant must be ordered to bear its own costs and to pay those of the Commission.

On those grounds,

THE COURT OF FIRST INSTANCE (Second Chamber)

hereby:

1. Dismisses the action;

2. Orders Denka International BV to bear its own costs and to pay those of the Commission of the European Communities.

Pelikánová Jürimäe Soldevila Fragoso

Delivered in open court in Luxembourg on 19 November 2009.

[Signatures]

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