JUDGMENT OF THE COURT OF FIRST INSTANCE (Eighth Chamber)

3 September 2009 *

In Case T-326/07,

Cheminova A/S, established in Harboøre (Denmark),

Cheminova Agro Italia Srl, established in Rome (Italy),

Cheminova Bulgaria EOOD, established in Sofia (Bulgaria),

Agrodan, SA, established in Madrid (Spain),

Lodi SAS, established in Grand-Fougeray (France),

represented by C. Mereu and K. Van Maldegem, lawyers, and P. Sellar, Solicitor,

applicants,

* Language of the case: English.

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

defendant,

APPLICATION for the annulment of Commission Decision 2007/389/EC of 6 June 2007 concerning the non-inclusion of malathion in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ 2007 L 146, p. 19),

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

composed of E. Martins Ribeiro (Rapporteur), President, S. Papasavvas and A. Dittrich, Judges,

Registrar: K. Pocheć, Administrator,

having regard to the written procedure and further to the hearing on 15 January 2009,

gives the following

Judgment

Legal context

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 on authorisation and withdrawal of authorisation for the placing of plant protection products on the market.

2 Article 2(1) of Directive 91/414 defines plant protection products as active substances and preparations containing one or more active substances, which are, among other things, intended to protect plants or plant products against all harmful organisms or prevent the action of such organisms. Article 2(4) of Directive 91/414 defines active substances as substances or micro-organisms, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

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

‘Member States shall ensure that a plant protection product is not authorised unless:

(a) its active substances are listed in Annex I [to Directive 91/414] and any conditions laid down therein are fulfilled …;

(b) it is established, in the light of current scientific and technical knowledge, directly or indirectly … [that] (iv) it has no harmful effect on human or animal health, … [and that] (v) it has no unacceptable influence on the environment …'

4 Under the terms of Article 5(1) of Directive 91/414:

'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).'

5 Active substances which are not included in Annex I to Directive 91/414 may, under certain conditions, benefit from a system of transitional derogation. Under Article 8(2) of Directive 91/414, a Member State could, during a period of 12 years following the notification of that directive, authorise the placing on its national 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 that notification, that is to say on 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 Directive 91/414. The Member States were to ensure that the relevant authorisations would be granted, withdrawn or varied, as appropriate.

6 The Commission commenced a programme of work for the gradual examination of active substances, as part of which interested parties wishing to secure the inclusion of such substances in Annex I had to submit all requisite data to the Commission and the Member States within a specified period.

7 Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Directive 91/414 (OJ 1992 L 366, p. 10) set out the evaluation procedure for an initial series of substances with a view to their possible inclusion in Annex I to that directive.

8 Subsequently, by 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), the Commission provided for the evaluation of a second and a third series of active substances with a view to their possible inclusion in Annex I to that directive.

9 The active substances in the second series include malathion — to which the present proceedings relate — an antiparasitic product used principally in agriculture against various insects on a vast range of agricultural and horticultural products and against mosquitoes, flies and household insects.

10 The procedure established by Regulation No 451/2000 begins with a notification of interest, provided for in Article 4(1) thereof, which had to be sent by the producer wishing to secure the substance's inclusion in Annex I to Directive 91/414, by 31 August 2000 at the latest to the rapporteur Member State ('the RMS') designated in Annex I to the regulation, that is to say the Republic of Finland for malathion.

11 By virtue of 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 that regulation.

12 The time-limit for the submission of those dossiers and for the submission 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).

13 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.

14 Under Article 8(1) of Regulation No 451/2000 as originally drafted, the RMS had to submit to the Commission as quickly as possible, and at the latest 12 months after the dossier had been considered to be complete, a report on its evaluation of the dossier, containing a recommendation to include, or not to include, the active substance in Annex I to Directive 91/414.

15 Article 8 of Regulation No 451/2000 was amended by Article 20 of 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), by according a role to the European Food Safety Authority ('EFSA').

16 Thus, the RMS — whilst recommending that the Commission should, or should not, include the active substance in Annex I to Directive 91/414 — is required, under Article 8(1) of Regulation No 451/2000, as amended, to send a draft assessment report ('DAR') on the dossier to EFSA 'as quickly as possible, and at the latest 12 months after the dossier was determined to be complete'. At that stage of the procedure, Article 8(2) of Regulation No 451/2000, as amended, provides that 'submission of new studies shall not [in principle] be accepted [but the RMS] may request the notifiers to submit further data which are necessary to clarify the dossier [and it] shall set a time-limit within which the information should be provided'.

17 Under the first subparagraph of Article 8(5) of Regulation No 451/2000, as amended, 'EFSA shall circulate the [RMS's DAR] to the Member States and may organise a consultation of experts including [the RMS]'. At that stage of the procedure, as 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 [EFSA], may request the

notifiers to submit within specified periods further data considered by the [RMS] or the [EFSA] necessary to clarify the dossier.'

18 Under Article 8(7) of Regulation No 451/2000, as amended,'… EFSA shall evaluate the rapporteur's [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 [RMS's DAR]'. Under the same provision,'[w]here appropriate, the EFSA shall give its opinion on the available options claimed to meet the safety requirements'.

19 Article 8(8) of Regulation No 451/2000, as amended, provides that '[a]t the latest six months after receipt of the EFSA opinion', the Commission is to submit, as appropriate, a draft directive to include the active substance in Annex I to Directive 91/414 or a draft decision refusing inclusion of the active substance in Annex I to Directive 91/414 and requiring withdrawal by the Member States of the marketing authorisations of plant protection products containing that substance.

20 The final measure is to be adopted in accordance with the 'comitology' procedure prescribed by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) in conjunction with Article 19 of Directive 91/414 and Article 2(b) of Regulation No 1490/2002, that is to say following an opinion from the Standing Committee on the Food Chain and Animal Health.

21 Finally, the period of 12 years set by Article 8(2) of Directive 91/414 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 active substances which were being evaluated as part of the second stage provided for by Regulation No 451/2000.

Background to the dispute

22 The applicant Cheminova A/S is a Danish company which was founded in 1938 and is engaged principally in the manufacture and sale of plant protection products. It sells to the market in two ways: either it sells its products directly to customers on the Community market using its own national authorisations or it chooses to sell via subsidiaries — such as Cheminova Agro Italia Srl, Cheminova Bulgaria EOOD and Agrodan, SA, which are also applicants in the present case — or customers. In the latter case, the subsidiaries and customers may also hold national authorisations.

23 The applicant Lodi SAS is a French company which specialises in the manufacture and sale of insecticides. It holds marketing authorisations in France for a number of malathion-based products.

24 On 24 August 2000, Cheminova notified the Commission of its wish to secure the inclusion of malathion in Annex I to Directive 91/414. The Commission accepted the notification and listed Cheminova among the 'notifying producers'.

25 On 25 April 2002, Cheminova submitted its summary and complete dossiers (together 'the dossier notified') requesting an evaluation of the use of malathion for four types of crop: apples, strawberries, alfalfa (a fodder plant used for animal feed) and ornamentals (greenhouse plants). On 28 October 2002, the RMS informed the Commission that the dossier submitted by Cheminova was complete.

26 The RMS carried out an evaluation of malathion and submitted its DAR to EFSA on 2 February 2004. In the DAR, the RMS recommended inclusion of malathion in Annex I to Directive 91/414, limiting its use to ornamentals in greenhouses.

27 On 15 April 2004, a copy of the DAR was sent to Cheminova by EFSA.

28 On 14 June 2004, Cheminova received an e-mail from a representative of EFSA's Pesticides Peer Review Co-Ordination Group, ('EPCO') stating that 'if [it] like[d] to have new information considered, [it] first ha[d] to ask the RMS for acception [sic] of the new studies' and that '[i]f the RMS accept[ed] the new studies they [(sic) would] prepare an addendum which [would] be discussed in due course'.

29 On 15 January 2005, the RMS submitted an addendum to the DAR to EFSA.

30 During the peer review carried out by EFSA, two concerns in particular were noted, namely one linked to the presence of isomalathion in malathion and the other related to the effects of certain toxicologically relevant metabolites.

31 Isomalathion is an impurity found in malathion. When a chemical compound is produced in a factory, it always contains a small proportion of other substances or impurities. The genotoxicity of isomalathion concerns the risk that it causes heritable genetic damage in humans exposed to it. The term 'mutagenic' covers the same concepts as the term 'genotoxic'.

32 A metabolite is a chemical compound which occurs when a first chemical compound is modified by processes that take place in the environment and by the metabolism of living organisms. For example, if malathion is used on crops, it will enter the human food chain either indirectly (via the feed eaten by livestock or from drinking water) or directly via food consumed by a person. In addition, the plant itself will create various chemical degradation products from malathion, to which the human being or animals will also be exposed.

33 It is apparent from the report of the EPCO expert meeting of 21 February 2005 ('EPCO 18') that the issue of the genotoxicity of isomalathion was raised at that meeting and that a data gap was identified in respect of it.

34 The desmethyl malathion metabolite issue was raised at the EPCO expert meeting of 23 February 2005 ('EPCO 19'). At point 3.3 of the relevant report, it is stated that 'desmethyl malathion cannot be considered as less toxic than malathion' and that 'the meeting decided to include desmethyl malathion in residue definitions for risk assessment'. In addition, it was decided that there was a 'new data gap' and that 'the notifier ha[d] to present data … concerning the levels of desmethyl malathion on [basic agricultural products] and processed products, unless it [could] be proven that desmethyl malathion is not of toxicological relevance' and that 'the notifier [had to] present data addressing the toxicological properties of desmethyl malathion'.

35 On 3 March 2005, a representative of the RMS sent an e-mail to Cheminova stating:

'I wonder whether you have any information available on desmethyl malathion levels in various commodities, because by this we could at least estimate its dietary intake levels.'

36 As regards the issue of the genotoxicity of isomalathion, an e-mail of 11 March 2005 from a representative of the RMS to Cheminova states that:

'… In case the specification with 0.2% isomalathion is accepted (which will be the case as far as I have the most current information from EFSA), a new Ames test with malathion containing the max[imum] content of all impurities is required. If the result of the Ames test is positive, an *in vivo* gene mutation test will be required. At the moment, according to EFSA, no further studies can not [sic] be accepted. Hence, the study requirements are listed as a data gap. …'

37 On 24 June 2005, Cheminova sent a protocol regarding a new Ames test to the RMS. On 5 August 2005, it forwarded to the RMS the new Ames test study and its results. The conclusion of the study states that '[t]he test material was considered to be non-mutagenic under the conditions of this test'.

38 On 7 October 2005, Cheminova sent the RMS a position paper 'to address the concerns about the metabolite desmethyl malathion'.

39 On 18 October 2005, the RMS sent an e-mail to Cheminova, confirming that the result of the new Ames test submitted in August 2005 was 'negative', that the study was 'acceptable' and that '[t]he assessment of the study [would] be sent to EFSA'.

40 On 26 October 2005, the RMS submitted a further addendum to the DAR indicating that 'malathion Technical was not mutagenic under the conditions of the [new Ames] test' and that the study was 'acceptable'.

41 By e-mail of 7 November 2005, Cheminova asked EFSA to ensure that the issue of isomalathion toxicity was reconsidered at Member State level, after the inclusion of malathion in Annex I to Directive 91/414. In that e-mail it also provided explanations concerning the toxicity of desmethyl malathion.

42 By e-mail of 24 November 2005, Cheminova sent the RMS a toxicity study on desmethyl malathion.

43 On 13 January 2006, EFSA submitted to the Commission its 'Conclusion regarding the peer review of the pesticide risk assessment of the active substance malathion' ('the EFSA report').

44 Regarding the genotoxicity risks, the EFSA report explains in paragraph 2.4:

'Malathion was tested in a number of *in vivo* and *in vitro* studies.

The chromosomal aberration test with human lymphocytes as well as a mouse lymphoma test (both studies are from 2001) gave positive results; the isomalathion content was 0.14%. An *in vitro* UDS test was negative (0.2% isomalathion). Although the Ames test was negative, a concern was raised on the quality since no information on the isomalathion content was provided.

Increased frequency of metaphases with chromosomal aberrations was observed in the absence of metabolic activation in a chromosome aberration test with human lymphocytes but the increased frequency was not seen later in a second test which was performed at lower concentrations. Both of the *in vivo* tests with assays of somatic cells were negative (isomalathion content was 0.2%).

It was considered by the experts that the positive results observed in the *in vitro* tests may be due to isomalathion and other impurities, as reported also in the open literature. However, the positive effects reported in the open literature were discussed during the meeting: all the available data support the conclusion that there is no genotoxic potential *in vivo*. No information on the genotoxic potential on isomalathion is provided in the DAR. For an isomalathion content of 0.03%, the experts agreed … that there was not a genotoxic potential. However, if the request on the 0.2% isomalathion content in the specification is maintained, the EPCO 20 meeting concluded that a new Ames test (with the isomalathion content of 0.2%) would be required or identified as a data gap. If this study would demonstrate a positive result it is not possible to set limit values and a secondary test, an UDS test, would be required. A new Ames test with 0.2% isomalathion was submitted in August 2005 and assessed by the RMS, but not peer reviewed.'

45 In its section entitled 'Conclusion and Recommendations', the EFSA report states that 'a data requirement for further genotoxicity studies to be performed has to be fulfilled and a non-genotoxic potential demonstrated in order to be able to cover (from a toxicological point of view) the specification of 0.2% of isomalathion in the technical

material'. Consequently, according to the EFSA report, 'until isomalathion is proven non-genotoxic, the operator risk assessment (AOEL) cannot be regarded as conclusive'.

46 As regards metabolites, the EFSA report noted four components of that type which could be of toxicological relevance, namely malathion monocarboxylic acid ('MMCA'), malathion dicarboxylic acid ('MDCA'), desmethyl malathion and malaoxon. The EFSA report finds that no study was supplied by Cheminova regarding MMCA and MDCA. Similarly, the EFSA report states that '[n]o studies have been provided by the notifier on desmethyl malathion (DMM)'. However, EFSA notes, in that regard, that 'DMM has been identified in rat metabolism studies (in urine in low dose males) and [that] it was concluded by the experts that without experimental data DMM cannot be considered as less toxic than malathion'.

47 The EFSA report also indicates, with regard to residues, that:

'… Shortly before the second discussion of malathion in the evaluation meeting the applicant provided EFSA with a position paper, indicating that apparently further data and information have been generated and submitted to the RMS in October 2005. It is noted, that in that position paper the applicant also questions the results reported in a metabolism study formerly considered valid and indicates the reassessment of that study. However, due to the very late submission this data was neither assessed nor peer reviewed and its acceptability is unclear. Thus, it is not referred to in the conclusion on the section of residues …'

48 The EFSA report also states:

> 'Further information to address the toxicological relevance of malathion metabolites are [sic] required. With regard to consumer exposure, a number of data gaps have been identified in the expert meeting on residues … Since there is a lack of data sufficiently addressing the hazard and/or the consumer exposure with regard to residues resulting from malathion use on food/feed crops, the consumer risk assessment cannot be concluded.'

49 Finally, the EFSA report confirms:

> 'The acute and chronic dietary risk assessment for consumers cannot be concluded. A sound risk assessment is only possible upon receipt of data addressing the identified data gaps for desmethyl-malathion and malaoxon. Furthermore, the relevance of the metabolites MMCA and MDCA for consumer risk is currently unclear …'

50 By letter dated 6 February 2006, the Commission informed Cheminova of the 'possibility to comment' on the EFSA report. In that letter, the Commission emphasises that 'given the strict deadlines imposed by the legislation and the repartition [sic] of competences between EFSA and the Commission, it is not possible at this stage of the procedure to take account of new data or studies nor to accept modifications to the supported uses which would be different from those that have been the subject of the assessment'.

51 By letter of 17 March 2006, Cheminova replied to the Commission's letter of 6 February 2006. Cheminova responded, in its letter, to the Commission's concerns linked to the presence of isomalathion in malathion and to the effects of certain toxicologically relevant metabolites. It also asked the Commission 'still to consider our response to these new issues … as this [would] not substantially delay the review'. On 31 July 2006, Cheminova again sent the Commission observations setting out the questions raised in its letter of 17 March 2006.

52 By letter of 5 September 2006, the Commission acknowledged receipt of the observations which Cheminova had sent it on 31 July 2006. After stating that '[t]he conclusions provided by … EFSA … are the scientific basis for the final decision-making on each substance', it added that it '[was] verifying each substance on its own merits, taking into consideration the nature of any remaining concerns before a final decision [was] taken'.

53 On 28 September 2006, the Standing Committee on the Food Chain and Animal Health gave an opinion favourable to the non-inclusion of malathion in Annex I to Directive 91/414.

The contested decision

54 In accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, the Commission, on 6 June 2007, adopted Decision 2007/389/EC

concerning the non-inclusion of malathion in Annex I to Directive 91/414 and the withdrawal of authorisations for plant protection products containing that substance (OJ 2007 L 146, p. 19; 'the contested decision'), the operative part of which is as follows:

'Article 1

Malathion shall not be included as an active substance in Annex I to Directive 91/414 …

Article 2

Member States shall ensure that:

(a) authorisations for plant protection products containing malathion are withdrawn by 6 December 2007;

(b) no authorisations for plant protection products containing malathion are granted or renewed from the date of publication of this Decision.

Article 3

Any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414 …, shall be as short as possible and shall expire on 6 December 2008 at the latest.

Article 4

This Decision is addressed to the Member States.'

55 The non-inclusion of malathion as an active substance in Annex I to Directive 91/414 is accounted for in the contested decision as follows, in recitals 5 and 6:

'(5) During the evaluation of this active substance, a number of concerns have been identified. Due to the presence of varying levels in the technical material of isomalathion, which is an impurity that contributes significantly to the toxicity profile of malathion and the genotoxicity of which cannot be excluded, the risk to operators, workers and bystanders could not be concluded. Moreover, based on the available information it has not been demonstrated that the estimated exposure of consumers resulting from the acute and chronic intake of edible crops is acceptable, due to the insufficient information on the effects of certain toxicologically relevant metabolites. Consequently, it was not possible to conclude on the basis of the information available that malathion met the criteria for inclusion in Annex I to Directive 91/414 …

(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forwards by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing malathion satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414 …'

Procedure and forms of order sought by the parties

56 By application lodged at the Registry of the Court of First Instance on 30 August 2007, the applicants brought an action for the annulment of the contested decision.

57 By a separate document lodged at the Registry of the Court of First Instance on 5 September 2007, the applicants lodged an application, under Articles 242 EC and 243 EC, for suspension of the operation of the contested decision and the grant of all appropriate interim measures.

58 By order of 4 December 2007 in Case T-326/07 R *Cheminova and Others* v *Commission* [2007] ECR II-4877, the President of the Court of First Instance dismissed that application and reserved the costs. On 13 February 2008, the applicants brought an appeal against that order which the President of the Court of Justice dismissed by order of 24 March 2009 in Case C-60/08 P(R) *Cheminova and Others* v *Commission* not published in the ECR.

59 On hearing the report of the Judge-Rapporteur, the Court of First Instance (Eighth Chamber) decided to open the oral procedure and, by way of measures of organisation of procedure pursuant to Article 64 of its Rules of Procedure, requested the applicants to produce a certain document. The applicants did so within the prescribed time-limit.

60 The parties presented oral argument and answered the questions put to them by the Court at the hearing on 15 January 2009.

61 At the hearing, the parties lodged, at the Court's request, a complete version of the EFSA report. The Court also allowed the Commission to add a document to the Court file, namely an e-mail of 11 April 2005 from the RMS to Cheminova. The applicants did not object to that document being put on the Court file.

62 The applicants claim that the Court of First Instance should:

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

— order the annulment of the contested decision;

— order the Commission to pay the costs.

63 The Commission contends that the Court of First Instance should:

— dismiss the action as inadmissible or, alternatively, as unfounded;

— order the applicants to pay the costs.

Admissibility

Arguments of the parties

64 The applicants maintain that their action is admissible.

65 The Commission submits that Cheminova, as a notifier under Directive 91/414, is directly and individually concerned by the contested decision. However, the other applicants are not individually concerned. Merely being a seller or user of malathion is not sufficient to individualise them for the purposes of the fourth paragraph of Article 230 EC. The action is therefore, in the Commission's submission, inadmissible in part.

Findings of the Court

66 First of all, the contested decision is addressed to the Member States. However, as the Commission notes, Cheminova is to be regarded, for the purposes of the fourth paragraph of Article 230 EC, as being entitled to bring the proceedings. As Cheminova is a 'notifier' under Article 4(1) of Regulation No 451/2000 seeking the inclusion of the active substance 'malathion' in Annex I to Directive 91/414, the contested decision by which the Commission refused such inclusion is of direct and individual concern to Cheminova.

67 The action is therefore, to the extent that it was brought by Cheminova, admissible.

68 According to case-law which is well established, since one and the same application is involved, there is no need to consider whether the other applicants are entitled to bring proceedings (Case C-313/90 *CIRFS and Others* v *Commission* [1993] ECR I–1125, paragraph 31; Case T-374/00 *Verband der freien Rohrwerke and Others* v *Commission* [2003] ECR II-2275, paragraph 57; and Case T-282/06 *Sun Chemical Group and Others* v *Commission* [2007] ECR II-2149, paragraph 50).

69 For reasons of economy of procedure, it would therefore be inappropriate to consider separately the admissibility of the applications by Cheminova Agro Italia, Cheminova Bulgaria, Agrodan and Lodi.

Substance

70 In support of their action, the applicants raise an objection of illegality under Article 241 EC and 10 pleas in law setting out grounds of annulment. The objection alleges the illegality of Article 20 of Regulation No 1490/2002. The pleas in law for

annulment make the following allegations: first, the lack of an objective scientific basis for the contested decision; second, infringement of Article 95 EC and Articles 4(1) and 5(1) of Directive 91/414; third, breach of the principle of protection of legitimate expectations; fourth, breach of the principle of proportionality; fifth, infringement of Article 8(7) of Regulation No 451/2000; sixth, breach of the 'principle of non-discrimination'; seventh, breach of the principle of sound administration; eighth, breach of the rights of the defence; ninth, breach of the principle of subsidiarity and infringement of Article 5 EC; and, tenth, infringement of Article 13 of Directive 91/414.

The objection that Article 20 of Regulation No 1490/2002 is illegal

Arguments of the parties

71 The applicants state that Article 20 of Regulation No 1490/2002, adopted on 14 August 2002, substantially altered their rights and expectations by amending Article 8 of Regulation No 451/2000 so as to provide for mandatory involvement of EFSA in the evaluation of active substances covered by the second stage of the work programme (such as malathion) and by requiring EFSA to give an opinion as to the conformity of the active substance with the safety requirements of Directive 91/414 and as to whether that substance should be included in Annex I to that directive. They state in that regard that Cheminova had already notified malathion in August 2000 and forwarded its complete dossier to the RMS in April 2002.

72 Article 20 of Regulation No 1490/2002 should be declared illegal and inapplicable to the applicants since that provision was applied retroactively to the procedure for the assessment of malathion whilst it was ongoing. In that regard, the applicants emphasise that neither Directive 91/414 nor Regulation No 451/2000 nor Article 20 of Regulation No 1490/2002 provides any explanation as to why EFSA should retroactively become involved in ongoing assessments. Moreover, Cheminova's legitimate expectations were

infringed since it could not envisage the involvement of a separate body, such as EFSA, in the review process and likewise could not have envisaged belated peer review of the DAR.

73 In their reply, the applicants state that, contrary to the Commission's contention, Regulation No 1490/2002 added to the procedure for assessment of an active substance an additional peer review step, requiring the intervention of an entirely new body. They state in that regard that Regulation No 1490/2002 renders mandatory a peer review by a third party — EFSA — while peer review was merely discretionary under the provisions in force prior to the changes made by Regulation No 1490/2002. Furthermore, the peer review is now carried out by EFSA, a totally autonomous body, whereas, under the previous rules, it was undertaken by the Commission and Member States in a rather ad hoc fashion.

74 The Commission contends that the applicants' objection of illegality is unfounded.

Findings of the Court

75 It is important to note, first, that the provisions of Article 8 of Regulation No 451/2000 were amended by Article 20 of Regulation No 1490/2002. Whereas before the entry into force of Regulation No 1490/2002 active substances were to be evaluated by the RMS and the Commission, which, under the second subparagraph of Article 8(3) of Regulation No 451/2000,'[might] organise a consultation of experts from one or several Member States', Regulation No 1490/2002 accorded EFSA a role in the evaluation of active substances. Thus, under Article 8(1) of Regulation No 451/2000, as amended, the RMS is to send, in respect of active substances for which a dossier has been determined to be complete, the DAR to EFSA, which, in accordance with Article 8(7) of that

regulation, is to evaluate the DAR and deliver to the Commission its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414.

76 Regulation No 1490/2002 does not provide for any retroactive application of its provisions, particularly Article 20 thereof which is the subject of the present objection of illegality. In fact, under Article 21 thereof, that regulation entered into force on the seventh day following its publication in the *Official Journal of the European Communities*, namely 28 August 2002, and its provisions have been directly applicable from that date. Moreover, for the purposes of the present objection of illegality, the applicants do not challenge the legality of Article 20 of Regulation No 1490/2002 as such. In their submissions, they put in issue the allegedly illegal application of that provision to the existing malathion evaluation procedure. The applicants' objection of illegality cannot therefore succeed.

77 In so far as the present objection of illegality could be reclassified as a plea in law for annulment alleging illegal application of Article 20 of Regulation No 1490/2002 to the malathion evaluation procedure, it must admittedly be noted that at the time when Cheminova notified the Commission of its wish to secure the inclusion of malathion in Annex I to Directive 91/414, that is on 24 August 2000, there was no provision for EFSA to play any role under the applicable rules. However, when its dossier was determined by the RMS to be complete, that is on 28 October 2002, and when the RMS finalised the DAR which it sent to EFSA on 2 February 2004, the amended provisions of Article 8 of Regulation No 451/2000 were already applicable so that, under those provisions read in conjunction with Article 21 of Regulation No 1490/2002, the RMS was bound to send the DAR to EFSA so that EFSA could evaluate whether malathion complied with the safety requirements of Directive 91/414.

78 The applicants cannot claim that the immediate application of the amended provisions of Article 8 of Regulation No 451/2000 to existing active substance evaluation procedures was illegal.

79 Indeed, it follows from settled case-law that in contrast to substantive Community law, which must be interpreted as not applying, in principle, to situations existing before its entry into force, procedural rules are of direct 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* v *Commission* [2007] ECR II-4331, paragraph 116 and the case-law cited).

80 The provisions of Regulation No 1490/2002, providing for EFSA's involvement in active substance evaluation procedures, are procedural rules which, in accordance with the case-law cited in the preceding paragraph, are of direct application, without requiring any specific statement of reasons in that regard in Regulation No 1490/2002.

81 Finally, as regards the allegation of breach of the principle of protection of legitimate expectations, it must be noted that the right to rely on the principle of protection of legitimate expectations extends to any individual who is in a situation in which it is clear that the Community administration has, by giving him precise assurances, led him to entertain reasonable expectations (Joined Cases C-37/02 and C-38/02 *Di Lenardo and Dilexport* [2004] ECR I-6911, paragraph 70; Case T-203/96 *Embassy Limousines & Services* v *Parliament* [1998] ECR II-4239, paragraph 74; and the judgment of 15 November 2007 in Case T-71/06 *Enercon* v *OHIM (Wind turbine)*, not published in the ECR, paragraph 36; see also, to that effect, Case C-104/97 P *Atlanta* v *European Community* [1999] ECR I-6983, paragraph 52). Since the applicants do not even allege that they received precise assurances from the Community administration that the new procedural rules requiring EFSA's involvement would not be applied to the malathion evaluation procedure, that allegation cannot be upheld.

82 It follows from all the foregoing that even if the objection of illegality could be reclassified as a plea in law for annulment, it would still be rejected.

The first plea in law, alleging the lack of an objective scientific basis for the contested decision

Arguments of the parties

83 The applicants state that the contested decision is based on the following scientific conclusions: the genotoxicity of isomalathion cannot be excluded, and there is insufficient information on consumer exposure via crops regarding certain toxicologically relevant metabolites.

84 However, neither of those conclusions is supported with scientific evidence.

85 First, it is apparent both from an *in vivo* UDS study submitted by Cheminova in 2002 and from an Ames test in 2005 that any genotoxicity of isomalathion can be excluded (see paragraph 37 above). The contested decision is 'diametrically opposite' to the conclusions of the laboratory that conducted the Ames test and the RMS study which agreed with the findings of that laboratory. Indeed, by an e-mail sent to Cheminova on 18 October 2005, the RMS confirmed that the result was 'negative' and updated its DAR by an addendum of 26 October 2005, forwarded the same day to EFSA, in which it emphasised that the Ames test confirmed that malathion containing a concentration of isomalathion of up to 0.2% posed no genotoxic potential.

86 The applicants give the history of the Ames test carried out in 2005. It is apparent from the report of the EPCO expert meeting held on 21 February 2005 (EPCO 18) that the experts considered that '[a] new Ames test would be required if … EPCO 20 confirm[ed] that the realistic isomalathion concentration [was] 0.2% (or higher)' and that '[i]f it [were] positive it [would] not [be] possible to set limit values and a secondary test [would be] required, an UDS test'. They emphasise, however, that such a UDS test, conducted with test material containing isomalathion at a concentration of 0.2%, was in

fact available in the dossier notified demonstrating that there was no genotoxicity potential. The request for an Ames test was therefore an irrelevance.

87 A positive finding from the Ames study would — from a scientific point of view — only have triggered the need to generate an *in vivo* UDS study, which Cheminova had already submitted as part of the dossier notified and which had already been reviewed, as is borne out by the DAR and the EFSA report, both by the RMS and by EFSA. The results of that *in vivo* study were negative: in other words they confirmed the non-genotoxicity findings of the Ames study. That conclusion was also reached by EFSA in its report, where it stated that '[o]verall, malathion does not show genotoxic potential, *in vivo*'.

88 Second, with regard to metabolites, and in particular desmethyl malathion, the applicants state that two issues were raised as concerns by the RMS and/or EFSA after the finalisation of the DAR by the RMS and its submission to EFSA on 2 February 2004. The first issue was the potential presence of desmethyl malathion as a plant metabolite in food crops. Studies on apples were submitted to the RMS by Cheminova on 24 December 2004. Desmethyl malathion was identified as a metabolite in that study. However, the significance of that metabolite from the toxicological point of view cannot be finally concluded on the basis of that study. Moreover, that study was not formally required by the risk assessment procedure because Cheminova had submitted plant metabolism studies for four different crop types, which is considered sufficient to meet that particular data requirement.

89 The second issue concerns the potential transformation of malathion during industrial or household processing of treated crops. To address that concern, a simulated crop processing study was conducted and submitted to the RMS in June 2004, which was followed by an explanation in August 2004 (provided in reply to a question from the RMS in July 2004). A more detailed assessment was submitted by Cheminova to the RMS on 19 November 2004.

90 On the basis of those studies concerning those two issues, the RMS drafted an addendum to the DAR and on 15 January 2005 submitted it to EFSA for review during the EPCO expert meetings.

91 The applicants state that any possible risk of consumer exposure can be excluded for two uses for which malathion was notified, namely ornamentals and alfalfa. Ornamentals and alfalfa are not consumed by humans. The discussion of residue definition and consumer exposure is therefore not applicable for those uses.

92 Conceding in its defence that the concerns regarding metabolite toxicity 'would make it impossible to include malathion in Annex I for use on edible crops', the Commission admits that the concern regarding metabolites is not relevant for one of the four applications for which inclusion was sought by Cheminova — use in ornamentals applications, where there is no consumer exposure via edible crops. The applicants state in that regard that the RMS had recommended, in the DAR, inclusion of malathion specifically for that application.

93 The applicants submit that the Commission has not taken into account all the information and data submitted by Cheminova regarding metabolites, especially desmethyl malathion. In particular, no account has been taken of Cheminova's position paper submitted to the RMS on 7 October 2005 'to address the concerns about the metabolite desmethyl malathion', of the detailed explanations concerning the open data requirements submitted by Cheminova to EFSA on 7 November 2005, or studies intended to address the open points and data gaps identified by EPCO expert meeting 19 (EPCO 19), submitted to the RMS on 24 November 2005. The relevant studies and data submitted conclude as follows: first, desmethyl malathion is not a major metabolite in fruit (apples) and should therefore not, on that basis, be included in the residue definition of malathion; second, desmethyl malathion is not more toxic than malathion and should therefore not be included in the residue definition of malathion on the basis of alleged toxicological concerns.

94 By failing to take into account all the information, data and studies mentioned in paragraphs 85 to 93 above, the finding, in the recitals in the preamble to the contested decision, of insufficient information is both factually unsubstantiated and unsupported by reasons. Referring to paragraph 165 in the judgment in Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, the applicants conclude that in the absence of valid, objective, scientific support for the scientific conclusion that one cannot exclude the genotoxic potential of isomalathion and that malathion's metabolites may pose a risk of consumer exposure via crops, the contested decision must be annulled.

95 Third, in their reply, with regard to the alleged incompleteness of the dossier notified, the applicants state that the RMS itself declared the dossier to be complete. Under Article 7 of Regulation No 451/2000, such a declaration necessarily implies that the RMS considered that the dossier notified contained all the data required pursuant to Directive 91/414 to carry out the assessment of the active substance. In any event, as a result of that declaration, a legitimate expectation arose on the part of Cheminova that all the required data had been provided. The fact that the RMS subsequently initiated assessment of the dossier notified and finally recommended inclusion — without requesting additional data — provides further evidence that the dossier was considered to be complete. Finally, even if the dossier notified had been incomplete, a declaration to the contrary amounts to contradictory behaviour on the part of the Commission which justifies a deferral of deadlines for completing the dossier.

96 Fourth, with regard to the Commission's argument that no request was made to Cheminova for additional data and that the latter reacted spontaneously to the issues raised in the peer review, the applicants maintain that the production of new data relating to the genotoxicity of isomalathion and the toxicity of desmethyl malathion was the subject of a clear request. After noting the delays incurred by the RMS (more than three months) in submitting the DAR to EFSA, then by EFSA (about one year) for the assessment of the active substance, the applicants observe that EPCO, at its meeting of 21 February 2005, identified a data gap as regards the genotoxicity potential of isomalathion and expressly requested further data. The report of that meeting states: 'the data gap concerning the genotoxic potential of malathion and a request for a new

Ames test (with 0.2% content of isomalathion) to be performed [had been] confirmed'. That information was sent to Cheminova by the RMS on 13 June 2005.

97 Similarly, at its meeting of 23 February 2005, EPCO identified a data gap regarding desmethyl malathion. The report of that meeting states: 'The notifier ha[d] to present data addressing the toxicological properties of desmethyl malathion'. The RMS then sent an e-mail to Cheminova on 3 March 2005, stating that 'in order to be able to carry out consumer assessment, which takes desmethyl malathion into account, information [was] needed on various dietary items'.

98 As regards the isomalathion genotoxicity concern, the applicants sent a protocol for a test to the RMS on 24 June 2005. The applicants then carried out the test and submitted the results to the RMS on 5 August 2005. On 18 October 2005, the RMS confirmed to Cheminova that the result was 'negative', that the study was 'acceptable' and that '[t]he assessment of the study [would] be sent to EFSA'. The RMS then amended the DAR by way of addendum dated 26 October 2005, which stated that '[a]ccording to the decision of the EPCO 18, the notifier ha[d] to perform an Ames test'; that '[t]he notifier submitted a study in August 2005' and that 'Malathion Technical was not mutagenic under the conditions of [that] test'.

99 EFSA did not subject the new Ames test to peer review. The contested decision also failed to take account of the results of the new test.

100 With regard to desmethyl malathion, the applicants sent a test proposal to the RMS on 4 April 2005. They sent further papers in that regard to the RMS and EFSA in October and November 2005 respectively. On 24 November 2005, the applicants submitted a study to the RMS addressing the issues identified and showing that desmethyl malathion did not give cause for concern. Those studies were not reviewed by the RMS or by EFSA. The contested decision fails also to take account of their results.

101 In the applicants' submission, EFSA and the Commission should have taken account of the additional data provided by Cheminova since the RMS and EFSA considered such data to be necessary to respond to the two concerns raised.

102 The applicants also state in their reply that the EFSA report serves — as, moreover, the Commission accepts — as the scientific basis for the contested decision. However, in its defence the Commission raises a number of concerns that were not mentioned in the EFSA report. The Court must ignore the areas of concern not cited in that report. In any event, if the contested decision was based on reasons other than those set out in that decision, it lacks an adequate statement of reasons, in breach of Article 253 EC.

103 The Commission contends that the first plea in law should be rejected.

Findings of the Court

104 The EFSA report constitutes the scientific basis for the contested decision. The non-inclusion of malathion in Annex I to Directive 91/414 is based, in recitals 4 to 6 in the preamble to the contested decision, on EFSA's conclusions. That point, which is not contested by the applicants, is also confirmed by the Commission's letter of 5 September 2006 to Cheminova in which it stated that EFSA's conclusions 'are the scientific basis for the final decision-making on each substance'.

105 It is stated in recital 5 in the preamble to the contested decision that EFSA's conclusions revealed '[a] number of concerns' justifying the non-inclusion of malathion in Annex I to Directive 91/414. The Commission identifies them in the contested decision as follows. First, given 'the presence of varying levels in the technical material of isomalathion, which is an impurity that contributes significantly to the toxicity profile

of malathion and the genotoxicity of which cannot be excluded, the risk to operators, workers and bystanders could not', in the Commission's view, 'be concluded [from the presence of malathion]' (recital 5 in the preamble to the contested decision). Second, 'based on the available information it has not been demonstrated that the estimated exposure of consumers resulting from the acute and chronic intake of edible crops is acceptable, due to the insufficient information on the effects of certain toxicologically relevant metabolites' (also recital 5 in the preamble to the contested decision).

106 For the purposes of examining whether the concerns identified in the contested decision lack, as the applicants allege, a valid objective scientific basis, it must be noted that, as is clear from recitals 5, 6 and 9 in its preamble, Directive 91/414 seeks to remove barriers to intra-Community trade in plant products, while maintaining a high level of protection of the environment and of human and animal health. 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, paragraphs 74 and 75).

107 However, the exercise of that discretion is not excluded from judicial review. It is clear from settled case-law that, as part of such a review, the Community judicature must determine whether the relevant procedural rules have been complied with, whether the facts established by the Commission are correct and whether there has been a manifest error of appraisal of those facts or a misuse of powers (see *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 76 and the case-law cited).

108 It is in the light of that case-law that the Court must consider, in turn, the applicants' arguments as regards, first, the concern linked to the presence of isomalathion in malathion, then the effects of certain toxicologically relevant metabolites and, finally, the alleged incompleteness of the dossier notified and the allegedly defective statement of the reasons for the contested decision.

— The first concern, linked to the presence of isomalathion in malathion

1. The relevance of the applicants' arguments

109 It must be recalled that isomalathion is an impurity occurring in malathion. In essence, the applicants claim that it is clear from various scientific tests that isomalathion's genotoxicity can be excluded. Therefore the Commission made a manifest error of assessment in finding, in recital 5 in the preamble to the contested decision, that 'the genotoxicity of [isomalathion] cannot be excluded'.

110 However, the first concern identified in the contested decision does not relate solely to isomalathion's genotoxicity. In fact, recital 5 in the preamble to the contested decision states that the Commission associates two issues with the presence of isomalathion, namely the fact that, first, that 'impurity … contributes significantly to the toxicity profile of malathion' and, secondly, that '[its] genotoxicity … cannot be excluded'. Questioned at the hearing, both parties confirmed that reading of the content of the contested decision, as was formally noted in the record of the hearing.

111 As regards 'isomalathion's contribution' to the toxicity profile of malathion, that issue was clearly identified in the EFSA report, which constitutes the scientific basis for the contested decision. The EFSA report states that '[f]our impurities are regarded as relevant of which isomalathion is of a toxicological concern' and that '[o]ne of the major problems is related to the toxicological impact of isomalathion on the toxicological profile of malathion'. The EFSA report states also that 'malathion spiked with 2% of isomalathion is approximately 10-fold more toxic than pure malathion without any isomalathion'. The assessment of isomalathion's toxicological impact is complicated further by the fact that, as stated in the EFSA report, 'the amount of isomalathion even increases during storage both in relation to time and temperature by a factor of 2–10'.

112 As was already clear from the EPCO meeting of 21 February 2005, 'it [was] evident that the toxicity of technical material increases with the increase of isomalathion' and that '[m]ore information [was] needed on this issue'. Likewise, the addendum to the DAR produced by the RMS on 15 January 2005 confirmed that '[i]somalathion influence[d] the acute oral toxicity of malathion to a greater extent than expected from its proportional contribution' and that '[s]mall additions of isomalathion ha[d] been shown to increase the acute oral toxicity of malathion markedly'.

113 While, admittedly, isomalathion's contribution to malathion's toxicity was not one of the 'critical areas of concern' identified in the EFSA report, the fact remains that its report describes the impact of isomalathion on malathion's toxicological profile as a 'major problem' and includes it in the list of 'endpoints' annexed to the report.

114 In any event, as pointed out in paragraph 110 above, the Commission, in recital 5 in the preamble to the contested decision, based its refusal to include malathion in Annex I to Directive 91/414, by reference, particularly, to isomalathion's significant contribution to the toxicity profile of malathion.

115 In their application, the applicants do not put in issue the fact that isomalathion contributes significantly to the toxicity profile of malathion. As they accepted at the hearing, their submissions were confined to the denial of isomalathion's genotoxicity.

116 Since the applicants' argument relating to the first concern applies exclusively to the finding that isomalathion's genotoxicity cannot be excluded, that argument must be

held to be immaterial (see, to that effect, Case T-126/99 *Graphischer Maschinenbau* v *Commission* [2002] ECR II-2427, paragraphs 49 to 51, and Case T-210/01 *General Electric* v *Commission* [2005] ECR II-5575, paragraph 43). It relates to only one of the two scientific findings on which the first concern is based in the contested decision.

117 None the less, the Court considers that it is worth examining, for the sake of completeness, the applicants' arguments putting in issue the contested decision's legality in its conclusion that isomalathion's genotoxicity cannot be excluded.

2. Isomalathion's genotoxicity

118 It is appropriate to note that the specification limit on the impurity 'isomalathion' which was notified by Cheminova was 0.2% in the active substance 'malathion'. The applicants submit that the genotoxicity of malathion with an isomalathion level of 0.2% can be excluded by reference to an *in vivo* UDS study, which was included in the dossier notified, and to an Ames test, which was submitted to the RMS in August 2005.

(a) The alleged failure to take account of the *in vivo* UDS study

119 It is important to examine, first, whether the findings made in the EFSA report, which constitutes the scientific basis for the contested decision, allowed the Commission to conclude that isomalathion's genotoxicity cannot be excluded.

120 While, admittedly, the EFSA report states that, '[f]or an isomalathion content of 0.03%, the experts agreed … that there was not a genotoxic potential', it must be held, on the basis of that same report, that EFSA and the Commission could not conclude, on the basis only of the materials contained in the dossier notified, that there was no genotoxicity for a specification of 0.2% of isomalathion. The studies concerning

isomalathion's genotoxicity included in the dossier notified could not lead to any reliable conclusions for an isomalathion level of 0.2% since certain studies had been carried out with a different percentage of that impurity and others did not even identify the isomalathion level.

121 Thus, first, the EFSA report refers to two tests in 2001 on malathion with an isomalathion content of 0.14% which had given positive results. They were the Edwards 2001a and Edwards 2001b tests mentioned in the report of the EPCO meeting of 21 February 2005 (EPCO 18). Second, it is stated in the EFSA report that, even if the result of an Ames test in 1987 contained in the dossier notified was negative, there was no mention of the isomalathion content which had been taken into account for the purposes of that test.

122 Finally, the EFSA report includes the conclusion that 'further genotoxicity studies ha[d] to be provided and a non-genotoxic potential demonstrated in order to be able to cover the specification of 0.2% of isomalathion in the technical material', making clear that, 'until isomalathion is proven non-genotoxic, the operator risk assessment (AOEL) cannot be regarded as conclusive'.

123 Having regard to the fact that the various tests comprised in the dossier notified had been carried out on the basis of a specification of isomalathion other than that notified by Cheminova or on the basis of an unknown one, EFSA and the Commission could conclude, without making a manifest error of assessment, that isomalathion's genotoxicity could not be excluded.

124 The alleged failure to take account of the result of the *in vivo* UDS test mentioned in the list of 'endpoints' annexed to the EFSA report, and in the DAR cast no doubt on that conclusion.

125 Indeed, it is clear from the list of 'endpoints' in the EFSA report, and from the statements of the applicants' expert at the hearing, that the *in vivo* UDS test in question was performed on test substances the isomalathion content of which was 0.14%. Even if the result of that test was negative, in that it did not prove the genotoxicity of the substance, it cannot be inferred that EFSA or the Commission made a manifest error of assessment in finding that the genotoxicity of malathion with an isomalathion content of 0.2% could not be excluded.

126 The argument based on the alleged failure to take account of the result of the *in vivo* UDS test must therefore be rejected.

(b) The alleged failure to take account of the 2005 Ames test

127 In August 2005, Cheminova submitted a new Ames test to the RMS. The result of that test was negative in the sense that it established that there was no genotoxicity potential for a specification of isomalathion of 0.2%. However, before considering whether the result of that test shows that the conclusion drawn in the contested decision concerning isomalathion's genotoxicity is vitiated by manifest error, it must be determined whether EFSA or the Commission was under a duty to take account of the result of that test.

EFSA's and the Commission's obligation to take account of the result of the 2005 Ames test

128 In the first place, it must be examined whether Cheminova was entitled, in August 2005, to submit a new Ames test to the RMS when the evaluation of the active substance in question had already been brought before EFSA. Indeed, the RMS had submitted the DAR to EFSA on 2 February 2004.

129 In that regard, Article 8 of Regulation No 451/2000 lays down, twice, in its paragraphs 2 and 5, that 'new studies' are not, in principle, to be accepted, once the RMS or EFSA respectively has commenced the evaluation of the active substance. Even though, according to those provisions, the RMS may, if appropriate with EFSA's agreement when the DAR has already been sent to that authority, request the notifier to submit, within specified periods, further data considered by the RMS or EFSA necessary to clarify the dossier, those provisions make no such exception for the submission of new studies.

130 Since it is common ground between the parties that the 2005 Ames test was a new study, as was confirmed at the hearing, its submission during the malathion evaluation procedure was, under the previously cited provisions, too late.

131 Secondly, the applicants, citing *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, submit that the competent authorities cannot seek to enforce 'to the letter' deadlines that apply to Cheminova where they themselves fail to comply with the deadlines to which they are subject.

132 In that case, both Industrias Químicas del Vallés ('IQV') and Syngenta had requested the inclusion of the active substance concerned in Annex I to Directive 91/414. However, Syngenta alone had submitted a complete dossier to the RMS. After Syngenta had withdrawn the active substance concerned from the evaluation procedure, IQV received, first, indications from the RMS and the Commission that all the information available, including the studies contained in the dossier submitted by Syngenta, would be used for the purposes of evaluating the active substance and that the competent authorities would, if necessary, ask it to provide no more than clarification or additional data (*Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 79). When, subsequently, the Commission asked IQV to produce a complete dossier, the latter found itself, in the view of the Court of Justice, in an unforeseen and complicated situation, account being taken, in particular, of the time and effort needed to organise the required scientific studies (*Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 80). The Court found that that situation was due, at least in part, to the competent authorities' contradictory behaviour (*Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 84). In those circumstances, the Court held that the Commission had committed a

manifest error of appraisal in refusing to grant IQV a deferral of the deadline for production of the studies missing from its dossier and in deciding as a consequence not to include the active substance concerned in Annex I to Directive 91/414 on the sole ground that the appellant had failed to submit a complete dossier before that deadline (*Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 88).

133 It must therefore be determined whether, in this case, Cheminova found itself in an unforeseen and complicated situation due, at least in part, to the competent authorities' contradictory behaviour. The applicants refer to the requests made to Cheminova to submit the new Ames test. In those circumstances, the applicants submit that EFSA's and the Commission's failure to take account of the result of that test constitutes contradictory behaviour.

134 In that regard, first, Cheminova does not allege that it received assurances from the competent authorities that it could use the contents of a dossier submitted by another notifier for the purposes of the evaluation of malathion. Its situation therefore differs from that of IQV in its case.

135 Secondly, under Article 6(1) of Regulation No 451/2000, a producer wishing to secure a substance's inclusion in Annex I to Directive 91/414 must send to the RMS a 'complete dossier'. It was therefore incumbent on Cheminova to submit a complete dossier on malathion which would enable the RMS, EFSA and the Commission to evaluate the harmful effects of malathion for the purposes of Article 5(1) of Directive 91/414, and particularly the potential of isomalathion's genotoxicity at a level of 0.2% in the active substance concerned.

136 Cheminova, which included in the dossier notified studies concerning isomalathion's genotoxicity on a sample containing a level other than that required for the active substance notified or which did not even mention the percentage of isomalathion which the study covered, cannot be regarded as finding itself in an 'unforeseen and complicated situation' within the meaning of the judgment in *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 80, when, during the period of evaluation of the active substance concerned, the competent authorities established a data gap in respect of the genotoxicity potential of isomalathion.

137 Thirdly, as regards the competent authorities' allegedly contradictory behaviour in that they sent Cheminova requests for the submission of a new Ames test, Article 8 of Regulation No 451/2000 states, twice, in its paragraphs 2 and 5, that 'new studies' are not, in principle, to be accepted, after the notifier has submitted the dossier. Having regard to the clear wording of those provisions, any contradictory behaviour by the competent authorities after the submission of the dossier could not have put the notifier in an 'unforeseen and complicated situation' within the meaning of the judgment in *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, paragraph 80. As a notifier of the active substance, Cheminova should, in fact, have ensured that all the studies and data relevant for the purposes of malathion's evaluation were already in the dossier notified.

138 In those circumstances, the argument based on *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, cannot be accepted.

139 In the third place, it is necessary to point out that, in the context of the present plea in law, the applicants do not claim that the attitude of the RMS, EFSA or the Commission prevented Cheminova submitting the new Ames test during the malathion evaluation procedure. On the contrary, it is accepted that despite its late submission, the RMS assessed the Ames test which Cheminova had submitted in August 2005 and that that assessment was set out in an addendum to the DAR which was sent to EFSA on 26 October 2005. The EFSA report notes, also, in effect the existence of the new Ames

test of August 2005 and the assessment which the RMS made of it. However, the EFSA report notes that the new Ames test was not peer reviewed.

140 The applicants insist that EFSA should have submitted the new Ames test to peer review before giving its advice to the Commission. At the hearing, they explained that such a duty on EFSA arose from the circumstances of the case and, in particular, the various requests to Cheminova during the malathion evaluation procedure that it submit a new Ames test with an isomalathion specification of 0.2%.

141 On that point, it is appropriate to note that the peer review to which the applicants refer, as they made clear at the hearing, relates to the 'consultation of experts' provided for in Article 8(5) of Regulation No 451/2000, as amended. Even if a request was made by the competent authorities regarding the submission of a new Ames test, EFSA was under no obligation to submit that study — the submission of which was in any event late — to peer review under Article 8(5) of Regulation No 451/2001, as amended. That provision states that EFSA 'may organise a consultation of experts', without creating any obligation to that effect.

142 Having regard, first, to the late submission of the Ames test of August 2005 and, second, to the optional nature of the peer review under Article 8(5) of Regulation No 451/2000, as amended, the applicants' argument relating to the alleged failure to take account of the 2005 Ames test must be rejected.

The effect of the 2005 Ames test's result on the contested decision's legality

143 Even if EFSA should have submitted the 2005 Ames test to peer review and the Commission was obliged to take account of the results of that test in the contested decision, which was not the case, the Court none the less considers it worthwhile to examine whether, having regard to the materials in the Court file, and to the Court's limited scrutiny of complex technical evaluations (see paragraphs 106 and 107 above), the result of that test shows that the conclusions in the EFSA report and in the contested decision are obviously wrong or lack a scientific basis.

144 In that regard, the fact that the result of the Ames test of August 2005 was as the applicants wanted does not show, beyond any reasonable doubt, that isomalathion's genotoxicity could be excluded.

145 First, it is important to point out that the RMS, in its addendum to the DAR of 26 October 2005, did not exclude any possibility of isomalathion's genotoxicity. The RMS confined itself to concluding, following the assessment of the new Ames test produced by Cheminova, that 'malathion Technical was not mutagenic under the conditions of [that] test' and that the study was 'acceptable'.

146 Secondly, it is clear from the contents of the Court file that EFSA considered that the uncertainties as to isomalathion's genotoxicity did not depend solely on the result of the new Ames test, suggested by EPCO and undertaken by Cheminova in August 2005. It is important to point out in that regard that, according to the EFSA report, 'further genotoxicity studies [had] to be provided' to show the 'non-genotoxic potential … [of] the specification of 0.2% of isomalathion'. The use of the plural seems to indicate that the results of a single new study could not be decisive as such. In any event, neither EPCO nor EFSA at any time stated that a negative result of an Ames test with an isomalathion specification of 0.2% would by itself eliminate any possibility of genotoxicity. It is important to recall in that regard that the new Ames test, which was suggested by the experts and carried out by Cheminova, must be put in the context of the finding that the Ames test of 1987 which had been included in the dossier notified and whose result had been negative provided no information concerning the

isomalathion content. However, it was never suggested that the new Ames test would as such be decisive of the outcome of the evaluation of malathion's genotoxicity.

147 It follows from all the foregoing that the applicants' arguments relating to the first concern must be rejected.

— The second concern, linked to the effects of certain toxicologically relevant metabolites

148 In the contested decision, the Commission found that 'it ha[d] not been demonstrated that the estimated exposure of consumers resulting from the acute and chronic intake of edible crops [was] acceptable, due to the insufficient information on the effects of certain toxicologically relevant metabolites' (recital 5 in the preamble to the contested decision).

149 In that regard, the EFSA report mentions various toxicologically relevant metabolites. They are, among others, desmethyl malathion, malaoxon, MMCA and MDCA. The EFSA report states that the dossier notified by Cheminova contains no study concerning desmethyl malathion, MMCA or MDCA. The dossier relating to metabolites thus did not enable EFSA to adopt a position in respect of the effects of metabolites on consumers. It is thus, that, at point 3.3 of the EFSA report, it is stated as follows:

'Currently, the acute and chronic dietary risk assessment for consumers cannot be concluded as long as the toxicological relevance of desmethyl-malathion is not clarified

and further residue data on desmethyl-malathion are not made available. Furthermore the relevance of the metabolites MMCA and MDCA for consumer exposure is currently unclear …

A provisional risk assessment would need to include a combination of a number of assumptions on the toxicological properties and/or on the residue behaviour of desmethyl-malathion, MMCA, MDCA and malaoxon.'

150 The applicants' argument that EFSA and/or the Commission should have taken account of information which was not included in the dossier notified, but which was submitted at a later stage by Cheminova to the RMS and to EFSA, cannot be accepted. Irrespective of any possible admissibility of that information in the light of the provisions of Article 8(2) and (5) of Regulation No 451/2000, the applicants do not even argue that such information covered all the various toxicologically relevant metabolites. In their application and in their reply, the applicants plead only the additional data concerning desmethyl malathion which Cheminova submitted, to the exclusion of the other metabolites identified in the EFSA report, particularly MMCA and MDCA, for which a data gap was also established in that report. In answer to a question posed by the Court of First Instance at the hearing, the applicants moreover admitted that, in the course of the malathion evaluation procedure, they had not provided to the RMS or EFSA any further information relating to metabolites other than desmethyl malathion.

151 In those circumstances, it can be concluded that, even if EFSA or the Commission had taken account of all the information produced by Cheminova in the course of the procedure which led to the adoption of the contested decision, its contents could not have been different since that information could not, in any event, have dispelled the doubts of EFSA or the Commission as to the risks for consumers linked to the effects of certain metabolites, and particularly of MMCA and MDCA.

152 Finally, as regards the applicants' argument that the concern linked to the effects of certain metabolites could not justify the non-inclusion of malathion in Annex I to Directive 91/414 for ornamental plants, it is appropriate to point out that two concerns were identified in the contested decision, one relating to the presence of isomalathion and the other relating to the effects of certain toxicologically relevant metabolites. However, it is not disputed that the concern linked to the presence of isomalathion affects all the envisaged applications of malathion and therefore also its application for ornamentals. In the light of the findings in paragraphs 109 to 147 above, it must therefore be concluded that the applicants have not shown that the Commission made a manifest error of assessment or founded its assessment on erroneous scientific bases when it decided, irrespective of the application envisaged, not to include malathion in Annex I to Directive 91/414.

— The alleged incompleteness of the dossier notified and the allegedly defective statement of the reasons for the contested decision

153 In the first place, the applicants' claim that the RMS's declaration that the dossier notified was complete could have created on Cheminova's part a legitimate expectation that all the information necessary for the assessment of the active substance had been provided (see paragraph 95 above) is inadmissible by virtue of Article 48(2) of the Rules of Procedure. The reason is that it was raised for the first time in the reply.

154 In any event, that argument is not valid. First, 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, including the summary dossier referred to in paragraph 2'. Under Article 6(2)(d) of Regulation No 451/2000, the summary dossier is to include 'a check by the notifier of the completeness of the dossier'. In the system established by Regulation No 451/2000, the primary responsibility for checking the completeness of the dossier thus rests with the notifier. That is confirmed by Article 7(1)(a) of Regulation No 451/2000, which requires the RMS to examine the dossiers and assess 'the completeness check(s) provided by the notifiers'.

155 Secondly, having regard to the foregoing, the fact that the dossier has been declared complete by the RMS for the purposes of Article 6(1) of Regulation No 451/2000 does not guarantee necessarily that it contains all the information enabling the RMS, EFSA and the Commission to adopt a position on the 'harmful effects' of the active substance concerned, under Article 5(1) of Directive 91/414. It is appropriate to state in that regard that a dossier which contains the studies and reports required by Article 6(3) of Regulation No 451/2000 will be regarded as complete by the RMS, which does not exclude, however, that some or other data which would enable the RMS and/or EFSA to carry out their scientific evaluation of the active substance in question could be missing. For that reason, Article 8(2) and (5) of Regulation No 451/2000 provides for the possibility, for the RMS and EFSA respectively, to ask notifiers to submit further data necessary to clarify the dossier. However, since the notifier must ensure that the dossier submitted is complete, Article 8(2) and (5) of Regulation No 451/2000 give the notifier no right to complete its dossier on its own initiative.

156 In the second place, as regards the allegation that the statement of the reasons for the contested decision is defective (see paragraph 102 above), it must be recalled that it was raised only if the non-inclusion of malathion was based on grounds other than those set forth in the contested decision. Since there is no indication to that effect, that allegation cannot be upheld either.

157 It follows from all the foregoing that the first plea in law must be rejected.

The second plea in law, alleging infringement of Article 95 EC, and of Articles 4(1) and 5(1) of Directive 91/414

Arguments of the parties

158 The applicants claim that the Commission did not adopt the contested decision on the basis of the current and latest science. By relying on Article 8(5) of Regulation No 451/2000 to refuse to have new data peer reviewed, the contested decision, which was adopted in 2007, has in fact been based upon science which dates from the year 2004. By so doing, the Commission infringed Article 95(3) EC and Article 5(1) of Directive 91/414, which 'gives effect' to the principles laid down in that Treaty provision. Article 4(1) of Directive 91/414 also refers, inter alia, to the obligation on Member States to adopt relevant decisions regarding active substances 'in the light of current scientific and technical knowledge'.

159 Even though Article 43 of the EC Treaty (now, after amendment, Article 37 EC) is the formal legal basis for Directive 91/414, the Community courts have confirmed that that directive has the dual objective of removing barriers to intra-Community trade in plant products and of improving plant production, on the one hand, and, on the other, of protecting human and animal health and the environment (Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraph 30). In those circumstances, the Commission is required to apply the rules underlying internal market legislation when it adopts decisions under Directive 91/414, and hence to apply Article 95 EC.

160 Directive 91/414 confers no discretion on the Commission to derogate from the requirement that relevant decisions be taken 'in the light of current scientific and technical knowledge'. The contested decision should therefore have been adopted in the light of the current scientific and technical knowledge available as at 8 June 2007 (the date of publication of the contested decision). In support of their argument, the

applicants refer to the judgments in Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraph 50, and Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraph 73, and to points 98 and 102 in the Opinion of Advocate General Léger in Case C-306/98 *Monsanto* [2001] ECR I-3279.

161 With regard to the genotoxicity potential of isomalathion, (i) since the submission of the complete dossier including a negative *in vivo* UDS test in 2002, (ii) since August 2005, through the RMS, (iii) since October 2005, through EFSA, and (iv) since March 2006, directly from Cheminova, the Commission has been in possession of scientific test results which unequivocally establish that the isomalathion content of the malathion subject to review under Directive 91/414 does not pose any concerns of genotoxicity. By ignoring such science, the Commission did not adopt the contested decision on the basis of current science or the latest scientific developments, as it includes the conclusion that 'the genotoxicity of [isomalathion] cannot be excluded'.

162 Moreover, in the period from June 2004 to March 2006, the RMS, EFSA and the Commission were all in possession of data and studies, together with relevant scientific analyses and assessments, which addressed the concerns raised by desmethyl malathion. However, that evidence was not considered by the Commission.

163 The applicants conclude that, by omitting to take into account the data submitted by Cheminova to EFSA, the RMS and the Commission well before the 30 September 2007 deadline imposed by Regulation No 1335/2005 by which list 2 substances such as malathion had to be assessed, the Commission failed to take into account the most recent scientific data, including all new developments based on scientific facts. The contested decision was not therefore adopted 'in the light of current scientific and technical knowledge' and thus infringes Article 95 EC, and Articles 4(1) and 5(1) of Directive 91/414.

164 The Commission contends that the second plea in law should be rejected.

Findings of the Court

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

166 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).

167 In those circumstances, it is not necessary to examine whether Article 95(3) EC, which provides that '[t]he Commission, in its proposals … concerning health … will take as a base a high level of protection, taking account in particular of any new development based on scientific facts', is applicable when the Commission adopts a decision not to include an active substance in Annex I to Directive 91/414. Indeed, the principles of Article 95(3) EC are reproduced in Article 5(1) of Directive 91/414, interpreted in combination with the precautionary principle.

168 The applicants submit that when the Commission adopted the contested decision, it failed to take account of the most recent scientific data. They are referring, in essence, to the 'new' Ames test submitted by Cheminova to the RMS in August 2005, then by the RMS to EFSA and the Commission, so far as isomalathion's genotoxicity is concerned,

on the one hand, and, on the other, to the information sent by Cheminova to the RMS, EFSA and the Commission, between June 2004 and March 2006, so far as metabolites are concerned.

169 In that regard, first, it is important 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 studies and data for as long as doubts persist regarding the safety of that active substance. Such an interpretation of that provision would run counter to the objective of a high level of protection of human and animal health and of the environment 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 the adoption of a decision not to include the substance in Annex I to Directive 91/414.

170 It must also be added that, as regards the evaluation of malathion, the applicants do not allege nor, a fortiori, have they shown that 'current scientific and technical knowledge' has developed since the notification of the dossier to the RMS. The repeat of a test which has long been known about, namely the Ames test, cannot, in any case, be assimilated to a change in 'current scientific and technical knowledge'. Without showing a new development in scientific knowledge concerning malathion since the notification of the dossier to the RMS which could cast doubt on the reliability of the information contained in that dossier, the applicants' argument that the Commission was under an obligation to take account of 'current scientific and technical knowledge' cannot, in any event, succeed.

171 Secondly, for the sake of completeness, even if the Commission was required, under Article 5(1) of Directive 91/414, to take account of all the information mentioned in paragraph 168 above before it adopted the contested decision, the applicants have not shown that all the evidence available to the Commission would have dispelled all reasonable doubt as to malathion's harmful effects. In that regard, it is sufficient to refer

to the analysis in paragraphs 109 to 152 above for the purposes of the examination of the first plea in law.

172 It follows from all the above that the second plea in law must also be rejected.

The third plea in law, alleging breach of the principle of the protection of legitimate expectations

Arguments of the parties

173 The applicants claim that Cheminova received an assurance that new data that it produced would be reviewed and peer reviewed at every stage of the review process for malathion. That assurance was precise and given in writing. They refer in that connection to the e-mail of 14 June 2004 from EPCO's representative to Cheminova, which stated that '[i]f [it] [liked] to have new information considered, [it] first ha[d] to ask the RMS for acception [sic] of the new studies' and that '[i]f the RMS accept[ed] the new studies they [(sic) would] prepare an addendum which [would] be discussed in due course'. That precise written assurance from the EPCO representative is, moreover, fully in line with the Aide mémoire with regard to certain aspects of the procedures for the evaluation of existing substances in view of their possible inclusion in Annex I to Directive 91/414, point 7 of which states: '[n]ew data available after the submission of the monograph [would] only be discussed at the peer review meetings if the RMS has been able to evaluate the data' and that '[a]ll new data tabled at the meeting [would] be noted in the reports of the meetings as being submitted' having stated that '[i]f it [had] not [been] possible to discuss certain new data this [would] be mentioned in the report'.

174 Applying the foregoing to the Ames test relating to the genotoxicity of isomalathion, the applicants state that (i) the RMS agreed to accept it after submitting the DAR to EFSA, (ii) the RMS reviewed it, (iii) the RMS drafted an addendum to the DAR, and (iv) the RMS submitted it to EPCO in October 2005. In other words, Cheminova and the RMS complied with every condition of the EPCO representative's communication in the e-mail of 14 June 2004.

175 The fact that neither EFSA (previously EPCO) nor the Commission did take the new data into account in the peer review procedure, despite (i) the precise written assurance that it would and (ii) the written practice/guidance of the Commission in that regard, means that Cheminova's legitimate expectations have been frustrated. The applicants add that had the data been taken into account and peer reviewed, the scientific conclusions and the contested decision would have been different.

176 In their reply, the applicants state that the procedure for the evaluation of active substances provided for by Directive 91/414 is conducted by two bodies — the RMS and EFSA — operating on behalf of, or under the authority of, the Commission. The decision ultimately adopted by the Commission is taken on the basis of that evaluation. An assurance and/or request from either of those bodies is therefore sufficient to raise a legitimate expectation. However, the requests from the RMS and EFSA for the production of additional data and the subsequent attitude of the RMS gave rise to a legitimate expectation on Cheminova's part that the data would be reviewed and taken into account in the evaluation process.

177 Finally, the applicants claim that they are not required in support of the present plea to 'adduce proofs' that the contested decision would have been different in order to show that the contested decision is illegal. It is sufficient for them to show that the contested decision might have been different.

178 The Commission submits that it has not infringed Cheminova's legitimate expectations and contends that the third plea in law should be rejected.

Findings of the Court

179 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 (*Di Lenardo and Dilexport*, cited in paragraph 81 above, paragraph 70; *Embassy Limousines & Services* v *Parliament*, cited in paragraph 81 above, paragraph 74; and see, to that effect, *Atlanta* v *European Community*, cited in paragraph 81 above, paragraph 52). Regardless of the form in which it is communicated, information that is precise, unconditional and consistent which comes from an authorised and reliable source constitutes such assurance (*Convertisseur d'énergie éolienne*, cited in paragraph 81 above, paragraph 36). 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).

180 It is appropriate to note, first of all, that as part of the procedure for evaluating an active substance for the purposes of its inclusion in or omission from Annex I to Directive 91/414, which is provided for in Article 8 of Regulation No 451/2000, EFSA is to evaluate the harmful effects of the substance concerned and deliver a scientific opinion on that point to the Commission. 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 EFSA in the procedure for evaluating an active substance, it could be considered that 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.

181 On the other hand, and irrespective of whether precise assurances made by the RMS in the course of the procedure for evaluating the active substance with a view to the preparation of the DAR could give rise to a legitimate expectation on the part of the notifier, it must be noted that the behaviour of the RMS, at a time when the DAR has already been submitted to EFSA and therefore at a time when the evaluation procedure has been taken up at the Community level, can no longer be regarded as being capable of giving rise to such a legitimate expectation or to affect the legality of the contested decision. Since, in this case, the DAR was sent to EFSA on 2 February 2004 and the

documents and behaviour which could have given rise to a legitimate expectation on Cheminova's part are all later than that date, only documents from and behaviour of EFSA and documents from and behaviour of the Commission should be examined in connection with the present plea in law.

182 However, there is no evidence in the Court file that EFSA or the Commission gave Cheminova any assurance capable of giving rise to a legitimate expectation on Cheminova's part that new data which it produced in the course of the malathion evaluation procedure would be taken into account.

183 First, as regards EFSA's attitude in the course of the procedure, it is appropriate to point out that, contrary to the applicants' assertions, the e-mail of 14 June 2004 contains no precise assurance on EFSA's part that it would examine every new study or all new data submitted by Cheminova in the course of the procedure. At the most, EFSA gave an assurance that it would examine any addendum drawn up by the RMS. Moreover, the content of Cheminova's e-mail of 5 August 2005 to the RMS reveals that Cheminova had not received from EFSA any precise assurance that it would evaluate any new study or data submitted. In that e-mail, Cheminova noted 'recent guidance … from the EPCO team that the notifier should not be allowed to comment' and stated that it would be 'most grateful if [the RMS] would consider presenting' the further data to EFSA.

184 As regards, secondly, the Commission's attitude in the course of the procedure, it is clear from the contents of the Court file and, particularly, from the Commission's letter of 6 February 2006 to Cheminova that it gave no assurance that Cheminova could lodge studies and data for as long as the evaluation procedure lasted. In fact, in that letter, the Commission made clear that 'it [was] not possible at this stage of the procedure, to take account of new data or studies'.

185 Moreover, the Aide-mémoire, which dates from 1998, cannot, as the Commission points out, be regarded as capable of giving rise to a legitimate expectation on

Cheminova's part as regards the procedure provided for by Regulation No 451/2000 and, in particular its Article 8, as amended in 2002.

186 Thirdly, and in any event, in their arguments, the applicants refer, in essence, to the failure to take account of the Ames test of August 2005. Even if EFSA or the Commission gave precise assurances in respect of the taking into account of that new test, which they did not, those assurances could not have founded a legitimate expectation on Cheminova's part since Article 8(2) and (5) of Regulation No 451/2000 provide expressly that new studies are not, in principle, to be accepted, once the RMS or EFSA respectively has commenced its evaluation of the active substance (see paragraph 129 above). 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).

187 It follows from all the foregoing that the third plea in law must be rejected.

The fourth plea in law, alleging breach of the principle of proportionality

Arguments of the parties

188 Referring to the judgment in *Industrias Químicas del Vallés* v *Commission* (cited in paragraph 106 above, paragraphs 76 and 77) and to point 77 in the Opinion of Advocate General Ruiz Jarabo Colomer in that case, the *applicants* claim that, in the present case, the Commission infringed the principle of proportionality.

189 First, it is apparent from the judgment in *Industrias Químicas del Vallés* v *Commission,* cited in paragraph 106 above, that Directive 91/414 and Regulation No 451/2000, and in particular Article 8(5) thereof, do not impose time-limits of a peremptory character when it comes to the submission of data by the notifier. To comply with the requirements of the principle of proportionality, the Commission should have deferred, as requested by Cheminova, whatever deadlines it was imposing in order to take account of — and review — any new data produced by that applicant. By prioritising compliance with the deadline under Article 8(5) of Regulation No 451/2000, which is not in any event peremptory, the Commission failed to examine carefully and impartially all the relevant facts of the case, facts which contradict the conclusions reached in the contested decision. On the contrary, because of the lack of proportionality in the Commission's approach, the prohibition of malathion in definitive effect as from 7 December 2007 is based on science which dates from 2004. The Commission's attitude is all the more questionable, given that the bodies with the legal mandate to conduct the review failed themselves to meet deadlines to which they were subject. Thus, EFSA took two years to conduct its peer review, while the applicable procedural deadline allowed only one year.

190 The applicants submit that an extension of the deadline under Article 8(5) of Regulation No 451/2000 would have been justified in this case. First, the Article 8(5) deadline applies 'only during the currency of the peer review'. In the case of malathion, that peer review was lawfully permitted to run from 2 February 2004 (the date of receipt of the DAR) until 1 February 2005. Instead, for malathion, the review in question ran from 2 February 2004 to 13 January 2006. Neither the Commission, as the Community authority with overall responsibility for the risk assessment of malathion, nor EFSA was entitled to refuse to accept new data on the basis of Article 8(5) of Regulation No 451/2000. Second, the applicable law requires the Commission to carry out the review by 30 September 2007. In other words, the Commission had adequate time to conduct a 'confirmatory' review of the RMS's conclusion that isomalathion presents no risk of genotoxicity. They state in that regard that a peer review of the Ames test could have been undertaken quickly, a competent person being able to do so in less than one day. Third, a precise assurance was given to Cheminova that its new data would be reviewed.

191 In their reply, the applicants claim, first, that clear requests for new data were made. Therefore, irrespective of when in the process those requests were made, the Commission should have taken account of the data submitted in response to those requests. Second, where the competent authorities extend the deadlines 'to suit themselves', the timing of the whole review process must also be adapted. Directive 91/414 contains rules concerning the deadlines for the assessment of active substances not only for the notifiers but also for the RMS, EFSA and the Commission. The competent authorities cannot seek to enforce 'to the letter' deadlines that apply to Cheminova where they fail themselves to comply with the deadlines to which they are subject. Thus, EFSA exceeded by almost one year the time-limit in Article 8(7) of Regulation No 451/2000. Third, deadlines can be moved in the light of the circumstances of the case. In its judgment in *Industrias Químicas del Vallés* v *Commission,* cited in paragraph 106 above, the Court of Justice held that where the evaluators (namely the RMS, EFSA and the Commission) place the notifying party in an unforeseen and complicated situation by changing their mind in relation to the data submitted or request new data without allowing it sufficient time to produce those data, they are required to extend the applicable deadlines. In this case, Cheminova was facing a change of circumstances (request for new data) inconsistent with earlier conduct on the part of the RMS (decision that the dossier was complete). Requests for data were sent to Cheminova at a late stage in the process and after the dossier had been declared complete, but it was not given sufficient opportunity by EFSA or the Commission to provide the data requested. In those circumstances, the Commission cannot legitimately claim that an indefinite extension of the time-limit for evaluating an active substance would be contrary to the objectives of Directive 91/414. Fourth, the Commission based the contested decision on data which no longer corresponded to 'current scientific and technical knowledge', in breach of Article 5(1) of Directive 91/414. The 'principle' laid down by that provision applies not only to Directive 91/414 itself but also to all measures adopted by the Commission pursuant to that 'framework directive', including the contested decision.

192 Second, the applicants allege that the Commission infringed the principle of proportionality in so far as it could have adopted a less restrictive decision than the contested decision which would have been equally able to address the human health and/or environmental concerns in the light of the current scientific knowledge and latest developments. First, the Commission could have 're-referred' the new data back to EFSA for assessment. The Commission was entitled to refer the case back to EFSA

for peer review of the new data which addressed the concerns identified and raised by EFSA during its delayed peer review. The only deadline which must be truly respected in that regard is the 12-year deadline established in Article 8 of Directive 91/414, as extended by the Commission to 30 September 2007. Second, in a manner consistent with its practice, the Commission could have chosen to refer the issues concerning the genotoxicity of isomalathion in concentrations of up to 0.2% in the 'technical grade malathion' product and the issue concerning the metabolite 'desmethyl malathion' to the scrutiny of the Member States. In that regard, Cheminova submitted several requests to the Commission to adopt that proportionate approach to malathion (see e-mail of 7 November 2005 from Cheminova to the Commission). In other words, instead of prohibiting malathion by not including it in Annex I to Directive 91/414, a more proportionate response to the concerns would have been to allow its inclusion subject to the submission of data at Member State level. Third, it is disproportionate to prohibit malathion in the knowledge that such new data need only be peer reviewed to demonstrate that the substance fulfils the criteria of Article 5(1) of Directive 91/414, and while Member States are capable of conducting that review and taking appropriate decisions.

193 The Commission replies that the fourth plea in law should be rejected.

Findings of the Court

194 It is settled case-law that the principle of proportionality, which is one of the general principles of Community law, requires that acts adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question; 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 C-137/85 *Maizena and Others* [1987] ECR 4587, paragraph 15, and *Pfizer Animal Health* v *Council*, cited in paragraph 94 above, paragraph 411).

195 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 in that field (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*, cited in paragraph 94 above, paragraph 412; and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 177).

196 In this case, the contested decision is based on Directive 91/414, the legal basis of which is Article 43 of the EC Treaty (now, after amendment, Article 37 EC). In those circumstances, it must be examined whether the contested decision is manifestly inappropriate to attain the objective envisaged by the re-evaluation system implemented by that directive, namely the protection of human and animal health and of the environment.

197 As regards the applicants' first complaint that the Commission, by prioritising compliance with the deadline in Article 8(5) of Regulation No 451/2000, failed to examine, carefully and impartially, all the relevant aspects of the individual case and, in particular, the information submitted by Cheminova after the dossier was sent to the RMS, it does not concern the proportionality of the measure adopted by the Commission. That complaint has already been partly examined in connection with the first plea in law (see paragraphs 131 to 138 above). As for the remainder, the first complaint will be examined in connection with the seventh and eighth pleas since it relates, in essence, to the alleged breach by the Commission of the principle of sound administration and of Cheminova's rights of the defence in the course of the procedure which led to the adoption of the contested decision. The same applies to the first argument relied upon in connection with the second complaint that the Commission should have referred the case back to EFSA so that the new data submitted by Cheminova could be the subject of peer review, which argument must be examined in connection with the seventh plea in law.

198 By the other arguments relied upon in support of the second complaint, the applicants maintain, in essence, that the Commission should have adopted a less restrictive measure.

199 To the extent that the applicants allege that the Commission could have chosen to subject the concerns raised to the scrutiny of the Member States, such an argument finds no support in the applicable legal framework. Indeed, when the Commission becomes involved in the evaluation of an active substance, EFSA has already, under Article 8(7) of Regulation No 451/2000, given an opinion on the compliance of the substance with the safety requirements of Directive 91/414. At that stage of the procedure, neither Directive 91/414 nor Regulation No 451/2000 provides for any involvement by the Member States for the purposes of the evaluation of the harmfulness of the active substance. It must be made clear in that regard that, under Article 8(8) of Regulation No 451/2000 and Article 19 of Directive 91/414, the Commission alone and, if appropriate, the Council, have the power to decide whether or not to include an active substance in Annex I to Directive 91/414.

200 Finally, to the extent that the applicants' argument must be understood as meaning that the Commission should have authorised the inclusion subject to conditions under Article 5(4) of Directive 91/414, it must be noted that the effect of that provision is to permit inclusion of active substances which do not fulfil the requirements of Article 5(1) of that directive subject to certain restrictions which exclude problematic uses of the substance involved (*Sweden* v *Commission*, cited in paragraph 166 above, paragraph 169).

201 Since Article 5(4) of Directive 91/414 is to be regarded as a limitation on Article 5(1) thereof, it must be interpreted in the light of the precautionary principle. Consequently, before including a substance in Annex I to Directive 91/414, it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid down in Article 5(1) of Directive 91/414 (*Sweden* v *Commission*, cited in paragraph 166 above, paragraph 170). However, in connection with the present plea in law, the applicants have not specified the conditions which the Commission could have imposed on the Member States which would have ensured that the use of

malathion complied with the requirements of Article 5(1) of Directive 91/414. In any event, a decision allowing the inclusion of malathion in Annex I to Directive 91/414 subject to the production of data at the level of the Member States, as is suggested by the applicants, could not exclude problematic uses of the substance in question.

202 Finally, it follows from the analysis of the first plea in law that the applicants' averment that it is disproportionate to prohibit malathion knowing that a simple peer review of that new data would be sufficient to establish that the substance satisfied the criteria of Article 5(1) of Directive 91/414 rests on a false premise. It has not been shown that the taking into account of all the information produced by Cheminova in the course of the malathion evaluation procedure could have dispelled any reasonable doubt on EFSA's and the Commission's parts in respect of the harmful effects of that active substance.

203 In those circumstances, the present plea in law cannot be upheld either.

The fifth plea in law, alleging infringement of Article 8(7) of Regulation No 451/2000

Arguments of the parties

204 In the alternative, and to the extent that the Commission is required to comply with 'strict' deadlines, the *applicants* claim that EFSA, which received the DAR on 2 February 2004, was required, under Article 8(7) of Regulation No 451/2000, to submit its report to the Commission by 1 February 2005. Yet EFSA forwarded that report to the Commission only on 26 January 2006. EFSA, which was therefore almost exactly one year late in the delivery of its report, conducted its review and the majority of its meetings with regard to malathion in a period (3 February 2005 to 26 January 2006) during which it was not competent to do so as a matter of law and for which it had not

been granted the required mandate in proper form by the Commission or another Community institution. EFSA therefore acted outside the scope of its competence.

205 Since the EFSA report served, under Article 8(8) of Regulation No 451/2000, as the basis for the contested decision (recital 4 in its preamble), the procedural defect by which that report is flawed affects the legality of the contested decision. If EFSA had complied with the 1 February 2005 deadline (or had the Commission imposed on EFSA the procedural deadline), the contested decision would have been different because the DAR drawn up by the RMS (recommending the inclusion of malathion) would have had to have served as the basis for that decision. Alternatively, the Commission would have 're-referred' the DAR to EFSA or to another independent scientific body for peer review at a later date. Had it done so, that would have allowed the RMS to indicate to Cheminova any more concerns it had and it would have allowed that applicant more time to assess the DAR and generate more studies or produce more confirmatory data in order to address all outstanding concerns.

206 The Commission contends that the fifth plea in law should be rejected.

Findings of the Court

207 Under Article 8(7) of Regulation No 451/2000, EFSA is to evaluate the DAR and deliver its opinion on whether the active substance could be expected to meet the safety requirements of Directive 91/414 to the Commission 'at the latest one year' after receipt of the DAR. EFSA did not, in this case, observe that time-limit. Whereas EFSA received the DAR on 2 February 2004, it did not deliver its opinion to the Commission until 26 January 2006.

208 Even if the time-limit under Article 8(7) of Regulation No 451/2000 is mandatory, its being exceeded could not affect the legality of the contested decision unless it was established that the decision could have been different if that irregularity had not occurred (see, to that effect, Joined Cases 209/78 to 215/78 and 218/78 *van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 47, and Case T-279/02 *Degussa* v *Commission* [2006] ECR II-897, paragraph 416).

209 In that regard, first, the dossier notified did not contain all the evidence necessary to enable EFSA to evaluate the harmful effects of malathion. Secondly, EFSA is not bound by the DAR. Indeed, were it otherwise, its involvement would be meaningless. If following the exchanges of views and information organised by EFSA over many months, it did not finally conclude, on 26 January 2006, that malathion had no harmful effects it could not, a fortiori having regard to the defective nature of the dossier notified, have arrived at a different result if it had adopted its decision within the period of a year from the submission of the DAR.

210 Therefore this plea in law cannot be upheld either.

The sixth plea in law, alleging breach of the 'principle of non-discrimination'

Arguments of the parties

211 The applicants claim that active substances which are subject to a risk assessment as part of the transitional review programme conducted by the Commission under Article 8(2) of Directive 91/414 and the implementing regulations are all in the same situation. After noting that, under Article 6(1) of Directive 91/414, the inclusion of an active substance in Annex I to Directive 91/414 may be made subject to certain conditions, they point out that several substances were included in Annex I to

Directive 91/414 despite displaying risks of toxicity on the basis of the data provided, subject to the requirement that the substances should be subjected to further testing (see 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 [an] 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 et propamocarb as active substances (OJ 2007 L 106, p. 34)).

212 The contested decision infringes the 'principle of non-discrimination'. There are no grounds which objectively justified the distinction made in applying Article 6(1) of Directive 91/414 to oxamyl, mancozeb and maneb, on the one hand, and to malathion, on the other. The lack of objective justification is particularly acute given that the Commission was made aware on numerous occasions of data which address the alleged scientific concerns and which could easily have been submitted to the relevant Member States' authorities for their assessment.

213 The Commission replies that the 'principle of non-discrimination' has not been infringed and contends that the sixth plea in law should be rejected.

Findings of the Court

214 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-106/83 *Sermide* [1984] ECR 4209,

paragraph 28; Case C-174/89 *Hoche* [1990] ECR I-2681, paragraph 25; and Case T-38/02 *Groupe Danone* v *Commission* [2005] ECR II-4407, paragraph 453).

215 In this case, the applicants submit that, as regards risks of harmful effects, malathion is comparable to the active substances covered by Directives 2005/72, 2006/16 and 2007/25. The difference in treatment of malathion compared to the active substances covered by those directives, such substances being included in Annex I to Directive 91/414, is not objectively justified.

216 The Court notes that it is stated in Directives 2005/72 (recital 5), 2006/16 (recital 4) and 2007/25 (recital 4) that the Commission found that it had appeared from the various examinations made that the active substances in question 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, subject to their further testing for confirmation of the risk assessment on certain points.

217 In contrast, for malathion, the Commission has never found that plant protection products containing that active substance satisfied the requirements of Article 5(1)(a) and (b) of Directive 91/414. On the contrary, it found, in recital 6 in the preamble to the contested decision, that 'assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings ha[d] not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing malathion satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414' (recital 6 in the preamble to the contested decision). In the Commission's view, 'it was not [therefore] possible to conclude on the basis of the information available that malathion met the criteria for inclusion in Annex I to Directive 91/414' (recital 5 in the preamble to the contested decision).

218 Since the evaluation of malathion's harmful effects and the evaluation of the active substances covered by Directives 2005/72, 2006/16 and 2007/25 had led to different results, the Commission could treat malathion 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.

219 Accordingly, the present plea in law must also be rejected.

The seventh plea in law, alleging breach of the principle of sound administration

Arguments of the parties

220 The applicants submit that the Commission infringed the principle of sound administration, as embodied in Article 211 EC, by failing to ensure that the RMS and EFSA expressed their views within the time-limits laid down by Directive 91/414 (see, by analogy, Case C-269/90 *Technische Universität München* [1991] ECR I-5469 and *Pfizer Animal Health* v *Council,* cited in paragraph 94 above). They observe that the RMS delivered its DAR to EFSA after the deadline provided for under Regulation No 451/2000 (2 February 2004 instead of at some point before 28 October 2003, that is to say at the latest 12 months after it had determined the dossier notified to be complete) and that EFSA submitted its report to the Commission after the deadline set by Regulation No 451/2000 (13 January 2006 instead of at some point before 1 February 2005, that is almost a year after receipt of the DAR).

221 The Commission's powers to review active substances belonging to the second stage of the work programme are to be exercised strictly within the limits of Directive 91/414 and, in that context, in accordance with the specific instructions of the Council and the implementing regulations. By refusing to accept current data representing the latest

science, the Commission acted outside those limits and, as a result, adopted a decision which contravenes Articles 4 and 5 of Directive 91/414 and Article 95 EC.

222 The Commission also acted in a disproportionate fashion by imposing 'artificial, mandatory' data submission deadlines 'which served no purpose'. It cannot claim to have 'carefully' examined (recital 6 in the preamble to the contested decision) the comments submitted by Cheminova given that the new Ames test of 2005 clearly states that malathion presents no mutagenicity potential.

223 The Commission contends that the seventh plea in law should also not be upheld.

Findings of the Court

224 The principle of sound administration is one of the guarantees conferred by the Community legal order in administrative proceedings (Case T-15/02 *BASF* v *Commission* [2006] ECR II-497, paragraph 501).

225 As part of their plea in law alleging breach of the principle of sound administration, the applicants complain, first, that the Commission failed to ensure that the RMS and EFSA complied with the time-limits imposed by Directive 91/414 and Regulation No 451/2000.

226 In that regard, even if the RMS and EFSA are involved in the procedure for evaluating active substances, the legal framework which applies to it does not install any hierarchical relationship between the RMS and EFSA, on the one hand, and the Commission, on the other. In those circumstances, the Commission's failure to ensure that the RMS and EFSA complied with the time-limits imposed by Directive 91/414 and Regulation No 451/2000 cannot be held to be an infringement of the principle of sound administration by the Commission (see, to that effect and by analogy, Case T-31/99 *ABB Asea Brown Boveri* v *Commission* [2002] ECR II-1881, paragraphs 100 to 104).

227 Next, the applicants claim that the principle of sound administration was infringed since the Commission failed to examine carefully and impartially all the relevant elements of the case and, in particular, all the data which the applicants had submitted in the course of the procedure which led to the adoption of the contested decision. That complaint was also made in connection with the plea in law alleging breach of the principle of proportionality.

228 In that regard, first, it is settled case-law that the principle of sound administration entails the obligation for the competent institution to examine carefully and impartially all the relevant elements of the case (see *ABB Asea Brown Boveri* v *Commission*, cited in paragraph 226 above, paragraph 99 and the case-law cited, and Case T-410/03 *Hoechst* v *Commission* [2008] ECR II-881, paragraph 129).

229 Secondly, in order to determine whether, in this case, the principle of sound administration was infringed in the procedure which led to the adoption of the contested decision, it is appropriate to recall, first of all, the respective responsibilities incumbent on the notifier, on the one hand, and on the RMS, EFSA and the Commission, on the other.

230 To that end, it must be noted that, first, under Article 6(1) of Regulation No 451/2000, it was for Cheminova to submit a complete dossier concerning malathion which would have enabled the RMS, EFSA and the Commission to conduct an evaluation of the

harmful effects of malathion for the purposes of Article 5(1) of Directive 91/414 (see paragraph 135 above). However, it is apparent from the examination of the first plea in law that the dossier notified did not contain sufficient information to enable those authorities to evaluate the harmfulness of the active substance in question.

231 Secondly, Article 8 of Regulation No 451/2000 states, twice, in its paragraphs 2 and 5, the rule that 'new studies' are not, in principle, to be accepted after the notifier has submitted the dossier (see paragraph 137 above). Even if, in accordance with those provisions, the RMS, if appropriate with EFSA's agreement when the DAR has already been sent to that authority, may invite the notifier to submit within certain time-limits, further data which the RMS or, if appropriate EFSA, consider to be necessary to clarify the dossier, there is no provision for such an exception for the submission of new studies.

232 It is therefore clear from Article 8(2) and (5) of Regulation No 451/2000 that a request by the RMS, for the purposes of those provisions, may cover 'further data' but not 'new studies', and is to specify the time-limits within which the data must be submitted.

233 Among the documents upon which the applicants rely in support of their argument that a request under Article 8(2) and (5) of Regulation No 451/2000 had been sent to Cheminova, only two documents are from the RMS, namely the e-mails from the RMS to Cheminova of 3 March and 13 June 2005. Since the DAR had been sent to EFSA on 2 February 2004, any purported request for further data made in 2005 had, under Article 8(5) of Regulation No 451/2000, to be made with EFSA's agreement.

234 The e-mail from the RMS to Cheminova of 3 March 2005 states that the RMS's representative 'wonder[ed] whether [Cheminova] ha[d] any information available on desmethylmalathion levels in various commodities, because by this [it would have been

possible] at least [to] estimate its dietary intake levels' (see paragraph 35 above). In the light of the terms used in that e-mail and of the fact that it does not mention any agreement by EFSA nor even the time-limit within which any information was to be provided, it cannot be regarded as a request for further data under Article 8(5) of Regulation No 451/2000. It follows, moreover, from Cheminova's e-mail in reply of 4 April 2005 that it regarded the RMS's e-mail of 3 March 2005 as 'unofficial feedback from the RMS concerning the EFSA/EPCO expert meetings'.

235 Likewise, the RMS's e-mail of 13 June 2005 to Cheminova cannot be regarded as a request for further data under Article 8(5) of Regulation No 451/2000. On the contrary, by that e-mail, the RMS sent Cheminova an evaluation table for malathion 'for information, but not for commenting'.

236 Admittedly, failure by EFSA and the Commission to take account of information submitted by the notifier at the RMS's express request in the course of the procedure for evaluating an active substance may constitute a breach of the principle of sound administration. That is not however the case when the omission is one of failing to take account of further data which the notifier has submitted in the absence of a request therefor from the RMS under Article 8(2) or (5) of Regulation No 451/2000, and a fortiori when it concerns 'new studies' such as the new Ames test of August 2005, the submission of which in the course of the procedure for evaluating the active substance was, in addition, incompatible with the terms of Article 8(2) and (5) of Regulation No 451/2000. Indeed, the dossier notified should already have contained, as a rule, all the relevant information to enable the RMS, EFSA and the Commission to assess the harmfulness of malathion under Article 5(1) of Directive 91/414.

237 In the light of what was stated in paragraph 236 above, the applicants cannot assert that the Commission should have referred the case back to EFSA so that the new studies and

data submitted by Cheminova in the course of the procedure for evaluating the active substance in question might be peer reviewed, which, in any event, is optional, under Article 8(5) of Regulation No 451/2000, as amended.

238 The applicants, referring to *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 106 above, submit finally that the competent authorities cannot seek to enforce 'to the letter' deadlines that apply to Cheminova where they fail themselves to comply with the deadlines to which they are subject.

239 That argument has already been considered as part of the examination of the first plea in law and must be rejected on the grounds set forth in paragraphs 131 to 138 above.

240 It follows from all the foregoing that the present plea in law must be rejected in its entirety.

The eighth plea in law, alleging breach of the rights of the defence

Arguments of the parties

241 The applicants state that the rights of the defence and the right to a fair hearing are fundamental principles of Community law recognised in Article 41 of the Charter of Fundamental Rights of the European Union proclaimed on 7 December 2000 at Nice (OJ 2000 C 364, p. 1). The principle of respect for the rights of the defence is a fundamental principle of Community law which must be upheld in all administrative proceedings, in particular those culminating in the adoption of a decision that could adversely affect the interested party.

242 By ignoring new evidence submitted by Cheminova and evaluated by the RMS during the assessment of malathion, the Commission infringed Cheminova's rights of defence. It should have taken account of that new evidence as a matter of good administration, to ensure that, first, the assessment was made in a scientifically and legally sound fashion and, second, that Cheminova was given sufficient time and opportunities to defend its position.

243 The Commission contends that it did not infringe Cheminova's right to be heard and that the eighth plea should be rejected.

Findings of the Court

244 According to settled case-law, observance of the right to a fair hearing 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 procedure in question (Case C-135/92 *Fiskano* v *Commission* [1994] ECR I-2885, paragraph 39, and Case T-228/02 *Organisation des Modjahedines du peuple d'Iran* v *Council* [2006] ECR II-4665, paragraph 91).

245 In this case, first, the contested decision adversely affects Cheminova since it refuses its application to include malathion in Annex I to Directive 91/414.

246 It must be noted, next, that Cheminova could have included in the dossier notified any studies or data relevant to the evaluation of malathion's harmfulness under Article 5(1) of Directive 91/414. Moreover, by letter of 6 February 2006, Cheminova was invited to submit comments on the EFSA report. It submitted its comments by letter of 17 March

2006. Finally, recital 6 in the preamble to the contested decision states that Cheminova's comments 'have been carefully examined' but that 'the concerns identified could not be eliminated'.

247 It follows that Cheminova's rights of the defence were respected during the procedure which led to the adoption of the contested decision. Cheminova was not only invited to submit its comments, but they were moreover carefully examined. In that regard, the applicants cannot confuse failure to respect the rights of the defence with failure to obtain the desired result by the exercise of those rights. The fact that the applicants consider that the comments submitted address all the concerns about malathion's harmfulness does not, however, show that the Commission infringed Cheminova's rights of the defence by holding, when the contested decision was adopted, that 'it was not possible to conclude on the basis of the information available that malathion met the criteria for inclusion in Annex I to Directive 91/414'.

248 As regards the question whether Cheminova's rights of the defence had been infringed because the new studies and data submitted at the stage of malathion's evaluation had been ignored by the Commission, it must be observed that such information was produced late since, as a rule, it should have been included in the dossier notified (see paragraph 236 above).

249 In any event, the applicants have not shown that, even if, in order to evaluate the active substance, the competent authorities had taken account of all the information submitted by Cheminova after the submission of the dossier to the RMS, that evaluation could have led to a different decision. In those circumstances, even if the Commission should have taken account of the new studies and data submitted by Cheminova, which is not the case, that irregularity cannot affect the legality of the contested decision (see, to that effect and by analogy, Case 30/78 *Distillers Company* v *Commission* [1980] ECR 2229, paragraph 26, and Case C-194/99 P *Thyssen Stahl* v *Commission* [2003] ECR I-10821, paragraph 31).

250 It follows from all the foregoing that the plea in law alleging breach of the rights of the defence must be rejected.

The ninth plea in law, alleging breach of the principle of subsidiarity and of Article 5 EC

Arguments of the parties

251 The applicants claim that when the Commission decides to ban an active substance and to terminate all authorisations relating thereto without considering whether that decision could be better taken at Member State level, it infringes the principle of subsidiarity on which, 'as it has itself remarked', Directive 91/414 is based (Report from the Commission to the European Parliament and the Council — Evaluation of the active substances of plant protection products, of 25 July 2001, (submitted in accordance with Article 8(2) of Directive 91/414 on the placing of plant protection products on the market (COM(2001) 444 final, paragraph 6)). The applicants explain that Directive 91/414 essentially defers to the Member State concerned, from which an authorisation is being sought, the ultimate scientific evaluation of the active substance contained in a plant protection product. It is the Member States therefore that decide whether the data submitted by a notifier at national level are sufficient to allay any concerns. That is a 'logical aspect of the system', given that a review of an active substance based on an objective risk assessment cannot, for example, take into full consideration the variations existing between the geographic and agricultural conditions in the various Member States.

252 Referring to the judgment in Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 180, the applicants claim that the Commission did not establish whether the objective of the envisaged action (the withdrawal of malathion authorisations because of health concerns) could be better achieved at Community level. In the first place, the statement in recital 6 in the preamble to the contested decision that 'despite the arguments put forwards by the notifier, the concerns identified could not be eliminated' could give the impression that

the Commission considered those concerns to be such that, regardless of variations between Member States' agricultural and geographic conditions, from Portugal to Finland, a ban of malathion could be justified under any and all circumstances. However, it responded to all the concerns raised, 'either categorically or at least on a prima facie basis'. Second, in view of the clear evidence in its possession, meeting the concerns mentioned in recital 5 in the preamble to the contested decision — whether or not the relevant evidence was submitted late in the procedure — the Commission was legally obliged to consider at that point the extent to which it was better placed than the Member States to deal with those issues. However, no such consideration was undertaken by the Commission.

253 The applicants insist on 'the need to change the balance between Community action and action by Member States' so that the Member States play a far greater role in achieving the objective of Directive 91/414, principally because the Commission was aware of the existence of data evaluated by the RMS which addressed the alleged concerns. 'Arbitrary deadlines' regarding the submission of data do not release the Commission from its legal obligations vis-à-vis the Member States under the principle of subsidiarity.

254 The Commission contends that the ninth plea in law should also be rejected.

Findings of the Court

255 Under Articles 3 and 4 of Directive 91/414, the authorisation of plant protection products is the responsibility of the Member States. On the other hand, Article 4(1) of

that directive provides that Member States may not, as a rule, authorise a plant protection product unless its active substances are listed in Annex I.

256 However, a Member State could, under the first subparagraph of Article 8(2) of Directive 91/414 authorise, for a transitional period and subject to certain conditions, the placing on its national market of plant protection products containing active substances not listed in Annex I.

257 Malathion is an active substance covered by the derogation under the first subparagraph of Article 8(2) of Directive 91/414. Under the second subparagraph of Article 8(2) of Directive 91/414, the Commission was to commence a programme of work for the gradual examination of those active substances which, like malathion, were covered by the first subparagraph.

258 The programme of work for the gradual examination of active substances mentioned in the preceding paragraph consists of three stages. The evaluation of malathion forms part of the second stage, under Article 1(2) of Regulation No 451/2000.

259 It is clear from Article 8(8) of Regulation No 451/2000 that only the Commission and the Council have power to decide that an active substance covered by the second stage of the work programme should be included in Annex I to Directive 91/414. Moreover, that provision lays down a procedure which must be followed for the evaluation of substances covered by the second stage and which does not permit, in any case, the

Member States to adopt a final decision on the question whether the active substance in question satisfies the criteria of Article 5(1) of Directive 91/414.

260 Admittedly, Article 5(4) of Directive 91/414 permits inclusion of active substances which do not fulfil the requirements of Article 5(1) thereof subject to certain restrictions which exclude problematic uses of the substance involved (*Sweden* v *Commission*, cited in paragraph 166 above, paragraph 169). Even though, for the purposes of the restrictions imposed, a certain role may be attributed to the Member States, the fact remains that the definitive evaluation concerning the active substance's compliance with the requirements of Article 5(1) of that directive is a matter for the Community authorities alone. Thus, even if Article 5(4) of Directive 91/414 applies, it is for the Commission, or if appropriate the Council, to establish beyond a reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid down in Article 5(1) of Directive 91/414 (*Sweden* v *Commission*, cited in paragraph 166 above, paragraph 170).

261 It follows from all the foregoing that this plea in law must also be rejected.

The tenth plea in law, alleging infringement of Article 13 of Directive 91/414

Arguments of the parties

262 The applicants claim that the contested decision deprives Cheminova of the data protection rights which it might have expected to enjoy under Article 13 of Directive 91/414 if malathion had been included in Annex I thereto. They submit

that the Commission infringed Article 13 of Directive 91/414 and the right to property in so far as the contested decision meant that Cheminova could not enjoy any right of data protection.

263 The Commission contends that the last plea in law should be rejected.

Findings of the Court

264 Article 13 of Directive 91/414 provides that the Member States must protect the confidentiality of data included in the dossier which accompanied the application for authorisation to place a plant protection product on the market. That protection applies, under Article 13(3) and (4) of Directive 91/414, only where the Member States 'grant … an authorisation'.

265 Even if the provisions of Article 13 of that directive apply, *mutatis mutandis*, to the dossier notified under Article 4 of Regulation No 451/2000 for the purpose of securing the inclusion of an active substance in Annex I to Directive 91/414, it must be held, in any event, that the data protection requirement under Article 13 of that directive could not apply in this case, since the active substance has not been the subject of any 'authorisation'.

266 In those circumstances, the plea in law alleging infringement of Article 13 of Directive 91/414 must be rejected.

267 It follows from all the foregoing considerations that the action must be dismissed in its entirety.

Costs

268 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. As the applicants have been unsuccessful, they must be ordered to pay the costs, including those relating to the application for interim measures, in accordance with the form of order sought by the Commission.

On those grounds,

THE COURT OF FIRST INSTANCE (Eighth Chamber)

hereby:

1. Dismisses the action.

2. **Orders Cheminova A/S, Cheminova Agro Italia Srl, Cheminova Bulgaria EOOD, Agrodan, SA and Lodi SAS to bear their own costs and to pay those incurred by the Commission, including those relating to the application for interim measures.**

Martins Ribeiro Papasavvas Dittrich

Delivered in open court in Luxembourg on 3 September 2009.

[Signatures]

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