JUDGMENT OF THE GENERAL COURT (Third Chamber)

9 September 2011 *

In Case T-475/07,

Dow AgroSciences Ltd, established in Hitchin (United Kingdom), and the 20 other applicants, the names of which are listed in the Annex, represented by C. Mereu and K. Van Maldegem, lawyers,

applicants,

v

European Commission, represented by L. Parpala and B. Doherty, acting as Agents, assisted by J. Stuyck, lawyer,

defendant,

APPLICATION for annulment of Commission Decision 2007/629/EC of 20 September 2007 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing that substance (OJ 2007 L 255, p. 42),

* Language of the case: English.

THE GENERAL COURT (Third Chamber),

composed of J. Azizi, President, E. Cremona and S. Frimodt Nielsen (Rapporteur), Judges,

Registrar: K. Pocheć, Administrator,

having regard to the written procedure and further to the hearing on 16 December 2010,

gives the following

Judgment

Facts of the case

1 Trifluralin is an active substance used as a selective broad spectrum herbicide which belongs to the class of dinitroaniline-type herbicides. It can be used to control grass and broad-leaved weeds. Trifluralin is absorbed by the roots and shoots and inhibits cell division. In most cases, trifluralin is incorporated in the soil in order to protect it against degradation by sunlight.

2 Trifluralin belongs to the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) and belongs to the list of substances which are subject to the procedures put in place by Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Directive 91/414 (OJ 2000 L 55, p. 25).

3 The representative formulated product for the evaluation which has to be carried out under Directive 91/414 is 'EF 1521' (also known as Treflan), that is to say, an emulsifiable concentrate registered under different trade names in Europe.

4 Dow AgroSciences Ltd (the first applicant), Makhteshim-Agan Holding BV (the second applicant), through its international coordination centre, Makhteshim Agan International Coordination Center (the third applicant), Dintec Agroquímica — Produtos Químicos Lda (the fourth applicant) and Finchimica SpA (the fifth applicant) notified the Commission of the European Communities of their desire to secure the inclusion of trifluralin in Annex I to Directive 91/414. The first applicant submitted its notification on 25 August 2000 in its own name and also on behalf of the fourth and fifth applicants. The second and third applicants submitted their notification on 29 August 2000.

5 All of the notifications (Annexes A.3 and A.4) were submitted before the expiry of the deadline of 31 August 2000 laid down in Article 4(1) of Regulation No 451/2000.

6 All of the parties which notified their requests for inclusion of the substance produce or manufacture trifluralin or trifluralin-based plant-protection products or hold national authorisations to market and sell those products in one or more Member States of the European Union.

7 The European Union Trifluralin Taskforce ('the EUTTF'), the role of which is to coordinate the efforts of the notifying undertakings to communicate with the Commission in the context of the trifluralin evaluation procedure, was set up in March 2001 with the participation of Agan Chemical Manufacturers Ltd and Dintec Agroquímica — Produtos Químicos Lda, the latter being an incorporated company formed by Dow AgroSciences BV (the sixth applicant) and Suroholi — Comercio Internacional e Servicios Lda.

8 Dow AgroSciences BV succeeded Dow AgroSciences Ltd in its role of notifier and was regarded as such by the Commission.

9 The Hellenic Republic was designated as rapporteur Member State responsible for evaluating trifluralin, as provided for in part B of Annex I to Regulation No 451/2000.

10 The applicants submitted their dossiers to the rapporteur Member State on 24 April 2002.

11 The rapporteur Member State submitted its draft assessment report on 11 July 2003. In it, it recommended that trifluralin be included in Annex I to Directive 91/414, subject to two conditions: a minimum purity of trifluralin of 950 g/kg and the adoption by Member States, when granting authorisations, of risk-mitigation measures for the protection of aquatic organisms.

12 As regards ecotoxicology, point 4.9 of the draft assessment report of the rapporteur Member State states that:

'For a refinement of the risk to aquatic organisms or for reducing the width of unsprayed buffer zones, the notifier may consider conducting new experimental tests to

address specific concerns at [Member State] level. Such studies are not a requirement for the inclusion of trifluralin in Annex I [to Directive 91/414].'

13 The European Food Safety Authority (EFSA) sent the draft assessment report to the Member States and the notifying parties on 24 July 2003 in order to initiate the peer review provided for in Article 8(5) of Regulation No 451/2000.

14 A number of Member States submitted their written comments on the draft assessment report and two of them, on that occasion, gave voice to their concerns as to the persistence, bioaccumulation and high volatility of trifluralin and expressed the view that that active substance should not be authorised.

15 At the first meeting of the EFSA 'Evaluation' working group, which took place on 15 January 2004 and was attended by representatives of the notifying undertakings and of the European Crop Protection Association, those comments were reiterated and it was decided that various further data would be necessary in regard to, inter alia, the storage stability of the substance; its shelf life; analytical methods for the determination of impurities; mammalian toxicology; a metabolism study in oilseeds; and a number of studies on the environmental behaviour and fate of the substance.

16 On 3 March 2004 a representative of the notifying parties sent an email to EFSA in the following terms:

'We received the Evaluation Table for Trifluralin from the [rapporteur Member State] and are preparing our comments but we would like to seek your advice on one particular issue.

Section 2, first column 2.4 [of the evaluation table for trifluralin] states "Notifier to submit in vitro genotoxicity … and acute oral toxicity tests for the plant metabolites TR-22 and TR-28 or alternatively metabolism study in oilseeds with identification of the metabolites in the seeds". As we explained at the Evaluation Meeting, our synthesis chemists have indicated that it will be very difficult and time-consuming to produce sufficient quantities of TR-28 with which to conduct the toxicity studies and therefore it may be easier, more successful and more relevant to conduct a metabolism study in oilseeds with identification of the metabolites in the seeds since the processed fractions of these portions of the plant are those that are consumed by humans and animals. Can you please advise on the deadline for submission of a new metabolism study as this is not a short-term study?'

17 By email of 5 March 2004, EFSA replied to that email in the following terms:

'In your email of 3 March, you addressed the data requirement for further studies for the plant metabolites TR-22 and TR-28 of trifluralin.

This data requirement was discussed and agreed by the [Member States] in the last evaluation meeting and was included together with other data requirements in the evaluation table. It is now your task to address the data requirements by either submitting the requested information or by providing confirmation when the requested data will be submitted.

Taking this information into account, the peer review of trifluralin will continue to stay in line with the deadlines given in [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 Council Directive

91/414/EEC and amending Regulation (EC) No 451/2000 (OJ 2002 L 224, p. 23)]. Any outstanding data will be referenced in EFSA's conclusion on the risk assessment.'

18 Owing to the disagreement of certain Member States with the report of the rapporteur Member State, it was decided to refer the matter to the sittings of the European Pesticides Co-ordination ('EPCO'), that is to say, the operational secretariat — composed of officials of the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (German Federal Ministry for Consumer Protection and Food Safety) and the United Kingdom Pesticides Safety Directorate — responsible, within EFSA, for the practical organisation of the rounds of experts responsible for peer review.

19 The evaluation, conducted by technical experts of the Member States with the aim of re-examining the draft assessment report and the comments which it generated, took place between April and June 2004, in the course of which period six meetings of EPCO were held, during which trifluralin and also other substances were examined:

— 27 and 28 April 2004: second EPCO meeting (environmental fate and behaviour);

— 28 and 29 April 2004: third EPCO meeting (ecotoxicology);

— 10 to 12 May 2004: fourth EPCO meeting (mammalian toxicology);

— 11 and 12 May 2004: fifth EPCO meeting (residues and analytical methods);

— 15 and 16 May 2004: sixth EPCO meeting (physical and chemical properties);

— 22 June 2004: eighth EPCO meeting (ecotoxicology).

20 In the conclusions of the EPCO Expert Meeting held on 22 June 2004 (pages 93 and 94), the following is stated:

'New data requirement: The initial PECs [predicted environmental concentrations] together with the NOEC [no observed effect concentration] of 0.3µg/l should be used for a new risk assessment. If the notifier disagrees on this, additional studies with different exposure regimes to identify the most critical exposure period should be conducted.

Notifier to submit exposure studies with different exposure times using the fathead minnow [*pimephales promelas*] as the most sensitive fish species.'

21 In an email of 6 October 2004 to the notifying parties, the rapporteur Member State stated:

'Please find attached the data requirements for ecotoxicology and residues as presented in the evaluation table for trifluralin that was produced following the EPCO meetings. The sections of fate and behaviour and toxicology have no data requirements and the section of phys-chem and methods of analysis has not prepared its part since a clarification by EPCO for some point is still missing.'

22 Attached to that email of 6 October 2004 was the text of the minutes of the EPCO Expert Meeting referred to in paragraph 20 above.

23 At the meeting of the 'Evaluation' working group held by EFSA on 8 and 9 November 2004, which the notifying parties attended, the rapporteur Member State stated that they would provide certain data — in this instance the study on chronic toxicity to fish — in July 2005.

24 At the meeting of the 'Evaluation' working group held by EFSA on 8 and 9 February 2005, which the notifying parties also attended, the working group stated, with respect to ecotoxicology, that:

'Two data requirements are still open for [this section]. No information has been submitted so far.'

25 Following that meeting, the rapporteur Member State informed the notifying undertakings, by email of 22 February 2005, of the following particulars:

'The draft EFSA conclusion on trifluralin has become final following long discussions that took place during all three days of the meeting. This is due to:

— a late comment from a MS [Member State] concerning the PBT [persistence, bioaccumulation and toxicity] and POP [persistent organic pollutant] properties of trifluralin;

— a new amendment … from a MS [that proposed] taking into consideration the new Council regulation on POPs …

Although there has been no evaluation [either] by EFSA [or] by [the rapporteur Member State] on the POP properties of trifluralin, the meeting considered that a relevant paragraph should be included in EFSA conclusion, so that it will draw attention to the POP issue.

Although POP is not a [criterion] for non-inclusion of any [active substance] in Annex I [to Directive] 91/414 …, however, according to the above regulation, a substance that has been classified as POP should be withdrawn from [the European Union] market.

This is to be considered under the Commission legislation meeting when trifluralin is going to be discussed there.

However, we have no official feedback for the future steps and the timelines for these next meetings.'

26 EFSA delivered its opinion on 14 March 2005.

27 EFSA's opinion includes a list of eight studies which were to be carried out or were ongoing with, for each of those studies, information on a possible submission date given by the notifying parties, going from July 2005 to March 2006, or information that no valid date had been proposed by the notifying parties. The study on chronic toxicity to fish was included among those studies.

28 In that opinion, EFSA observed that it was unable to take into account Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ 2004 L 158, p. 7) because it had entered into force when the peer review was at an advanced stage, but that the available information assessed during the peer review should allow the Commission and the Member States to assess trifluralin with respect to the provisions of that regulation as well.

29 EFSA refers, in its conclusions, to the following matters for concern and states that various studies remain necessary:

— high toxicity for aquatic organisms, in particular fish;

— a high risk of bioaccumulation;

— high persistence in soil;

— risk of propagation over great distance by air by reason of its high volatility.

30 As regards high toxicity for aquatic organisms, EFSA takes the view that further data are needed and that risk assessment in that regard can be concluded only when those data have been evaluated (pages 33 and 34 of the report). It further considers that appropriate risk mitigation measures risks are required with respect to the high risk for aquatic organisms (page 35 of the report).

31 By letter of 2 May 2005 to Dow AgroSciences, the Commission invited the applicants to submit their comments on EFSA's final report within four weeks of receipt of that letter. The Commission also stated that, owing to the strict deadlines applicable to the assessment procedure, no further studies or modifications to the uses notified would be accepted.

32 The Commission pointed out again, in a letter of 23 June 2005 to Dow AgroSciences, that it would be unable to take new data or studies into account and that the comments could not serve to re-open the evaluation procedure. The Commission further stated that it refused to respond to the technical issues raised by the applicants or to give indications as to the positions of the Member States in that regard.

33 A draft directive for the inclusion of trifluralin in Annex I to Directive 91/414 was included on the agenda for the meeting of the Standing Committee on the Food Chain and Animal Health (SCFCAH) held on 14 and 15 July 2005 and the applicants were informed of that matter by an email from the rapporteur Member State.

34 The agenda for the next meeting of the SCFCAH, which was held on 22 and 23 September 2005, again refers to a draft directive for the inclusion of trifluralin.

35 In a note of 21 October 2005, the Commission's Directorate-General for the Environment ('the Environment DG') expressed the view that it was necessary that trifluralin be examined by the 'Technical Committee on New and Existing Substances' sub-group ('the TC-NES sub-group') against the persistent organic pollutant criteria ('POP'). The Environment DG proposed in that note, in view of the time constraints under Directive 91/414, that trifluralin should be submitted to a group of experts as

soon as possible, despite the absence of a formal decision on this procedure. It stated that such an opinion would be very helpful for the SCFCAH and the Commission in the procedure carried out in the context of Directive 91/414. In that note, the Environment DG also expressed the wish that the TC-NES sub-group should discuss that point at its meeting on 25 and 26 October 2005.

36 At the meeting of the SCFCAH held on 17 and 18 November 2005, it was stated that the dossier had been referred to the TC-NES sub-group.

37 In a letter of 6 January 2006, the EUTTF took note of the examination undertaken on the basis of the POP criteria and submitted its comments on the POP evaluation to the TC-NES sub-group.

38 The applicants wrote to the Commission on 19 January 2006 in order to challenge the legality, in the context of the evaluation required under Directive 91/414, of the evaluation of trifluralin against the POP criteria.

39 In a working document drawn up by the Environment DG and dated 3 February 2006, the following is stated:

'Trifluralin has been identified as a potential POP substance and the … TC-NES [subgroup] has, on request of the [competent] authorities [under Directive 91/414], reviewed the dossier in the light of the POP screening criteria …

The conclusion of the … sub-group was that trifluralin fulfils the POP screening criteria. However, this conclusion has been drawn having in mind that some of the comments indicate that a conclusion on the relevance of the persistence for the identification of a global concern may need more detailed investigation.

The case of trifluralin is the first of this kind under [Directive 91/414] and, in its meeting, the [relevant] working group ["Legislation"] could not agree on how Article 3(3) of Regulation [No] 850/2004 should be interpreted in this type of case. Therefore, the [working group] decided to ask advice from the competent authorities of Regulation [No] 850/2004 on this matter.

…

Conclusions

Trifluralin is an example of an existing active substance used in plant protection products exhibiting POP characteristics. Therefore Article 3(3) of Regulation [No] 850/2004 has to be applied when considering inclusion of trifluralin in Annex I [to Directive 91/414] and when granting a national authorisation for a plant-protection product containing trifluralin.

The wording of Article 3(3) of Regulation [No] 850/2004 concerning existing chemicals and pesticides leaves a lot to the discretion of authorities involved in the assessment and authorisation schemes. In the case of a plant-protection product which is intentionally applied to field crops and therefore also spread into the environment, exposure can only be fully eliminated by prohibiting the use. However, one cannot directly deduce an obligation to eliminate all exposure from the Regulation or the Stockholm Convention [on POPs, signed on 22 May 2001]. The decision on what can

be regarded as "an appropriate measure to control" a POP-like substance is therefore left to be made, case by case, [by] the authorities working within the particular assessment and authorisation scheme.

The POP competent authorities are requested to discuss the issue with their counterparts [under Directive 91/414] before the meeting, give their views on the above and, if possible, to agree on an opinion/advice concerning the interpretation of Article 3(3) of the Regulation that can be forwarded to the … competent authorities [under Directive 91/414].'

40 The Commission replied to the applicants' letter of 19 January 2006 by letter of 14 March 2006, in which it, first, stated that EFSA assumed sole responsibility for the content of its report and, secondly reminded them of the functional separation between EFSA and the Commission.

41 On 17 May 2006 the applicants submitted to the rapporteur Member State a study on chronic toxicity to fish undertaken in March 2005 by an independent laboratory, together with an updated chronic risk assessment. That study was also submitted on 12 June 2006 to the Commission, which communicated it to the Member States via the Commission's 'Circa' internet page.

42 It follows from the draft minutes of the SCFCAH meeting held on 22 and 23 May 2006, the agenda for which this time included the examination of a proposal for a decision for the non-inclusion of trifluralin in Annex I to Directive 91/414, that the Commission took the view that the chronic toxicity study submitted by the applicants was out of time and that there was thus no need to take it into consideration.

43 At the SCFCAH meeting held on 13 and 14 July 2006, the Commission again submitted a proposal for a decision for the non-inclusion of trifluralin in Annex I to Directive 91/414. The minutes of that meeting state, however:

'Comments and.. information on a late study on the chronic risk [of trifluralin] to fish have been circulated. … Since the internal discussion has not been finalised yet, no proposal can be voted.'

44 The minutes of the SCFCAH meeting held on 28 and 29 September 2006, the agenda of which again included the legal position in regard to trifluralin, state:

'A number of [Member States] call [for] a rapid conclusion of this dossier. [The Commission] explains that no vote can be taken as the [Commission's] internal agreement procedure could not be finalised.'

45 The dossier was once again on the agenda of the SCFCAH meetings held on 23 and 24 November 2006 and on 22 and 23 January 2007, but no vote was taken.

46 The minutes of the meeting held on 23 and 24 November 2006 state:

'[The Commission] notes that the chronic toxicity to fish had been during the entire procedure a point of dispute between [the] notifier, [the rapporteur Member State] and EFSA, which would indicate that it is not possible to decide on the study without the need [for] a peer review on this subject. [The Commission] expresses also its concern as regards the taking into account of non-peer-reviewed data or data used at national levels. It recalls the principle of a system which expects the [Commission] to

base its decision on the scientific evidence as provided by EFSA. Doing otherwise is not only against the legal provisions but could entirely undermine the current review process.

[The Federal Republic of Germany] declares that on the basis of Directive [91/414] it has to take the latest scientific knowledge into account when evaluating and deciding on applications for national authorisations. This latest scientific knowledge cannot be ignored when at the same time a national position regarding Annex I inclusion of the active substance has to be defined.'

47 On 16 March 2007, the SCFCAH delivered an opinion in favour of the non-inclusion of trifluralin in Annex I to Directive 91/414.

48 As may be seen from the summary report of that meeting, however, a number of Member States made certain observations on that occasion, including the rapporteur Member State, which had a declaration noted down in the minutes stating that it was in a position to vote in favour of the proposal for the non-inclusion of trifluralin, in order to allow the notifying parties to take advantage of the 18-month period to submit formally the study on chronic toxicity to fish and to allow it, as rapporteur Member State, formally to evaluate that study.

49 On 20 September 2007, the Commission adopted the decision concerning the non-inclusion of trifluralin in Annex I to Directive 91/414 and the withdrawal of authorisations for plant-protection products containing that substance (OJ 2007 L 255, p. 42) ('the contested decision').

50 The contested decision states as follows:

‘(4) The assessment report has been peer reviewed by the Member States and the EFSA within its Working Group Evaluation and presented to the Commission on 14 March 2005 in the format of the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance trifluralin. This report has been reviewed by the Member States and the Commission within the [SCFCAH] and finalised on 16 March 2007 in the format of the Commission review report for trifluralin.

(5) During the evaluation of this active substance, a number of concerns were identified. Trifluralin is of high toxicity to aquatic organisms, in particular fish. It is also highly persistent in soil and not readily biodegradable. Moreover, it shows potential for accumulation. In particular, it exceeds significantly the maximum bioconcentration factor (BCF) laid down in Directive 91/414 … for aquatic organisms, indicating a potential for bioaccumulation in such organisms. Due to its high volatility, transport through air cannot be excluded and, despite a rapid photochemical degradation, monitoring programmes have shown migration to places distant from application. These concerns made it appear that trifluralin does not meet 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 forward 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 trifluralin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414 …

(7) Trifluralin should therefore not be included in Annex I to Directive 91/414 …

…

Article 1

Trifluralin 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 trifluralin are withdrawn by 20 March 2008;

(b) no authorisations for plant-protection products containing trifluralin 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 20 March 2009 at the latest.

Article 4

This Decision is addressed to the Member States.'

51 On 11 April 2008 the applicants informed the Commission of their intention to submit a fresh request for inclusion of trifluralin in Annex I to Directive 91/414, as permitted by Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414 as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that directive but have not been included in its Annex I (OJ 2008 L 15, p. 5).

52 The contested decision was repealed by Article 2 of Commission Decision 2010/355/EU of 25 June 2010 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414 (OJ 2010 L 160, p. 30).

Procedure and forms of order sought

53 By application lodged at the Registry of the General Court on 21 December 2007, the applicants brought an action under the fourth paragraph of Article 230 EC for annulment of the contested decision and also for a declaration that Article 3(3) of Regulation No 850/2004 is illegal.

54 By separate document lodged at the Court Registry on 19 March 2008, Dow AgroSciences Ltd, Dow AgroSciences LLC, Dow AgroSciences, Dow AgroSciences Export, Dow AgroSciences BV, Dow AgroSciences Hungary kft., Dow AgroSciences Italia Srl, Dow AgroSciences Polska sp. z o.o., Dow AgroSciences Iberica SA, Dow AgroSciences s.r.o., Dow AgroSciences Danmark A/S, Dow AgroSciences GmbH, Dintec Agroquímica — Produtos Químicos Lda and Finchimica Spa lodged an application under Article 242 EC for suspension of the operation of the contested decision. That application was dismissed by order of the President of the General Court of 18 June 2008.

55 By letter lodged at the Registry of the General Court on 23 July 2010, the Commission informed the Court that it had adopted Decision 2010/355, by which it had decided, subsequent to the procedure established by Regulation No 33/2008, first, not to include trifluralin in Annex I to Directive 91/414 and, second, to repeal the contested decision.

56 The Court addressed to the parties, on 3 September 2010, a written question as to the consequences to be drawn from the repeal of the contested decision.

57 By application lodged at the Court Registry on 17 September 2009, Dow AgroSciences Ltd and Dintec Agroquímica — Produtos Químicos Lda brought an action for annulment of Decision 2010/355, which forms the subject-matter of Case T-446/10.

58 By letter lodged at the Court Registry on 29 September 2010, the Commission requested that the Court find that there was no need to give a decision in the present case in so far as, in view of the repeal of the contested decision, the action had become devoid of purpose.

59 By letter lodged at the Court Registry on the same date, the applicants submitted that they retained an interest in having the contested decision annulled and they requested the Court to allow them to amend the form of order sought in such a way as to extend their application for annulment to cover Decision 2010/355.

60 The parties set out their observations on their respective applications by letters of 15 October 2010.

61 By letter from the Court Registry sent to them on 9 November 2010, the parties were informed of, inter alia, the fact that the Court refused to grant to the applicants the possibility of amending the form of order sought in such a way as to extend their application for annulment to cover Decision 2010/355, the Court having noted that, in the meantime, an action for annulment of that decision had been brought by Dow AgroSciences Ltd and Dintec Agroquímica — Produtos Químicos Lda.

62 The applicants claim that the Court should:

— annul the contested decision;

— declare Article 3(3) of Regulation No 850/2004 illegal and inapplicable to them in so far as it concerns the examination of trifluralin;

— order the Commission to pay the costs incurred by the applicants, together with interest at 8 %.

63 The Commission contends that the Court should:

— declare the application for annulment of the contested decision to be devoid of purpose and, as a consequence, reject the applicants' application for annulment as inadmissible or, alternatively, reject it as unfounded;

— reject the plea of illegality with respect to Article 3(3) of Regulation No 850/2004;

— order the applicants to pay the costs incurred by the Commission.

Law

The subject-matter of the dispute

64 The Commission submits, in essence, that the applicants have lost any interest in securing the annulment of the contested decision since it has been repealed by Decision 2010/355.

65 The applicants dispute that argument.

66 According to settled case-law, an applicant's legal interest in bringing proceedings must exist on the day on which they are brought, failing which they will be inadmissible. Furthermore, the applicant's interest in obtaining satisfaction must continue until the final decision, failing which there will be no need to adjudicate (see, to that effect, Case 14/63 *Forges de Clabecq* v *High Authority* [1963] ECR 357, at p. 371, and Case C-362/05 P *Wunenburger* v *Commission* [2007] ECR I-4333, paragraph 42).

67 It is also settled case-law that there is no longer any need to adjudicate on a claim for annulment in the event that an applicant has, on account of an event occurring since the action was brought, lost all legal interest in having the contested measure annulled (see the order in Case T-28/02 *First Data and Others* v *Commission* [2005] ECR II-4119, paragraphs 36 and 37 and the case-law cited), which means that the annulment of that measure is, of itself, no longer capable of having legal consequences (see, to that effect, the order in Case T-25/96 *Arbeitsgemeinschaft Deutscher Luftfahrt-Unternehmen and Hapag-Lloyd* v *Commission* [1997] ECR II-363, paragraph 16 and the case-law cited).

68 However, an applicant may continue to have an interest in securing the annulment of a measure which has been repealed, in so far as a repeal does not give rise to the same legal effects as annulment by the General Court. The repeal of a measure of an institution does not amount to recognition of its illegality and takes effect *ex nunc*, whereas its annulment would take effect *ex tunc* (see, to that effect, Joined Cases 16/59 to 18/59 *Geitling and Others* v *High Authority* [1960] ECR 17, and Joined Cases T-481/93 and T-484/93 *Exporteurs in Levende Varkens and Others* v *Commission* [1995] ECR II-2941, paragraphs 46 to 48).

69 Moreover, an institution whose act has been declared void is required to take the necessary measures to comply with the judgment. Those measures involve, inter alia, the removal of the effects of the illegal conduct found in the judgment annulling the act. The institution concerned may thus be required to take adequate steps to restore the applicant to his original position or to avoid the adoption of an identical measure

(see *Exporteurs in Levende Varkens and Others* v *Commission*, cited in paragraph 68 above, paragraph 47 and the case-law cited).

70 In the present case, the contested decision was repealed, and not withdrawn, by the Commission. Consequently, it continues to produce legal effects in respect of the applicants' position for the period between the time when it entered into force and the time when it was repealed. Its annulment may therefore have, in itself, consequences for the legal position of the applicants, with the result that they retain their legal interest in bringing proceedings.

71 The Commission's request for an order that there is no need to adjudicate must therefore be rejected.

Substance

72 In support of their application, the applicants put forward six pleas in law and a plea of illegality relating to Article 3(3) of Regulation No 850/2004.

73 The first plea alleges that the contested decision is not based on the EFSA report provided for in Article 8(8) of Regulation No 451/2000 and was adopted in breach of the procedural rules applicable.

74 In support of their second plea, the applicants claim that the Commission made a number of manifest errors of assessment.

75 The third plea alleges that the contested decision fails to comply with the applicable legislative procedure and breaches Article 5 EC, Article 7 EC, Article 8(8) of Regulation No 451/2000 and Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23) ('the comitology decision').

76 The fourth plea alleges failure to observe the procedural deadlines provided for by Article 8(7) and (8) of Regulation No 451/2000.

77 The fifth plea alleges that the contested decision is inadequately reasoned.

78 Lastly, the sixth plea alleges infringement of the principles of legal certainty, of the protection of legitimate expectations and of proportionality, and also infringement of the rights of the defence and of the right to a fair hearing.

The first plea: the contested decision is not based on the EFSA report, contrary to Article 8(8) of Regulation No 451/2000, and was adopted in breach of the applicable procedural rules

79 The applicants submit, in essence, that the Commission is required to follow EFSA's opinion. According to the applicants, EFSA, like the rapporteur Member State, recommended in the present case that trifluralin be included in Annex I to Directive 91/414, in so far as the risks which that substance presented were acceptable, subject to compliance with a number of conditions. Since the Commission proposed that trifluralin should not be included in Annex I to Directive 91/414, it did not base

its proposal on EFSA's opinion and therefore breached Article 8(8) of Regulation No 451/2000.

80 Furthermore, the applicants submit, in essence, that the Commission reopened the evaluation procedure to analyse trifluralin in the light of the POP criteria provided for by Regulation No 850/2004. In so far as there was no legal basis for acting in that manner in the context of the evaluation provided for by Directive 91/414, the Commission was not competent to order such a reopening of the evaluation procedure and it therefore, according to the applicants, intervened in EFSA's evaluation. In so doing, they argue, it abused its powers.

81 The Commission disputes those claims.

82 First, it must be borne in mind that Article 22(6) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) provides that EFSA is to provide opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission. Furthermore, under Article 23(c) of that regulation, it is the task of EFSA to provide scientific and technical support to the Commission in the areas within its mission and, when so requested by the Commission, in the interpretation and consideration of risk assessment opinions.

83 Under Article 8(7) of Regulation No 451/2000, EFSA is to evaluate the rapporteur Member State's draft assessment report and to 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 rapporteur Member State's

draft assessment report. Where appropriate, EFSA is, moreover, to give its opinion on the available options claimed to meet the safety requirements.

84 Lastly, Article 8(8) of Regulation No 451/2000 provides that, at the latest six months after receipt of the EFSA opinion referred to in paragraph 7, the Commission is to submit a draft review report and, on the basis of the finalised review report, is to submit to the Committee either a draft directive to include the active substance in Annex I to Directive 91/414 or a draft decision addressed to the Member States to withdraw the authorisations of plant-protection products containing the active substance, mentioning the reasons for the non-inclusion. The directive or decision of the Commission is to be adopted in accordance with the regulatory procedure as laid down by the comitology decision.

85 Thus, refusal to authorise marketing must be based on a detailed assessment of the risk to public health, based on the most reliable scientific data available and the most recent results of international research (Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraph 50).

86 Furthermore, it must be borne in mind that, as is clear from the fifth, sixth and ninth recitals in the preamble thereto, Directive 91/414 seeks to remove barriers to intra-Community trade in plant-protection products, while maintaining a high level of protection of the environment and of human and animal health. 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 (see Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, paragraphs 74 and 75 and the case-law cited).

87 In that regard, the Court has repeatedly held that, under the provisions of Article 8 of Regulation No 451/2000, the Commission is not bound by the opinion of EFSA. Although, admittedly, the Commission adopts its decision not to include, or to include, the substance in question in Annex I to Directive 91/414 after obtaining the opinion of EFSA, note must be taken of the fact that there is nothing in Regulation No 451/2000 to suggest that the Commission is obliged to comply with EFSA opinions in substantive terms and therefore has no discretion (orders of the Court of 17 June 2008 in Case T-312/06 *FMC Chemical* v *EFSA*, not published in the ECR, paragraphs 52 to 54, in Case T-397/06 *Dow AgroSciences* v *EFSA*, not published in the ECR, paragraph 49, and in Case T-311/06 *FMC Chemical and Arysta Lifesciences* v *EFSA*, not published in the ECR, paragraph 52).

88 As EFSA's opinion does not bind the Commission, the applicants err in their contention that the Commission could not deviate from that opinion of EFSA without thereby breaching Article 8 of Regulation No 451/2000.

89 Moreover, the fact remains that it is not apparent from EFSA's conclusions that, in the present case, it expressly recommended that trifluralin be included in Annex I to Directive 91/414, as the applicants maintain.

90 EFSA, in its opinion, assesses the risks which trifluralin poses in the light of the scientific knowledge available at the time of that assessment, and states, in essence, that there are a number of uncertainties which have not been dispelled as regards the safety of the substance.

91 EFSA goes on to outline, in accordance with the provisions of Article 8(7) of Regulation No 451/2000, certain mechanisms which may make it possible to manage the risks highlighted during the evaluation procedure in the event that the Commission should decide to authorise the substance.

92 Consequently, the fact that EFSA envisages such risk management procedures cannot be interpreted as constituting a recommendation that trifluralin be included in Annex I to Directive 91/414.

93 The applicants' line of argument in this regard must therefore be rejected.

94 Secondly, under Article 8 of Regulation No 451/2000, the rapporteur Member State must evaluate and report on those active substances for which at least one dossier has been determined to be complete in accordance with Article 6(2) and (3) of that regulation. In its report, it must make a recommendation to the Commission either to include the active substance in Annex I to the directive, stating the conditions for inclusion, or not to include the active substance in that annex, stating the reasons for the non-inclusion. Next, EFSA must evaluate the rapporteur Member State's draft assessment report and deliver to the Commission its opinion on whether the active substance can be expected to meet the safety requirements of Directive 91/414. The Commission, on the basis of the finalised review report, must then submit to the competent committee either a draft directive to include the active substance in Annex I to Directive 91/414 or a draft decision to withdraw the authorisations of plant-protection products containing the active substance, with the result that that active substance is not included in that annex.

95 Consequently, it is clear from the legislative framework that the view of the rapporteur Member State in the evaluation process is not decisive (see, by analogy, Case T-75/06 *Bayer CropScience and Others* v *Commission* [2008] ECR II-2081, paragraph 164).

96 The applicants cannot therefore validly rely on information which has been given to them by the rapporteur Member State regarding the possible outcome of the procedure (see, by analogy, *Bayer CropScience and Others* v *Commission*, cited in paragraph 95 above, paragraph 164).

97 Thirdly, in so far as the applicants seek to argue that the Commission disregarded EFSA's opinion, it must be pointed out that recitals 4 to 6 in the preamble to the contested decision show clearly that the Commission took that opinion into consideration during the adoption of that decision. That line of argument cannot therefore succeed.

98 Fourthly, and lastly, it must be pointed out, as regards the head of claim alleging that the evaluation of the substance was carried out in the light of the POP criteria deriving from Regulation No 850/2004, that that head of claim is indissociable from the fourth part of the second plea in law. That head of claim will therefore be examined in that context.

99 The first plea must, accordingly, be dismissed.

The first and second parts of the second plea in law: manifest errors of assessment, in that the Commission failed to comply with the obligation to take all available scientific evidence into account, in particular a study which was requested from the notifiers, and ought to have extended the applicable deadline in order to have that additional information

100 As regards the first part of their second plea, the applicants submit, in essence, that the rapporteur Member State and EFSA requested that they submit a study on chronic toxicity to fish. They refer, in that regard, to the reporting tables of EFSA's meeting of 22 June 2004 and to the email from the rapporteur Member State of 6 October 2004, by which that Member State communicated those tables to them. According to the applicants, the confirmation that such a request was indeed made to the notifiers is also to be found on pages 30 and 33 of EFSA's opinion.

101 The applicants maintain that they submitted the requested study to the Commission as soon as it was available and deny having shown a lack of diligence in that regard. According to the applicants, it was therefore for the Commission, under the combined provisions of Article 5(1) of Directive 91/414 and Article 8(5) of Regulation No 451/2000, to examine the new data submitted. The Commission, however, considered that that study had been submitted out of time and took the view, which it stated to the members of the SCFCAH, that the study could not, therefore, be taken into consideration.

102 According to the applicants, the Commission thus failed to take account of the most recent scientific evidence available and of current scientific and technical knowledge, in breach of Article 5(1) of Directive 91/414. The contested decision is, they submit, therefore vitiated by a manifest error of assessment. It also follows that there was an infringement of the principle of legal certainty and of the principle of the protection of legitimate expectations.

103 As regards the second part of their second plea, the applicants submit, in essence, that it was impossible to respond to the request for a new study which had been made to the notifiers within the procedural deadlines fixed for the evaluation procedure. However, according to the applicants, as those deadlines were not complied with either by EFSA or by the Commission in the context of the evaluation of trifluralin, it was for the Commission to establish new deadlines in order to take the study into consideration instead of taking refuge behind the alleged lateness of that study. They claim, first, that the possibility of extending such deadlines has been recognised by the case-law, in which it has been held that a refusal to extend deadlines may be equated with a manifest error of assessment (*Industrias Químicas del Vallés* v *Commission*, cited in paragraph 86 above), and, secondly, that that possibility has been used by the Commission in the evaluation of other plant-protection substances. They refer in that regard to Commission Decision 2008/353/EC of 29 April 2008 allowing Member States to extend provisional authorisations granted for the new active substances cyflufenamid, FEN 560 and flonicamid (OJ 2008 L 117, p. 45).

104 The relevance of the study for the evaluation of trifluralin appears, however, according to the applicants, to be clearly established as the rapporteur Member State which examined that study concluded that the additional data in it addressed the concerns which had been raised during the evaluation procedure.

105 Furthermore, the applicants submit that the Commission ought also to have extended the deadlines, since it had instructed the TC-NES sub-group to examine the substance against the POP criteria, in order to enable the notifiers to address any concerns which might have been expressed during that examination and to submit, if necessary, relevant data and studies for the purposes of that examination.

106 The applicants contend that the Commission thus failed to comply with its obligation to put in place adequate procedural guarantees to ensure that they would be given the opportunity to comment and to defend themselves as notifiers.

107 The Commission disputes those claims.

108 It must be borne in mind that Article 6(1) and (3) of Regulation No 451/2000 provides that notifiers must submit to the designated authority of the rapporteur Member State for any given active substance a complete dossier which must contain physically the individual test and study reports concerning all the information referred to in Article 6(2)(c), or the protocols and the undertakings referred to in Article 6(2)(c) where work is in progress.

109 The information referred to in Article 6(2)(c) of Regulation No 451/2000 is the following:

— for each point of Annex II to the directive, the summaries and results of studies and trials, and the name of the person or institute that has carried out the trials;

— the same information for each point of Annex III to the directive relevant to the assessment of the criteria referred to in Article 5 of the directive for one or more preparations which are representative for the uses referred to in Article 6(2)(b);

— for studies not yet fully completed, the evidence that these studies have been commissioned at the latest three months after the entry into force of Regulation No 451/2000 with an undertaking that they will be submitted at the latest within 12 months after the time-limit for submission to the rapporteur Member State of the dossiers referred to in Article 6.

110 Furthermore, it must be borne in mind that Article 8(5) of Regulation No 451/2000 provides that, without prejudice to Article 7 of Directive 91/414, submission of new studies will not be accepted. However, the rapporteur Member State, with the agreement of EFSA, may request the notifiers to submit within specified periods further data considered by the rapporteur Member State or EFSA to be necessary to clarify the dossier.

111 The communication of further data can therefore have the purpose only of clarifying information already submitted in the complete dossier which must be presented by the notifiers.

112 The submission of new studies, which is precluded, cannot therefore be equated, for the purposes of that provision, with the communication of further clarifying data, which is, by contrast, possible.

113 The submission of an additional study will be possible only in so far as the study was ongoing at the time of submission of the complete dossier, the communication of that study was announced when the dossier was submitted, and the study was submitted no later than one year after the submission of that dossier.

114 Consequently, only a request for further clarifying data is permitted after the submission of the complete dossier, and this on condition that that request complies with the conditions set out in Article 8(5) of Regulation No 451/2000, which provides, in essence, that the request must come from the rapporteur Member State, must take place with the agreement of EFSA and must specify the period within which those data are to be communicated.

115 It must, however, be pointed out that, in the present case, none of those conditions is satisfied.

116 It is true that it is not disputed that the need to have available further studies concerning the chronic toxicity of the substance in respect of fish was pointed out by EPCO's experts at their meeting on 22 June 2004, that this was referred to by EFSA in its opinion ('[n]otifier to submit exposure studies with different exposure times using the fathead minnow as most sensitive fish species'), and that the notifiers were made aware of that information by the rapporteur Member State in its email of 6 October 2004.

117 That email does not, however, imply that a request for further clarifying data, within the meaning of Regulation No 451/2000, was made to the notifiers, as they claim.

118 First, EPCO, the rapporteur Member State and EFSA mention the need to have additional studies. EPCO's minutes, the rapporteur Member State's email and EFSA's opinion thus make it possible to reject the idea that the notifiers were requested to submit further data designed to clarify the dossier.

119 Furthermore, it must be pointed out that the applicants themselves claim that the work submitted by the notifiers on 17 May 2006 constitutes a study.

120 Secondly, even if it is assumed that the need to have additional studies could be categorised as a request for further data, it must be stated that the dossier does not contain any indication that EFSA gave its agreement to such a request. It must be pointed out in that regard that EPCO, which is a group of experts which carries out specific assessments for the purpose of drawing up EFSA's opinion, is consequently separate from EFSA and cannot therefore bind EFSA without the latter's express approval.

121 Thirdly, it must pointed out that, in the present case, no deadline was specified for the submission of the studies referred to by EPCO and subsequently by the rapporteur Member State.

122 Contrary to what the applicants submit, that absence of a deadline constitutes an additional indication which permits the inference that there was no request for further data.

123 If, by reason of an omission, no deadline were established for the submission of further data, the notifiers would be able to continue the peer review procedure indefinitely and thus to delay without justification EFSA's adoption of its opinion.

124 It follows that nothing allows the inference to be drawn that a request for further data in accordance with the applicable provisions was made to the notifiers.

125 The facts put forward by the applicants in support of their claims tend, by contrast, to suggest that EPCO and the rapporteur Member State, and subsequently EFSA, found and stated to the notifiers that further studies were still necessary in order to assess the safety of the substance, while fully aware that those studies could no longer be submitted at that stage of the procedure.

126 That assessment is confirmed by the minutes of the meeting on 15 and 16 March 2007 of the SCFCAH's 'Legislation' working group, in which the Hellenic Republic, which was the rapporteur Member State, had a declaration noted down stating that it was in a position to vote in favour of the proposal for the non-inclusion of trifluralin, in order to allow the notifying parties to take advantage of the 18-month period to formally submit the study on fish and to allow it, as rapporteur Member State, to formally evaluate that study.

127 Fourthly, and lastly, it must be pointed out, for the sake of completeness, that the applicants have never claimed that the study submitted to the rapporteur Member State on 17 May 2006 had been announced by the notifiers, in accordance with the third indent of Article 6(2)(c) of Regulation No 451/2000, at the time when they submitted their complete dossier.

128 Accordingly, it must be held that no request for a further study was made to the notifiers.

129 It follows that the Commission cannot be criticised for refusing to take into consideration the study submitted by the notifiers in May 2006.

130 The head of claim alleging infringement of the principle of the protection of legitimate expectations will be examined in the context of the sixth plea.

131 As the Commission thus did not err in law or make a manifest error of assessment, the first part of the second plea must be rejected.

132 As regards the head of claim submitted by the applicants in the context of the second part of their second plea, to the effect that the deadlines should have been extended to take account of the requested study, the fact remains that this has no factual basis since no request of that kind was made to the notifiers.

133 Moreover, it must be borne in mind that, at the meeting of the EFSA 'Evaluation' working group, which took place on 15 January 2004, it was, inter alia, found that various data and studies, including a study on metabolism in oilseeds, were necessary. That study is separate from that which was provided by the applicants in May 2006. On 3 March 2004, however, a representative of the notifying undertaking sent an email to EFSA in which he asked it, inter alia, to advise on the deadline for submission of that study. On 5 March 2004, EFSA replied to that email, stating, first, that it was the task of the notifying undertaking to provide that study or to state when it could be submitted and, secondly, that the peer review would continue to stay in line with the deadlines provided for by Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Directive 91/414 and amending Regulation No 451/2000 (OJ 2002 L 224, p. 23).

134 It follows that, as of that time, the applicants had been clearly informed that no additional period would be granted to them to supplement their dossier and it must be held that they have failed to establish that specific assurances to the contrary were expressly given to them with regard to the study relating to chronic toxicity to fish.

135 As the Commission did not err in law or make a manifest error of assessment by refusing to extend the procedural deadlines to take account of the study on chronic toxicity to fish, the second part of the second plea must also be rejected.

136 The head of claim alleging that the Commission ought to have extended the deadlines, since it had made trifluralin subject to an assessment against the POP criteria, will be examined in the context of the fourth part of the second plea.

137 The head of claim alleging infringement of the rights of the defence will be examined in the context of the second part of the sixth plea.

The third part of the second plea: manifest error of assessment, in that the Commission's findings are not supported by any scientific justification

138 The applicants submit that the Commission's finding that trifluralin is of high chronic toxicity for aquatic organisms, which is set out in recital 5 in the preamble to the contested decision, is meaningless in the context of a risk assessment under Directive 91/414. They maintain that what matters is the risk assessment in order to determine whether, in spite of the particular hazard identified, that risk is acceptable for a given

use. They state that the chronic toxicity study which they provided showed clearly that the risk was acceptable, a finding which had been accepted by the rapporteur Member State.

139 EFSA, they claim, reached the same conclusion, since it took the view that trifluralin met the safety requirements laid down in Directive 91/414, provided that a number of conditions were satisfied. EFSA considered that the risk of chronic toxicity for fish could be managed by imposing appropriate conditions of use and that the risks identified did not preclude the inclusion of trifluralin in Annex I to Directive 91/414. EFSA and the rapporteur Member State also concluded that trifluralin presented an acceptable risk in respect of persistence in soil, potential for accumulation and transport through air.

140 Furthermore, the Federal Republic of Germany authorised trifluralin-based products marketed by the applicants for a further 10 years, thereby rejecting the existence of an unacceptable risk.

141 The applicants take the view that the findings made in the contested decision are therefore based on hazards and not on risks, which is the consequence of a fundamental methodological error. In so far as there is no scientific justification for the Commission's findings, the Commission, they submit, therefore made a manifest error of assessment.

142 The Commission disputes those claims.

143 It must be borne in mind that Article 152(1) EC provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities. The protection of human health takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see, to that effect, Case T-158/03 *Industrias Químicas del Vallés* v *Commission* [2005] ECR II-2425, paragraph 134).

144 The precautionary principle constitutes a general principle of Community law, stemming from Articles 3(1)(p) EC, 6 EC, 152(1) EC, 153(1) and (2) EC and 174(1) and (2) EC, requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests (see Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR II-4945, paragraphs 183 and 184, and Case T-392/02 *Solvay Pharmaceuticals* v *Council* [2003] ECR II-4555, paragraph 121 and the case-law cited).

145 The risk assessment consists, for the Community institution faced with potentially negative effects stemming from a phenomenon, in assessing, on the basis of a scientific assessment of the risks, whether they exceed the level of risk deemed unacceptable for society. Thus, in order for the Community institutions to be able to carry out a risk assessment, it is important for them, first, to have a scientific assessment of the risks and, secondly, to determine what level of risk is deemed unacceptable for society (see, to that effect, Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 145, and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 162).

146 A scientific risk assessment is a scientific process which is commonly accepted as consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk (*Pfizer Animal Health* v *Council*, cited in paragraph 145 above, paragraph 156, and *Alpharma* v *Council*, cited in paragraph 145 above, paragraph 169).

147 In such a situation, 'risk' thus constitutes the degree of probability that the acceptance of certain measures or practices will adversely affect the interests safeguarded by the legal order. 'Hazard' is commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health (see, in that regard, *Pfizer Animal Health* v *Council*, cited in paragraph 145 above, paragraph 147).

148 The responsibility for determining the level of risk which is deemed unacceptable lies, provided that the applicable rules are observed, with the Community institutions responsible for the political choice of determining an appropriate level of protection for society. It is for those institutions to determine the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects which, in their judgment, is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty (see, to that effect, Case C-473/98 *Toolex* [2000] ECR I-5681, paragraph 45, and *Pfizer Animal Health* v *Council*, cited in paragraph 145 above, paragraphs 150 and 151).

149 In determining that level of risk, the Community institutions are bound by their obligation, under the first subparagraph of Article 152(1) EC, to ensure a high level of human health protection. That high level does not necessarily, in order to be compatible with that provision, have to be the highest that is technically possible (Case C-284/95 *Safety Hi-Tech* [1998] ECR I-4301, paragraph 49).

150 It should be noted that, as is clear from the fifth, sixth and ninth recitals in the preamble thereto, Directive 91/414 seeks to remove barriers to intra-Community trade in plant-protection products, while maintaining a high level of protection of the environment and of human and animal health. 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 (see Case C-326/05 P *Industrias Químicas del Vallés* v *Commission*, cited in paragraph 86 above, paragraphs 74 and 75 and the case-law cited).

151 That broad discretion and those complex technical assessments imply that the judicial review of the merits of the assessments made by the Commission is limited to verifying whether there has been a manifest error of appraisal or a misuse of powers on the part of the Community institutions, or whether they have manifestly exceeded the limits of their discretion (Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 135, and Case C-425/08 *Enviro Tech (Europe)* [2009] ECR I-10035, paragraph 47).

152 As regards the assessment by the European Union Courts as to whether there has been a manifest error of assessment, it must be stated that, in order to establish that the Commission committed a manifest error of assessment in assessing complex facts such as to justify the annulment of a decision which is contested, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the decision implausible (Case T-380/94 *AIUFFASS and AKT* v *Commission* [1996] ECR II-2169, paragraph 59, and Case T-308/00 *Salzgitter* v *Commission* [2004] ECR II-1933, paragraph 138). Without prejudice to that examination of plausibility, it is not for the General Court to substitute its assessment of complex facts for that of the institution which adopted the decision (*Enviro Tech (Europe)*, cited in paragraph 151 above, paragraph 47).

153 The abovementioned limits to the review by the European Union Courts do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, whether that evidence contains all the information which

must be taken into account in order to assess a complex situation, and whether it is capable of substantiating the conclusions drawn from it (Case C-525/04 P *Spain* v *Lenzing* [2007] ECR I-9947, paragraph 57, and Case C-405/07 P *Netherlands* v *Commission* [2008] ECR I-8301, paragraph 55).

154 Moreover, it must be recalled that, where a Community institution has a wide discretion, the review of observance of guarantees conferred by the Community legal order in administrative procedures is of fundamental importance. The Court of Justice has had occasion to specify that those guarantees include, in particular for the competent institution, the obligations to examine carefully and impartially all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14; Joined Cases C-258/90 and C-259/90 *Pesquerias De Bermeo and Naviera Laida* v *Commission* [1992] ECR I-2901, paragraph 26; *Spain* v *Lenzing*, cited in paragraph 153 above, paragraph 58; and *Netherlands* v *Commission*, cited in paragraph 153 above, paragraph 56).

155 In the present case, first, it must be pointed out that EFSA's opinion deals with the analysis of the risk to various species of animal and macro-organisms (section 5: risks to terrestrial vertebrates, aquatic organisms, bees, other arthropod species, earthworms, other soil non-target macro-organisms, soil non-target micro-organisms, other non-target-organisms (flora and fauna) and to biological methods of sewage treatment); states that trifluralin is strongly absorbed by soil and could be classified as immobile; that it is not readily biodegradable; that its high volatility makes the occurrence of trifluralin in air and transport through air possible, and mentions a high degree of risk as regards aquatic organisms (see page 3 of the summary of the opinion and, in particular, in respect of the latter issue, section 5.4 and the conclusion of the opinion). Lastly, EFSA suggests measures to manage the risks identified if a decision to include trifluralin in Annex I to Directive 91/414 is adopted (the section 'Conclusions and recommendations' in the opinion).

156 It is therefore apparently from EFSA's opinion that it is clearly based on an assessment of the risks which trifluralin presents and not solely on the hazards to which it gives rise.

157 Furthermore, the opinion also invalidates the applicants' claims that trifluralin presents an acceptable risk in respect of its persistence in soil, potential for accumulation and transport through air.

158 Moreover, the fact that EFSA envisaged, in accordance with the provisions of Article 8(7) of Regulation No 451/2000, certain mechanisms which may make it possible to manage the risks highlighted during the evaluation procedure if the Commission were to decide to authorise the substance, in no way means that EFSA must be regarded as having recommended that trifluralin be included in Annex I to Directive 91/414 (see paragraphs 91 and 92 above). Furthermore, it must be borne in mind that EFSA's opinion does not bind the Commission (see paragraphs 87 and 88 above) and that the Commission is recognised as enjoying a broad discretion in order to enable it to pursue effectively the objective assigned to it, account being taken of the complex technical assessments which it must undertake (see paragraph 86 above). The Commission could therefore legitimately decide that such a risk justified the non-inclusion of trifluralin in Annex I to Directive 91/414, notwithstanding the possibilities of reducing the risk described by EFSA.

159 Furthermore, the fact remains that the contested decision is based on the risks identified by EFSA. It must be borne in mind that recital 5 in the preamble to the contested decision states as follows:

'During the evaluation of this active substance, a number of concerns were identified. Trifluralin is of high toxicity to aquatic organisms, in particular fish. It is also highly persistent in soil and not readily biodegradable. Moreover, it shows potential for accumulation. In particular, it exceeds significantly the maximum bioconcentration

factor (BCF) laid down in Directive 91/414 … for aquatic organisms, indicating a potential for bioaccumulation in such organisms. Due to its high volatility, transport through air cannot be excluded and, despite a rapid photochemical degradation, monitoring programmes have shown migration to places distant from application. These concerns made it appear that trifluralin does not meet the criteria for inclusion in Annex I to Directive 91/414...'

160 The contested decision is therefore indeed based on an assessment of the risks, that is to say, on an analysis of the degree of probability that the inclusion of trifluralin in Annex I to Directive 91/414 would adversely affect the interests safeguarded by the legal order, and not on an analysis solely of the hazards which trifluralin presents.

161 The argument put forward by the applicants, which merely submit that the Commission based the contested decision on hazards and not on risks, without providing any other evidence in support of their claims, must therefore be rejected.

162 Secondly, the applicants cannot reasonably maintain that the study which they provided on chronic toxicity to fish could have altered the risk assessment, as carried out by the Commission, if the Commission had agreed to take it into account.

163 It is clear that, in addition to the belated nature of its communication to the Commission, that study did not, in any event, provide an answer with regard to the other risks which had been identified, in particular trifluralin's persistence in soil, the fact that it is not readily biodegradable, its potential for accumulation and the risks of its transport through air.

164 Thirdly, the authorisation issued by the German authorities, even if it is based on the same criteria and the same assessment factors, cannot prejudge the decision taken by the Community authorities. The Commission's argument that the peer review characterises the evaluation carried out at Community level, which is not the case in respect of the evaluation carried out at national level, appears to be relevant in that regard.

165 Consequently, it must be held that the applicants have not provided any evidence capable of establishing a manifest error of assessment on the Commission's part as regards the assessment of the risks presented by trifluralin.

166 The third part of the second plea must accordingly be rejected.

The plea of illegality relating to Article 3(3) of Regulation No 850/2004 and the fourth part of the second plea, alleging that the Commission was not competent to evaluate trifluralin under Regulation No 850/2004 and, in addition, made an error of assessment when applying the criteria laid down in that regulation

167 In support of the plea of illegality which they put forward with regard to Article 3(3) of Regulation No 850/2004, the applicants maintain, in essence, that that provision altered their rights and failed to have regard for the legitimate expectations on which they were entitled to rely vis-à-vis the Commission. They submit that it was unlawful for the Commission to apply that regulation retroactively and to make the ongoing review of trifluralin subject to the POP criteria set out in Annex D to the Stockholm Convention.

168 The applicants submit that the Commission thus had no valid reason to invoke Regulation No 850/2004 or the criteria set out in Annex D to the Stockholm Convention for the purpose of adopting the contested decision by departing from the criteria provided for by Directive 91/414 and applying a procedure which was not yet formally established.

169 The applicants further submit that the risk of long-range transport, a criterion provided for in the context of the POP examination, is not a criterion which is provided for in the context of the evaluation organised by Directive 91/414.

170 The applicants also maintain that the Commission reopened the evaluation procedure in order to analyse trifluralin in the light of the POP criteria and that, in so far as there was no legal basis for acting in that way in the context of the evaluation provided for by Directive 91/414, the Commission was not competent to do so and therefore misused its powers.

171 As regards the fourth part of the second plea, which is put forward in the alternative, the applicants maintain that, in the event that Regulation No 850/2004 is applicable, the Commission once again disregarded the distinction between the concepts of 'hazard' and 'risk'. The TC-NES sub-group completed its review after a very short period and concluded that trifluralin satisfied the POP criteria. In the applicants' submission, the Commission thus merely conducted an examination of the hazardous nature of trifluralin and failed to carry out a risk assessment.

172 The applicants maintain that, in thus failing to comply with its obligation to assess whether the presumed hazards with respect to the alleged POP characteristics of trifluralin gave rise to an unacceptable risk, that is to say, by failing to have regard for the distinction between risks and dangers, the Commission also acted at variance with Directive 91/414 and the Community case-law. It follows, in their submission, that the contested decision is based on a fundamental methodological flaw and is thus vitiated by a manifest error of assessment.

173 Lastly, the applicants submit, in essence, that the Commission ought to have extended the deadlines to allow them to respond to the concerns of the TC-NES sub-group and that, by not doing so, it infringed their rights of defence.

174 The Commission takes issue with those arguments.

175 It must be pointed out that Regulation No 850/2004 introduces an evaluation mechanism which is unconnected with the mechanism put in place by Directive 91/414 and by Regulation No 451/2000.

176 It is true that it is not disputed by the Commission that an evaluation — at least in a basic form — of trifluralin was carried out in the light of the POP criteria.

177 However, it is apparent from the minutes of the SCFCAH meetings of 26 and 27 January 2006 and of 3 and 4 April 2006 that that examination was not carried out in the context of the evaluation of trifluralin under Directive 91/414, but in the context of a parallel evaluation, which the Commission in particular considered should not affect the current procedure.

178 Furthermore, it must be stated that the contested decision is based not on the evaluation of the substance in the light of the criteria under Regulation No 850/2004 but solely on the evaluation of the substance carried out in the light of the criteria under Directive 91/414, as is demonstrated by recitals 4 to 7 in the preamble to the contested decision.

179 In that regard, the Court cannot uphold the applicants' argument that the criteria of persistence in soil, biodegradability, bioaccumulation and propagation through air of the substance, which are referred to in recital 5 in the preamble to the contested decision, in actual fact constitute proof that the substance was not authorised by reason of its characteristics as a POP.

180 It must be pointed out that, under Article 5(2)(c) of Directive 91/414, for inclusion of an active substance in Annex I, particular account is to be taken of, where relevant, an estimate of its fate and distribution in the environment.

181 Furthermore, point 7 of part A of Annex II to Directive 91/414 refers specifically to the fate and behaviour of the substance in the environment and deals with its fate and behaviour in soil, water and air and with its bioaccumulation and biodegradability.

182 Consequently, the evaluation of the substance in the light of those criteria was required in order to allow for the inclusion of an active substance in Annex I to the directive.

183 The applicants' argument that the basis for the contested decision was the evaluation of trifluralin under Regulation No 850/2004 must therefore be rejected.

184 It follows that the plea of illegality put forward with regard to Article 3(3) of Regulation No 850/2004, even if it were assumed to be well founded, is irrelevant and must be rejected.

185 The same is true of the fourth part of the second plea, alleging that the Commission is not competent to evaluate trifluralin under Regulation No 850/2004, which must also be rejected as irrelevant.

186 That also applies to the head of claim alleging a manifest error of assessment in the application of the evaluation criteria laid down in Regulation No 850/2004 and the head of claim alleging infringement of the rights of the defence in that context, as that evaluation does not constitute the basis of the contested decision.

The third plea: the contested decision was not adopted in accordance with the applicable legislative procedure and therefore breaches Article 5 EC, Article 7 EC, Article 8(8) of Regulation No 451/2000 and Article 5 of the comitology decision

187 The applicants submit, in essence, that the Commission was required to submit EFSA's report to the SCFCAH, together with a draft directive for inclusion of the substance in Annex I to Directive 91/414 or a draft decision requiring its withdrawal from the market, within six months from receipt of that report, that is to say, in the present case, by 13 September 2005. The applicants maintain that the Commission has no discretion in that regard.

188 The Commission, they argue, failed, however, to comply with its obligation to submit a proposal for a directive or a decision within the period required.

189 Furthermore, the Commission did not put its proposal for a directive to the vote at the SCFCAH meeting on 14 and 15 July 2005 or at the SCFCAH meeting on 22 and 23 September 2005. It continued to act in that manner on a number of occasions in July, September and November 2006 and in January 2007.

190 The applicants maintain, in essence, that the Commission thus deviated from the procedure provided for by the comitology decision. If the SCFCAH disagreed with the Commission's proposal, the Commission was required to submit a proposal to the Council. In acting as it did, it prevented the Council from playing its role in the legislative process and exceeded the scope of its delegated powers, thereby acting in breach of Articles 5 EC and 7 EC and also Article 8(8) of Regulation No 451/2000.

191 The Commission disputes those arguments.

192 Article 8(8) of Regulation No 451/2000 provides that, at the latest six months after receipt of the EFSA opinion, the Commission must submit a draft review report. On the basis of the finalised review report, it must submit to the Committee a draft directive to include the active substance in Annex I to the directive, setting out, where appropriate, the conditions, including the time-limit, for such inclusion, or a draft decision addressed to the Member States to withdraw the authorisations of plant-protection products containing the active substance, pursuant to the fourth subparagraph of Article 8(2) of Directive 91/414, with the consequent non-inclusion of that substance in Annex I to that directive, and mentioning the reasons for that non-inclusion.

193 Article 8(9) of Regulation No 451/2000 provides that, where the Commission submits a draft directive or a draft decision in accordance with paragraph 8, it must at the same time submit the conclusions of the Committee's examination in the format of a finalised review report to be noted in the summary record of the meeting.

194 Article 8 of Regulation No 451/2000 thus draws a distinction between two stages: that of the submission of a draft review report — which must occur at the latest six months after receipt of the EFSA opinion — and that of the submission of a draft directive or a draft decision on the basis of the finalised review report, which is not subject to compliance with that time-limit.

195 The applicants' argument seeking to establish that the Commission was required to submit simultaneously, as from the first meeting of the Committee, the draft review report and a draft directive or draft decision cannot therefore be upheld.

196 Furthermore, it must be borne in mind that, in the present case, EFSA's opinion was adopted on 14 March 2005.

197 It is common ground that an initial exchange of views took place within the 'Legislation' working group of the SCFCAH during its meeting on 14 and 15 July 2005 on a preliminary draft of a Commission directive concerning the inclusion of trifluralin in Annex I to Directive 91/414.

198 It is also common ground that the preliminary draft of a directive (bearing the same reference as the document of 21 June 2005) and a preliminary draft of a review report dated 15 September 2005 — and thus to all appearances adopted by the Commission within the six-month period laid down in Article 8(8) and (9) of Regulation No 451/2000 — was on the agenda of the meeting of the 'Legislation' working group at the time of the SCFCAH meeting on 22 and 23 September 2005.

199 The Commission states that it did not comply with the six-month period for submission of the draft review report and that only the annex to that document, containing the list of studies relied upon for the assessment, was tabled at that meeting of the 'Legislation' working group. The Court, however, notes that the body of the draft review report, which the Commission communicated to it as an annex to the replies to the questions which the Court had put to it, was amended following that meeting, which suggests that that draft had also been submitted on that occasion to that working group.

200 However, even if, following the Commission, the six-month period was to be regarded as having expired when the Commission submitted its draft review report, the view would none the less have to be taken that the failure to comply with that time-limit — to which Regulation No 451/2000 does not attach any penalty — had no bearing on the tenor of the contested decision.

201 In the first place, regard must be had to the fact that the procedure provided for by the comitology decision commenced as from the time of the exchange of views which took place within the 'Legislation' working group on 14 and 15 July 2005.

202 In that respect, the artificial distinction which the Commission seeks to make between the SCFCAH and its 'Legislation' working group must be regarded as irrelevant so far as concerns the applicability of the rules relating to comitology and to the procedure set out in Article 8(8) and (9) of Regulation No 451/2000 since, as the Commission acknowledges, the Committee and the working group consist of the same persons.

203 In the second place, it must be borne in mind that, in the absence of a provision setting out either expressly or implicitly the consequences of failure to comply with a procedural time-limit such as that in the present case, such failure can entail the annulment, in whole or in part, of the act to be adopted within the period in question only if it is shown that, had it not been for such an alleged irregularity, that act might have been substantively different (see Case T-299/05 *Shanghai Excell M&E Enterprise and Shanghai Adeptech Precision* v *Council* [2009] ECR II-565, paragraph 138 and the case-law cited).

204 The applicants claim in essence, in that regard, that, if the contested decision had been adopted within the period provided for, that decision would have been to include trifluralin in Annex I to Directive 91/414 in so far as EFSA had recommended such inclusion.

205 First, it must be borne in mind that EFSA's opinion did not recommend that trifluralin be included in Annex I (see paragraphs 89 and 92 above). It cannot therefore be argued that the decision which should have been adopted would inevitably have been favourable to the applicants.

206 Secondly, in any event, the Commission initially proposed the inclusion of trifluralin. It was only in the course of the discussions within the Committee that the tenor of the decision was amended, as the applicants themselves acknowledge.

207 Lastly, the contested decision was not adopted in the light of the POP criteria, as the applicants maintain (see paragraphs 175 to 185 above).

208 Consequently, it must be held that the applicants have failed to show that compliance with the six-month period for the submission of the draft review report would have been capable of changing the tenor of the contested decision.

209 Their line of argument on that point must therefore be rejected.

210 Secondly, since the draft review report is the only document which the Commission has to submit within the six-month period, in accordance with Article 8(8) of Regulation No 451/2000, the applicants' line of argument that the proposal for a directive ought likewise to have been submitted within the six-month period must also be rejected.

211 Thirdly, it is apparent from Article 5(4) of the comitology decision that, if the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must, without delay, submit to the Council a proposal relating to the measures to be taken and must inform the European Parliament.

212 It must be borne in mind that, in the present case, it is apparent from the information provided by the Commission in its replies to the questions put by the Court and from the extracts from the minutes of the various meetings which took place that the fate of trifluralin was discussed during the meetings of the SCFCAH's 'Legislation' working group which were held on 14 and 15 July, 22 and 23 September and 17 and 18 November 2005; 26 and 27 January, 3 and 4 April, 22 and 23 May, 13 and 14 July, 25 and 26 September and 23 and 24 November 2006; and, lastly, on 22 and 23 January and 15 and 16 March 2007, before the proposal was voted for — by a majority of 23 Member States — on 16 March 2007.

213 The proposal for a non-inclusion decision was therefore put only once to the vote, on 16 March 2007, contrary to what the applicants claim, as a result of which vote the proposal secured the qualified majority necessary for its adoption.

214 It cannot, consequently, be argued that the Commission infringed the provisions of Article 5(4) of the comitology decision by failing to submit to the Council, without delay, a proposal relating to the measures to be taken.

215 The fact remains that the Committee did not adopt an opinion contrary to the measures proposed and was also not in a position in which it was impossible for it to secure a qualified majority either in favour of or against the measures proposed.

216 It is, however, only in those two cases that the Commission is required to bring the matter without delay before the Council, within the terms of that provision.

217 It is therefore necessary to examine whether the Commission may be criticised for not putting the proposal for a measure to the vote for a period of 20 months, as was the case here.

218 In that regard, it must be borne in mind that the Court of Justice, in the judgment in Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, confirmed that Article 8(3)(b) of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down

a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ 1990 L 224, p. 1), did not specify exactly the period within which the Commission had to propose to the Council the measures to be adopted and that, on the contrary, in using the expression 'without delay', the Community legislature, whilst requiring it to act swiftly, did allow the Commission a certain degree of latitude (paragraph 25 of that judgment).

219 The Court of Justice also held that the amount of time which the Commission had to consider the various courses of action open to it had to be appraised in the light of the complexity of the matter concerned. In the case which gave rise to the judgment in *Pharos* v *Commission*, cited in paragraph 218 above, the risk that the substance in question might be used had been raised for the first time in the adaptation committee, in which four delegations had opposed the Commission's draft and six had abstained from the vote. In those circumstances, according to the Court of Justice, a period of 11 months, during which the Commission had initially reconsidered the file for six months and had then sought a second scientific opinion, could not be considered to be an excessively long period (*Pharos* v *Commission*, cited in paragraph 218 above, paragraphs 30 to 32).

220 Furthermore, in its judgment in Case C-244/95 *Moskof* [1997] ECR I-6441, the Court of Justice held — in a case concerning compliance with the procedure relating to a management committee, and not to a regulatory committee — that the fact that the Commission considered the possibility of compromise could not be interpreted as an implicit withdrawal of the initial text, which had already been approved by all the other delegations. To hold otherwise would render more difficult any attempt at compromise intended to resolve the problems experienced by certain delegations, and the Commission would no longer wish to take the risk of not immediately adopting an approved text. Such a solution would do more harm as regards the proper functioning of the management committee procedures than would tolerating the lapse, between the management committee's vote on a text and its adoption as a regulation by the Commission, of the reasonable time necessary in order to be able to consider what compromises might better resolve the problems raised by certain delegations (*Moskof*, paragraph 40).

221 It follows from that case-law that, after a negative vote or where it is not possible to achieve a qualified majority in favour of or against the proposed measure, the Commission may seek a compromise within the committee and has available to it, in order to do so, a certain amount of time, which will depend on the difficulty, complexity and sensitive nature of the matter concerned, before bringing the matter before the Council.

222 In other words, in order to assess whether the Commission acted without delay, it is necessary to ascertain whether it acted within a reasonable period of time, having regard to the circumstances of the case, and the Commission must be afforded a broad degree of latitude to reach a compromise.

223 Consequently, and *a fortiori* in the case of a regulatory committee, the Commission must have available to it a broad degree of temporal latitude, depending on the difficulty, complexity and sensitive nature of the matter, to seek a compromise within the committee before putting a draft measure to the vote.

224 That is manifestly the case here, as the fate of trifluralin was regularly discussed during the meetings of the SCFCAH's 'Legislation' working group which were held in the period from July 2005 to March 2007 (see paragraph 212 above).

225 Consequently, the Commission cannot be criticised for failing to have regard for the rules of procedure established by the comitology decision. The plea must for that reason be rejected.

The fourth plea: the applicable procedural deadlines were not complied with, contrary to Article 8(7) and (8) of Regulation No 451/2000

226 The applicants submit, in essence, that Directive 91/414 establishes a number of procedural deadlines in connection with the evaluation procedure. Such deadlines are given to, inter alia, EFSA and the Commission. The applicants maintain, however, that several of those deadlines were not complied with, an assertion which the Commission, moreover, does not dispute.

227 Thus, by sending its opinion to the Commission on 14 March 2005, EFSA failed to comply with the deadline for submitting its opinion, which, in the present case, expired on 10 July 2004. The Commission put its proposal for a directive to the vote only in mid-March 2007. The draft inclusion or non-inclusion proposal should, however, normally have been submitted within six months of receipt of EFSA's opinion, that is to say, in the present case, by 13 September 2005, whereas the Commission adopted the contested decision only on 20 September 2007, that is to say, more than two years after it had received EFSA's opinion.

228 That, the applicants submit, constitutes a breach of Article 8(7) and (8) of Regulation No 451/2000, that is to say, a breach of a substantial procedural requirement, which had the consequence that the contested decision was not based on the current scientific knowledge which existed at the time of the evaluation. According to the applicants, EFSA's opinion should have been issued on 10 July 2004. They submit that the POP issue, which ultimately had a decisive influence on the refusal to include the substance, arose only during the last evaluation meeting in February 2005, that is to say, seven months later. Consequently, the contested decision would have been different if EFSA's opinion had been issued in good time.

229 Furthermore, the applicants submit, in essence, that there was nothing to prevent the Commission from granting them more extensive deadlines since it and EFSA had failed to comply with the deadlines imposed on them.

230 The Commission disputes those claims.

231 First, since the draft review report is the only document which the Commission is required to submit within the six-month period in accordance with Article 8(8) of Regulation No 451/2000, the applicants' line of argument that the proposal for a directive should also have been submitted within the six-month period must be rejected (see paragraph 210 above).

232 Secondly, it must be pointed out that it is not disputed that EFSA failed to comply with the deadline for the submission of its report.

233 Furthermore, the consequences of failure to comply with that procedural deadline are not set out either expressly or implicitly by the applicable legislation.

234 It is for that reason necessary to determine whether, in the absence of that irregularity, the applicants' claims that the content of that document might have been different — in so far as the assessment of the substance in the light of Regulation No 850/2004 would not have been taken into consideration if the opinion had been adopted in good time — are established (see paragraph 228 above).

235 First, however, it follows expressly from EFSA's opinion (see paragraph 28 above) that the evaluation of the substance in the light of the POP criteria was not taken into consideration by EFSA.

236 Secondly, the contested decision is not based on the evaluation of the substance in the light of the POP criteria (see paragraph 183 above).

237 Consequently, the applicants have failed entirely to show that the content of the act would have been different if EFSA's opinion had been issued in good time. The fourth plea must, for that reason, be rejected.

The fifth plea: failure to state reasons for the contested decision

238 The applicants submit, in essence, that the Commission fails to explain why trifluralin presents, in its view, an unacceptable risk as regards chronic toxicity. According to the applicants, the mere finding that trifluralin is of high toxicity to aquatic organisms constitutes, if that is the case, a finding that there is a hazard, but ought subsequently to have been followed by a risk assessment.

239 Nor does the Commission explain why it did not take account of the evidence provided by the applicants in the context of the additional study on chronic toxicity to fish, even though the rapporteur Member State, after examining that evidence, concluded that there was no unacceptable risk of chronic toxicity.

240 Furthermore, since the rapporteur Member State and EFSA concluded that trifluralin presented no risk to human health in respect of the notified uses, it was for the Commission to explain why it departed from those conclusions, something which, in the applicants' view, it failed to do.

241 The applicants also submit that the contested decision makes no mention of Regulation No 850/2004, of the POP criteria or of the review carried out by the TC-NES sub-group, even though, in their view, the evidence set out in the contested decision suggests that it was those points that led the Commission to change its mind and to propose a non-inclusion decision.

242 The applicants also take issue with the Commission for not having explained why the retroactive application of Regulation No 850/2004 was justified or did not adversely affect the applicants' legitimate expectations.

243 Lastly, the applicants contend that, given that the Commission had initially proposed that trifluralin be included in Annex I to Directive 91/414, it was particularly important to know the reasons why it had changed its mind during the procedure.

244 The Commission disputes those claims.

245 It should be borne in mind first that, according to case-law, a plea based on infringement of Article 253 EC is a separate plea from one based on a manifest error of assessment. While the former, which alleges absence of reasons or inadequacy of the reasons stated, goes to an issue of infringement of essential procedural requirements within the meaning of Article 230 EC and, involving a matter of public policy, must be raised by the Community judicature of its own motion, the latter, which goes to the substantive legality of a decision, is concerned with the infringement of a rule of law relating to the application of the Treaty, again within the meaning of Article 230 EC, and can be examined by the Community judicature only if raised by the applicant. The obligation to state reasons is thus a separate question from that of the merits of those reasons (Case C-367/95 P *Commission* v *Sytraval and Brink's France* [1998]

ECR I-1719, paragraph 67; Case C-159/01 *Netherlands* v *Commission* [2004] ECR I-4461, paragraph 65; Case T-158/99 *Thermenhotel Stoiser Franz and Others* v *Commission* [2004] ECR II-1, paragraph 97; and Case T-445/05 *Associazione italiana del risparmio gestito and Fineco Asset Management* v *Commission* [2009] ECR II-289, paragraph 66).

246 It is settled case-law that the statement of reasons required by Article 253 EC must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted that measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Court to exercise its power of review. The requirement to state reasons must be assessed according to the circumstances of the case. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons meets the requirements of Article 253 EC must be assessed with regard not only to its wording but also to its context and all the legal rules governing the matter in question. In particular, the Commission is not obliged to adopt a position on all the arguments relied on before it by the parties concerned; rather, it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision (see *Associazione italiana del risparmio gestito and Fineco Asset Management* v *Commission*, cited in paragraph 245 above, paragraph 67 and the case-law cited).

247 It must be borne in mind that EFSA issued an opinion in which, essentially, it stated its findings, but also its uncertainties, as regards the safety of trifluralin, having regard to the scientific knowledge available at the time of the peer review.

248 Consequently, the crucial point is to establish whether there is a sufficient balance between the content of EFSA's opinion, on the one hand, and the wording of the contested decision and its statement of reasons, on the other.

249 It must be stated that the contested decision sets out the scientific reasons which led the Commission — in agreement with the SCFCAH — to take the view that the substance at issue should not be included in Annex I to Directive 91/414.

250 Furthermore, that statement of reasons makes it possible to understand why, regard being had to its broad discretion, the Commission dismissed the possibility, envisaged by EFSA, of including trifluralin in Annex I to Directive 91/414, subject to compliance with certain conditions.

251 It must also be held that the statement of reasons for the contested decision was sufficient to allow the Court to exercise its power of review and to deal with the various pleas which have been put forward by the applicants in their action.

252 The contested decision is not, therefore, vitiated by a failure to state reasons.

253 That finding is not called into question by the arguments put forward by the applicants in support of their plea.

254 First, the applicants are not justified in claiming that the contested decision is based only on an assessment of the hazards, and not of the risks, which trifluralin poses (see, in particular, recital 5 in the preamble to the contested decision; see paragraph 159 above).

255 Secondly, the applicants cannot validly argue that the Commission failed to take account of the evidence which they provided in the context of the study on chronic toxicity to fish, on the basis of which the rapporteur Member State, they submit, concluded that there was no unacceptable risk of chronic toxicity. No request for such

a study was made to the notifiers (see paragraph 128 above) and could not, in any event, have been provided after the submission of the complete dossier which they were obliged to submit pursuant to Article 6(1) and (3) of Regulation No 451/2000. Furthermore, it must be pointed out that, following the meeting of the SCFCAH's 'Legislation' working group on 15 and 16 March 2007, the Hellenic Republic, which was the rapporteur Member State, had a declaration noted down stating that it was prepared to vote in favour of the proposal for the non-inclusion of trifluralin, in order to allow the notifying parties to take advantage of the 18-month period to submit formally the study on chronic toxicity to fish and to allow it, as rapporteur Member State, formally to evaluate that study.

256 Thirdly, since the contested decision is based, not on an evaluation of trifluralin under Regulation No 850/2004, but solely on the evaluation of the substance carried out in the light of the criteria under Directive 91/414, as is demonstrated by recitals 4 to 7 in its preamble (see paragraph 178 above), the applicants cannot criticise the Commission on the ground that it failed to explain why the contested decision was based on such an evaluation.

257 Fourthly, although it is true that the Commission initiated the discussions within the SCFCAH and, more specifically, the 'Legislation' working group by submitting a proposal for a directive to include trifluralin in Annex I to Directive 91/414, the fact none the less remains that such a proposal is, by definition, liable to change in the course of the discussions which take place within the SCFCAH (see paragraph 221 above). In the present case, however, the statement of reasons for the contested decision makes it possible to understand the scientific reasons which justified its adoption. That statement of reasons cannot, by contrast, be required to recount all the twists and turns of the discussions which took place within the SCFCAH.

258 The fifth plea must therefore be rejected.

The sixth plea: infringement of fundamental principles of Community law, and the head of claim alleging infringement of the principles of legal certainty and the protection of legitimate expectations, put forward in support of the first part of the second plea

— The first part of the sixth plea, alleging infringement of the principles of legal certainty, non-retroactivity and the protection of legitimate expectations, and the head of claim alleging infringement of the principles of legal certainty and the protection of legitimate expectations, put forward in support of the first part of the second plea

259 First, according to the applicants, the fact that an additional study was requested of them by the rapporteur Member State and EFSA created a legitimate expectation on their part that that study would be evaluated and taken into account in the appraisal of trifluralin. The Commission, however, took the view that that study had been submitted out of time and informed the members of the SCFCAH of its opinion that it could not therefore be taken into consideration, thereby infringing the applicants' legitimate expectations.

260 Secondly, the applicants claim that, in so doing, the Commission failed to take account of the most recent scientific evidence available and of current scientific and technical knowledge, contrary to the principles of legal certainty and the protection of legitimate expectations.

261 Thirdly, the applicants submit that they had a legitimate expectation, in the light of the relevant provisions of Regulation No 451/2000, that the contested decision would be based on EFSA's opinion, which, they claim, recommended inclusion of the substance in Annex I to Directive 91/414. As the contested decision was not based on that conclusion, it follows, according to the applicants, that their legitimate expectations have been infringed.

262 Fourthly, they submit, the Commission retroactively applied Regulation No 850/2004 and thus changed the applicable provisions in the course of the evaluation. The applicants were, as a result, unable to ascertain unequivocally their rights or to take appropriate steps to safeguard those rights. By reason of the absence of clarity and predictability, the principles of legal certainty and the protection of legitimate expectations were also infringed by the Commission.

263 The Commission disputes those claims.

264 It must be borne in mind that, according to settled case-law, the principle of legal certainty — which is one of the general principles of Community law — requires, in particular, that rules of law be clear, precise and predictable in their effects, especially where they may have negative consequences for individuals and undertakings (see Case C-158/07 *Förster* [2008] ECR I-8507, paragraph 67 and the case-law cited).

265 Furthermore, according to settled case-law, the right to rely on the principle of the protection of legitimate expectations extends to any individual who is in a situation in which it is clear that the Community authorities have, by giving him precise assurances, led him to entertain legitimate expectations (Joined Cases C-37/02 and C-38/02 *Di Lenardo Adriano and Dilexport* [2004] ECR I-6911, paragraph 70; Case T-203/96 *Embassy Limousines & Services* v *Parliament* [1998] ECR II-4239, paragraph 74; see also, to that effect, *Bayer CropScience and Others* v *Commission*, cited in paragraph 95 above, paragraph 153). Regardless of the form in which it is communicated, precise, unconditional and consistent information which comes from authorised and reliable sources constitutes such assurances (see, to that effect, Case C-82/98 P *Kögler* v *Court of Justice* [2000] ECR I-3855, paragraph 33). However, a person may not plead infringement of that 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 judgment in Joined Cases C-182/03 and C-217/03 *Belgium and Forum 187* v *Commission* [2006] ECR I-5479, paragraph 147). Moreover, 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; Case T-282/02 *Cementbouw Handel & Industrie* v *Commission* [2006] ECR II-319, paragraph 77; and Case T-334/07 *Denka International* v *Commission* [2009] ECR II-4205, paragraph 132).

266 First, without even needing to ascertain whether the applicants could have received, in the circumstances of the present case, precise assurances that they could have submitted a study at the request of the rapporteur Member State or EFSA, such assurances could not in any way have given rise to a legitimate expectation on their part, since Article 8(5) of Regulation No 451/2000 provides expressly that new studies will no longer be accepted at the time when EFSA has initiated its evaluation of the active substance and that only assurances which comply with the applicable rules may give rise to legitimate expectations.

267 Secondly, in so far as no additional study was requested of the notifiers, the Commission cannot be criticised on the ground that it did not take into account the study which they belatedly submitted on chronic toxicity to fish.

268 Thirdly, since there is nothing in Regulation No 451/2000 to suggest that the Commission is obliged to comply with EFSA opinions in substantive terms and therefore has no discretion (see paragraphs 87 and 88 above), the applicants cannot validly claim that their legitimate expectations were infringed by reason of the fact that that regulation made it possible for them to believe that the Commission was necessarily going to follow EFSA's opinion, which they, moreover, incorrectly maintain recommended inclusion of the substance in Annex I to Directive 91/414 (see paragraph 89 above).

269 Fourthly, as the contested decision was not based on the evaluation of trifluralin under Regulation No 850/2004, the applicants cannot validly claim that the principle of legal certainty was infringed by reason of a retroactive application of that regulation in the context of the evaluation of the substance under Directive 91/414. The same holds true with regard to their claim that their legitimate expectations were also infringed in this respect.

270 Consequently, the first part of the sixth plea, and likewise the head of claim alleging infringement of the principles of legal certainty and the protection of legitimate expectations put forward in support of the first part of the second plea, must be rejected.

— The second part of the sixth plea: infringement of the rights of the defence and of the right to a fair hearing

271 The applicants maintain, in essence, that, if the Commission had been correct to apply Regulation No 850/2004, it ought to have given them sufficient opportunity to safeguard their rights by extending the relevant deadlines and by making it possible for them to submit comments in order to ensure their defence.

272 The Commission, they contend, therefore infringed the right to a fair hearing, which forms an integral part of the principle of good administration.

273 The Commission disputes those claims.

274 Since the contested decision is not based on an evaluation of trifluralin under Regulation No 850/2004, the applicants' arguments are irrelevant and must consequently be rejected.

— The third part of the sixth plea: infringement of the principle of proportionality

275 First of all, the applicants submit that the total ban on trifluralin is disproportionate since it is their view that EFSA considered that the hazards presented by trifluralin could be managed by imposing appropriate conditions as to use.

276 Secondly, they submit that the Commission acted disproportionately by failing to take account of the study on chronic toxicity to fish and by not extending the applicable deadlines to make it possible for that study to be properly taken into consideration.

277 Finally, in the applicants' submission, the contested decision has the consequence of restricting the range of weed-control products available, the repercussions of which have serious implications for the control of weeds and diseases. The applicants see in this a risk of reduced crop yields, a consequent reduction in food production, reliance on imports into the European Union and, lastly, higher prices. Against a background of worldwide food shortages, the contested decision is disproportionate in this regard as well.

278 The Commission disputes those claims.

279 According to settled case-law, the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions must 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 137/85 *Maizena and Others* [1987] ECR 4587, paragraph 15; *Pfizer Animal Health* v *Council*, cited in paragraph 145 above, paragraph 411; and *Bayer CropScience and Others* v *Commission*, cited in paragraph 95 above, paragraph 223).

280 It must be borne in mind that the Commission must be recognised as enjoying a broad discretion when it adopts, in the context of the procedure to include a substance in Annex I to Directive 91/414, risk-management measures. That domain involves, inter alia, political choices and complex assessments on its part (see paragraph 86 above). 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 145 above, paragraph 412; and *Alpharma* v *Council*, cited in paragraph 145 above, paragraphs 177 to 180).

281 In the present case, since it is incorrect to claim that EFSA's opinion recommended that trifluralin be included in Annex I to Directive 91/414 (see paragraph 89 above), it must be held that the head of claim which the applicants put forward in support of their position that the total ban on trifluralin is disproportionate has no factual basis.

282 It is true that EFSA's opinion includes recommendations directed at making it possible to manage the risks highlighted during the evaluation procedure if the Commission were to propose the inclusion of trifluralin.

283 However, it must be borne in mind that such recommendations were submitted by EFSA in accordance with the provisions of Article 8(7) of Regulation No 451/2000, that it cannot therefore be deduced from this that EFSA recommended the inclusion of trifluralin in Annex I to Directive 91/414 and that, in any event, the Commission had a broad discretion in order to pursue effectively the objective assigned to it by Directive 91/414, account being taken of the complex technical assessments which it must undertake in that domain (see paragraph 87 above and the case-law cited, as well as paragraphs 92 and 93 above).

284 Furthermore, it must be pointed out that the Commission submitted, in essence, in its written pleadings and at the hearing, without being effectively contradicted on this point, that a limited inclusion of trifluralin in Annex I to Directive 91/414 had not been envisaged because it would have been impossible to maintain the active substance under control by simple risk-mitigation measures, particularly in the light of the risk of propagation over great distance by air, and having regard to numerous data on the safety of the substance in question which were still outstanding.

285 It follows that the fact that the Commission did not propose the inclusion of trifluralin in Annex I to Directive 91/414, by making such inclusion subject to the conditions upheld by EFSA, cannot be considered to be manifestly disproportionate.

286 Furthermore, the Commission did not have to take into account the study on chronic toxicity to fish or extend the deadlines to enable that study to be taken into consideration (see paragraphs 128 and 132 above). The allegedly disproportionate nature of the contested decision cannot, therefore, follow from the fact that that study was not taken into account or that those deadlines were not extended in order to take it into account.

287 Moreover, the applicants have failed to adduce any evidence whatsoever in support of their claims that the contested decision has the various harmful consequences which they claim and which allegedly show that the contested decision is disproportionate.

288 Lastly, it must be borne in mind that EFSA, in its opinion, identified a number of risks which trifluralin presents.

289 Having regard to the broad discretion which the Commission must be recognised as enjoying in order to be able to pursue effectively the objective assigned to it by Directive 91/414, and in light of the complex technical assessments which it must undertake, it must be held that the contested decision does not appear to be manifestly disproportionate.

290 Consequently, the third part of the sixth plea is unfounded and must therefore be rejected.

291 In conclusion, the sixth and final plea must be rejected and the action, consequently, must be dismissed in its entirety.

Costs

292 Under Article 87(2) of the Court's 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, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Third Chamber)

hereby:

1. Dismisses the action;

2. Orders Dow AgroSciences Ltd and the 20 other applicants, the names of which are listed in the Annex, to bear their own costs and also to pay the costs incurred by the European Commission.

Azizi Cremona Frimodt Nielsen

Delivered in open court in Luxembourg on 9 September 2011.

[Signatures]

Annex

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

Makhteshim Agan International Coordination Center, established in Brussels (Belgium),

Dintec Agroquímica — Produtos Químicos, Lda, established in Funchal (Portugal),

Finchimica SpA, established in Manerbio (Italy),

Dow Agrosciences BV, established in Rotterdam,

Dow AgroSciences Hungary kft, established in Budapest (Hungary),

Dow AgroSciences Italia Srl, established in Milan (Italy),

Dow AgroSciences Polska sp. z o.o., established in Warsaw (Poland),

Dow AgroSciences Iberica, SA, established in Madrid (Spain),

Dow AgroSciences s.r.o., established in Prague (Czech Republic),

Dow AgroSciences LLC, established in Indianapolis, Indiana (United States),

Dow AgroSciences GmbH, established in Stade (Germany),

Dow AgroSciences Export, established in Mougins (France),

Dow AgroSciences, established in Mougins,

Dow AgroSciences Danmark A/S, established in Lyngby-Taarbæk (Denmark),

Makhteshim-Agan Poland sp. z o.o., established in Warsaw,

Makhteshim-Agan (UK) Ltd, established in London (United Kingdom),

Makhteshim-Agan France, established in Sèvres (France),

Makhteshim-Agan Italia Srl, established in Bergamo (Italy),

Alfa Agricultural Supplies SA, established in Halardri (Greece).

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