JUDGMENT OF THE GENERAL COURT (First Chamber)

12 April 2013 (*)

(Plant protection products – Active substance flusilazole – Inclusion of flusilazole in Annex I to Directive 91/414/EEC – Actions for annulment – Partial annulment – Non-severability – Inadmissibility – Non contractual liability – Limiting the inclusion for a period of 18 months and for four crops – Precautionary principle – Principle of proportionality – Right to be heard – Equal treatment – Statement of reasons – Misuse of powers – Sufficiently serious breach of a rule of law conferring rights on individuals)

In Case T 31/07,

Du Pont de Nemours (France) SAS, established in Puteaux (France),

Du Pont Portugal – Serviços, Sociedade Unipessoal L^{da}, established in Lisbon (Portugal),

Du Pont Ibérica, SL, established in Barcelona (Spain),

Du Pont de Nemours (Belgium) BVBA, established in Mechelen (Belgium),

Du Pont de Nemours Italiana Srl, established in Milan (Italy),

Du Pont De Nemours (Nederland) BV, established in Dordrecht (Netherlands),

Du Pont de Nemours (Deutschland) GmbH, established in Bad Homburg vor der Höhe (Germany),

DuPont CZ s.r.o., established in Prague (Czech Republic),

DuPont Magyarország Kereskedelmi kft, established in Budaors (Hungary),

DuPont Poland sp. z o.o., established in Warsaw (Poland),

DuPont Romania Srl, established in Bucharest (Romania),

DuPont (UK) Ltd, established in Stevenage (United Kingdom),

Dy-Pont Agkro Ellas AE, established in Halandri (Greece),

DuPont International Operations SARL, established in Le Grand Saconnex (Switzerland),

DuPont Solutions (France) SAS, established in Puteaux,

represented initially by D. Waelbroeck and N. Rampal, and subsequently by D. Waelbroeck, lawyers,

applicants,

supported by

European Crop Protection Association (ECPA), established in Brussels (Belgium), represented by U. Zinsmeister and E. Antypas, lawyers,

intervener,

European Commission, represented initially by L. Parpala and B. Doherty, and subsequently by Parpala and G. von Rintelen, acting as Agents,

defendant,

ACTION for (i) annulment of Commission Directive 2006/133/EC of 11 December 2006 amending Council Directive 91/414/EEC to include flusilazole as active substance (OJ 2006 L 349, p. 27) in so far as it includes flusilazole in Annex I to Directive 91/414 in respect of only four crops and for a period of 18 months and (ii) damages,

THE GENERAL COURT (First Chamber),

composed of J. Azizi (Rapporteur), President, I. Labucka and S. Frimodt Nielsen, Judges,

Registrar: N. Rosner, Administrator,

having regard to the written procedure and further to the hearing on 27 March 2012,

gives the following

Judgment

Legal context

I – Introduction

1 Under Article 3(1) 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), a plant protection product may not, as a rule, be placed on the market and used in the territory of a Member State unless it has been authorised by the competent authorities of that Member State in accordance with that directive.

II – Criteria for the inclusion of an active substance in Annex I to Directive 91/414

2 Article 4(1) of Directive 91/414 provides that a plant protection product may not be authorised by a Member State unless, inter alia, its active substances are listed in Annex I to Directive 91/414 and unless the conditions laid down therein are fulfilled.

3 Article 5 of Directive 91/414 lays down the conditions to be complied with for an active substance to be included in Annex I thereto:

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

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

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

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

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

(b) an acceptable operator exposure level if necessary;

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

3. For the first inclusion of an active substance which was not yet on the market two years after notification of this Directive, the requirements shall be deemed to be satisfied where this has been established for at least one preparation containing the said active substance.

4. Inclusion of an active substance in Annex I may be subject to requirements such as:

– the minimum degree of purity of the active substance,

– the nature and maximum content of certain impurities,

– restrictions arising from evaluation of the information referred to in Article 6 [the dossier supplied by the notifier], taking account of the agricultural, plant health and environmental (including climatic) conditions in question,

– type of preparation,

– manner of use.

5. On request, the inclusion of a substance in Annex I may be renewed once or more for periods not exceeding 10 years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in paragraphs 1 and 2 are no longer satisfied. Renewal shall be granted for the period necessary to complete a review, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, and shall be granted for the period necessary to provide information requested in accordance with Article 6(4).'

4 Article 6(1) of Directive 91/414 provides inter alia that the inclusion of an active substance in Annex I thereto can be made subject to conditions.

III – Transitional measures for active substances already on the market

5 Article 8(2) of Directive 91/414 provides for transitional measures and derogations for active substances not listed in Annex I thereto but already on the market two years after the date of notification of the directive. The placing on the market of plant protection products containing those active substances may be authorised by Member States for a transitional period of 12 years. Article 8(2) provides that, during that transitional period, the active substances concerned must undergo a programme of assessment after which it may – following examination of an active substance by the committee referred to in Article 19 of Directive 91/414 – be decided by the procedure laid down in Article 19 that the substance can be included in Annex I to the directive and under which conditions. Alternatively, in cases where the requirements of Article 5 of Directive 91/414 are not satisfied or the requisite information and data have not been submitted within the prescribed period, it may be decided that the active substance will not be included in Annex I.

6 That transitional period, which was to expire initially on 26 July 2003, was extended, first, until 31 December 2005, by Article 1 of Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414 and concerning the non-inclusion of certain active substances in Annex I thereto and the withdrawal of authorisations for plant protection products containing these substances (OJ 2002 L 319, p. 3) and, second, until 31 December 2006, by Article 1 of Commission Regulation (EC) No 1335/2005 of 12 August 2005 amending Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC,

2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Council Directive 91/414 and the continued use of certain substances not included in its Annex I (OJ 2005 L 211, p. 6), unless a decision to include an active substance in Annex I to Directive 91/414 had been taken before those dates.

IV – Decision-making procedure

7 Article 6(1) of Directive 91/414 provides that the inclusion of an active substance in Annex I thereto and any conditions to which such inclusion may be subject is to be decided in accordance with the procedure laid down in Article 19 of Directive 91/414.

8 Article 19 of Directive 91/414, in the version applicable in the present case, provides that once adopted by the Standing Committee on the Food Chain and Animal Health ('Standing Committee on Plant Health') the Commission of the European Communities is to adopt the measures envisaged if they are in accordance with the opinion of that committee. If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission of the European Communities is, without delay, to submit to the Council of the European Communities a proposal relating to the measures to be taken. The Council shall decide by qualified majority.

9 In addition, the decision-making procedure applicable to those measures is the regulatory procedure laid down by 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).

V – Detailed rules for the implementation of the first stage of the programme of work

10 Article 5(2) of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414 (OJ 1992 L 366, p. 10) provides that, following the examination of the notifications of interest, the list of active substances adopted for assessment with a view to their possible inclusion in Annex I to the Directive 94/414 will be drawn up – in the form of a regulation – and a rapporteur Member State will be designated for each active substance concerned.

11 Pursuant to Article 6(1) of Regulation No 3600/92, each notifier has the task of sending to the rapporteur Member State a 'summary dossier' and a 'complete dossier', as defined in Article 6(2) and (3) of that regulation.

12 Article 6(2)(b) of Regulation No 3600/92, as amended by Commission Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27), provides that the notifier must demonstrate that the inclusion criteria are met for one or more preparations for a 'limited range of representative uses'.

13 After the notifiers have submitted a summary dossier and a complete dossier to the rapporteur Member State, the latter must, pursuant to Article 7(1) of Regulation No 3600/92, examine the dossiers and send to the Commission, at the latest 12 months after receipt of those dossiers, a report of its assessment of the dossier. That report must contain, in particular, a recommendation whether or not to include the active substance in Annex I to Directive 91/414, or a recommendation to remove the active substance from the market, or a recommendation to suspend the active substance from the market or a recommendation to postpone any decision on possible inclusion pending the submission of the results of additional trials or information specified in the report.

14 Article 7(3) of Regulation No 3600/92 provides that, after receiving the assessment report, the Commission shall refer the updated summary dossier and the assessment report to the Standing Committee on Plant Health for examination.

15 However, before submitting the summary dossier and the assessment report to the Standing Committee on Plant Health, the Commission distributes the report of the rapporteur Member State to the other Member States for information and may consult with experts from the Member States ('peer review') and the notifiers of one of the active substances.

16 Following the examination by the Standing Committee on Plant Health, Article 7(3A) of Regulation No 3600/92, inserted by Commission Regulation (EC) No 1199/97 of 27 June 1997 amending Regulation (EEC) No 3600/92 (OJ 1997 L 170, p. 19), provides that the Commission is to present to that committee either a draft directive to include the active substance in Annex I to Directive 91/414, setting out where appropriate the conditions for such inclusion; a draft decision to withdraw the authorisations of plant protection products containing the active substance; a draft decision to suspend plant protection products, with the option of reconsidering the inclusion of the active substance in Annex I thereto after submission of the additional trials or of additional information; or a draft decision to postpone inclusion of the active substance pending the submission of the results of additional trials or information.

17 Article 7(4), first indent, of Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that, where, following the examination by the Standing Committee on Plant Health, the submission of the results of additional trials or of additional information is required, the Commission is to determine a time-limit for the submission, inter alia, to the rapporteur Member State, of those results or that information. That time-limit expires on 25 May 2002 except for the results of long term studies, where there is proof that they were under way on 25 May 2002, in which case that time-limit expires on 25 May 2003.

18 Pursuant to Article 2 of Commission Decision 2001/679/EC of 29 August 2001 concerning the decision on the possible inclusion of certain active substances into Annex I to Directive 91/414 (OJ 2001 L 239, p. 39), a rapporteur Member State must ensure that the notifier undertakes to submit particular studies by 5 May 2002 at the latest.

19 Article 8(1) of Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that, after receiving the results of the additional trials or the additional information, the rapporteur Member State must examine it in conjunction with the results of the dossier already submitted for the substance concerned and communicate as quickly as possible, and within six months at the latest following receipt of all the required information, its assessment of the dossier as an addendum to the assessment report already submitted to the Commission. That report is to be communicated to the Standing Committee on Plant Health for examination.

20 Article 8(3), fourth indent, of Regulation No 3600/92, as amended by Regulation No 2266/2000, provides that, after that examination, the Commission is to present to the Standing Committee on Plant Health either a draft directive to include the active substance in Annex I to Directive 91/414, setting out, where appropriate, the conditions, including the time limit, for such inclusion, or a draft decision addressed to the Member States to withdraw the authorisations of plant protection products containing the active substance, whereby that active substance is not included in Annex I thereto, mentioning the reasons for the non inclusion.

Facts

I – Flusilazole

21 Flusilazole is an active substance which is used in fungicides for agricultural crops. The applicants, Du Pont de Nemours (France) SAS, Du Pont Portugal – Serviços, Sociedade Unipessoal L^{da}, Du Pont Ibérica, SL, Du Pont de Nemours (Belgium) BVBA, Du Pont de Nemours Italiana Srl, Du Pont De Nemours (Nederland) BV, Du Pont de Nemours (Deutschland) GmbH, DuPont CZ s.r.o., DuPont Magyarország Kereskedelmi kft, DuPont Poland sp. z o.o., DuPont Romania Srl, DuPont (UK) Ltd, Dy-Pont Agkro Ellas AE, DuPont International Operations SARL et DuPont Solutions (France) SAS, are active in the production and sale of flusilazole but also of flusilazole-based plant protection products. They hold marketing authorisations for flusilazole-based plant protection products registered in 15 Member States for use on 26 crops.

II – Notification and assessment report of Ireland

22 On 23 July 1993, DuPont de Nemours (France) notified the Commission of its wish to secure the inclusion of flusilazole in Annex I to Directive 91/414. It was accepted by the Commission as the notifier and Ireland was designated as rapporteur Member State for the assessment of flusilazole.

23 In July 1996, Ireland submitted an assessment report. In that report, Ireland recommended that the Commission should include flusilazole in Annex I to Directive 91/414 for ten years, subject to compliance with certain restrictions and provision of missing information within four years.

III – Peer review

24 On 17 October, the Commission forwarded for consultation that assessment report to all Member States. On 20 November 1996, it forwarded that report to the notifier for consultation.

25 From October 1996 to April 1997, the assessment report was subject to review by technical experts from a number of Member States. During that review, experts came to the conclusion that some of the issues raised could not be resolved by providing data after flusilazole was included in Annex I to Directive 91/414 as the rapporteur Member State had proposed.

26 On 14 April 1997, the report of the peer review was circulated to the Member States and to the notifier for comments.

27 On 4 November 1997, the Commission organised a meeting with the notifier and the Member State rapporteur. During that meeting the Commission noted that there were major problems with respect to flusilazole, in particular concerning teratogenic effects.

IV – Studies on fish

28 In August 1999, the notifier submitted an addendum to the monograph of July 1996 containing supplementary information required following the initial assessment. As regards the effects of flusilazole on the aquatic environment, the notifier examined, inter alia, the chronic risk for fish by conducting an early life stage study on rainbow trout.

29 In December 1999, the Commission adopted the Communication to the Council and European Parliament on a Community Strategy for Endocrine Disrupters (COM(1999) 706).

30 On 8 November 2001, the Commission drew up a draft review report for flusilazole in which it stated that that draft review was confidential and did not necessarily represent the Commission's views. The overall conclusion from the evaluation set out in the draft review was that it may be expected that plant protection products containing flusilazole would fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414, subject to compliance with the requirements in sections 4 to 6 of that draft report and in Annex IV to Directive 91/414. As regards the lists of studies to be generated by the notifier, the conclusion of that draft report in question was that '[N]o further studies [had been] identified which were at this stage considered necessary in relation to the inclusion of flusilazole in Annex I [to Directive 91/414] under the current inclusion conditions' but that 'in view of the known reproductive toxicity of the active substance in rats and birds and its slow degradation in soil, the Standing Committee for Plant Health identified the need to confirm, by additional data, the environmental safety of flusilazole occurring in soil and water by requesting a full fish life cycle study, and a litter bag study on organic matter breakdown in soil'.

31 In December 2001, the Commission's services discussed with the Standing Committee for Plant Health a draft directive including flusilazole in Annex I to Directive 91/414. One clause in that draft directive would have required a long term study on fish, which could have been lodged after flusilazole was included in Annex I thereto.

32 In the light of concerns expressed by Member States in the Standing Committee for Plant Health, the vote on the inclusion of flusilazole in Annex I to Directive 91/414 was, however, removed from the agenda of that committee and the Commission submitted two specific questions to the Scientific

Committee on Plants as a result of the slight inhibitory effects of flusilazole on aromatase. First, the Commission asked the Scientific Committee on Plants to comment on whether, in the specific case of flusilazole, the no observed effect concentration ('NOEC') for long-term effects on fish was adequate to ensure a sufficient protection of fish from adverse effects on reproduction, and to make general observations on the 'comparative sensitivity of the early life stage test versus the full fish life cycle study'. Second, it was asked to comment on the potential impact of flusilazole on organic matter decomposition under the intended use conditions.

33 In July 2002, the Scientific Committee on Plants responded to those two questions in an opinion. As regards the first question, the committee took the view that: 'Although fish early life-stage tests provide useful information on sensitive life stages of fish, ... there [was] evidence that flusilazole [could] have specific effects on the reproductive process' that '[t]herefore [it could] not conclude that a NOEC based on a fish early life-stage test for a single species was necessarily adequate in this particular case to ensure sufficient protection of fish populations from adverse effects on reproduction' that 'early life-stage tests [were] not designed to detect potential effects on reproduction (including mating behaviour, time to sexual maturity, reproductive output and timing, fertilisation success, and sex ratio of offspring)' and finally that 'if there [were] reasons to expect such processes to be adversely affected (e.g., because the substance has shown endocrine-disrupting effects), a test that incorporates such endpoints should be conducted'.

34 As regards the second question, the Scientific Committee on Plants concluded that given the persistence of flusilazole in soil and the environmental and agronomical importance of the organic matter breakdown for soil fertility, a risk assessment based solely on the existing data was not adequate.

35 In February 2003, the notifier submitted studies on both questions. In the notifier's view, the study on flathead minnows showed 'no conclusive impact on gonadal development' although there appeared to be a 'general tendency for the higher dose groups to be associated with lower gonadal stage scores (juvenalisation)'. In addition, the notifier concluded that, first, there was only a 'low chronic risk to fish' if flusilazole was used as recommended, and, second, that the residues of flusilazole in surface water '[would] not present a chronic risk to the maturation, development or reproduction of exposed fish'.

36 In September 2003, the rapporteur Member State examined those studies and drew up an addendum to its draft assessment report. In that addendum, the Member State took the view, inter alia, that:

'The revised assessment for risk to aquatic life based on the NOEC established following chronic exposure in the fish full lifecycle study and the environmental concentrations predicted to arise in surface water following the recommended use of Flusilazole clearly [indicated] a wide margin of safety and a very low chronic risk to fish life from use in arable cropping. [In addition,] it was concluded that Flusilazole does not adversely impact on the reproductive processes in fish or interfere with the process of sexual differentiation or development and is not considered to act [as] a potentially endocrine modulating compound at the levels of exposure tested.'

37 In the September 2003 addendum, the rapporteur Member State accordingly concluded that the further evidence on lack of long-term effects to fish and soil functions confirmed the environmental safety of flusilazole use at recommended rates and supported the listing of the active substance in Annex I to Directive 91/414.

38 In October 2003, the evaluation of those additional studies was circulated to the European Community Co-ordination (ECCO) which concluded that the study results fully addressed the concerns raised by the Member States.

V – Discussions 2004-2005

39 In January 2004, the rapporteur Member State issued a final addendum to the monograph,

summarising the last toxicology study conducted on the initiative of DuPont de Nemours, which did not modify the overall conclusion that safe uses of flusilazole exist.

40 On 11 March 2004, the 'Evaluation' working group met, and the issue of endocrine disruption was again raised by representatives of the Member States. The Commission's services underlined that there were deadlines for reaching a decision.

41 On 28 June 2004, at the meeting of the 'Evaluation' working group, one Member State representative asked if flusilazole should not be prohibited on the grounds that other less dangerous products were available. A discussion on this issue continued over several meetings, in which the Commission's services pointed out that such an approach was not possible given the existing legal framework. A further Member State representative pointed out that the Organisation for Economic Cooperation and Development (OECD) was examining the issue of endocrine disruption and suggested that the Community assessment should be delayed until there was further information. The Commission's services again argued that it was important not to delay decision-making. Italy stated that it had concerns about including a substance which was considered to be carcinogenic, mutagenic and reprotoxic, and that levels of exposure below which no adverse effects were seen should be defined.

42 On 27 July 2004, the Commission's services prepared a draft directive to include flusilazole in Annex I to Directive 91/414 for ten years, without any crop restrictions. Inclusion was conditional upon further studies being carried out, to be co-ordinated by the rapporteur Member State.

43 In October 2004, that proposal for a directive was considered during a number of meetings of the 'Legislation' working group of the Standing Committee for Plant Health. Eight Member States indicated that they could not support such a proposal.

44 On 8 October 2004, the Commission decided not to submit its proposal to the vote of the Standing Committee for Plant Health.

45 On 14 April 2005, a meeting of the 'legislation' working group of the Standing Committee for Plant Health was held, during which the Commission's services proposed a directive which would have included flusilazole in Annex I to Directive 91/414 for seven years as opposed to ten. In addition, there was a requirement that flusilazole be tested according to OECD guidelines for endocrine disruption within two years following the publication of such guidelines. No qualified majority seemed to emerge either for or against that proposal and the draft was not submitted to a vote of that committee. The Commission's services raised the possibility of a decision withdrawing flusilazole.

46 On 22 July 2005, DuPont (UK) Ltd wrote to the Commission, and all the Member States, arguing that the classification of flusilazole in the category 2 of carcinogenic, mutagenic and reprotoxic products for the reproduction as well as its interaction with endocrine systems did not fall within the scope of the risk analysis required by Directive 91/414.

47 On 2 August 2005 the Commission's services replied to letter of DuPont (UK) of 22 July 2005, stating that they were considering the possibility of not including flusilazole in Annex I to Directive 91/414 and they referred to the 'endocrine disrupting potential of the substance, its toxicity to reproduction and the risk to birds and mammals and aquatic organisms'.

48 By letter of 19 August 2005, DuPont (UK) replied to the Commission that all of the areas referred to by the Commission as a basis for a possible decision not to include flusilazole – inter alia, the endocrine-disrupting potential of the substance – had been addressed during the evaluation process and that safe uses had been demonstrated. It therefore asked the Commission to set out the reasons why it proposed not to include flusilazole and requested a meeting on that matter.

49 On 9 and 22 September 2005 two meetings took place between the notifier and representatives of the Commission during which it was indicated to the notifier that no definitive decision concerning the assessment of flusilazole had yet been made.

50 In a letter of 20 October 2005, the Commission stated that if no decision was adopted before 31 December 2006, flusilazole would automatically be excluded from the market. In addition, the notifier was asked to put forward detailed risk mitigation measures before 14 November 2005. Lastly, the Commission stated that if the outcome was a directive including flusilazole in Annex I to Directive 91/414, this would at most cover the specific crops which had been assessed at Community level.

51 On 7 November 2005, DuPont (UK) wrote to the Commission and, on a without prejudice basis, proposed to it certain risk mitigation measures, which included restricting the types of crops on which flusilazole could be used. It made clear that its proposal should in no way be interpreted as implying that other uses or conditions of use were unsafe.

52 On 15 November 2005, the Kemikalieinspektionen (KEMI, Swedish national chemical inspectorate) and the Lantbrukarnas Riksförbund (LFR, Federation of Swedish Farmers) wrote to the Commission asking it not to include flusilazole in Annex I to Directive 91/414. They submitted that 'the existing methodology is not sensitive enough to detect the lowest effect levels of these endocrine disrupters.'

53 In December 2005, the Commission launched a new inter-services consultation for an amended draft proposal for inclusion of flusilazole in Annex I to Directive 91/414. In recital 5 of its amended proposal, the Commission stated that 'considering the hazardous profile and the remaining scientific uncertainties as regards the potential endocrine disrupting properties of flusilazole, it [was] necessary, in order to achieve the high level of protection of human and animal health and the environment chosen in the Community, to restrict the uses of flusilazole to those crops that [had] been effectively assessed within the Community evaluation and [had been] found acceptable'. The inclusion proposed was valid for cereals (other than rice), oilseed rape, maize and sugar beet, with a validity of seven years.

54 On 23 January 2006, the rapporteur Member State objected to the Commission's latter proposal to include flusilazole in Annex I to Directive 91/414, on the ground that that inclusion encouraged uses on major crops at the expense of 'minor uses' and that it acted negatively on the principle of subsidiarity. That Member State also argued in favour of a ten-year inclusion, because the approach proposed would bring further pressure to bear when the 're-review' commenced.

VI – Vote in the standing committee in March 2006

55 On 3 March 2006, the Commission completed the final review report for flusilazole. The Commission concluded in the report that flusilazole could be included in Annex I to Directive 91/414 subject to compliance with particular requirements and with the uniform principles laid down in Annex VI to Directive 91/414. The Commission took the view that further studies should be requested by the Member States to address the potential endocrine-disrupting properties of flusilazole within two years of the adoption of the Test Guidelines on endocrine disruption by the OECD.

56 On that same date, the Commission put to a vote of the Standing Committee for Plant Health the amended draft in which the proposed inclusion of flusilazole in Annex I to Directive 91/414 covered cereals (other than rice), oilseed rape, maize and sugar beet, for a period of seven years. That committee failed, however, to reach a qualified majority on the Commission's proposal and therefore did not deliver an opinion.

57 On 8 June 2006, DuPont (UK) wrote to the Commission urging it to propose a Council directive including flusilazole in Annex I to Directive 91/414.

VII – Discussion in the Council

58 On 13 June 2006, the Commission proposed a Council directive with the same contents as the text submitted to the Standing Committee for Plant Health. The technical experts from a certain number of Member States objected to the inclusion of an endocrine disrupter in Annex I to Directive 91/414, on the basis that the long-term effects were too uncertain. Other experts considered that, given the

available data, the issue of endocrine disruption had been resolved.

59 On 25 June 2006, in accordance with Article 5(4) of Decision 1999/468, the Commission submitted to the Council a proposal for a directive including flusilazole in Annex I to Directive 91/414 for a period of seven years and restricted to the same four crops. However, no qualified majority could be achieved on that proposal.

60 On 4 July 2006 and 26 July 2006, the Finnish Presidency of the Council sounded out the Member States, without success, on a variety of possible decisions concerning the status of flusilazole, ranging from inclusion to non-inclusion of that active substance in Annex I to Directive 91/414.

61 On 8 September 2006, the European Council Permanent Representatives (COREPER) decided to include as an A point (vote without discussion) a 'no Council position' vote on the agenda of the 18 September 2006 Council.

62 On 13 September 2006, the Members of the Commission met and decided to present a proposal for a Council Directive to include flusilazole as active substance in Annex I to Directive 91/414, in the hope that it would obtain a qualified majority in the Council. As a number of Member States continued to express concerns, the Commission revised its proposal and restricted the inclusion of flusilazole to four crops and a renewable period of 18 months.

63 On 15 September 2006, COREPER decided to check delegations' voting intentions on the amended proposal at its next meeting, and then to submit it to the Council on 25 September 2006, as an 'A' Agenda item (vote without discussion). At the meeting of COREPER of 21 September 2006 no qualified majority could be achieved on the proposal in question.

64 On 25 September 2006, although the Council formally confirmed that it would not oppose the new proposal, at the vote no qualified majority was reached.

65 On 11 December 2006, the Commission adopted Directive 2006/133/EC amending Directive 91/414 to include flusilazole as active substance (OJ 2006 L 349, p. 27, the 'contested directive') which entered into force on 1 January 2007.

VIII – Contested Directive

66 The contested directive included flusilazole in Annex I to Directive 91/414 subject to certain conditions.

67 The inclusion of flusilazole in Annex I to Directive 91/414 was only valid for 18 months, namely 1 January 2007 to 30 June 2008. During that period, it was only authorised for use as a fungicide on cereals (other than rice), on maize, on oilseed rape and on sugar beet at rates not exceeding 200 g active substance per hectare per application. Moreover, the contested directive excluded the use of fungicides containing flusilazole for home gardening as well as for air application by way of knapsacks or of hand-held applications. It also required that appropriate risk mitigation measures be taken by Member States and specified measures to be taken for the protection, in particular, of aquatic organisms, birds and mammals as well as operators (see Part A of the column 'Specific provisions' of the annex to the contested directive).

68 In addition, the Member States were required to impose certain information obligations on operators and subject the notifier to the obligation to submit certain studies (see part B of the column 'Specific provisions' of the annex to the contested directive).

69 Finally, the Member States, were required to verify existing authorisations before the entry into force of the inclusion of flusilazole in Annex I to Directive 91/414 and to re-evaluate products authorised during the inclusion period (see Articles 2 and 3 of the contested directive).

IX – Application for renewal

70 On 20 December 2006, the notifier sought from the Commission the renewal of the inclusion of flusilazole in Annex I to Directive 91/414 for a period of ten years and without crop restrictions. Ireland was designated as rapporteur Member State and a dossier was lodged by the notifier on 27 April 2007. The Commission asked the Irish authorities to send to it a report of its assessment by April 2007 with a view to completing the assessment before 30 June 2008.

71 In response to a written question from the General Court, the Commission stated that the renewal process for the inclusion of flusilazole lost its priority status following the adoption of the order of the President of the General Court of 19 July 2007 in Case T 31/07 R *Du Pont de Nemours (France)* v *Commission* [2007] ECR II 2767. The renewal process had still not been completed at the date of the hearing.

Procedure and forms of order sought

72 By application lodged at the Court Registry on 12 February 2007, the applicants brought the present action.

73 The applicants, supported by the intervener, the European Crop Protection Association (ECPA), claim that the General Court should:

– annul the annex to the contested directive in so far as it fixes the expiration date of the inclusion period for flusilazole at 30 June 2008 in Annex I to Directive 91/414;

– annul Article 3(2) of the contested directive in so far as it fixes the date by which Member States shall, after re-evaluation, amend or withdraw the authorisation of products containing flusilazole at 30 June 2008;

– annul Part A of the 'Specific provisions' column contained in the annex to the contested directive in so far as it places a restriction on the types of crops on which the use of flusilazole may be authorised by the Member States following its inclusion in Annex I to Directive 91/414/EEC which must be implemented by 30 June 2007;

– order the European Community, represented by the Commission, to repair any damage suffered by the applicants as a result of the contested restrictions and to set the amount of this compensation for the damage suffered by the applicants currently estimated at [*confidential*](1) or any other amount reflecting the damage suffered or to be suffered by the applicants as further established by them in the course of these proceedings especially to take due account of future damage;

– in the alternative, order the parties to produce to the Court, within a reasonable period of time of the date of the judgment, figures as to the amount of the compensation arrived at by agreement between the parties or, in the absence of agreement, to order the parties to produce to the Court within the same period their conclusions with detailed figures;

– order interest at the rate set at the time by the European Central Bank for main refinancing operations, plus two percentage points, or any other appropriate rate to be determined by the Court, be paid on the amount payable as from the date of judgment until actual payment;

– order the Commission to pay the costs.

74 The Commission contends that the Court should:

– dismiss the action as inadmissible or, in the alternative, as unfounded; and

– order the applicants to pay the costs.

75 By order of 19 July 2007, the President of the General Court suspended, at the request of the

applicants, the limitations restricting the inclusion of flusilazole to 30 June 2008 and to cereals (other than rice), maize, oilseed rape and sugar beet contained in the contested directive ('the contested restrictions') until judgment is delivered in the main proceedings (see the order in *Du Pont de Nemours (France)* v *Commission*, cited in paragraph 71 above).

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

77 Upon hearing the Report of the Judge-Rapporteur, the General Court (First Chamber) decided to open the oral procedure and, in respect of the measures of organisation of procedure provided for in Article 64 of the Rules of Procedure, put some written questions to the parties, which answered them within the period prescribed.

78 The parties, assisted by their experts, presented oral arguments and answered the oral questions put to them by the General Court at the hearing on 27 March 2012.

The applications for annulment

I – Admissibility

79 Following the questions put by the General Court at the hearing, the Commission withdrew its challenge to the admissibility of the applications for annulment of the applicants on the grounds that they were not directly and individually concerned by the contested directive, which was noted in the minutes of the hearing.

80 It follows that the challenge by the Commission to the admissibility of the applications for annulment of the applicants only relates to the non-severable character of the contested restrictions from the contested directive.

81 As stated in paragraph 73 above, the applicants claim that the contested directive should be annulled in so far as it fixes at 30 June 2008 both the expiration date of the inclusion period for flusilazole in Annex I to Directive 91/414 and the date by which Member States are, after re evaluation, to amend or withdraw the authorisation of products containing flusilazole. In addition, the applicants claim that the contested directive should be annulled in so far as it places a restriction on the types of crops on which the use of flusilazole may be authorised by the Member States following its inclusion, which must be implemented by 30 June 2007 at the latest.

82 The Commission submits, in essence, that none of those restrictions is severable from the rest of the contested directive because they constitute the core of the directive. Moreover, it submits that the application for annulment is intended to achieve a partial annulment of the contested measure. As a result, the Commission submits that the application is inadmissible.

83 In that regard, it must be recalled, as has been well established in case-law, that partial annulment of a Community act is possible only if the elements the annulment of which is sought may be severed from the remainder of the act. Similarly, the Court of Justice has repeatedly held that that requirement of severability is not met where partial annulment of a measure would have the effect of changing its substance (see, inter alia, Case C 29/99 *Commission* v *Council* [2002] ECR I 11221, paragraphs 45 and 46; Case C 239/01 *Germany* v *Commission* [2003] ECR I 10333, paragraphs 33 and 34; and Case C 540/03 *Parliament* v *Council* [2006] ECR I 5769, paragraphs 27 and 28). Moreover, it was made clear that the question whether partial annulment would alter the substance of the contested measure is an objective criterion, and not a subjective criterion linked to the political intention of the authority which adopted the measure at issue (see *Germany* v *Commission*, cited above, paragraph 37, and Case C 244/03 *France* v *Parliament and Council* [2005] ECR I 4021, paragraph 14).

84 In the present case, since the applicants seek the annulment only of the provisions of the contested

directive which (i) fix at 30 June 2008 the expiration date of the inclusion period for flusilazole in Annex I to Directive 91/414, (ii) fix at 30 June 2008 the date by which Member States are, after re-evaluation, to amend or withdraw the authorisation of products containing flusilazole and (iii) place a restriction on the types of crops on which the use of flusilazole may be authorised by the Member States following its inclusion in that annex which must be implemented by 30 June 2007, it must be held that the applicants are claiming the partial annulment of the contested directive.

85 However, such a claim, if allowed, would in fact alter the actual substance of the contested directive. The contested directive forms part of the system for authorising the placing of plant protection products on the market established by Directive 91/414 for the purpose of, inter alia, ensuring a high level of protection for human health and the environment, and the partial annulment of the contested directive would result in the inclusion of flusilazole in Annex I to Directive 91/414 beyond 30 June 2008, the possibility of re-evaluating the authorisations granted to products containing flusilazole after 30 June 2008 and the absence of any limitation to only cereals (other than rice), maize, oilseed rape and sugar beet. The scope of an authorisation resulting from the inclusion of flusilazole in Annex I to Directive 91/414 with less severe restrictions than those of the contested directive would thus differ from the scope of the contested directive. The limitations contested by the applicants in fact constitute mandatory and essential conditions for the inclusion of that substance in the annex in question and a modification of those conditions as a result of a partial annulment of the contested directive would therefore change the actual substance of the contested directive.

86 Therefore, it must be held that the provisions of the contested directive setting out conditions for the inclusion of flusilazole in Annex I to Directive 91/414, which the applicants seek to have annulled, are not severable from the rest of the contested directive.

87 Furthermore, it is not possible to construe the form of order sought by the applicants as seeking the annulment of Directive 91/414 in its entirety. Indeed, in response to a written question of the Court the applicants specifically opposed such an interpretation of the form of order sought. They reiterated that position at the hearing.

88 Therefore, given the case-law cited in paragraph 83 above and the fact that the provisions of the contested directive setting out conditions for the inclusion of flusilazole in Annex I to Directive 91/414 which the applicants seek to have annulled are not severable from the rest of the contested directive, the applicants' applications for annulment must be rejected as inadmissible.

89 The various arguments put forward by the applicants cannot invalidate that conclusion.

90 First of all, the applicants wrongly allege that the Commission has not demonstrated that the provisions of the contested directive setting out conditions for the inclusion of flusilazole in Annex I to Directive 91/414 were not severable from the rest of the contested directive. Indeed the absence of such a demonstration does not mean that the Court cannot conclude that applications for annulment are inadmissible. Since the conditions of admissibility of an action under Article 230 EC can be examined by the Court of its own motion (see, to that effect, Case T 55/99 *CETM* v *Commission* [2000] ECR II 3207, paragraph 21; see also Case 294/83 *Les Verts* v *Parliament* [1986] ECR 1339, paragraph 19), failure by the Commission to demonstrate the inadmissibility of such an application does not mean that the General Court will not find that application inadmissible. Moreover, clearly the Commission has, in the present case, correctly established to the requisite legal standard the reasons for which the provisions of the contested directive setting out conditions for the inclusion of flusilazole in Annex I to Directive 91/414 were not severable from the rest of the contested directive. It is apparent from the Commission's written pleadings that it has shown that the deletion of the contested restrictions would leave the contested directive with an entirely different set of risk mitigation measures and that there was an objective difference between including an active substance in Annex I to Directive 91/414 without conditions, and including it subject to certain conditions since, without the power to impose conditions, it might not be possible to include the substance in that annex.

91 Second, the applicants incorrectly submit that declaring their applications for annulment inadmissible would amount to a denial of justice.

92 The applicants allege that they have no interest in seeking annulment of the contested directive in its entirety, since such an annulment would result in the prohibition of future marketing of plant protection products containing flusilazole (see the order in *Du Pont de Nemours (France) and Others* v *Commission*, cited in paragraph 71 above, paragraphs 121 and 122). According to the applicants, such an application would have no useful purpose and would be declared inadmissible due to the resulting lack of legal interest. They consider that if the provisions of the contested directive setting out conditions for the inclusion of flusilazole in Annex I to Directive 91/414 were not severable from the rest of the contested directive, they could not apply for either complete annulment of the contested directive or its partial annulment and that, if they were refused a partial annulment, they could not protect themselves against any serious and irreparable damage resulting from the contested directive. Therefore, they submit that the inadmissibility of their applications for annulment, in accordance with the case-law cited in paragraph 83 above, would lead to a denial of justice.

93 In that regard, it must be borne in mind that, under the second paragraph of Article 231 EC (now the second paragraph of 264 TFEU), the Court of Justice may, if it considers it necessary to do so, state which of the effects of the measures that it has declared void are to be considered as definitive. The Court of Justice has stated that that provision allows the competent court of the European Union to maintain for the time being all the effects of the directive annulled (see Case C 295/90 *Parliament* v *Council* [1992] ECR I 4193, paragraphs 26 to 27).

94 Likewise, the Court of Justice has ruled that that provision can also be applied to a decision which has the effect of amending an annex contained in a directive and that, in view of the wording of that provision, it may, even of its own motion, limit the annulling effect of its judgment (see, to that effect, Case C 21/94 *Parliament* v *Council* [1995] ECR I 1827, paragraphs 31 and 32, and Joined Cases C 14/06 and C 295/06 *Parliament and Denmark* v *Commission* [2008] ECR I 1649, paragraphs 84 to 86).

95 Thus, it is permissible for the General Court, in a particular case and, inter alia, for a measure of general application, to limit the effects of an annulment of a measure in order to take account of the interests of the undertakings concerned and on grounds of legal certainty (see *Parliament and Denmark* v *Commission*, cited in paragraph 94 above paragraph 86).

96 In the present case, in the event that the applicants' complaints as to the merits are upheld, the General Court could therefore maintain in force the inclusion of flusilazole in Annex I to Directive 91/414 even if the contested measure were to be annulled and pending the entry into force of a new directive including flusilazole in that annex.

97 Accordingly, the annulment of the contested decision in its entirety is neither irrelevant nor without a useful purpose for the applicants as long as the effects of that annulment are limited until the adoption by the Commission of a new directive as a result of the judgment annulling the contested directive pursuant to Article 266 TFEU.

98 However, when questioned in writing and then at the hearing, after they had been reminded of the scope of the second paragraph of Article 264 TFEU as set out above, the applicants maintained that the form of order sought by them should be understood as seeking solely the annulment of the restrictions in the contested directive pertaining to the duration of the inclusion and the authorised crops. In these circumstances, an interpretation by the General Court that the form of order sought by the applicants seeks the annulment of the contested directive in its entirety would be ultra petita. The scope of the annulment which it pronounces may not go further than that sought by the applicants (see, to that effect, Joined Cases T 90/07 P and T 99/07 P *Belgium and Commission* v *Genette* [2008] ECR II 3859, paragraph 72 and the case-law cited).

99 In light of the above, the inadmissibility of the applications of the applicants is not a denial of justice since they could have sought the annulment of the contested directive in its entirety and requested that the General Court suspend the effects of that annulment until the adoption by the Commission of necessary measures for implementing the judgment bringing about the annulment.

100 Third, the applicants invoke Case T 380/06 *Vischim* v *Commission* [2009] ECR II 3911, in support of their argument that just the temporal effects of the measure may be subject of an action for annulment.

101 It must however be pointed out the case-law of the Court of Justice to which the General Court makes reference in that case (Case C 368/89 *Crispoltoni* [1991] ECR I 3695 and Joined Cases C 260/91 and C 261/91 *Diversinte and Iberlacta* [1993] ECR I 1885) concerns the possibility of challenging the retroactivity of the provisions of a given measure, the annulment of such provisions having in fact no impact on the future effects of that measure.

102 That situation is, however, clearly distinct from a situation where an authorisation which limited in time is provided for by a measure and where only that time limit is being contested. Indeed, in such a case, the annulment of just that limitation would have an impact on the future effects of that measure, inasmuch as it would modify the scope of the authorisation, and it follows that it does not concern provisions which are separable from the authorisation as such.

103 In addition, clearly in *Vischim* v *Commission* (cited in paragraph 100 above, paragraph 55) the General Court expressly relied on the possibility offered to the Court to limit the effects of an annulment, as laid down in the second paragraph of Article 231 EC, in order to support the admissibility of the application in that case.

104 However, as stated at paragraphs 98 and 99 above, such a possibility supposes that the action for annulment is admissible. At the hearing, the applicants stated that the form of order sought by them could not be interpreted as seeking the annulment of the contested directive in its entirety while at the same time seeking a limitation of the annulment's effects until the adoption of a new directive in implementation of the judgment of the General Court.

105 Therefore, the applicant's argument based on *Vischim* v *Commission* (paragraph 100 above) does not allow in the present case the applicants' action for partial annulment to be declared admissible.

The application for damages

I – Introduction

106 The applicants claim that the unlawful conduct of which they complain is also capable of giving rise to non-contractual liability on the part of the Community.

107 In particular, according to the applicants, by adopting the contested restrictions, the Commission has disregarded the results of the risk assessment and has, as a result, violated European Community law, as they claim in their applications for annulment.

II – Admissibility

A – Preliminary considerations

108 The applicants and the Commission agree on the fact that all detailed arguments on damages can be postponed until the Court decides on whether the Community has incurred non-contractual liability in the present case.

109 Accordingly, the parties accept that, as regards the claim for damages, the General Court is to give an interlocutory judgment concerning only the non-contractual liability of the Community due to the limitations of the inclusion of flusilazole in Annex I to Directive 91/414 for four crops only, until 30 June 2008, with a re-evaluation of the authorisations granted to products containing flusilazole for that date.

110 However, the Commission casts doubt on whether the applicants' claim for damages is sufficiently

precise for it to be admissible.

111 It should be borne in mind that under the first paragraph of Article 21 of the Statute of the Court of Justice – applicable to the General Court by virtue of the first paragraph of Article 53 of that Statute and Article 44(1)(c) of the Rules of Procedure – the application must indicate the subject-matter of the proceedings and a summary of the pleas in law. Those elements must be sufficiently clear and precise to enable the defendant to prepare its defence and the Court to rule on the application, if necessary without any further information. In order to guarantee legal certainty and sound administration of justice, it is necessary, for an action to be admissible, that the basic legal and factual particulars relied on be indicated, at least in summary form, coherently and intelligibly in the application itself (orders in Case T 85/92 *De Hoe* v *Commission* [1999] ECR II 523, paragraph 20; in Case T 154/98 *Asia Motor France and Others* v *Commission* [1993] ECR II 1703, paragraph 49; and judgment in Case T 277/97 *Ismeri Europa* v *Court of Auditors* [1999] ECR II 1825, paragraph 29).

112 In order to satisfy those requirements, an application seeking compensation for damage allegedly caused by a European Union institution must state the evidence from which the conduct alleged against the institution may be identified, the reasons why it considers that a causal link exists between that conduct and the damage which it claims to have suffered, and the nature and extent of that damage. A claim for any unspecified form of damages, however, is not sufficiently precise and must therefore be regarded as inadmissible (see Case 5/71 *Aktien-Zuckerfabrik Schöppenstedt* v *Council* [1971] ECR 975, paragraph 9; Case T 64/89 *Automec* v *Commission* [1990] ECR II 367, paragraph 73, and the order in Case T 91/05 *Sinara Handel* v *Council and Commission* [2007] ECR II 245, paragraph 87).

113 Furthermore, the fact that the Court of Justice and the General Court have already had occasion to decide, by way of interlocutory judgment, on the principle of the Community's non contractual liability, whilst reserving the precise determination of the compensation to a later decision, cannot absolve the applicant from observance of the minimum formal requirements laid down in Article 44(1)(c) of the Rules of Procedure. It follows also that an applicant who seeks such a judgment from the General Court not only continues to be bound to provide the evidence necessary to identify the conduct of which the Community is accused, the nature and type of damage and the causal link between the conduct and that damage, but must, in addition, state the reasons justifying dispensation from the requirement that the application must contain a detailed quantification of the damage claimed (the order in *Sinara Handel* v *Council and Commission*, cited in paragraph 112 above, paragraph 111).

114 Consequently, it must be assessed whether the applicants have complied with that minimum requirements laid down in Article 44(1)(c) of the Rules of Procedure and whether they have provided reasons in support of the interlocutory application.

B – Compliance with the minimum requirements

115 As regards the sufficiently precise character of the applicants' claim for damages, it should be noted that the applicants submit that the damage arises, first of all, from the prohibition on the use of flusilazole on crops other than those listed in the contested directive as of 30 June 2007 and, second, from the prohibition on the marketing of plant protection products containing flusilazole as of 30 June 2008. That damage is said to amount to approximately [*confidential*]. For that purpose the applicants attach two documents. The first document is a table entitled 'Flusilazole Business Evaluation' which includes an estimate of the revenues generated by the activity linked to flusilazole from 2007 until 2017. The second document contains an economic assessment entitled 'Preliminary economic impact assessment of the non-inclusion of flusilazole in Annex I to Directive 91/414'. In addition, the applicants claim as damages [*confidential*].

116 In light of those factors, the applicants' submissions as regards the damage for which they seek compensation, resulting from the Commission's alleged unlawful conduct, are sufficiently precise.

117 This finding is not affected by the fact that the applicants have not identified the share of the damage suffered by each one of them individually as a result of the Commission's alleged unlawful

conduct. The need for precision required by Article 44 of the Rules of Procedure can, in the present case, be considered satisfied since the estimate of the damage incurred by all the applicants belonging to one and the same group of companies has been provided in the application.

C – The reasons for the application requesting an interlocutory judgment

118 The applicants submit, in essence, that the General Court is justified in giving an interlocutory judgment since the damages at issue were future damages, the final amount of which, at the time of lodging the initial application, was difficult to establish.

119 The General Court considers that the fact that the exact amount of the damages incurred can only be established, if illegal conduct is established, after proceedings have been brought, justifies the delivery in the present case, of an interlocutory judgment.

D – Conclusion

120 For the foregoing reasons, the Commission wrongly contests the admissibility of the applicants' claim for damages on the grounds that it does not satisfy the minimum formal requirements laid down in Article 44(1)(c) of the Rules of Procedure. In addition, the circumstances of the present case lend themselves to an interlocutory judgment being delivered on the question whether or not the Community incurred non-contractual liability.

III – Substance

A – The conditions under which the Commission's non contractual liability arises

121 The non-contractual liability of the Community for unlawful conduct on the part of its institutions, within the meaning of the second paragraph of Article 288 EC, depends on fulfilment of a set of conditions, namely the unlawfulness of the conduct alleged against the institutions, the fact of damage and the existence of a causal link between that conduct and the damage complained of (see Case C 243/05 P *Agraz and Others* v *Commission* [2006] ECR I 10833, paragraph 26 and the case law cited, and T 16/04 *Arcelor* v *Parliament and Council* [2010] ECR II 211 paragraph 139 and the case law cited).

122 Given the cumulative nature of those conditions, the action must be dismissed in its entirety where one of those conditions is not satisfied (see *Arcelor* v *Parliament and Council*, cited in paragraph 121 above, paragraph 140 and the case-law cited).

123 With regard to the first of these conditions, there must be a sufficiently serious breach of a rule of law intended to confer rights on individuals (Case C 352/98 P *Bergaderm and Goupil* v *Commission* [2000] ECR I 5291, paragraph 42, and Joined Cases C 120/06 P and C 121/06 P *FIAMM and Others* v *Council and Commission* [2008] ECR I 6513, paragraph 173). As regards the requirement that the breach must be sufficiently serious, the decisive test for determining whether that requirement is met is whether the institution concerned has manifestly and gravely disregarded the limits on its discretion. It is solely where that institution has only considerably reduced, or even no, discretion, that the mere infringement of Community law may suffice to establish the existence of a sufficiently serious breach (Case C 312/00 P *Commission* v *Camar and Tico* [2002] ECR I 11355, paragraph 54; see *Arcelor* v *Parliament and Council*, cited in paragraph 121 above, paragraph 141 and the case-law cited).

124 The applicants' arguments relating to the Commission's alleged unlawful conduct must therefore be assessed in the light of those criteria.

125 In this regard, it should be made clear that the restrictions relating to the inclusion of flusilazole in Annex I to Directive 91/414 that the applicants are challenging have been imposed in the context of that directive with a view to protecting human health and the environment, a technical, complex and evolving subject in which the legislator enjoys a broad discretion.

126 It follows that a sufficiently serious breach of the rules of law at issue must be based on a manifest and serious failure to have regard to the limits of the broad discretion enjoyed by the Commission when exercising its powers on issues concerning the protection of human health and the environment (see, to that effect and by analogy, Case T 13/99 *Pfizer Animal Health* v *Council* [2002] ECR II 3305, paragraph 166).

127 Consequently, it is necessary to assess whether the alleged infringement of the rules of law invoked by the applicant involves a manifest and grave failure to have regard to the limits of the broad discretion which the Commission enjoyed when adopting the contested directive.

B – Illegality based on the first and second pleas, alleging an assessment of the danger and not of the risks, and a breach of the principle of proportionality

1. Introduction

128 The applicants contend, in essence, that the contested restrictions are illegal because the notifier has established flusilazole was safe for certain uses.

129 In particular, the applicants consider that the results of the assessment of flusilazole, which was made in compliance with the provisions of Directive 91/414 with a view to its inclusion in Annex I thereto, cannot justify the contested restrictions. They contend that those restrictions are the result of an assessment of the danger and not of the risk. Therefore, according to the applicants, the contested restrictions are contrary to the EC Treaty, to Directive 91/414, to the precautionary principle and to the principle of proportionality and justify the payment of compensation for the damage that they have suffered.

130 Before considering those various complaints (see paragraphs 165 to 281 below), it is appropriate to recall the scope of the applicable rules in the present case (see paragraphs 131 to 159 below) and to set out the reasons in the contested directive justifying the contested restrictions (see paragraphs 160 to 164 below).

2. Considerations of principle

a) Introduction

131 As is clear from the fifth, sixth and ninth recital in its preamble, 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 (Case C 138/05 *Stichting Zuid-Hollandse Milieufederatie* [2006] ECR I 8339, paragraph 43; Case C 326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, paragraph 74; and Case T 334/07 *Denka International* v *Commission* [2009] ECR II 4205, paragraph 92).

132 By requiring the maintenance of a high level of human health protection, Directive 91/414 applies Article 152(1) EC, which provides that a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities. That 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, the order in Case C 180/96 R *United Kingdom* v *Commission* [1996] ECR I 3903, paragraph 93).

133 In addition, the prior authorisation procedure put in place by Directive 91/414 for plant protection products emanates from the general principle of European Union law that is the precautionary principle. That principle is an integral part of the decision-making process leading to the adoption of any measure for the protection of human health, where the Commission or the Council, as the case may be, rules on a request for the inclusion of an active substance in Annex I to Directive 91/414 (see Case C 77/09 *Gowan Comércio Internacional e Serviços* [2010] ECR I 13533, paragraph 74).

b) Precautionary principle

Definition

134 The precautionary principle requires 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, T 84/00, 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).

135 Where there is scientific uncertainty as to the existence or extent of risks to human health, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (see, to that effect, Case C 180/96 *United Kingdom* v *Commission* [1998] ECR I 2265, paragraph 99; Case C 236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I 8105, paragraph 111; Case C 504/04 *Agrarprodukton Staebelow* [2006] ECR I 679, paragraph 39; and Case T 177/02 *Malagutti-Vezinhet* v *Commission* [2004] ECR II 827, paragraph 54) or until the adverse health effects materialise (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraphs 139 and 141, and Case T 70/99 *Alpharma* v *Council* [2002] ECR II 3495, paragraphs 152 and 154).

136 Within the process leading to the adoption by an institution of appropriate measures to prevent specific, potential risks to public health, safety and the environment by reason of the precautionary principle, three successive stages can be identified: firstly, identification of the potentially adverse effects arising from a phenomenon; secondly, assessment of the risks to public health, safety and the environment which are related to that phenomenon; thirdly, when the potential risks identified exceed the threshold of what is acceptable for society, risk management by the adoption of appropriate protective measures. Although the first of those stages does not require further explanation, the two subsequent stages call for clarification.

Risk assessment

– Introduction

137 Assessment of the risks to public health, safety and the environment consists, for the institution required to consider potentially adverse effects arising from a phenomenon, in scientifically assessing those risks and in determining whether they exceed the level of risk deemed acceptable for society. Thus, in order for the institutions to be able to carry out a risk assessment, it is important for them, firstly, 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, *Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 149, and *Alpharma* v *Council*, cited in paragraph 135 above, paragraph 162).

– The scientific assessment

138 A scientific risk assessment is a scientific process consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to that hazard and the characterisation of the risk (*Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 156, and *Alpharma* v *Council*, cited in paragraph 135 above, paragraph 169).

139 In its communication COM(2000) 1 final of 2 February 2000 on the precautionary principle, the Commission defined those four components of a scientific risk assessment as follows (see Annex III):

‘Hazard identification means identifying the biological, chemical or physical agents that may have adverse effects ...

Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity ...

Appraisal of exposure consists of quantitatively or qualitatively evaluating the probability of exposure to the agent under study ...

Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and of the severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process.'

140 The scientific risk assessment is not required to provide the institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality. A situation in which the precautionary principle is applied by definition coincides with a situation in which there is scientific uncertainty. Furthermore, the adoption of a preventive measure, or, conversely, its withdrawal or relaxation, cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice (see, to that effect, *Solvay Pharmaceuticals* v *Council*, cited in paragraph 134 above, paragraph 130). However, a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified (*Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraphs 142 and 143; see also, to that effect, Case T 229/04 *Sweden* v *Commission* [2007] ECR II 2437, paragraph 161).

141 Indeed, the scientific risk assessment should be based on the best scientific data available and should be undertaken in an independent, objective and transparent manner (see, to that effect, Case C 343/09 *Afton Chemical* [2010] ECR I 7027, paragraph 60; *Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 158, *Alpharma* v *Council*, cited in paragraph 135 above, paragraph 171).

142 Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (see *Afton Chemical*, cited in paragraph 141 above, paragraph 61).

143 It follows that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken (*Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraphs 144 and 146).

144 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' ('danger') is commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 147, and Case T 475/07 *Dow AgroSciences and Others* v *Commission* [2011] ECR I 0000, paragraph 147).

– The determination of the level of risk deemed acceptable

145 The responsibility for determining the level of risk which is deemed unacceptable for society lies, provided that the applicable rules are observed, with the 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 public health, safety and the environment and for the degree of those potential effects which, in their judgment, is no longer acceptable for society and above which it is necessary, in the interests of protecting public health, safety and the environment, to take preventive measures in spite of the 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 126 above, paragraphs 150 and 151).

146 In determining the level of risk deemed unacceptable for society, the institutions are bound by their obligation to ensure a high level of protection of public health, safety and the environment in order to be compatible with Article 152(2) EC. That high level of protection does not necessarily have to be the highest that is technically possible (see, to that effect, Case C 284/95 *Safety Hi-Tech* [1998] ECR I 4301, paragraph 49). Moreover, those institutions may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero risk' (*Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 152).

147 The level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on public health, safety and the environment were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge (see, to that effect, *Pfizer Animal Health* v *Council*, cited in paragraph 126 above, paragraph 153).

Risk management

148 Risk management corresponds to the body of actions taken by an institution faced with a risk in order to reduce it to a level deemed acceptable for society having regard to its obligation, in accordance with the precautionary principle, to ensure a high level of protection of public health, safety and the environment.

149 Those actions include the adoption of provisional measures, which must be proportionate, non-discriminatory, transparent, and consistent with similar measures already taken (see, to that effect, Case C 286/02 *Bellio F.lli* [2004] ECR I 3465, paragraph 59).

150 The principle of proportionality, as set out in Article 5(4) TEU, is one of the general principles of Community law. This principle requires that measures adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when 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 (see *Afton Chemical*, cited in paragraph 141 above, paragraph 45, and the case-law cited).

c) The inclusion of an active substance in Annex I to Directive 91/414

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

152 It has been held that it followed from Article 5(1) of Directive 91/414, interpreted in combination with the precautionary principle, that, in the domain of human health, the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance, justified, in principle, the refusal to include that substance in Annex I thereto (*Sweden* v *Commission*, cited in paragraph 140 above, paragraph 161).

153 Nevertheless, the case-law also makes it clear, following a systematic interpretation of Articles 4 and 5 of Directive 91/414, that the effect of Article 5(4) thereof, which provides that inclusion of an active substance in Annex I thereto may be subject to restrictions on use, is to permit inclusion of active substances which do not fulfil the requirements of Article 5(1) thereof but subject to certain restrictions which exclude problematic uses of the substance involved. Since Article 5(4) of

Directive 91/414 is to be regarded as a limitation on Article 5(1) thereof, it must be interpreted in the light of the precautionary principle. Consequently, before including a substance in Annex I to Directive 91/414, it must be established beyond any reasonable doubt that the restrictions on the use of the substance involved make it possible to ensure that use of that substance will be in accordance with the requirements laid down in Article 5(1) thereof (*Sweden* v *Commission*, cited in paragraph 140 above, paragraphs 169 and 170).

154 Lastly, it must be borne in mind that – as is clear from Article 6(2)(b) of Regulation No 3600/92, as amended by Regulation No 2266/2000 – it is the notifier who has to demonstrate that, on the basis of the information submitted for one or more preparations for a limited range of representative uses, the requirements of Directive 91/414 in relation to the criteria referred to in Article 5 thereof are met.

d) The incurring of the non-contractual liability of the Community in the context of Directive 91/414

155 In the framework of their assessment of the risks that an active substance poses to human health and the environment, as required by Directive 91/414, the Community institutions must carry out complex technical and scientific assessments. In addition, they enjoy a broad discretion in exercising their powers relating to the protection of human health and the environment. They also enjoy a broad discretion regarding the conditions that can be imposed for the inclusion of an active substance in Annex I thereto.

156 As was stated at paragraph 125 et seq. above, that broad discretion and those complex assessments mean that only manifest and grave failure to have regard to the limits of that discretion can result in a sufficiently serious breach of a rule of law capable of resulting in the Community's incurring non-contractual liability.

157 Moreover, it should be borne in mind that the legality of a Community measure must be assessed on the basis of the elements of fact and of law available to the institution at the time when the measure was adopted. As a result, elements post-dating the adoption of the Community measure cannot be taken into account in assessing the legality of that measure (see, to that effect, Case C 390/06 *Nuova Agricast* [2008] ECR I 2577, paragraph 54, and Case T 322/01 *Roquette Frères* v *Commission* [2006] ECR II 3137, paragraph 325).

158 In the present case, the applicants base their claim for damages on the alleged illegality of certain restrictions imposed in the contested directive including flusilazole in Annex I to Directive 91/414. In particular, they contend that the scientific evidence adduced at the time of the risk assessment of flusilazole with a view to its inclusion in that Annex I does not justify the contested restrictions.

159 It follows that the Community can incur non-contractual liability only if the applicants establish that there was unlawful conduct of such a kind as to give rise to such liability on the basis of the elements of fact and of law available to the institution at the time that the contested directive was adopted.

3. The statement of the reasons on which the contested directive is based

160 According to the preamble to the contested directive the Commission justified the adoption of the contested restrictions for the following reasons.

161 First of all, the Commission considered that flusilazole was a dangerous substance. According to the Commission, the various assessments carried out on that active substance had led to concerns about its intrinsic toxic effects, including potential endocrine disrupting properties. There was, however, no scientific consensus on the exact extent of the risk. Consequently, applying the precautionary principle and based on the scientific knowledge available when the contested directive was adopted, the Commission considered that risk mitigation measures should be imposed in order to achieve the high level of protection of human and animal health and the environment which has been adopted in the Community (see recital 5 to the contested directive).

162 Secondly, the Commission found that plant protection products containing flusilazole may be

expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414, with regard to the uses which were examined and detailed in the Commission review report, provided that adequate risk mitigation measures were applied (see recital 5 to the contested directive).

163 The risk mitigation measures included limiting the inclusion of flusilazole in Annex I to Directive 91/414 to only the proposed uses that had actually been assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of that directive. The Commission considered that that limitation ensured that each use would be subject to a complete assessment before its inclusion in that annex could be considered, and that it made it possible to avoid discrepancies in the high level of protection sought. It took the view that, due to the hazardous nature of flusilazole, it had been considered necessary to provide for a minimum harmonisation, at Community level, of certain risk mitigation measures that were to be applied by Member States when granting authorisations (see recital 6 to the contested directive).

164 The risk mitigation measures also included an 18-month limitation on the inclusion of flusilazole in Annex I to Directive 91/414. The Commission considered that that limitation further reduced the risks by ensuring a priority re-assessment of flusilazole (see recital 8 to the contested directive).

4. The legality of the contested measures

a) Premisses

The endocrine disrupters

165 It is clear from the case-file that the endocrine system is defined as a complex network of glands, hormones and receptors. Endocrine glands secrete hormones which are transported by the blood system to specific receptors in the organs, where they produce biological effects. The endocrine system provides the key communication and control link between the nervous system and bodily functions such as reproduction, immunity, metabolism and behaviour.

166 Moreover, it is not in dispute that endocrine disruption is a complex area and the state of scientific knowledge in that area is incomplete. Accordingly, there are still problems in establishing causal links between exposure to a suspected endocrine disrupter and any effects measured, particularly as regards human health. More scientific research is therefore needed in order to understand the potential effects of endocrine disruption.

167 The scientific uncertainty about endocrine disrupters affects the account to be taken of those uncertainties when an active substance is included in Annex I to Directive 91/414. Indeed, it is not in dispute that the lack of understanding about endocrine inhibitors restricts the putting in place of a harmonised methodology for the assessment of risks that they pose to human and animal health as well as the environment.

168 The Scientific Committee on Plants expressed a view on the importance of that question in an opinion of 2 December 1999 entitled ‘Opinion of the Scientific Committee on Plants on Endocrine disruption relevance in the context of Council directive 91/414/EEC concerning the placing of plant protection products on the market’.

169 In its opinion of 2 December 1999 the Scientific Committee on Plants considered that the data to be provided by the notifier of an active substance permitted a rather comprehensive appreciation of the endocrine disruption-related toxicological risk, provided that due attention was paid to the elements which might alert the assessors to the presence of an endocrine disruption-related mechanism of action or outcome.

170 As regards the ecotoxicological properties of an active substance, the Scientific Committee on Plants considered that the situation was less favourable, because a proper risk assessment implied taking into account all ecotoxicological relevant effects of the active substance. However, the existing tests did not cover all the effects. According to that committee, gaps in basic knowledge of aquatic and

terrestrial invertebrates as well as the large variety of endocrine systems in invertebrates prevented international experts from being able to recommend suitable standard tests for regulatory purposes.

171 The Scientific Committee on Plants stressed that, in the presence of alerting outcomes showing an endocrine effect, particularly when they represent the critical effect in terms of dose, it is recommended that a peer review be carried out in order to ascertain the possible origin of such effects and, whenever appropriate, further specific studies be requested for a complete elucidation of the phenomenon. For ecotoxicology, the committee recommended that the evaluation of plant protection products in the future should follow a flexible approach. It took the view that assessors should make use of the mammalian toxicology package, which not only was valuable to assess the risk for wild mammals, but also indicated endocrine mechanisms for vertebrates in general much better than any screening method.

172 The Scientific Committee on Plants also indicated that those evaluations concerning the toxicological tests required under Directive 91/414 had been developed at a time when scientific knowledge about endocrine disruption was rather limited and this had resulted in a lack of specificity for certain of the tests concerning the endocrine disruption-related mechanisms as well as biological and toxicological indicators. It was therefore of the opinion that the guidelines for toxicological testing could be improved with the aim of increasing sensitivity and specificity of detection of endocrine disruption related effects. However, it recommended waiting for the results of the OECD programme aimed at increasing the sensitivity and specificity of those tests for the detection of endocrine disruption related effects before amending Annex II of Directive 91/414.

173 Commission Staff Working Document of 28 October 2004, on implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife [SEC (2004) 1372], confirmed the approach that additional testing was carried out where there is a suspicion of endocrine disrupting potential of an active substance, while waiting for the endorsement by the OECD of a specific endocrine disruption testing methodology.

The assessment of flusilazole

174 It is not disputed that flusilazole is a fungicide with protective, eradicative and curative activity against a range of pathogens affecting agricultural crops. Flusilazole is part of the group of azole fungicides whose usefulness results from the inhibition of Cytochrome P450 enzymes involved in ergosterol biosynthesis.

175 Flusilazole was subject to the required tests allowing an assessment under the various criteria laid down in Annexes II and III to Directive 91/414 for the purposes of its inclusion in Annex I thereto.

176 The inherent toxicological properties of flusilazole were revealed and assessed following the tests needed to satisfy the requirements of Annexes II and III to Directive 91/414. Those tests in particular revealed that flusilazole has carcinogenic and toxic effects on reproduction. The flusilazole toxicology database identifies maternal toxicity and a carcinogenic response in male rats that may result from impacts on the endocrine system.

177 Flusilazole was revealed as potentially inhibiting aromatase, which may cause endocrine disruption in mammals (see *Trösken et al*. (2004), 'Comparative assessment of the inhibition of recombinant human CYP19 (aromatase) by azoles used in agriculture and as drugs for humans').

178 Specifically, it is clear from the evidence provided by the applicants that one of the secondary effects of flusilazole is that it can also be an enzyme inhibitor of Cytochrome P450 enzymes in mammals. The applicants indicate that flusilazole creates an enzyme inhibition of aromatase involved in steroidogenesis and produces an inhibition of two enzymes involved in testosterone synthesis.

179 In the light of the latter properties, flusilazole has been subject to additional tests that exceed the tests needed to satisfy the requirements of Annexes II and III of Directive 91/414. The results of those additional tests include a 'fish full-life cycle' test and studies on rodents concerning the effect of

flusilazole on mental development as well as the multigenerational and chronic toxicity of flusilazole.

180 The parties agree on the fact that the potential endocrine disrupting properties of flusilazole have been assessed in accordance with the best practice available at the time of the adoption of the contested directive. This case therefore does not concern the existence of illegality resulting from the scientific risk assessment which has been carried out, but on the existence of an illegality due to the risk management measures adopted following that assessment that is capable of leading to the Community's non-contractual liability.

b) The contested restrictions

Preliminary observations

181 As regards the properties of flusilazole liable to affect human health, the Commission was able, without acting unlawfully, to consider that, by applying the precautionary principle, certain restrictions should be attached to the inclusion of flusilazole in Annex I to Directive 91/414 (see, by analogy, *Gowan Comércio Internacional e Serviços*, cited in paragraph 133 above, paragraph 79). Indeed, a sufficient scientific basis was available to the Commission for it to consider that the use of flusilazole carries a risk to human and animal health, as well as to the environment.

182 This case however raises the question of whether the Commission was able to adopt the contested restrictions without acting unlawfully in such a way as to result in the Community incurring non-contractual liability.

183 In that regard, it is clear from the judgment in *Gowan Comércio Internacional e Serviços* case (cited in paragraph 133 above) that to limit inclusion of an active substance in Annex I to Directive 91/414 to certain crops and for a short duration is not, in principle, contrary to Directive 91/414. However, the legality of the inclusion of an active substance in that annex must be assessed in the light of the circumstances of the case.

The limitation on flusilazole's inclusion in Annex I to Directive 91/414 to four crops

– Introduction

184 In 1995, in the dossier prepared by the notifier for the purposes of flusilazole's inclusion in Annex I to Directive 91/414, the notifier set out the uses for which it was authorised by the Member States at that date, namely for pome fruit, stone fruit, cereals, maize, sweet corn, oilseed rape, sunflower, sugar beet, grapes, endives and roses.

185 Following a review of the rapporteur Member State's draft assessment report by the scientific experts from other Member States, assessment tables were drawn up by those experts. It is clear from those tables that, on 23 September 1999, for certain crops, the data relating to residues was not available. The evaluation group indicated, at that stage, that that data should be taken into account at the Member State level. Among the tables in question also figured a table of 23 March 2004 entitled 'List of uses supported by available data', which sets out the four crops or groups of crops authorised by the contested directive.

186 By letter of 20 October 2005, the Commission requested the notifier to provide a proposal for highly detailed conditions of use and risk mitigation measures for flusilazole and informed the notifier that, if that substance were included in Annex I, only uses that had been the subject of the European Union level evaluation would be covered.

187 Having regard to the risk of flusilazole not being included in Annex I to Directive 91/414 before the 31 December 2006 deadline (see paragraph 6 above), on 7 November 2005 the notifier had responded to that request stating that, without prejudice, it proposed limiting the inclusion of flusilazole as a fungicide to crops of cereals, maize, oilseed rape, beets, sunflowers and grapes.

188 Ultimately, in the contested directive, the inclusion of flusilazole in Annex I to Directive 91/414 was restricted to crops of cereals (other than rice), maize, oilseed rape and sugar beets on the grounds that it was necessary to avoid discrepancies in the high level of protection sought. Such a high level of protection implied, according to the Commission, that only uses of flusilazole that had been actually assessed at the Community level and for which the proposed uses were considered to comply with the conditions of Article 5 thereof could be included in Annex I thereto (see recital 6 of the contested directive).

189 The applicants contest that restriction on the inclusion of flusilazole in Annex I to the Directive 91/414.

190 First of all, the applicants submit that, where a safe use of the active substance has been demonstrated, it is not for the Community authorities to assess in detail all the possible uses of an active substance because that assessment falls within the competence of the Member States. They contend that Directive 91/414 sets out in that respect, in Annex VI, a set of uniform principles for risk assessment and a set of decision-making criteria that the Member States should apply in that assessment. The rapporteur Member State agreed with that approach.

191 Second, the applicants claim to have shown that flusilazole was safe for certain uses and that that active substance ought therefore to have been included in Annex I to Directive 91/414 without restriction as to its use for certain crops. The rapporteur Member State evaluated more uses than those included in the contested directive. Those assessments were not referred to in the review report because the Member State had not considered it important to list them all in order to 'secure inclusion'.

192 It follows, according to the applicants, that the restriction on the inclusion of flusilazole in Annex I to Directive 91/414 to crops of cereals (other than rice), maize, oilseed rape and sugar beets is illegal because it is contrary to the precautionary principle, the principle of proportionality, the principle of subsidiarity and that directive.

– The principle of the inclusion of an active substance in Annex I to Directive 91/414 being limited to certain crops

193 Insofar as the applicants claim that it not within the competence of the Community institutions to limit the inclusion of an active substance in Annex I to Directive 91/414 to certain crops only, the General Court notes that inclusion in that annex is decided on by the competent Community authorities and that is a precondition for the grant by competent Member State authorities of an authorisation for plant protection products containing that active substance (see Articles 4 to 6 of that directive).

194 The inclusion of an active substance in Annex I to Directive 91/414 is possible only if that active substance satisfies the conditions of Article 5(1) thereof, which requires that it be expected that the uses and residues of plant protection products containing that active substance, consequent on application consistent with good plant protection practice, do not have any harmful effects on human or animal health or any unacceptable influence on the environment.

195 Article 5(4) of Directive 91/414 qualifies the scope of Article 5(1) thereof by permitting the inclusion of active substances in Annex I thereto which do not fulfil the requirements of Article 5(1), in so far as the inclusion of those substances is subject to certain requirements which exclude problematic uses of it (*Sweden* v *Commission*, cited in paragraph 140 above, paragraph 169).

196 Article 5(4) of Directive 91/414 does not exhaustively enumerate the requirements to which the inclusion of an active substance in Annex I thereto can be subject. That provision provides that the inclusion of an active substance can be subject to requirements – which are not exhaustively stated ('such as') – and is therefore limited to setting out a certain number of possible requirements. It follows that the wording of that provision allows for the inclusion of an active substance to be limited to certain crops only. That textual interpretation is, moreover, in conformity with the objective of that

directive which, applying the precautionary principle, provides for the inclusion only of active substances, the residues and uses of which may be expected not to have any harmful effects on human or animal health or on the environment. Lastly, that interpretation is confirmed by Article 6(1) thereof, which refers to 'any conditions for inclusion'.

197 That assessment is not called into question by the argument put forward by the applicants that Article 6(2)(b) of Regulation No 3600/92, in the version applicable in the present case, states that the requirements of Directive 91/414 are met on the basis of the information submitted for one or more preparations for a limited range of representative uses which must be proved by the notifier.

198 Article 6(2)(b) of Regulation No 3600/92, in so far as it constitutes a measure implementing of Directive 91/414, must, as far as possible, be interpreted in accordance with the higher-ranking legal norm, namely that directive. Its application cannot therefore call into question the object of that directive, namely to ensure a high level of protection of both human and animal health as well as the environment at Community level.

199 Since the information provided for the representative uses at issue relate to certain crops only and the safety of the active substance for other crops cannot be inferred therefrom with a sufficient degree of probability, the competent authorities must be able to limit the inclusion of the active substance to only the crops coming under the representative use of that substance in order to ensure a high level of protection of both human and animal health as well as the environment (see, to that effect, *Gowan Comércio Internacional e Serviços*, cited in paragraph 133 above, paragraphs 72 to 85).

200 Accordingly, if the information submitted by the notifier, in accordance with Article 6(2)(b) of Regulation No 3600/92, for one or more preparations corresponding to a limited series of representative uses proposed by it, does not allow it to be inferred with a sufficient degree of probability that the requirements of that directive will be satisfied for uses other than those supported uses, the competent authorities must be able to restrict the inclusion to only uses for which the notifier has demonstrated that the requirements of Directive 91/414 are met in relation to the criteria referred to in Article 5 thereof.

201 Moreover, the interpretation of the scope of Article 5(4) of Directive 91/414 referred to in paragraph 196 above is not contrary to the principle of subsidiarity as the applicants claim.

202 In that regard, it must be recalled that in accordance with that principle, set out in the second paragraph of Article 5 EC, the Community, in areas which do not fall within its exclusive competence, is to take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community.

203 In the present case, the applicants do not contest the division of powers under which the assessment of the active substance falls within the competence of the Community authorities whereas that of plant protection products falls within the competence of the Member State authorities. The exclusive competence conferred by Directive 91/414 on the Community authorities concerning the assessment of the active substance is also justified by the objective, in the interest of the establishment and operation of the internal market, of eliminating obstacles to the free movement of plant protection products resulting from the divergences between national rules (see the fifth and sixth recitals to that directive) while ensuring a high level of protection of human health at Community level, in accordance with Article 152 EC.

204 Since the decision to include an active substance in Annex I to Directive 91/414 falls within the exclusive competence of the Community, the decision to place restrictions on the inclusion of an active substance, in order to ensure that it satisfies the requirements of Article 5(1) thereof, also falls within the exclusive competence of the Community authorities.

205 It follows that the measure adopted in the exercise of that competence is not covered by application of the principle of subsidiarity (Case T 420/05 R *Vischim* v *Commission* [2006] ECR II 3841,

paragraph 223, and *Denka International* v *Commission*, cited in paragraph 131 above, paragraph 200). Therefore, the applicants' argument that the interpretation of the scope of Article 5(4) of Directive 91/414, referred to in paragraph 196 above, is contrary to the principle of subsidiarity must be rejected.

– The limitation of inclusion of flusilazole in Annex I to Directive 91/414 to crops of cereals (other than rice), oilseed rape, maize and sugar beet

206 The applicants contend that limiting the inclusion of flusilazole in Annex I to Directive 91/414 to only crops of cereals (other than rice), oilseed rape, maize and sugar beet is illegal because it is contrary to Directive 91/414 and to the principle of proportionality and the precautionary principle.

207 In that regard, it should be observed that the applicants have stated in their responses to the written questions that certain studies carried out under Annex II of Directive 91/414 were crop-specific and related to crops which were concerned by the representative uses that the notifier had chosen to defend in its dossier.

208 Among the studies carried out under Annex II to the directive which were linked to crops that the notifier had chosen to defend in its dossier were studies on residues. In that regard, it is clear from the assessment tables drawn up for the inclusion of flusilazole in that directive (see paragraph 185 above) that, on 22 September 1999, the applicants had not provided conclusive data on residues for a certain number of crops on which they envisaged using flusilazole. It is pointed out that certain data relating to the residues are to be assessed at a Member State level. However, those tables also included a table, entitled 'List of uses supported by available data', which, in the Commission's opinion, uncontested by the applicants, included a revised list of the supported uses which had finally been considered acceptable. That list contained the following crops: the cereals wheat, rye, barley and oats, sugar beet, maize and oilseed rape. Thus, according to that table and the Commission's explanations, only those crops have been subject to a complete assessment concerning the effects of flusilazole, in particular concerning the residues. Furthermore, in the final report of the Commission on the assessment of flusilazole of 3 March 2006 entitled 'Review report for the active substance flusilazole finalised in the standing Committee on Plant Health at its meeting on 3 March 2006 in view of the inclusion of flusilazole in Annex I to directive 91/414/EEC', which is relied on by the applicants, it is stated that, with particular regard to residues, the review had established that the residues arising from the proposed uses, namely crops of cereals, maize, oilseed rape, and sugar beet, consequent on application consistent with good plant protection practice, had no harmful effects on human or animal health.

209 Moreover, the applicants have not contested that, at the time of the Community level assessment of flusilazole, its safety had only been established for the four crops referred to in the contested directive. Indeed in their response to the written question of the General Court asking on which crops had the effects of flusilazole been evaluated for the purposes of the inclusion of that active substance in Annex I to Directive 91/414 the applicants stated that assessment at issue had established the existence of safe uses for the four crops or crop groups mentioned in the contested directive but that did not mean however that other uses could not be proven safe had Member States been allowed to review them following the inclusion of that substance.

210 However, in accordance with Article 5(1) of Directive 91/414, an active substance is to be included in Annex I thereto only if it may be expected that the residues of plant protection products containing the active substance consequent on application consistent with good plant protection practice will not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment.

211 Given that flusilazole is an active substance which is carcinogenic and has toxic effects on reproduction and is capable of affecting the endocrine system of humans and of animals (see points 176 and 177 above), the Community institutions could not reasonably expect that, in the absence of other relevant evidence, the residues of plant protection products containing flusilazole would not have any harmful effects on human or animal health.

212 In addition, as the applicants explained at the hearing, the results of the reviews of the residues required by Directive 91/414 may vary from one crop to another. However, the applicants have not explained on which basis it should be considered that, for other crops than those referred to in the contested directive, the review of the exposure of persons using flusilazole, in particular as a result of residues, would have been conclusive under Article 5 of Directive 91/414. They have not explained how it could be considered that the analysis of flusilazole residues for the four crops for which that active substance has been included in Annex I thereto was significant for other crops. In particular they have not set out the reasons why the Commission should have considered that, concerning the exposure of persons to those residues, the assessments which had been carried out for the four crops referred to in the contested directive were indicative or even representative of other crops for which they requested the inclusion of that active substance.

213 As a result, in the light of the properties of flusilazole that were likely to affect human and animal health as well as the provision of results of flusilazole residues for certain crops only, the Commission could, without breaching the provisions of Directive 91/414, restrict the inclusion of that active substance in Annex I thereto to only those crops for which the residues had been assessed and for which the conditions of Article 5(1) thereof were fulfilled.

214 The limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to only crops of cereals (other than rice), maize, oilseed rape and sugar beet does not constitute a breach of the precautionary principle. Where, as in the present case, the applicants do not provide data in relation to the exposure and to the residues for all the crops on which they intend to use that active substance, where they fail to prove satisfactorily why those crops are indicative as far as concerns exposure and residues of other crops, and where that active substance is likely to affect human health due to its carcinogenic and reprotoxic properties and potential endocrine disrupter, which cannot be considered hypothetical, the Community authorities can consider that the precautionary principle justifies restricting the inclusion to only the crops for which they have data permitting the conclusion that the risk of that active substantive is acceptable for society. The need to ensure a high level of protection of both human and animal health at Community level moreover justifies that it be reviewed at Community level and not at Member State level whether, on each crop, the conditions of Article 5(1) of that directive are fulfilled as far as exposure and residues are concerned.

215 Nor, by restricting the inclusion of flusilazole in Annex I to Directive 91/414 to four crops only, did the Commission breach the principle of proportionality as defined at paragraph 150 above.

216 In that regard, it should be borne in mind that the objectives pursued by Directive 91/414 are to improve plant production by authorising plant protection products and to eliminate obstacles to the free movement of plant protection products resulting from differences between the national rules while ensuring a high level of protection of human health, animal health, groundwater and the environment. Given the proven carcinogenic and reprotoxic properties as well as the possible effects of flusilazole on the endocrine system of men and animals, it is not inappropriate to restrict the use of that substance only to the crops which have actually been assessed in order to achieve those objectives.

217 As regards the necessity of the contested restrictions, it should be noted that if the inclusion of flusilazole in Annex I to Directive 91/414 were not limited just to the crops whose residues have been analysed at the Community level that would entail a risk of a lower protection of human and animal health at that level. It cannot therefore be held that the measures at issue exceed what is necessary in order to achieve the objectives pursued.

218 Accordingly, regardless of the content of the Commission's letter of 20 October 2005, it must be held that the restriction of the inclusion of flusilazole in Annex I to Directive 91/414 to only crops of cereals (other than rice), maize, oilseed rape and sugar beet is not contrary to that directive, the precautionary principle or the principle of proportionality.

On the limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to a period of 18 months

– Introduction

219 Under Article 5(1) of Directive 91/414 an active substance is to be included in Annex I thereto for a maximum of ten years.

220 Moreover, Article 5(5) of Directive 91/414 provides that on request, the inclusion of an active substance in Annex I may be renewed once or more for periods not exceeding ten years; such inclusion may be reviewed at any time if there are indications that the criteria referred to in Article 5(1) and (2) thereof are no longer satisfied. In addition it provides that, where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, renewal is to be granted for the period necessary to complete a review and to provide complementary information requested.

221 In the present case, flusilazole was included in Annex I to Directive 91/414 for a period of 18 months on the grounds that that limitation reduces risk still further by ensuring a priority re-assessment of flusilazole (see recital 8 of the contested directive).

222 The applicants consider that the limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to a period of 18 months is illegal because it is not justified for any objective reason. In particular, that limitation is contrary to the precautionary principle and disproportionate because it could not be justified by the need to ensure that the renewal process begins quickly so that any new data relevant to the assessment could be assessed. In addition, that limitation is contrary to Article 5(5) of that directive. According to the applicants, a renewal procedure could not be completed usefully in 18 months.

– Article 5(5) of Directive 91/414

223 The applicants consider that, since the 18-month period, at the end of which the inclusion of flusilazole in Directive 91/414 expires, is shorter than the minimum two-year period required under Article 5(5) thereof, it would be not legally possible for them to obtain a renewal of that inclusion. They also claim that the explanations given by the Commission as to the scope of that article are at the very least cryptic and lacking conviction (see the order in *Du Pont de Nemours (France) and Others* v *Commission*, cited in paragraph 71 above, paragraph 153, and Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market, Brussels, 12 July 2006 – COM/2006/0388 final – COD 2006/0136 SEC(2006) 930 SEC(2006) 931).

224 In that regard, it should be noted that, in the first sentence of Article 5(5) of Directive 91/414 the legislature lays down the rule that a trader whose active substance has been included in Annex I thereto can request the renewal of the inclusion of that active substance. In addition, in the second sentence, the legislature states that where an application has been made for such renewal in sufficient time, and in any case not less than two years before the entry is due to lapse, renewal is to be granted for the period necessary to complete a review and to provide the complementary information requested.

225 Accordingly, the second sentence of Article 5(5) of Directive 91/414 does not impose a minimum period for the inclusion of an active substance in Annex I thereto. Neither does it lay down the period necessary to complete a review. It requires only that the holders of an inclusion who wish to benefit from a renewal of the inclusion throughout the period necessary to complete a review introduce their application for renewal at least two years before the expiration of the period of inclusion.

226 Moreover, whilst a limitation of the inclusion of an active substance in Annex I to Directive 91/414 to a period less than two years does not permit, pursuant to Article 5(5) thereof, an automatic renewal of that inclusion for the period necessary to complete a review, it does not preclude an application for renewal of that inclusion nor prejudge the outcome of that request.

227 In addition, it is clear from a systematic reading of the various language versions of Article 4(4) and (5) and Article 5(5) of Directive 91/414 that a review can take place at any moment if there are reasons to believe that the requirements imposed by Article 4 and Article 5 thereof are no longer

fulfilled. Accordingly, the concept of review entails a reassessment of whether the requirements laid down by that directive have been complied with solely during the period covered by the authorisation or by the inclusion.

228 It is apparent from Articles 4 and 5 of Directive 91/414 that the concept of review is different from that of renewal. Renewal refers to the granting of an authorisation or inclusion for a new period following the initial period for which it had been adopted and after it has been verified that the conditions of authorisation or inclusion are still satisfied. In addition, it is apparent from Article 4(4) of that directive that a renewal entails a verification of the conditions for authorisation.

229 Given the distinction between the notions of review and renewal, as well as the use of the term 'review' and not the term 'verification' in the second sentence of Article 5(5) of Directive 91/414, that latter provision does not apply in the case of a verification, following an application for renewal, of the inclusion of an active substance in Annex I to Directive 91/414. Accordingly, that provision does not expressly provide that a renewal be automatically granted for the period necessary to carry out the verification of the application for renewal of the inclusion of active substance in Annex I to Directive 91/414 if that request is introduced two years before the expiration of the inclusion.

230 It follows that, a reading of the wording of the second sentence of Article 5(5) of Directive 91/414 shows that the applicants' argument based on the fact that the inclusion of flusilazole was for less than the two years provided for in that provision is ineffective. For the reasons set out in paragraphs 227 to 229 above, that provision applies only in the case of a review and not in the case of a verification of an application for renewal of an inclusion of an active substance in Annex I. In addition, it should be noted that the first sentence of Article 5(5) of Directive 91/414 does not preclude the applicants from being able to request and, where appropriate, obtain, where an application for renewal has been made, a provisional renewal for the period that the authorities need in order to carry out the verifications required by the application for renewal. The interpretation of that provision as offering such a possibility follows from the scheme of Articles 4 and 5 of that directive, read as whole, and their underlying purpose of making it possible to ensure, in principle, the protection of acquired rights during a transitional period. At the hearing, the Commission agreed with that interpretation. It stated that Article 5(5) of that directive permitted undertakings to apply for an extension of the period of inclusion in order to allow for the completion of the assessment by the peer review committee and to allow the decision to be finalised.

231 It follows that the inclusion of flusilazole in Annex I to Directive 91/414 for an 18 month period neither prevents an application for renewal of that inclusion nor an application for provisional renewal of that inclusion for the period that the authorities need in order to carry out the required verifications.

232 Therefore, the applicants cannot claim that the limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to a period of 18 months is illegal and adversely affects them in that it does not permit a renewal of that inclusion, given the period necessary to complete a review under Article 5(5) thereof.

– On the renewal of the inclusion

233 According to the applicants, a renewal process for the inclusion of an active substance in Annex I to Directive 91/414 serves only to assess whether new elements affect the risk assessment made at the time of the inclusion of that active substance. Thus, that process is intended to evaluate what has happened during the ten years which normally elapse between inclusion and renewal of that application.

234 The applicants also submit that, given the duration of the initial assessment of flusilazole, namely nine years, and the consideration of non-specified concerns of some Member States as to the hazardous properties of the active substance, they do not see the difference that the Commission believes another 18 months would make and, in particular, what new experience would have been gained in that period or, how it would be assessed in this short timeframe. This is all the more so when the contested directive already explicitly includes a requirement that flusilazole be tested

according to OECD guidelines for endocrine disruption within two years following their availability.

235 The applicants further contend that, even if it were accepted, which is not the case, that it would be proportionate to accord a higher level of priority for the review of products containing flusilazole than for other products, as the Commission maintains, the contested restrictions are manifestly disproportionate with regard to the alleged objective.

236 It is indeed unrealistic to expect both the holders of marketing authorisations and the Member States to carry out in 18 months an assessment which usually takes them four years. That is all the more unrealistic given that Article 3(2) of the contested directive fixes the date by which Member States are, after re-evaluation, to amend or withdraw the authorisation for products containing flusilazole on the same date as that on which the Annex I inclusion expires, namely 30 June 2008, and given that no renewal for the inclusion of an active substance in that annex has ever taken less than 24 months.

237 In addition, the applicants contend that the Commission's alleged objective of granting a higher level of priority for reviewing products containing flusilazole could in any event as easily have been achieved without limiting the period of inclusion of that active substance in Annex I to Directive 91/414. The Commission could for instance have reduced the period during which Member States are, after re-evaluation, to amend or withdraw the authorisation of products containing flusilazole, from the normal 4 years to what the Commission would have considered necessary to guarantee its objective. That would have allowed products not in compliance with the conditions of the inclusion to be removed within that period, whilst all products containing flusilazole which had been shown to be safe in accordance with the contested directive and the harmonised criteria laid down in Directive 91/414 would have remained on the market.

238 Lastly, the applicants contend that the disproportional nature of the duration of the inclusion of flusilazole in Annex I to Directive 91/414 is particularly patent since Article 5(5) thereof provides that the inclusion of an active ingredient in that annex may be reviewed at any time if there are indications that the criteria for obtaining the inclusion are no longer satisfied. Furthermore, according to the applicants, the holder of an authorisation for a plant protection product must inform the competent authority of any new information on potentially dangerous effects of a plant protection product or its residues. Finally, according to the applicants, Article 4(6) of that directive provides for the possibility of immediate withdrawal of the authorisations for plant protection products by Member States when the safety requirements are no longer satisfied.

239 In the light of those arguments, it should be recalled that Article 5(1) of Directive 91/414 provides that the initial period during which an active substance is to be included in Annex I cannot exceed ten years. It cannot however be inferred from this that 'normally' an inclusion is granted for ten years. Indeed, applying both the precautionary principle and that provision, the duration of the inclusion must be fixed in the light of current scientific and technical knowledge and risks to human and animal health as well as to the environment.

240 In the present case, it is not in dispute that flusilazole is an active substance which may cause disruptions of the endocrine system in particular in humans (see paragraphs 177 and 178 above) and that the state of scientific knowledge on endocrine disruption is incomplete (see paragraph 166 above).

241 Given the scientific uncertainties and flusilazole's potential effect on human health, the competent Community authorities, applying the precautionary principle, had to adopt risk management measures to ensure that the level of risk does not go beyond what is acceptable for society. Those authorities enjoy a broad discretion in the choice of the level of risk judged acceptable by society and, consequently, in the choice of measures to be adopted to safeguard that level (see paragraphs 145 to 147 and 155 above).

242 In the present case, contrary to what the applicants submit (see paragraph 234 above), applying the precautionary principle does not require the Commission to state what new experience will be gained in the initial period during which flusilazole has been included in Annex I to Directive 91/414 or how it

will be assessed in that period, but to state why it considered that the measures adopted were required in order to reduce the level of risk of that active substance to human and animal health, as well as to the environment, to a level acceptable for society.

243 By restricting the inclusion of flusilazole in Annex I to Directive 91/414 to 18 months, the Commission has ensured that, provided that an application for renewal of that inclusion has been introduced by the end of this period, a review of that active substance will be undertaken quickly. In this way, the Commission ensured that, where an application for renewal has been made, an application for review of flusilazole will be quickly submitted to the competent Community authorities and a review will be carried out taking into account all the relevant new scientific developments. Furthermore, the review of flusilazole would in fact take priority over other active substances which have been included in that annex, whose inclusion would expire a long time after that of flusilazole and for which an application for renewal would only be introduced a reasonable time before the expiry date.

244 Moreover, that measure cannot be regarded as being disproportionate to the objectives pursued. Having regard to the objectives of Directive 91/414 (see paragraph 216 above), to the primacy of the protection of human health among those objectives, to the scientific uncertainties about endocrine disruptors and to the possible scientific advances in that area, the imposition of a review at Community level in a short timeframe is not inappropriate to attain those objectives.

245 As regards the necessity to limit the inclusion of flusilazole in Annex I to Directive 91/414 to 18 months, it should be noted that an inclusion for a longer period would not guarantee that that active substance would be subject to review within a short time after and that a review of that substance over a longer period would imply a lower protection of human and animal health at Community level.

246 While, under Article 5(5) of Directive 91/414, any inclusion may be reviewed or re-examined at any moment if there are reasons to think that the criteria referred to in Article 5(1) and (2) thereof are no longer satisfied, the review or re-examination depends on elements having been identified that indicate that those criteria are no longer satisfied. By contrast, a review within a short period, like in the present case, requires the Community institutions to carry out a reassessment in the short term, independently of the prior identification of those elements, but in the course of which any new possible elements will have to be assessed. Neither the applicants' obligation to inform nor the Member States' power to revoke authorisations offers the same guarantee of reassessment by the competent authorities at the Community level.

247 In addition, the fact, even if correct, that it is unrealistic to expect Member States to carry out their assessment in 18 months, cannot call into question the appropriateness of the limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to 18 months. First of all, it should be recalled that the adequacy of that limitation must be assessed in light of the priority given to the need to protect human and animal health. Second, it should be noted that, if there is no new scientific data in the limited period during which an active substance is included in that annex, the reassessment of the substance at issue must be rapid. As the applicants state (see paragraph 233 above), that limited period is only to assess if new elements affect the risk assessment made at the time of inclusion of the active substance in that annex. The fact that, in the present case, the application for renewal of the inclusion of flusilazole in the annex in question still has not been completed and the fact that the Commission admitted at the hearing that so far it had never managed to complete an application for renewal of the inclusion in the same annex within 18 months, are not the subject-matter of the present action, which concerns the legality of the imposition of the contested restrictions and not the legality of the renewal process initiated by the applicants.

248 Lastly, the applicants claim that to bestow a higher level of priority for reviewing products containing flusilazole could in any event as easily have been achieved without limiting the period of inclusion of that active substance in Annex I to Directive 91/414. They contend that the Commission could, for example, have reduced the period during which the Member States are, after re-evaluation, to amend or withdraw the authorisation of products containing flusilazole, from the normal 4 years to what the Commission would have considered necessary to guarantee its objective. In that regard, it is clear that

the applicants have not shown that an absence of limitation of that inclusion to 18 months guarantees in the same manner a priority review of flusilazole at the Community level. The example invoked by the applicants concerns a re-evaluation at the Member State level of plant protection products containing an active substance, which cannot be considered as equivalent to a re-evaluation of that active substance by the competent Community authorities. The Community level examination ensures a uniformity in the assessment of that active substance in relation to the criteria referred to in Directive 91/414. By contrast, at the level of the review of plant protection products by the Members States, the same degree of uniformity of assessment is not guaranteed, notwithstanding the harmonised criteria included in that directive.

249 It follows that the limitation of inclusion of flusilazole in Annex I to Directive 91/414 to 18 months is not contrary to what can be considered to be appropriate and necessary to attain the objectives pursued.

250 The limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to 18 months does not therefore breach either that directive, the precautionary principle or the principle of proportionality.

– Conclusion

251 Accordingly, given the scientific uncertainties in the area of endocrine disrupters, the fact that scientific advances in that area can be achieved at any moment and the broad discretion enjoyed by the Commission, the latter did not act unlawfully by limiting the inclusion of flusilazole in Annex I to Directive 91/414 to a period of 18 months.

c) The account taken of the prior use of flusilazole

252 The above assessment of the contested restrictions cannot be called into question by the applicants' argument that flusilazole has been used and marketed in the Community for more than 20 years on over 100 million hectares with no substantiated adverse effects ever having been reported either on human health or on the environment.

253 The inclusion of an active substance is assessed on the basis of an assessment of it in relation to the criteria referred to in Directive 91/414 in response to scientific data produced for that purpose; inclusion is not assessed in light of its use for more than 20 years on over 100 million hectares with no substantiated adverse effects ever having been reported either on human health or on the environment.

d) The failure to take account of conclusive results in the studies provided by the applicants

– Arguments of the applicants

254 Having stated that the flusilazole toxicology database contains studies for each test category described in Annexes II and III of Directive 91/414, the applicants point out that the 'fish early life-stage' and 'fish full-life cycle' tests as well as studies on rodents relating to developmental toxicity, multigenerational and chronic toxicity were conducted to assess all phases of the development likely to be affected by flusilazole.

255 According to the applicants, the studies in question showed the absence of effects on endocrine related endpoints at environmentally relevant concentrations as well as the absence of significant effects on organic matter decomposition following long term exposure to the substance. Accordingly, in their view, these studies allowed the competent authorities, in accordance with the Commission Working Document on the implementation of the Community Strategy for Endocrine Disrupters, published in 2004, to resolve doubts about endocrine disruptors. Those studies set out the levels of exposure at which there were no adverse impacts on survival or reproduction, meaning that the risks were not unacceptable within the labelled uses of flusilazole. That conclusion was shared by the rapporteur Member State and the Commission in the Commission's final review report for flusilazole of 3 March 2006.

256 The applicants state, in addition, that, where harmful effects for flusilazole have been identified, a minimal dose beyond which enzyme inhibition has a harmful effect and a dose with no observed adverse effect level have been established. The effects taken into account for the identification of this latter dose are effects occurring at lower doses likely to reflect a direct response to flusilazole administration, rather than higher doses that produce higher toxicity. Additional tests, in the form of multiple tests, have confirmed the reliability of a dose with no observed adverse effect level.

257 The applicants also contend that the primary contributor to harmful effects observed in the rat reproduction and carcinogenicity studies is at the level of steroidogenesis.

258 However, the impact of flusilazole on the endocrine system is only indirect, that is to say, not linked to an effect from oestrogen receptors. According to the applicants, that enzyme inhibition is reversible and follows a more traditional dose-response curve, meaning that the potential risks posed by exposure to flusilazole can be managed in the same way as risks from chemicals that do not impact the endocrine system.

259 In the applicants' view, the conclusions from the General report on the vulnerability of children to pesticides ordered by the Netherlands Government ('the Dutch report'), relied on by the Commission, therefore do not apply to flusilazole. According to the applicants, the concerns regarding non traditional dose-response relationships (or the inverted-U-shaped dose response curve) highlighted in the Dutch report are only valid for chemicals interacting directly with oestrogen receptors and mimicking the response of natural oestrogen.

260 In addition, the applicants consider that the concerns regarding the inverted-U-shaped dose response curve highlighted in the Dutch report are based on a hypothesis challenged by numerous credible scientists (Kamrin, M.A., (2007), 'The 'Low Dose' Hypothesis: Validity and Implications for Human Risk', International Journal of Toxicology, 26, 13-23).

261 The applicants also explain that, as the mode of action of flusilazole involves an inhibition of enzymes involved in steroidogenesis and that mode of action is conserved across species and follows a traditional dose-response relationship, it is not likely that additional testing will result in significant changes in the current ecological risk assessment. According to them, additional tests may in this regard provide refinements to the mode of action but are unlikely to establish additional harmful effects at lower doses that impair functional capacity. Thus, if flusilazole is subjected to the tests undergoing validation within the OECD and the United States Environmental Protection Agency ('EPA'), the applicants expect that the mode of action, namely inhibition of steroidogenesis, will be confirmed but that the risk assessment will not be significantly impacted.

262 According to the applicants, the Danish Ministry of the Environment study (Kjaerstad, M.B., Andersen, R., Taxvig, C., Hass, u., Acelstad, M., Metzdorff, S., and Vinggaard, A.M., (2007), 'Effects of azole fungicides on the function of sex and thyroid hormones', Danish Ministry of the Environment, Pesticides Research, 111, 1-75) cannot change the risk assessment that flusilazole poses. In the applicants' view, it follows from that study that a weak binding of azole fungicides other than flusilazole with the oestrogen receptor and the androgen receptor in cell culture (in vitro) have been demonstrated even if this finding could not be duplicated when tests were carried out on the whole animal. However, the authors of the study concluded, according to the applicants, that although these fungicides had the potential to act via several mechanisms, the inhibition of steroidogenesis rather than the oestrogen receptor or the androgen receptor binding was responsible for the effects observed in whole animal studies. They contend, on the basis of the study in question, that it is not unexpected that flusilazole would demonstrate similar responses with respect to weak oestrogen receptor and androgen receptor binding to those with respect to the azole fungicides which were the subject of that study. However, the flusilazole toxicology database is already consistent with steroidogenesis as the primary contributor to observed harmful effects of that active substance in the rat reproduction and carcinogenicity studies. The applicants further state that the other harmful effects reported in the same study, among which only increased gestational length have been reported for flusilazole, were observed at high dose levels associated with significant inhibition of steroidogenesis. Those effects could however be managed by limiting the exposure doses to below those which produced effects.

The Acceptable Daily Intake and occupational exposure limits for flusilazole are, according to the applicants, set on the basis of effects observed at doses considerably lower than those which produced effects on offspring or maternal health. Therefore, in the applicants' view, the current risk assessment provides protection from effects that may be observed at higher doses and that significantly impact steroidogenesis.

263 The applicants contest the relevance of the result of the study published on 5 June 2005 by Anway M.D., Cupp A. S., Uzumcu, M. et Skinner M. K. entitled 'Epigenetic Transgenerational Actions of Endocrine Disruptors and Male Fertility' (Science 308, 1466) relied on by KEMI during the administrative procedure in order to justify the imposition of restrictions on the inclusion of flusilazole in Annex I to Directive 91/414. In that study, it has been reported that exposure of pregnant rats to either vinclozolin or methoxychlor resulted in effects in male offspring up to the fourth generation. However, in the applicants' view, that study is not likely to affect the risk assessment of flusilazole because, first of all, the experimental design included a single dose that was much higher than expected human exposure and was administered via injection into the peritoneal cavity of pregnant rats; second, the studies' authors acknowledged the need for additional studies; third, a later study from BASF, presented in 2007, could not reproduce the observed effects; fourth, multigenerational rat reproduction studies have been carried out in accordance with Directive 91/414 and a dose with no observed adverse effect level has been reported; and, fifth, unlike vinclozolin and methoxychlor which are the subject of that study, flusilazole has an indirect impact, namely an inhibition of enzymes involved in testosterone and oestrogen synthesis.

264 In the light of the above, the applicants consider that all the evidence available as regards the potential concerns about the intrinsic toxic effects of flusilazole – including the potential endocrine disrupting properties – have been evaluated during the risk assessment procedure and the notifier has demonstrated the safety of that active substance.

265 According to the applicants, the parties to the administrative procedure, including the Commission, have accepted the result of that assessment and were favourable to the unrestricted inclusion of flusilazole in Annex I to Directive 91/414.

266 Therefore, the applicants consider that the results of the risk assessment show that there is no scientific uncertainty as to the possible risks to human health, animal health or the environment from flusilazole, so that the contested restrictions are manifestly inappropriate. They contend that they cannot be required to produce evidence which is not yet available or still less to prove a zero risk. Since it has been demonstrated that safe uses for flusilazole exist, the applicants contend that there is no risk which will justify the application of the precautionary principle in the present case.

– Assessment

267 It should be noted at the outset that the Community can incur non-contractual liability only if the applicants establish that there was an illegality of such a kind as to give rise to such liability on the basis of the elements of fact and of law available to the institution at the time when the contested directive was adopted (see paragraphs 157 et seq. above).

268 It follows that the Kamrin study published in 2007 (see paragraph 260 above), the Danish Ministry of the Environment study, also published in 2007 (see paragraph 262 above), and the BASF study presented in 2007 (see paragraph 263 above) do not prove that the contested measures were illegal.

269 In addition, in so far as the applicants ground their complaints on the assessments of the EPA or of the rapporteur Member State, those assessments do not lead to the conclusion that the Community has incurred non-contractual liability in the present case. As regards the EPA's assessments, it should be noted that they do not bind the Community institutions. In addition, the authorisation for the use of flusilazole granted by the EPA was only a provisional authorisation for urgent use against a pest affecting soy beans. As regards the position of the rapporteur Member State, it has already been held that it is clear from the legislative framework that the view of the rapporteur Member State in the evaluation process is not decisive. The rapporteur Member State gathers the data and suggests a

decision, but it is the Commission which decides ultimately on the basis of the opinion of the Standing Committee on Plant Health. The mere expression of a view by the rapporteur Member State at a particular stage of the evaluation procedure on the identification of a safe use in respect of operator exposure cannot therefore be regarded as sufficient to give rise to certainty on the part of the applicants that that problem had been completely resolved (Case T 75/06 *Bayer CropScience and Others* v *Commission* [2008] ECR II 2081, paragraph 164).

270 Furthermore, it should be recalled that, while studies and scientific opinion have to be taken into account by the Community institutions, the political choice of determining an appropriate level of protection for society lies with those institutions and not with the scientists (see paragraph 145 above).

271 Also, it should be noted that the inclusion of flusilazole in Annex I to Directive 91/414 for cereals (other than rice), maize, oilseed rape and sugar beet is justified in particular by, first of all, the fact that the tests carried out in accordance with Directive 91/414 revealed the absence of effects on endocrine related endpoints at environmentally relevant concentrations; second, the fact that those tests allowed the values such as a dose with no observed adverse effect level to be established; and, third, the fact that harmful effects of flusilazole result from an aromatase inhibition, implying in turn a classic dose-effect relationship.

272 The inclusion of flusilazole in Annex I to Directive 91/414 for those four crops means that the Commission cannot rely on the limitations of the tests referred to in that directive to justify the non-inclusion of other crops. The fact that the results of the fish full-life cycle study refer to only one study, that the method is not harmonised and that the results were not automatically transposable to humans and other species apply equally to all the crops at issue. Consequently, since the Commission considered that flusilazole could be included in that annex for four crops, it must have considered that the risk caused by those limitations was not sufficient to prohibit it.

273 Similarly, the Commission cannot rely on the less direct dose-effect link in potential endocrine disrupters and the possible vulnerability of foetuses or young children set out in the Dutch report in order to justify the limitation of the inclusion of flusilazole in Annex I to Directive 91/414 to four crops only. Indeed that risk, identified in the Dutch report, applies equally to all the crops in question. That inclusion implies that the Commission must have considered that the risk caused by flusilazole due to an atypical dose-effect relationship was not sufficient to prohibit it.

274 By contrast, the elements set out in paragraph 272 above do not justify disregarding the fact that the applicants have not sufficiently established to the requisite legal standard the reasons why crops other than those for which flusilazole has been included in Annex I to Directive 91/414 fulfil the requirements laid down in Article 5 thereof. As was stated at paragraph 207 et seq. above, in order to fulfil the requirements of Article 5(1), it is for the applicants to explain why the crops included in the contested directive were representative of other crops which were not included in that directive or explain why the exclusion of other crops constituted a manifest error of assessment on the part of the Commission.

275 Moreover, the set of factors relied on by the applicants in paragraph 254 et seq. above do not call into question the fact that there is scientific uncertainty about potential endocrine disrupters such as flusilazole, that the research in the area can potentially evolve rapidly and that the existing tests are imperfect for the purposes of learning about potential endocrine disrupters. It follows that those elements cannot lead to the conclusion that the justification for the duration of the inclusion put forward by the Commission is unlawful (see paragraph 239 et seq. above).

e) Analysis of the danger instead of the risk

276 The applicants allege that the Commission undertook an analysis of the danger and not of the risks caused by flusilazole. However, according to them, where the risk assessment is positive for at least one use, the Commission has the obligation, under Article 5 of Directive 91/414, to propose that the active substance be included in Annex I to the directive.

277 In that regard, it should be noted that if, as the applicants submit, flusilazole had only been the subject of an assessment of the danger, it could not have been included in Annex I to Directive 91/414 for a duration of 18 months and for four crops only. The fact that that active substance was included in that annex for four crops and a duration of 18 months indicates that for those crops and that duration the Commission deemed that the risk was acceptable.

278 In addition and in any event, the applicants' present complaint is clearly just a reformulation of their complaints alleging breach of Directive 91/414, of the precautionary principle and of the principle of proportionality which have been analysed in paragraphs 182 to 250 above.

f) The phase-out period

279 The applicants submit that the duration of the inclusion is nothing other than a 'phase-out period', that is to say, a period granted to allow the withdrawal of plant protection products containing flusilazole from the market (see Article 4(6) of Directive 91/414). Thus, the contested restrictions amount to a pure and simple prohibition of that active substance as flusilazole is banned as of 30 June 2007 for all crops apart from the four at issue and from 30 June 2008 for all uses. Those limitations therefore infringe the principle of proportionality.

280 In that regard, it should be noted that, although the inclusion of flusilazole in Annex I to Directive 91/414 has been limited to an 18 month period, that temporal limit does not prevent a potential renewal of its inclusion in accordance with the provisions of Article 5(5) of Directive 91/414. Similarly the fact that that inclusion is limited to only those uses judged to be compliant with the conditions of Article 5 of Directive 91/414 does not prevent other uses being included in Annex I thereto after a full assessment of them.

281 In these circumstances, having regard to the broad discretion enjoyed by the Commission in the area of plant protection product authorisations, the contested restrictions cannot be considered to exceed what is appropriate and necessary to attain the objectives pursued by Directive 91/414 as described in paragraph 216 above (see, by analogy, *Gowan Comércio Internacional e Serviços*, cited in paragraph 133 above, paragraphs 84 to 86).

5. Conclusion

282 For all the above reasons, it must be held that the adoption of the contested restrictions did not breach the EC Treaty, Directive 91/414, the precautionary principle or the principle of proportionality, with the result that the applicants cannot claim that those restrictions are illegal on that basis.

C – Illegality based on the third plea, alleging breach of the principle of sound administration

283 The applicants, supported by the intervener, consider that the principle of sound administration has been breached in that the Commission has changed its position concerning the inclusion of flusilazole in Annex I to Directive 91/414 by passing from an unrestricting inclusion, supported by scientific conclusions, to an inclusion restricted to 18 months and for four crops only, without any objective justification. The Commission has not ensured that the adoption of the contested measures followed a scientifically and legally sound approach.

284 The complaints put forward by the applicants in support of their plea alleging a breach in the duty of care have, however, already been considered in the course of assessing unlawful acts allegedly committed by the Commission in the context of the adoption of the contested restrictions, as set out at paragraph 128 et seq. above. The reclassification of those complaints as a breach of the principle of sound administration does not affect the assessment of them. Therefore, for the same reasons as those set out in that assessment, those complaints are unfounded, with the result that no illegality capable of giving rise to the non-contractual liability of the Community can be established.

D – Illegality based on the fourth plea, alleging a breach of the right to be heard

285 The applicants, supported by the intervener, submit that their right to be heard and the principle of sound administration have been breached because the Commission did not allow them sufficient time to effectively defend their position and address any of the concerns of the Member States. In that regard, it relies on the refusal by the Commission, in the letter of 5 August 2005, to allow the submission of new data to address any possible remaining concerns which still existed in August 2005 about flusilazole. They also invoke the refusal by the Commission, in the letter of 20 October 2005, to disclose the concerns expressed by some Member States.

286 In that respect, it is to be borne in mind that respect for the rights of the defence is, in all procedures which are initiated against a person and are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the procedure in question (see, inter alia, Joined Cases C 48/90 and C 66/90 *Netherlands and Others* v *Commission* [1992] ECR I 565, paragraph 44, and Case C 135/92 *Fiskano* v *Commission* [1994] ECR I 2885, paragraph 39). That principle requires that any person who may be adversely affected by the adoption of a decision must be placed in a position in which he may effectively make known his views on the evidence against him which the Commission has taken as the basis for the decision (Case C 32/95 P *Commission* v *Lisrestal and Others* [1996] ECR I 5373, paragraph 21).

287 It has already been held that neither the process of enacting acts of general application nor the acts of general application themselves require, by virtue of general principles of Community law, the participation of the persons affected as the interests of those persons are deemed to be represented by the political bodies called to adopt those acts (see, to that effect, the orders of 15 September 1998 in Case T 109/97 *Molkerei Großbraunshain and Bene Nahrungsmittel* v *Commission* [1998] ECR II 3533, paragraph 60, and of 14 December 2005 in Case T 369/03 *Arizona Chemical and Others* v *Commission* [2005] ECR II 5839, paragraph 73).

288 First of all, irrespective of the nature of the measure including an active substance in Annex I to Directive 91/414, it should be recalled that the inclusion of flusilazole in that annex was initiated by Du Pont de Nemours (France) acting as the notifier. Du Pont de Nemours (France) and, through it, the other applicants, were able to give their view about the safety of flusilazole under the conditions laid down in that directive. In addition, it is made clear in the summary of the facts (see paragraph 22 et seq. above) as well as the applicants' arguments as regards the adoption of the contested measures (see paragraph 128 et seq. above) that the applicants were informed, during the administrative procedure leading to the contested directive, of the concerns that flusilazole raised, in particular on account of its potential endocrine disruption, and that they were able to express an opinion about those concerns and their implications for the inclusion of that active substance in Annex I to that directive.

289 Next, in so far as the applicants claim that the Commission did not allow them to present new data in order to address the concerns which remained in August 2005, it should be noted that the Commission did in fact indicate in its letter of 20 October 2005 to DuPont (UK) that, at that stage of the procedure, new data would no longer be examined.

290 However, that restriction clearly flows directly from the regulatory framework. Article 7(4) of Regulation No 3600/92, as supplemented by Regulation No 2266/2000, provides that no new study may be submitted after 25 May 2002 or 25 May 2003 for long-term studies proven to be underway on 25 May 2002. Those deadlines ensured that the final deadline of 31 December 2006 for the examination of the active substances which were already on the market at the time of the introduction of Directive 91/414 was respected (see paragraph 6 above).

291 Moreover, that prohibition did not deprive the applicants of the opportunity of properly putting their views on the inclusion of flusilazole in Annex I to Directive 91/414, since they were able to submit, starting from the time of their notification on 23 July 1993 until 25 May 2002, all the studies that they considered useful for the purposes of demonstrating the safety of flusilazole. They were also able to make their views known as regards the concerns that the Commission raised with them in its letter of 5 August 2005, as demonstrated in particular by the letter of DuPont (UK) of 19 August 2005 and the

holding of the meetings of 9 and 22 September 2005 (see paragraph 48 et seq. above).

292 Inasmuch as the applicants allege that, in the letter of 20 October 2005, the Commission refused to provide them with specific details on the concerns allegedly expressed by certain Member States, it should be noted that the access to those documents had been requested by the applicants both on the basis of Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding access to European Parliament, Council, and Commission documents (OJ 2001 L 145 p. 43) and on the basis on the applicants' position as the notifier. Furthermore, in that letter, the Commission refused access to certain documents pursuant to the first subparagraph of Article 4(3) of that regulation on the grounds that those documents related to a matter where the decision had not yet been taken and the disclosure of those documents would seriously undermine the ongoing decision-making process. The applicants did not challenge this refusal pursuant to Article 7(2) of that regulation and it is not at issue in the present proceedings. That refusal is relied on by the applicants only in that it is said to constitute an infringement of their rights of defence.

293 However, in the light of the case-law cited in paragraph 287 above, for acts of general application, such as the contested directive, the right to be heard does not require the participation of the persons affected, as their interests are deemed to be represented by the political bodies called to adopt those acts.

294 In addition, it must be borne in mind that the applicants' right of defence relates only to the evidence on which the Commission based the contested restrictions and is not intended to guarantee that the applicants have access to any documents whatsoever that were referred to or produced during the administrative procedure.

295 In the present case, the applicants do not specify which specific details of the concerns expressed by certain Member States during the decision-making process were not communicated to them, but on which the Commission nonetheless based the contested restrictions. As the Commission stated, the applicants have not identified any argument which they were prevented from making as a result of this lack of communication of the specific details regarding the concerns expressed by some Member States during the decision making process and which might have called into question the Commission's assessment in the contested directive.

296 Furthermore, it is not in dispute, in the present case, that, first of all, the contested restrictions are based on the risks that flusilazole represents owing to its intrinsic toxic effects and its endocrine-disrupting potential and, second, the applicants were able to effectively make known their views on the safety of that active substance for the purposes of its inclusion in Annex I to Directive 91/414 and, in particular, on its endocrine disrupting properties and the consequences of those properties for that inclusion.

297 The Commission's refusal in its letter of 20 October 2005 to disclose the positions taken by the Member States at a very advanced stage of the decision making concerning the inclusion of flusilazole in Annex I to the Directive 91/414 did not therefore constitute an infringement of the rights of the defence of the applicants.

298 Therefore, it must be held that the applicants wrongly claim that their right to be heard has been infringed and thus that no illegality can be established on that basis.

E – Illegality based on the fifth plea, alleging an infringement of the principles of legal certainty and of legitimate expectations

299 The applicants, supported by the intervener, contend that, given the risk assessment of flusilazole by the experts and the rapporteur Member State, the Commission had an obligation to include that active substance in Annex I to Directive 91/414 for ten years and without any crop restrictions. The adoption of the contested directive while ignoring the conclusions of the scientific review made that adoption arbitrary and unpredictable. The Commission thereby infringed the principle of legal certainty, which implies that the application of the law to a specific situation must be predictable, as well as the

applicants' legitimate expectation of an objective scientific review of flusilazole carried out in compliance with the legal criteria.

300 In that regard, it must be borne in mind that the principle of legal certainty requires that legal rules be clear and precise, and aims to ensure that situations and legal relationships governed by Community law remain foreseeable (Case C 63/93 *Duff and Others* [1996] ECR I 569, paragraph 20, and *Vischim* v *Commission*, cited in paragraph 205 above, paragraph 228). That must be the case especially where those rules may have negative consequences for individuals and undertakings (*Dow AgroSciences and Others* v *Commission*, cited in paragraph 144 above, paragraph 264).

301 The principle of legitimate expectations is a corollary to the principle of legal certainty. 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 administration has, by giving him precise assurances, led him to entertain well-founded expectations (Joined Cases C 37/02 and C 38/02 *Di Lenardo and Dilexport* [2004] ECR I 6911, paragraph 70; Case T 203/96 *Embassy Limousines & Services* v *Parliament* [1998] ECR II 4239, paragraph 74; see also, to that effect, *Bayer CropScience and Others* v *Commission*, cited in paragraph 269 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 the principle unless he has been given precise assurances by the administration (Case C 506/03 *Germany* v *Commission*, not published in the ECR, paragraph 58; Joined Cases C 182/03 and C 217/03 *Belgium and Forum 187* v *Commission* [2006] ECR I 5479, paragraph 147; and *Denka International* v *Commission*, cited in paragraph 131 above, paragraph 148). Furthermore, the right to claim the protection of legitimate expectations presupposes that the assurances given comply with the applicable rules (Case T 282/02 *Cementbouw Handel & Industrie* v *Commission* [2006] ECR II 319, paragraph 77, and Case T 145/06 *Omya* v *Commission* [2009] ECR II 145, paragraph 117).

302 Respect for the principles of legal certainty and the protection of legitimate expectation implies that Community legislation must be clear and predictable for those who are subject to it (see, to that effect, Joined Cases 212/80 to 217/80 *Meridionale Industria Salumi and Others* [1981] ECR 2735, paragraph 10).

303 In the present case, the applicants neither demonstrate nor even claim that the Commission gave them a precise assurance within the meaning of the case-law cited in paragraph 300 to 302 above as regards the inclusion of flusilazole in Annex I to Directive 91/414. Furthermore, the rapporteur Member State and the experts relied on by the applicants cannot be equated to the Commission or the Council, which are the decision-making bodies under Article 19 of that directive for the inclusion of an active substance in that annex. It follows that the positions taken by the rapporteur Member State or the experts cannot provide the applicants with a legitimate expectation such as to give rise to the Community's non-contractual liability.

304 Directive 91/414 itself does not provide any precise assurance as regards the inclusion of flusilazole in Annex I thereto. It only sets out the criteria to be taken into consideration in order to permit such an inclusion, which depends on the safety of that active substance in light of the criteria that it lays down.

305 Therefore, the applicants have not established the existence of an infringement of the principle of legitimate expectations.

306 Insofar as the applicants allege an infringement of the principle of legal certainty, the applicants are clearly not claiming that the rules are unclear or imprecise and do not ensure that situations are foreseeable. Their complaint relates only to the application of those rules in the present case.

307 Therefore, the infringement of the principle of legal certainty claimed by the applicant must also be rejected.

308 The absence of infringements of the principles of legitimate expectation and of legal certainty in the present case renders inoperative the illegality claimed by the applicants based on those infringements.

F – Illegality based on the sixth plea, alleging an infringement of the principle of equal treatment

309 The applicants contend that the principle of equal treatment has been breached in so far as active substances subjected to a review, namely paraquat, linuron, flumioxazine, warfarine, dinocap and carbendazime were not treated in the same manner.

310 In that respect, the principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way, unless such treatment is objectively justified (Case T 38/02 *Groupe Danone* v *Commission* [2005] ECR II 4407, paragraph 453; *Bayer CropScience and Others* v *Commission*, cited in paragraph 269 above, paragraph 236; and *Denka* v *Commission*, cited in paragraph 131 above, paragraph 169).

311 Given that it is the applicants who are invoking a breach of that principle it falls to them to set out and establish what comparable situation has been treated differently or how a different situation has been treated identically.

312 Whether one situation is comparable to another must be assessed in the context in which the breach of the principle of equal treatment had been invoked. Indeed it has been held that the elements which characterise different situations, and hence their comparability, must be determined and assessed in particular in the light of the subject-matter and purpose of the Community act which makes the distinction in question. The principles and objectives of the sector to which the act relates must also be taken into account (see, to that effect, Case 6/71 *Rheinmühlen Düsseldorf* [1971] ECR 823, paragraph 14; Joined Cases 117/76 and 16/77 *Ruckdeschel and Others* [1977] ECR 1753, paragraph 8; Case C 280/93 *Germany* v *Council* [1994] ECR I 4973, paragraph 74; Joined Cases C 364/95 and C 365/95 *T. Port* [1998] ECR I 1023, paragraph 83; and Case C 127/07 *Arcelor Atlantique et Lorraine and Others* [2008] ECR I 9895, paragraph 26).

313 Concerning the infringement of the principle of equal treatment of flusilazole compared to paraquat, the applicants claim that paraquat, whose toxicity to humans and wildlife has been established, has been included in Annex I to Directive 91/414 for ten years whereas flusilazole, of which harmful effects on flusilazole on humans or the environment have never been observed after more than 20 years of use, has been included for a duration of 18 months only. The applicants contend therefore that paraquat should have been subject to greater restrictions than flusilazole, not the contrary.

314 In that regard, it must be noted that, according to the applicants, paraquat and flusilazole have been included in Annex I to Directive 91/414 subject to different conditions. A breach of the principle of equal treatment therefore requires a demonstration that those active substances are in a comparable situation in light of the criteria in Article 5 of that directive for their inclusion in that annex. However, the applicants have not demonstrated this. On the contrary, according to the applicants, paraquat is different from flusilazole in terms of its toxicity to humans and wildlife.

315 In addition and in any event, in must be stated that the directive including paraquat in the Annex I to Directive 91/414 relied on by the applicants has been annulled by the General Court in *Sweden* v *Commission* (see paragraph 140 above), which has become final. The applicants cannot therefore claim a breach of the principle of equal treatment on the basis of that directive which has been annulled. The annulment at issue results in the retroactive elimination of the measure in question from the legal order as if it never existed (see, to that effect, Case T 228/02 *Organisation des Modjahedines du peuple d'Iran* v *Council* [2006] ECR II 4665, paragraph 35 and Case T 291/04 R *Enviro Tech Europe and Enviro Tech International* v *Commission* [2005] ECR I 0000, paragraph 88).

316 Consequently, the applicants are wrong to claim a breach of the principle of equal treatment as regards the conditions of inclusion in Annex I to Directive 91/414, for flusilazole, on the one hand, and paraquat, on the other.

317 As regards linuron, flumioxazine and warfarine, the applicants contend that those substances have been included in Annex I to Directive 91/414 for periods of seven or ten years without any crop restrictions whereas those active substances are, like flusilazole, endocrine disrupters and/or belong to Categories 1 or 2 of the classification of carcinogens, mutagens or substances toxic to reproduction (CMR) (see Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 2001 L 225, p. 1)). As a result, they also claim a breach of the principle of equal treatment on that basis.

318 In addition, as regards dinocap and carbendazime, the applicants claim that those active substances have been included in Annex I to Directive 91/414 for a duration of three years whereas flusilazole, fenarimol, methamidophos and procymidone were included for a duration of 18 months despite the fact that the directives concerned were adopted at the same time and were based on the 'hazardous' properties of those active substances. The applicants allege that no plausible reasons were provided to explain why certain of those substances were included for duration of three years and others for a duration of 18 months. Furthermore, Commission failed to explain why methamidophos, fenarimol and procymidone gave rise to concerns comparable to flusilazole. Consequently, the applicants also submit, on this basis, that the principle of equal treatment has been breached.

319 In that regard, it must be recalled that the inclusion of an active substance in Annex I to Directive 91/414 is not assessed by only taking into account whether or not there exists a risk of endocrine disruption, but by taking account, in accordance with Article 5 thereof, of its harmful effects on human and animal health as well as on the environment.

320 It follows that the allegations that linuron, flumioxazine and warfarine are, like flusilazole, active substances which have endocrine-disrupting effects and/or which belong to Categories 1 or 2 of the classification of CMR, or that dinocap and carbendazime are, like flusilazole, hazardous active substances, is not sufficient to demonstrate that those active substances are in a comparable situation from the point of view of their inclusion in Annex I to Directive 91/414.

321 The comparability of the active substances to which the applicants refer and flusilazole requires that the assessment of the risk at issue be taken into consideration in the light of the available scientific knowledge. However, the applicants have not shown that those active substances can be considered as comparable in terms of the risks for human health or the environment.

322 The applicants also stated, in their response to the written question of the General Court concerning to the possible relevance of *Gowan Comércio Internacional e Serviços* (paragraph 133 above), which related to the validity of restrictions on use imposed at the time of fenarimol's inclusion in Annex I to Directive 91/414, that each active substance was different and that, in each case, different studies and documents had been relied on. The conclusions drawn in one case cannot therefore be transposed as such to other cases.

323 In addition, the applicants are wrong to criticise the Commission for not having set out to the requisite legal standard the reasons why methamidophos, fenarimol and procymidone have raised concerns comparable to those relating to flusilazole. Indeed, as those active substances were all included in Annex I to Directive 91/414 for a duration of 18 months and as the applicants submit that the principle of equal treatment has been breached, it is not for the Commission to adduce evidence to show that those active substances were not in comparable situations; it is for the applicants to show that they were not.

324 Lastly, it is clear that the applicants have not put forward arguments which call into question the Commission's argument that carbendazim and dinocap are distinct from flusilazole, since they are not endocrine disrupters and do not require the same risk mitigation measures. Neither have they called into question the Commission's argument that warfarine, unlike flusilazole, could be included in Annex I to Directive 91/414 because the risk mitigation measures provided that warfarine could be used only in pre-prepared bait, placed in specially constructed hoppers.

325 Finally, in their responses to the written questions and at the hearing, the applicants argued that the principle of equal treatment had also been breached in the present case because flusilazole had been included subject to less favourable conditions than prochloraz and epoxiconazole. However, the applicants have not proved satisfactorily that those substances were in a situation comparable to that of flusilazole. In particular, they have not shown that the assessment of those active substances under the criteria of Directive 91/414 was comparable. The fact that those active substances were all potential endocrine does not satisfactorily prove that they were in a comparable situation. Indeed, as the applicants themselves stated, each active substance is different and, in each case, different studies and documents have been relied on. The conclusions drawn in one case cannot therefore be transposed as such to other cases. The fact that, according to the applicants, prochloraz has a higher potency in its mode of action to that of all other triazoles tested in the Danish study does not sufficiently prove that flusilazole was in a comparable situation. It follows that their complaint cannot be upheld on this basis.

326 Consequently, it must be concluded that the applicants have not satisfactorily proven that flusilazole was in a comparable situation to the other active substances, invoked by them, which were included in Annex I to Directive 91/414 for a longer period and without crop restrictions. It must therefore be concluded that the applicants have not sufficiently proved that the Commission acted unlawfully by not treating flusilazole in the same manner as other active substances subject to a review.

G – Illegality based on the seventh plea, alleging an infringement of the obligation to state reasons

327 The applicants claim that the inclusion of flusilazole in Annex I to Directive 91/414 for a duration of 18 months and for certain crops is not supported by an adequate statement of reasons. The elements on which those restrictions are founded are mere undocumented concerns expressed by several Member States. The alleged intrinsic toxic effects and endocrine disruption potential are not capable of supporting the contested restrictions.

328 In that regard, it should first be recalled that a claim that there is no or only an inadequate statement of reasons for a decision, constitutes a plea of infringement of an essential procedural requirement, which, as such, is different from a plea that the grounds of the decision are inaccurate, the latter plea being a matter to be reviewed by the Court when it examines the substance of that decision (Case T 310/94 *Gruber + Weber* v *Commission* [1998] ECR II 1043, paragraph 41, and Case T 311/94 *BPB de Eendracht* v *Commission* [1998] ECR II 1129, paragraph 66).

329 By submitting that the concerns put forward by the Commission in the contested directive are incapable of supporting the contested restrictions, the applicants are not pleading a lack of reasoning but are contesting the validity of the grounds contained in the contested directive.

330 In addition, quite apart from the fact that the contested directive is a legislative measure, which, according to the Court's case-law, precludes the Community from incurring non-contractual liability on the ground that the statement of reasons was inadequate (Case C 119/88 *AERPO and Others* v *Commission* [1990] ECR I 2189, paragraph 20 and Case C 76/01 P *Eurocoton and Others* v *Council* [2003] ECR I 10091, paragraph 98), it is clear that the Commission set out in the contested directive its reasons for imposing the contested restrictions.

331 Indeed, at recital 6 to the contested directive, the Commission stated that, in order to avoid discrepancies in the level of protection sought, the inclusion in Annex I to Directive 91/414 had to be limited to the uses of flusilazole that had been actually assessed within the Community evaluation and for which the proposed uses had been considered to comply with the conditions of that directive. Furthermore, at recital 8 to the contested directive, the Commission stated that the period of inclusion of flusilazole in that directive had been reduced to 18 months in order to further reduce any risk, by ensuring a priority re-assessment of that substance.

332 Therefore, it must be held that the applicants have not proven that the Commission had acted unlawfully by not providing an adequate statement of reasons for the inclusion of flusilazole in Annex I to Directive 91/414.

H – Illegality based on the seventh plea, alleging a misuse of powers

333 The applicants claim that the Commission misused its powers by restricting the inclusion period for flusilazole in Annex I to Directive 91/414 to 18 months and for certain crops only, because those restrictions were based on vague and unsubstantiated concerns allegedly expressed by some Member States as to the 'hazardous' properties of the substance and ignored the positive results of the scientific risk assessment. Consequently, according to them, those restrictions were imposed for political reasons in breach of the criteria provided by that directive.

334 In that regard, it must be observed that the concept of misuse of powers has a precisely defined scope in Community law and refers to cases where an administrative authority has used its powers for a purpose other than that for which they were conferred on it. A decision amounts to a misuse of powers only if it appears, on the basis of objective, relevant and consistent factors, to have been taken to achieve an end other than that stated (Case C 285/94 *Italy* v *Commission* [1997] ECR I 3519, paragraph 52; Case T 254/97 *Fruchthandelsgesellschaft Chemnitz* v *Commission* [1999] ECR II 2743, paragraph 76; and *Bayer CropScience and Others* v *Commission*, cited in paragraph 269 above, paragraph 254).

335 In the present case, the applicants have produced no objective, relevant or consistent evidence from which it may be concluded that the contested directive was adopted to achieve an end other than that stated. They do not even state which end, other than the protection of animal and human health and the environment, was being pursued in the present case.

336 Therefore, the applicants are wrong to claim the existence of a misuse of powers in the present. Accordingly, they cannot show an illegality on the basis of the existence of that alleged misuse of powers.

I – Conclusions

337 In light of all the foregoing, none of the complaints or elements put forward by the applicant allows the conclusion that there is an illegality resulting in the Community's incurring non-contractual liability following the adoption by the Commission of the contested restrictions. In these circumstances, the applicants' claim for damages must be rejected as unfounded.

Costs

338 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

339 Since the applicants has been unsuccessful, they must be ordered to bear their own costs and to pay those of the Commission in respect of the main proceedings and the interlocutory proceedings, in accordance with the form of order sought by the Commission.

340 The ECPA shall bear its own costs. As the Commission did not request that the ECPA be ordered to pay the costs which the Commission incurred in connection with its intervention, the ECPA shall not bear those costs.

On those grounds,

THE GENERAL COURT (First Chamber)

hereby:

1. Dismisses the action;

2. Orders Du Pont de Nemours (France) SAS, Du Pont Portugal – Serviços, Sociedade

Unipessoal L[da], Du Pont Ibérica, SL, Du Pont de Nemours (Belgium) BVBA, Du Pont de Nemours Italiana Srl, Du Pont De Nemours (Nederland) BV, Du Pont de Nemours (Deutschland) GmbH, DuPont CZ s.r.o., DuPont Magyarország Kereskedelmi kft, DuPont Poland sp. z o.o., DuPont Romania Srl, DuPont (UK) Ltd, Dy-Pont Agkro Ellas AE, DuPont International Operations SARL and DuPont Solutions (France) SAS, to bear their own costs and to pay those of the Commission in respect of the main proceedings and the interlocutory proceedings;

3. Orders the European Crop Protection Association (ECPA) to bear its own costs.

Azizi Labucka Frimodt Nielsen

Delivered in open court in Luxembourg on 12 April 2013.

[Signatures]

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* Language of the case: English.

1 – Confidential information omitted.