JUDGMENT OF THE COURT (Second Chamber)

22 December 2010 *

In Case C-77/09,

REFERENCE for a preliminary ruling under Article 234 EC from the Tribunale amministrativo regionale del Lazio (Italy), made by decision of 17 December 2008, received at the Court on 20 February 2009, in the proceedings

Gowan Comércio Internacional e Serviços Lda

v

Ministero della Salute,

* Language of the case: Italian.

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of Chamber, A. Rosas, U. Lõhmus, A. Ó Caoimh and P. Lindh (Rapporteur), Judges,

Advocate General: N. Jääskinen,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 29 April 2010,

after considering the observations submitted on behalf of:

— Gowan Comércio Internacional e Serviços Lda, by C. Mereu, S. Ambrosetti and M. Velardo, avvocati,

— the German Government, by M. Lumma and J. Möller, acting as Agents,

— the Greek Government, by V. Kontolaimos, K. Marinou, I. Chalkias and M. Tassopoulou, acting as Agents,

— the European Commission, by D. Nardi and L. Parpala, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 15 July 2010,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the validity of Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as an active substance (OJ 2003 L 349, p. 32).

2 The reference was made in proceedings brought by Gowan Comercio Internacional e Serviços Lda ('Gowan'), a company incorporated under Portuguese law, against Ministero della Salute (Ministry of Health), seeking the annulment of certain decisions concerning authorisations granted in Italy to place plant protection products containing fenarimol on the market.

Legal context

Directive 91/414/EEC

3 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) establishes uniform rules on the conditions and procedures for authorisation to place plant protection products on the market and for their review and withdrawal. Its objective is not only to harmonise the rules relating to the conditions and procedures for approval of those products, but also to ensure a high level of protection of human and animal health and also of the environment from the threats and risks posed by unrestricted use of those products. The directive also aims to eliminate barriers to the free movement of those products.

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

'Member States shall prescribe that plant protection products may not be placed on the market and used in their territory unless they have authorised the product in accordance with this Directive … '

5 Article 4 of the directive sets out, inter alia, the conditions which a plant protection product must satisfy before it can be authorised. It requires, inter alia, that its active substances be listed in Annex I and any conditions laid down therein be fulfilled. The authorisations must stipulate the requirements relating to the placing on the market

and use of the product. They are to be granted for a fixed period of up to 10 years only, determined by the Member States. They can be reviewed at any time and must, in certain circumstances, be cancelled. Where a Member State withdraws an authorisation, it must immediately inform the holder.

6 Article 5 of Directive 91/414 lays down the conditions for the inclusion of such substances in Annex I. It reads as follows:

'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, 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).'

7 The first subparagraph of Article 8(2) of Directive 91/414 provides that, 'by way of derogation from Article 4 …, a Member State may, during a period of 12 years following the notification of this Directive, authorise the placing on the market in its territory of plant protection products containing active substances not listed in Annex I that are already on the market two years after the date of notification of this Directive'.

8 The second subparagraph of Article 8(2) of Directive 91/414 states that within the same 12-year period the Commission is to commence a programme of work for the gradual examination of those active substances.

9 According to the fourth subparagraph of Article 8(2), 'during [that] period … it may, following examination by the Committee referred to in Article 19 of such active substance, be decided by the procedure laid down in that Article that the substance can be included in Annex I and under which conditions, or, in cases where the requirements of Article 5 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance will not be included in Annex I'. This provision adds that 'the Member States shall ensure that the relevant authorisations are granted, withdrawn or varied, as appropriate, within a prescribed period'.

10 According to Articles 6(1) and 19 of Directive 91/414, as amended by Council Regulation (EC) No 806/2003 of 14 April 2003 (OJ 2003 L 122, p. 1), inclusion of an active substance in Annex I to that directive is to be decided in accordance with the regulatory procedure laid down in Article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23), the Commission being assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1).

Regulation (EEC) No 3600/92

11 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/EEC concerning the placing of plant protection products on the market (OJ 1992 L 366, p. 10), as amended by Commission Regulation (EC) No 2266/2000 of 12 October 2000 (OJ 2000 L 259, p. 27,

'Regulation No 3600/92'), organises the procedure for the assessment of several active substances, including fenarimol, with a view to their possible inclusion in Annex I to that directive.

12 The first subparagraph of Article 8(3) of Regulation No 3600/92 states:

'After the examination … the Commission shall … present to the Committee:

(a) a draft decision to include the active substance in Annex I to the Directive, setting out where appropriate the conditions, including the time limit, for such inclusion

…'

Directive 2006/134/EC

13 Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance (OJ 2006 L 349, p. 32) established the restrictions on the use of that substance during the time when it was included in Annex I to Directive 91/414, from 1 January 2007 to 30 June 2008.

14 Article 3 of Directive 2006/134 provides that 'Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing fenarimol as an active substance by 30 June 2007. By that date they shall in particular verify that the conditions in Annex I to that Directive relating to fenarimol are met, with the exception of those identified in part B of the entry concerning that active substance'.

15 The annex to Directive 2006/134 contains the following specific provisions:

'PART A

Only uses as fungicide on the following crops may be authorised:

— Tomatoes,

— peppers in greenhouses,

— eggplants (aubergines),

— cucumbers in greenhouses,

— melons,

— ornamentals, nursery trees and perennial plants,

…

The following uses must not be authorised:

— air application,

— knapsack and hand-held applications by amateur users,

— home gardening.

Member States shall ensure that all appropriate risk mitigation measures are applied. Special attention has to be paid to the following issues:

— aquatic organisms …

— earthworms …

— birds and mammals …

— operators …

— workers …

PART B

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenarimol, and in particular Appendices I and II thereof, shall be taken into account.

Member States must ensure that the authorisation holders report at the latest on 31 December of each year on incidences of operator health problems. Member States may require that elements, such as sales data and a survey of use patterns, are provided so that a realistic picture of the use conditions and the possible toxicological impact of fenarimol can be obtained.

Member States shall request the submission of further studies to address the potential endocrine disrupting properties of fenarimol within two years after the adoption of the Test Guidelines on endocrine disruption by the Organisation for Economic Cooperation and Development (OECD). They shall ensure that the notifier at whose request fenarimol has been included in this Annex provide such studies to the Commission within two years of the adoption of the above test guidelines.'

The main proceedings and the question referred for a preliminary ruling

16 On 28 July 1993, DowElanco Europe notified the Commission of its interest in the inclusion of fenarimol in Annex I to Directive 91/414. After it had taken over the activities of DowElanco Europe, Gowan pursued the procedure for the inclusion of fenarimol in its own name.

17 In order to comply with the provisions of Directive 2006/134, the Italian Republic, by ministerial decree of 8 June 2007, revoked the authorisations for placing plant protection products containing fenarimol on the market.

18 By ministerial decree of 17 October 2007, fenarimol was included in the list of active substances authorised in Italy. That list appeared in Annex I to legislative decree No 194 of 17 March 1995.

19 At a later date not specified by the Tribunale amministrativo regionale del Lazio, the ministerial decree of 8 June 2007 was partially revoked in order to reinstate provisionally certain products containing fenarimol amongst those authorised in Italy, in accordance with the terms of legislative decree No 194, as amended by the ministerial decree of 17 October 2007.

20 Gowan contested those ministerial decrees in an action before the Tribunale amministrativo regionale del Lazio seeking to have them annulled. In that action, Gowan pleads the illegality of Directive 2006/134. It argues essentially that the severity of the restrictions on the use of fenarimol is not justified by the scientific studies carried out during the assessment procedure. The terms of the inclusion of fenarimol in Annex I to Directive 91/414 restricted the use of that substance for a period of 18 months to certain crops of marginal importance compared with those which hitherto

constituted its main market (vines, apples, pears, peaches, watermelons, courgettes, non-greenhouse peppers and strawberries).

21 The referring court finds that the scientific assessment procedure resulted in positive conclusions and that the Commission had initially proposed the inclusion of fenarimol in Annex I to Directive 91/414 without restrictions.

22 Under these circumstances, the Tribunale amministrativo regionale del Lazio decided to stay proceedings and to refer the following question to the Court:

'In view of the fact that the conclusion of the technical and scientific assessment carried out by the rapporteur State appears to be that the risk arising from the use of fenarimol is acceptable, is Directive 2006/134/EC, which significantly limited such use, valid?'

Admissibility of the reference for a preliminary ruling

23 The Federal Republic of Germany, the Hellenic Republic and the Commission have doubts as to the admissibility of the reference for a preliminary ruling. They take the view that the terms of the order for reference are not sufficiently clear and precise to allow the Court to determine the law and the facts which form the basis for the doubts expressed by the national court as to the validity of Directive 2006/134.

24 When a question on the validity of a measure adopted by the Community institutions is raised before a national court, it is for that court to decide whether a decision on the matter is necessary to enable it to give judgment and consequently whether it should request the Court to rule on that question. Accordingly, where the national court's questions relate to the validity of a provision of Community law, the Court is obliged in principle to give a ruling (Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 34, and Case C-308/06 *Intertanko and Others* [2008] ECR I-4057, paragraph 31).

25 The Court is unable to rule on a question referred by a national court only where it is manifest that the interpretation or the assessment of the validity of Community law sought by that court bears no relation to the true nature of the main action or its purpose, or where the problem is hypothetical and the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (see, in particular, Case C-415/93 *Bosman and Others* [1995] ECR I-4921, paragraph 61, and C-45/09 *Rosenbladt* [2010] ECR I-9391, paragraph 33).

26 According to the order for reference, Gowan brought an action before the Tribunale amministrativo regionale del Lazio seeking the annulment of the ministerial decrees adopted in implementation of Directive 2006/134 as regards plant protection products containing fenarimol. It is not disputed before the Court that the question raised regarding the validity of Directive 2006/134 is relevant to the resolution of the dispute in the main proceedings. It is therefore not manifest that the ruling sought by the national court on the validity of Directive 2006/134 bears no relation to the actual facts of the main action or its purpose or concerns a hypothetical problem.

27 In its order for reference, the national court explained that it had doubts regarding the validity of Directive 2006/134, essentially because of the inconsistency between the restrictions on the use of fenarimol laid down by that directive and the technical and scientific assessments of the substance which were, overall, positive. Although the order for reference does not contain an exhaustive account of the heads of claim in the main proceedings, it must be observed that that order and the written and oral observations have given the Court sufficient information to enable it to examine the validity of Directive 2006/134 in relation to the situation which is the subject of the main proceedings (see, inter alia, to that effect, Joined Cases C-295/04 to C-298/04 *Manfredi and Others* [2006] ECR I-6619, paragraph 29, and the case-law cited).

28 The reference for a preliminary ruling is therefore admissible.

The question referred for a preliminary ruling

29 By its question, the referring court seeks to know, essentially, whether Directive 2006/134 is valid in light of the fact that the restrictions on the use of fenarimol under it exceed what was considered to be necessary on conclusion of the risk assessment.

Preliminary observations

30 In order to give a useful answer to the referring court, the validity of Directive 2006/134 must be examined in the light of the principle of legal certainty, the possibility of a manifest error of assessment, the precautionary principle and the principle of proportionality.

31 To begin with it is important to explain the background to the adoption of Directive 2006/134.

32 According to the preamble to Directive 2006/134, the effects of fenarimol on human health and the environment have been assessed in accordance with the provisions laid down in Regulation (EEC) No 3600/92 for a range of uses proposed by the notifier.

33 On 30 April 1996, the United Kingdom of Great Britain and Northern Ireland, acting in its capacity as rapporteur Member State, presented a draft assessment report, accompanied by recommendations, to the Commission. It is apparent from the file, and in particular from the documentation produced by the Commission at the request of the Court, that that document favoured the inclusion of fenarimol in Annex I to Directive 91/414, subject to the submission of certain supplementary information.

34 In November 2000, in order to assess the risk of endocrine disruption posed by fenarimol, the Commission asked the notifier to carry out a supplementary study on fish ('full fish life cycle study'). On conclusion of that study, produced by Gowan in the time allowed, the United Kingdom took the view that the level of chronic risk for fish posed by the use of fenarimol was acceptable without any further analysis or risk management measures being required. On 16 January 2004, the 'evaluation' working group of the Standing Committee on the Food Chain and Animal Health validated the result of that study and, more generally, the assessment report submitted by the United Kingdom, before closing the procedure on 11 March 2004.

35 Furthermore, the documents before the Court show that the Commission submitted several questions to the Scientific Committee on Plants, concerning, in particular, the risks of endocrine disruption linked to the aromatase inhibition effects of fenarimol.

36 According to recital 4 in the preamble to Directive 2006/134, that committee took the view that the effects of fenarimol on male fertility seen in rats had to be considered relevant for human risk assessment. It took the view that the effects of fenarimol on parturition in rats could be considered not to be relevant for human risk assessment. It concluded that 'apart from male-mediated reduced fertility and effects associated with delayed parturition, there was no convincing evidence for other adverse reproductive effects associated with aromatase inhibition by fenarimol'.

37 During the period from June 2004 to March 2006, risk management measures were discussed in the 'legislation' working group of the Standing Committee on the Food Chain and Animal Health. In that connection, it is apparent from the documents put before the Court by the Commission that, having presented, on 7 October 2004, to the 'legislation' working group an informal document recommending the inclusion of fenarimol in Annex I to Directive 91/414 (document SANCO/10321/2004-rev 0) for a period of 10 years, the concerns of several Member States regarding the question of endocrine disruptors led the Commission to consider restrictions on the use of fenarimol and a shorter period of authorisation.

38 Thus, by letter of 2 August 2005, the Commission informed Gowan that, following 'intensive consultation' of experts from the Member States, it was considering the possibility of not including fenarimol in Annex I to Directive 91/414, citing as a reason, inter alia, the risk of endocrine disruption. In reply to that letter, Gowan proposed to the Commission, by letter of 11 November 2005, that it should limit, inter alia, the number of uses of fenarimol in respect of which it sought its inclusion in Annex I to Directive 91/414.

39 In February 2006 the Commission submitted to the Standing Committee on the Food Chain and Animal Health a draft assessment report (document 6847/VI/97-rev 4 of

5 January 2006) and a proposal for a Directive including fenarimol in Annex I to Directive 91/414, while limiting its use to a period of seven years and for more restricted uses that those envisaged by Gowan in its letter of 11 November 2005 (document SANCO/10321/2005-rev 5 of 19 January 2006).

40 Recital 6 in the preamble to Directive 2006/134 states, with regard to the initial draft that '[i]n order to avoid discrepancies in the high level of protection sought, the inclusion in Annex I to Directive 91/414/EEC was intended to be limited to the uses of fenarimol that have been actually assessed within the Community evaluation and for which the proposed uses were considered to comply with the conditions of Directive 91/414/EEC … Finally, due to the hazardous nature of fenarimol, it was 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.'

41 The Commission pointed out, moreover, as is recalled in recital 10 in the preamble to Directive 2006/134, that '[w]ithout prejudice to the conclusion that plant protection products containing fenarimol may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, it is appropriate to obtain further information on certain specific points. The potential endocrine disrupting properties of fenarimol have been assessed in tests which follow the best currently available practice. The Commission is aware that the Organisation for Economic Cooperation and Development (OECD) is developing test guidelines in order to further refine the assessment of potential endocrine disrupting properties. Therefore it is appropriate to require that fenarimol should be subjected to such further testing as soon as agreed OECD Test Guidelines exist and that such studies should be presented by the notifier. In addition, Member States should require authorisation holders to provide

information on the use of fenarimol including any information on incidences on operator health.'

42 The Standing Committee on the Food Chain and Animal Health did not succeed in adopting an opinion on that draft at its meeting of 3 March 2006.

43 As is recalled in recitals 7 and 8 in the preamble to Directive 2006/134, as a consequence of concerns expressed by several Member States which reflect their judgment that additional restrictions are necessary to reduce the risk to a level that can be considered acceptable and consistent with the high level of protection that is sought within the Community, the Commission re-examined its position. It considered it appropriate, in addition to the principles set out in recital 6, to further reduce the period of inclusion to 18 months instead of seven years. That reduction further reduces any risk by ensuring a priority re-assessment of this substance.

44 The Commission sent to the Council a proposal for a directive to that effect as is apparent from recital 16 in the preamble to Directive 2006/134. As, on the expiry of the period laid down in the second subparagraph of Article 19(2) of Directive 91/414/EEC, the Council had neither adopted the proposed implementing act nor indicated its opposition to the proposal for implementing measures, the Commission adopted the measures concerned in Directive 2006/134.

Breach of the principle of legal certainty

45 Gowan submits that the restrictions on the use of fenarimol laid down by Directive 2006/134 are based on assessment criteria which do not appear in Article 5(1)(a)

and (b) of Directive 91/414, and that this is contrary to the principle of legal certainty. The Commission relied on the existence of adverse effects on the endocrine system. However, according to Gowan, there is no established scientific method at Community level capable of verifying the existence of such effects (Commission Staff Working Document 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, 2004, p. 22)).

46 Gowan points out, further, that Directive 2006/134 is based on considerations relating to the danger posed by fenarimol. Concerns of that nature did not support a conclusion that there was an unacceptable risk to the environment and to human health within the meaning of Directive 91/414.

47 According to settled case-law, the general principle of legal certainty, which is a fundamental principle of Community law, requires, in particular, that rules should be clear and precise, so that individuals may be able to ascertain unequivocally what their rights and obligations are and may take steps accordingly (see Case 169/80 *Gondrand and Garancini* [1981] ECR 1931, paragraph 17; Case C-110/03 *Belgium* v *Commission* [2005] ECR I-2801, paragraph 30; Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 68; and *Intertanko and Others*, paragraph 69).

48 The criteria on the basis of which active substances may be included in Annex I to Directive 91/414 are set out in general terms in Article 5 of that directive. According to Article 5(1) there are two conditions for the inclusion of a substance in Annex I to that directive. It must be possible to expect, in the light of current scientific and

technical knowledge, 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…;

(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).'

49 Article 5(2) of Directive 91/414 provides that, for inclusion of an active substance in Annex I of that directive, the following are to 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.'

50 Finally, the requirements for the dossier to be submitted for the inclusion of an active substance in Annex I to Directive 91/414 are set out in Annex II to that directive.

51 It is common ground that none of those provisions contains specific criteria for the assessment of the effects of an active substance on the endocrine system. However, such effects unequivocally fall under the assessment of the harmful effects on human or animal health referred to in Article 5(1)(b) of Directive 91/414. Accordingly, no breach of the principle of legal certainty can be found and Directive 2006/134 is not invalid on the ground of breach of that principle.

Manifest error of assessment

52 Gowan takes the view that Directive 2006/134 is not justified by any of the scientific studies carried out in accordance with Directive 91/414, which, taken together, demonstrate that the uses of fenarimol in respect of which the inclusion of that substance was requested meet the criteria of that directive. By disregarding the scientific opinions submitted to it, the Commission breached the principle of scientific excellence.

53 Gowan considers that as the United Kingdom proposed the inclusion of fenarimol following its scientific assessment, the Commission could not, without stating any reason or scientific justification, go back on its initial assessment and adopt unjustified restrictions on the use of that substance.

54 In that regard, it should be noted that, as is clear from recitals 5, 6 and 9 in the preamble thereto, Directive 91/414 aims to remove barriers to intra-Community trade

in plant protection products, while maintaining a high level of protection of the environment and of human and animal health (Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, paragraph 74).

55 To enable it to accomplish effectively the task entrusted to it and having regard to the complex scientific assessments which it must make when, in the course of examining requests for the inclusion of active substances in Annex I to Directive 91/414, it assesses the risks posed by the use of those substances, the Commission must be allowed a wide discretion.

56 The exercise of that discretion is not, however, excluded from review by the Court. The Court has consistently held that in the context of such a review the courts of the European Union must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of powers (Case 98/78 *Racke* [1979] ECR 69, paragraph 5, and Case C-16/90 *Nölle* [1991] ECR 1-5163, paragraph 12).

57 In particular, where a party claims that the institution competent in the matter has committed a manifest error of appraisal, the the courts of the European Union must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case, facts which support the conclusions reached (see, inter alia, Case C-269/90 *Technische Universität München* [1991] ECR 1-5469, paragraph 14).

58 It must also be borne in mind that — as is clear from Article 6(2)(b) of Regulation No 451/2000 — it is the notifier who has to demonstrate that, on the basis of the information submitted for one or more preparations for a limited range of representative

uses, the requirements of Directive 91/414 in relation to the criteria referred to in Article 5 are met.

59 It is in the light of the above considerations that it should be examined whether Directive 2006/134 lacks a scientific basis.

60 It should be pointed out that, under Directive 91/414, although the Commission is required to take account of the scientific assessment prepared by the rapporteur Member State, that assessment is not binding on the Commission, or the Council, as the case may be, who remain entitled, in the procedure provided for by Article 19 of that directive, to adopt different risk management measures from those proposed by the rapporteur Member State.

61 As regards Directive 2006/134 it must be observed that the conclusions of the rapporteur member State following its scientific assessment of the properties of fenarimol and the risks posed by the use of that substance for the uses planned by the notifier were validated by the 'evaluation' working group of the Standing Committee on the Food Chain and Animal Health.

62 As regards, more specifically, the question of the risk of endocrine disruption connected with use of fenarimol, the documents before the Court show that the information provided by the notifier, and a supplementary study produced in 2003 on the basis of a full life cycle analysis on fish in particular, confirmed the initial assessment of the rapporteur Member State as regards the absence of any unacceptable risk and was accepted by the 'evaluation' working group.

63 As regards the decision to include fenarimol in Annex I to Directive 91/414, it must be pointed out that Directive 2006/134 does not undermine the results of the scientific assessment of risks posed by that active substance because the latter directive serves to authorise its use in plant protection products.

64 In that connection, it is recalled in the fifth recital in the preamble to Directive 2006/134 that it 'has appeared from the various examinations made that plant protection products containing fenarimol may be expected to satisfy the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, with regard to the uses which were examined and detailed in the Commission review report, provided that adequate risk mitigation measures are applied.'

65 In those circumstances it cannot be claimed that the Commission failed to take into account with care and impartiality the scientific evidence produced by the rapporteur Member State at the stage of assessment of the risks posed by the use of fenarimol.

66 The question asked by the referring court seeks essentially to determine whether the restrictions on the use of fenarimol resulting from Directive 91/414 go beyond what is necessary to achieve the objective pursued by that directive, in the light of the scientific assessment carried out on the basis of the data supplied by Gowan. That question falls within the scope of the examination of Directive 2006/134 in the light of the precautionary principle and the principle of proportionality.

67 It must, therefore, be concluded that, in the light of the scientific evidence resulting from the assessment of the risks posed by the uses of fenarimol envisaged by the notifier, examination of the file has revealed nothing to suggest that Directive 2006/134 is vitiated by a manifest error of assessment on the part of the Commission.

Breach of the precautionary principle and the principle of proportionality

68 Gowan challenges the reliance on the precautionary principle as a justification for the restrictions imposed on the use of fenarimol. That principle may be applied only in the case of scientific uncertainty (Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 142), resulting, inter alia, from data which are are inadequate, inconclusive, or imprecise (Communication from the Commission on the precautionary principle of 2 February 2000 COM (2000) 1 final). However, recourse may not be had to that principle on the ground that it has not been proven that there is no risk (Opinion of Advocate General Mischo in Case C-6/99 *Greenpeace France and Others* [2000] ECR I-1651).

69 Gowan states that it has submitted all the studies which shed light on the effects of fenarimol on the endocrine system. In those circumstances, to rely on the precautionary principle, as the Commission does, amounts to requiring those who seek the inclusion of an active substance in Annex I to Directive 91/414 to furnish proof of the complete absence of a risk which is not even one of those cited by that directive as relevant for the purposes of such inclusion.

70 According to Gowan, even if there were scientific uncertainty over the effects of fenarimol on the endocrine system, any measure adopted under the precautionary principle would have to be proportionate to the objectives of Directive 91/414, given that such measures can rarely reduce the risk to zero (Communication from the Commission on the precautionary principle of 2 February 2000, p. 3, point 6). Yet the

restrictions on the use of fenarimol resulting from that directive amount, in practice, to a ban on the substance.

71 It should be borne in mind that, according to Article 191(1) and (2) TFEU, Community policy on the environment is to pursue the objective inter alia of protecting human health. That policy, which seeks a high level of protection, is based, inter alia, on the precautionary principle. The requirements of that policy must be included in the definition and implementation of the other policies of the Union. Moreover, as provided in Article 168 TFEU, requirements relating to the protection of human health are a part of all the policies and actions of the Union and must therefore be taken into account in the implementation of the common agricultural policy by the institutions of the Union.

72 The precautionary principle applies where the institutions of the Union take measures to protect human health under the common agricultural policy (see, to that effect, Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 64, and Case C-180/96 *United Kingdom* v *Commission* [1998] ECR I-2265, paragraph 100).

73 It follows from the precautionary principle that, where there is uncertainty as to the existence or extent of risks to the health of consumers, the institutions may take protective measures without having to wait until the reality and the seriousness of those risks become fully apparent (*National Farmers' Union and Others*, paragraph 63, *United Kingdom* v *Commission*, paragraph 99, and Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 111)..

74 Although Directive 91/414 provides for a procedure for the prior authorisation of plant protection products as one of the possible expressions of the precautionary principle, it must be accepted that as the precautionary 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, those institutions may take protective measures, under the precautionary principle, without having to wait for the reality and the seriousness of those risks to be fully demonstrated.

75 A correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of the substance at issue, and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research (see Case C-333/08 *Commission* v *France* [2010] ECR I-757, paragraph 92, and the case-law cited therein).

76 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 *Commission* v *France*, paragraph 93 and the case-law cited therein).

77 As regards the procedure for the inclusion of fenarimol in Annex I to Directive 91/414, it must be found that, although the scientific assessment of the properties and the risks posed by the use of that active substance allowed the conclusion, set out in recital 5 in the preamble to Directive 2006/134, that it 'appeared from the various examinations made that plant protection products containing fenarimol 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', it none the less emerged, when the draft decision seeking to include fenarimol in Annex I to Directive 91/414 was drawn up that there were still certain concerns regarding the intrinsic toxic effects of fenarimol 'including potential endocrine disrupting properties', justifying the view that 'its use should not be unrestricted'.

78 Such concerns cannot be considered to be based on purely hypothetical considerations. In addition to the scientific evidence put forward by certain Member States during the work of the Standing Committee on the Food Chain and Animal Health, it must be pointed out that, in its written observations the Commission referred to several studies and reports on the question of the effect of disruption of the endocrine system produced by certain substances, and the Communication from the Commission to the Council and the European Parliament - Community strategy for endocrine disrupters - A range of substances suspected of interfering with the hormone systems of humans and wildlife of 17 December 1999 (COM (1999) 706 final), in particular. Moreover, as pointed out in recital 10 in the preamble to Directive 2006/134, the work of the OECD on the development of test guidelines in order to further refine the assessment of potential endocrine disrupting properties was not yet completed by the date of the adoption of Directive 2006/134.

79 In the light of this evidence which tends to demonstrate that there was still some scientific uncertainty regarding the assessment of the effects on the endocrine system of substances such as fenarimol, the Commission cannot be considered to have applied the precautionary principle in a manifestly erroneous manner in attaching restrictions on use to the authorisation of that substance.

80 It remains to examine whether those restrictive effects are consistent with the principle of proportionality.

81 It is settled case-law that the principle of proportionality, which is one of the general principles of European Union law, requires that measures implemented by acts of the European Union are appropriate for attaining the objective pursued and do not go beyond what is necessary to achieve it (Case C-58/08 *Vodafone and Others* [2010] ECR I-4999, paragraph 51, and the case-law cited).

82 As regards the judicial review of the conditions mentioned in the preceding paragraph, it must be acknowledged that the Commission has a wide discretion when it adopts risk management measures under the procedure for the inclusion of a substance in Annex I to Directive 91/414. That procedure entails political choices on its part and complex assessments. The legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate (see by analogy, Joined Cases C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraph 52, and Case C-558/07 *S.P.C.M. and Others* [2009] ECR I-5783, paragraph 42 and the case-law cited).

83 As regards the question whether the measures restricting the use of fenarimol are suitable for achieving the objectives pursued by Directive 91/414, it appears from the procedure leading to the adoption of Directive 2006/134 and the recitals in the preamble to that directive, that the Commission endeavoured to strike a balance between the objectives of Directive 91/414 relating to the improvement of plant production, the protection of human and animal health, groundwater and the environment and the interest of the notifier in obtaining the inclusion of fenarimol in Annex I to Directive 91/414 on conclusion of the scientific assessment of the risks posed by that substance. Given the concerns on the subject of the potential endocrine disrupting effects of fenarimol and the scientific uncertainty in that regard which justified the Commission's application of the precautionary principle, the restrictions which

Directive 2006/134 imposes on the use of that substance do not appear unsuitable for the achievement of those objectives.

84 Gowan disputes that the measure at issue was necessary on the ground that the terms of the inclusion of fenarimol amounted, purely and simply, to a ban on that active substance and thus went beyond what was necessary to achieve the intended objectives. In that regard, it must be observed that, although the inclusion of fenarimol in Annex I to Directive 91/414 was reduced to a period of 18 months, it appears from recital 11 in the preamble to Directive 2006/134 that that time limit does not preclude the possible renewal of that inclusion pursuant to the provisions of Article 5(5) of Directive 91/414.

85 Similarly, it is clear from recital 6 in the preamble to Directive 2006/134 that the fact that the authorisation of fenarimol is limited to only those uses which have actually been assessed and judged compliant with the conditions of Directive 91/414 does not prevent other uses being included in Annex I to that directive after a full assessment of them.

86 In those circumstances, and having regard in particular to the wide discretion which the Commission has in this field, the measures restricting the use of fenarimol cannot be considered to exceed what is necessary to achieve the objectives pursued.

87 Having regard to those considerations, Directive 2006/134 is not invalid by reason of the breach of the precautionary principle and the principle of proportionality.

88 It follows from all the foregoing that consideration of the question referred for a preliminary ruling has disclosed nothing to affect the validity of Directive 2006/134.

Costs

89 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Second Chamber) hereby rules:

Consideration of the question referred for a preliminary ruling has disclosed nothing to affect the validity of Commission Directive 2006/134/EC of 11 December 2006 amending Council Directive 91/414/EEC to include fenarimol as active substance.

[Signatures]