JUDGMENT OF THE COURT (Second Chamber)

15 October 2009 *

In Case C-425/08,

REFERENCE for a preliminary ruling under Article 234 EC from the Conseil d'État (Belgium), made by decision of 17 September 2008, received at the Court on 26 September 2008, in the proceedings

Enviro Tech (Europe) Ltd

v

État belge,

THE COURT (Second Chamber),

composed of C. Toader (Rapporteur), President of the Eighth Chamber, acting as President of the Second Chamber, C.W.A. Timmermans, K. Schiemann, P. Kūris and L. Bay Larsen, Judges,

* Language of the case: French.

Advocate General: Y. Bot,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 18 June 2009,

after considering the observations submitted on behalf of:

— Enviro Tech (Europe) Ltd, by C. Mereu and E. Cusas, avocats,

— the Belgian Government, by T. Materne, acting as Agent, and by P. Legros, S. Rodrigues and J. Sohier, avocats,

— the Swedish Government, by A. Falk and A Engman, acting as Agents,

— the Commission of the European Communities, by P. Oliver and O. Beynet, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 The reference for a preliminary ruling concerns the validity of Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th 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 2004 L 152, p. 1), in the light of Council Directive 67/548/EEC of 27 June 1967 (English special edition: Series I Chapter 1967, p. 234), as amended by Commission Directive 2001/59/EC of 6 August 2001 (OJ 2001 L 225, p. 1; 'Directive 67/548') and in particular Annexes V (Title A.9) and VI (point 4.2.3) thereto.

2 This reference has been made in proceedings between Enviro Tech (Europe) Ltd ('Enviro Tech'), a company governed by English law, and the Belgian State and concerns annulment of the classification of n-propyl bromide in Annex III to the Royal Decree of 11 March 2005 amending the Royal Decree of 11 January 1993 on the classification, packaging and labelling of dangerous substances with a view to their marketing or use (arrêté royal du 11 mars 2005 modifiant l'arrêté royal du 11 janvier 1993 réglementant la classification, l'emballage et l'étiquetage des préparations dangereuses en vue de leur mise sur le marché ou de leur emploi) (*Moniteur belge*, 5 June 2005, p. 30680; 'the Royal Decree of 11 March 2005'), which transposes the provisions of Directive 2004/73.

Legal context

Community law

Directive 67/548

3 Directive 67/548, which has frequently been amended, constitutes, in the field of chemical products, the first harmonising directive laying down rules on the marketing of certain substances and certain preparations.

4 That first harmonising directive was the subject, prior to the amendments introduced by Directive 2001/59 to Annex VI thereto, of amendments made, inter alia, by Council Directive 92/32/EEC of 30 April 1992 (OJ 1992 L 154, p. 1), with regard to the principal provisions at issue in the present case, and by Commission Directive 92/69/EEC of 31 July 1992 (OJ 1992 L 383, p. 113), with regard to the methods for determining the flash point laid down in Title A.9 of Annex V thereto.

5 Article 2(2) of Directive 67/548 classifies as 'dangerous', within the meaning of that directive, substances and preparations which are, inter alia, 'extremely flammable', 'highly flammable' and 'flammable' or 'toxic for reproduction'.

6 In accordance with the criteria for classification of a substance as a flammable substance which are set out in points 2.2.3 to 2.2.5 of Annex VI to Directive 67/548, liquids may be classified as follows:

— 'flammable' if their flash point is between 21 °C and 55 °C. Those liquids will therefore be labelled R10;

— 'highly flammable' if their flash point is lower than 21 °C. Those liquids are to be labelled R11; and

— 'extremely flammable' if their flash point is lower than 0 °C and their boiling point (or in case of a boiling range the initial boiling point) is lower than 35 °C. Those liquids must be labelled R12.

7 Title A.9 of Annex V to Directive 67/548 lays down the methods for determination of flash points. To that end, it identifies two methods, the equilibrium method and the non-equilibrium method, on the basis of which the apparatus and measuring instruments and the corresponding ISO standards are chosen.

8 Thus, the equilibrium method is based on ISO standards 1516, 3680, 1523 and 3679. The non-equilibrium method uses certain flash point measuring instruments, of which one is known as the Pensky-Martens apparatus, use of which is based on the following standards: ISO 2719, EN 11, DIN 51758, ASTM D 93, BS 2000-34 and NF M07-019.

9 With regard to substances toxic for reproduction, point 4.2.3 of Annex VI to Directive 67/548 divides them into three categories:

— category 1: 'substances known to impair fertility in humans' and 'substances known to cause developmental toxicity in humans';

— category 2: 'substances which should be regarded as if they impair fertility in humans' and 'substances which should be regarded as if they cause developmental toxicity to humans', and

— category 3: 'substances which cause concern for human fertility' and 'substances which cause concern for humans owing to possible developmental toxic effects'.

10 Point 4.2.3.1 to Annex VI to Directive 67/548 provides:

'For the purposes of classification and labelling and having regard to the present state of knowledge, such substances are divided into three categories:

…

Category 2

Substances which should be regarded as if they impair fertility in humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of:

— clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary non-specific consequence of the other toxic effects,

— other relevant information.

…'

11 With regard to the tests which may be carried out in order to classify chemical substances, Article 3 of Directive 67/548 provides:

'1. Tests on chemicals carried out within the framework of this Directive shall as a general principle be conducted according to the methods laid down in Annex V. The physico-chemical properties of substances shall be determined according to the methods specified in Annex V. A …'

12 Article 4(2) of Directive 67/548 provides that the general principles of the classification and labelling of substances and preparations are to be applied according to the criteria in Annex VI, save where contrary requirements for dangerous preparations are specified in separate directives.

13 Point 1.6.1(b) of Annex VI to Directive 67/548 states that the data required for classification and labelling may be obtained, inter alia, from the results of previous tests, information taken from reference works, or information derived from practical experience. It also states that, more generally, 'expert judgement may also be taken into account'.

14 Article 28 of Directive 67/548 has foreseen the need for adaptation thereof to technical progress by providing that '[t]he amendments necessary for adapting the Annexes to technical progress shall be adopted in accordance with the procedure laid down in Article 29'.

15 The procedure laid down in Article 29 of Directive 67/548 is the following:

'1. The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

2. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

4. (a) Except in the cases referred to in subparagraph (b) below, if, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission. This period shall be six weeks in the case referred to in Article 31(2).

(b) In the case of measures for adaptation to technical progress in Annexes II, VI, VII and VIII, if, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority'.

Directive 2004/73

16 Article 1 of Directive 2004/73 makes a number of amendments to Annexes I and V to Directive 67/548.

17 With regard to the labelling of n-propyl bromide, Annex I B to that directive requires the following to appear: R60, R11, R36/37/38, R48/20, R63, R67, S53, or S45, the meaning of which is as follows: R60 (may impair fertility), R11 (highly flammable), R36/37/38 (irritating to eyes, respiratory system and skin), R48/20 (danger of serious damage to health by prolonged exposure through inhalation), R63 (possible risk of harm to the unborn child), R67 (vapours may cause drowsiness and dizziness), S53 (avoid exposure — obtain special instructions before use) and S45 (in case of accident or if you feel unwell seek medical advice immediately (show the label where possible)).

National law

18 The Royal Decree of 11 March 2005 transposed Directive 2004/73 into Belgian law.

19 With regard to the labelling of n-propyl bromide, that Decree repeated the instructions contained in Annex I B to Directive 2004/73.

The dispute in the main proceedings and the questions referred for a preliminary ruling

20 Enviro Tech manufactures products under the name Ensolv®, a group of patented solvents based on n-propyl bromide, the formula of which is specifically designed for vapour degreasing of delicate apparatus.

21 In a case brought on 23 December 2003 before the Court of First Instance of the European Communities, registered as Case T-422/03, Enviro Tech and Enviro Tech International Inc. are seeking the annulment of two letters from the Commission of 3 November 2003 concerning the future reclassification of n-propyl bromide.

22 On 16 July 2004, the same applicants brought an action before the Court of First Instance, registered as Case T-291/04, for annulment of Directive 2004/73.

23 In those two cases, which have been joined, Enviro Tech is also seeking compensation for the harm which it considers it has suffered by the fact of the measures which it seeks to have annulled. The actions before the Court of First Instance are stayed, pending the decision in the present case.

24 Enviro Tech has also taken action at a national level to contest the classification of n-propyl bromide as a dangerous substance.

25 Thus, according to the documents in the file, national proceedings are ongoing before the High Court of Justice of England and Wales, Queen's Bench Division (United Kingdom). Those proceedings have also been stayed pending the decision of the Court of First Instance in Joined Cases T-422/03 and T-291/04.

26 In Belgium, on 6 September 2005, Enviro Tech brought an application before the Conseil d'État for annulment of the classification of n-propyl bromide by Annex III to the Royal Decree of 11 March 2005.

27 In that action, the national court has doubts as to whether Directive 2004/73, which classifies n-propyl bromide as a highly flammable substance and toxic for reproduction, complies with Directive 67/548. If the answer to that question is in the negative, the Conseil d'État asks the Court whether the Kingdom of Belgium should have refrained from transposing the classification of n-propyl bromide that stems from Directive 2004/73 or rejected that classification.

28 The Conseil d'État, taking the view that the judicial protection guaranteed by Community law includes the right for persons to contest, indirectly, the lawfulness of Community standards before the national courts in proceedings against the national transposing standard, decided to stay the proceedings and to refer the following two questions to the Court for a preliminary ruling:

'1. In so far as it classifies [n-propyl bromide] as a highly flammable substance (R11) on the basis of a single test carried out at a temperature of -10 °C, does Directive [2004/73] comply with [Directive 67/548], in particular with Title A.9 of Annex V to that directive which lays down the methods for determining flash points?

Does Directive [2004/73] comply with [Directive 67/548], in particular with point 4.2.3 of Annex VI to that directive, in so far as it classifies [n-propyl bromide] as a category 2 substance which is toxic for reproduction (R60), first, without clear results in appropriate animal studies where toxic effects have been observed to justify a strong presumption that human exposure to the substance may result in developmental toxicity and, secondly, on the basis of tests in which toxicity was detected only in animals subjected to a concentration of 250 ppm, that is to say 11 times the maximum and 40 times the average of the concentration of [n-propyl bromide] to which a person is exposed when handling the product?

Does Directive [2004/73] comply with [Directive 67/548], in particular with Annexes V and VI thereto, in so far as it classifies [n-propyl bromide] as highly flammable (R11) and as a category 2 substance which is toxic for reproduction (R60) on the basis of the precautionary principle without complying with the methods and criteria set out in Annexes V and VI to [Directive 67/548]?

Does Directive [2004/73] comply with [Directive 67/548] in so far as it classifies [n-propyl bromide] as highly flammable (R11) and as a category 2 substance which is toxic for reproduction (R60) on the basis of tests which are different from those carried out on competing products, inter alia chlorinated halogens, and without regard to the principle of proportionality?

2. If Directive [2004/73] does not comply with Directive [67/548], should the Kingdom of Belgium have refrained from transposing into national law the classification of [n-propyl bromide] which stems from Directive [2004/73] or even rejected that classification, even though under Article 2 of Directive [2004/73] "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 October 2005 at the latest"?'

The questions referred

The first question

Observations of the parties

29 Enviro Tech puts forward a number of arguments against Directive 2004/73.

30 Firstly, Enviro Tech submits that the Directive, by classifying n-propyl bromide as a highly flammable substance, is unlawful in that the methods for determining the flash point laid down in Title A.9 of Annex V to Directive 67/548 were not followed. The Commission acted unlawfully in taking as its basis a single test carried out at a temperature of -10 °C using the Pensky-Martens apparatus under ISO 1523 and in failing to follow the method linked to that specification, which requires the value to be determined between 10 °C and 110 °C.

31 Secondly, concerning the classification of n-propyl bromide as a substance toxic for reproduction in category 2, Enviro Tech takes the view that the Commission erred in following the recommendation of the working group to that effect. In particular it submits that the tests carried out on rats do not provide sufficient evidence for a finding that human exposure to that substance gives rise to effects toxic for reproduction. Enviro Tech also alleges that the toxicity for animals which had been observed was after levels of exposure 16 times higher than the average human exposure and more than 40 times higher than the level of exposure in normal handling and use by Enviro Tech.

32 Thirdly, Enviro Tech submits that, under Directive 2004/73, n-propyl bromide is classified as a highly flammable substance and toxic for reproduction in category 2 under the precautionary principle, without the methods and criteria laid down in Annexes V and VI to that directive having been followed.

33 Fourthly, by virtue of Directive 2004/73, n-propyl bromide is considered a highly flammable substance and toxic for reproduction in category 2 on the basis of tests different from those carried out on competing products and in disregard of the principle of proportionality.

34 In that regard, Enviro Tech submits that the classification of the substance at issue in the main proceedings, as stems from Directive 2004/73, is contrary to the principle of proportionality if the description as highly flammable which may be attributed to it is based on a flash point which has been found only at a temperature of -10 °C, while the substance is normally handled at ambient temperature. Arriving at such results thus implies a certain intellectual dishonesty since, otherwise, no flash point has been found between 10 °C and 110 °C, and the same is true of the proof of the toxic effects and the strong presumption of harmful effects on human fertility.

35 The Belgian Government proposes that the answer should be that Directive 2004/73 complies with Directive 67/548 on the four points raised by the applicant in the main proceedings.

36 The Swedish Government takes the view, like the Belgian Government, that Directive 2004/73 complies with Directive 67/548 and that the classification of n-propyl bromide as a highly flammable substance (R11) was reached in accordance with the prescribed criteria and methods.

37 Firstly, both the results of the two laboratory tests carried out, independently of each other, and the information published, which was subject to other calculations, show that the flash point of n-propyl bromide is markedly lower than 21 °C. In the view of the Swedish Government, therefore, n-propyl bromide must be classified as a highly flammable substance (R11).

38 Secondly, information obtained from quality tests carried out on animals show that n-propyl bromide has clearly toxic effects for reproduction. Those effects do not appear only at high dosages and are considered relevant to humans. The Swedish Government therefore submits that n-propyl bromide must also be classified as a substance which should be regarded as one which may impair fertility in humans (R60) and as a substance which causes concern for humans owing to possible developmental toxic effects (R63).

39 In the view of the Commission, the answer to the national court should be that examination of the questions referred to the Court by the Conseil d'État has shown no factor capable of affecting the validity of Directive 2004/73 in that it classifies n-propyl bromide as a highly flammable substance (R11) and toxic for reproduction in category 2 (R60).

40 Thus, with regard to flammability, point 2.2.4 of Annex VI to Directive 67/548 stipulates, regarding classification in the category of 'highly flammable' substances, a flash point lower than 21 °C, without setting a lower, minimum value. The temperature of -10 °C therefore indisputably meets the criteria laid down in the definition of the 'highly flammable' category.

41 In the view of the Commission, the provisions of Title A.9 of Annex V to Directive 67/548 do not stipulate the manner in which the flammability tests are to be undertaken. In reality, Title A.9 describes rather than lays down certain specifications for the tests. Thus there is flexibility in the use of the test methods. In

addition, point 1.6.3.2 of Title A.9 expressly mentions the ISO standard 1523 and, consequently, use of that particular specification cannot be contrary to Annex V to Directive 67/548.

42 With regard to the toxicity for reproduction of n-propyl bromide, the Commission takes the view that, since the criteria for classification in category 2 of Annex VI to Directive 67/548 of a substance which impairs fertility in humans are clearly met, as regards both the evidence obtained from experiments on an animal species and the corroborating factors, the working group was correct to conclude that n-propyl bromide was to be classified as such. Furthermore, a margin of flexibility is necessary in interpreting the results of tests carried out on animals in terms of the possible effects on humans.

43 Finally, with regard to the complaints relating to the alleged disregard of the precautionary principle and the principle of proportionality, the Commission submits that they are unfounded.

44 Thus, Directive 2004/73 followed the methods and criteria laid down in Annexes V and VI to Directive 67/548 and the Commission in no way based its classification solely on the precautionary principle.

45 With regard to the alleged disregard of the principle of proportionality, the Commission submits that the classification of n-propyl bromide as a dangerous substance is based on considered scientific views and precise criteria laid down in Annexes V and VI to Directive 67/548, and that it is proportionate to the potential risks identified.

Answer of the Court

— Preliminary observations

46 First of all, it must be pointed out that, in this complex technical and legal context, essentially in a state of flux, Directive 67/548 basically gives the Commission wide powers of assessment as to the scope of the measures to be taken to adapt the Annexes to that directive to technical progress.

47 As the Court has already held, where the Community authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the Community judicature is limited to verifying whether there has been a manifest error of appraisal or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the Community judicature cannot substitute its assessment of scientific and technical facts for that of the institutions on which alone the Treaty has placed that task (see Case C-326/05 P *Industrias Químicas del Vallés* v *Commission* [2007] ECR I-6557, paragraphs 75 to 77).

— The question of flammability

48 In accordance with point 1.2 of Title A.9 of Annex V to Directive 67/548, a liquid's flammability is determined, initially, by measuring its flash point. The flash-point is the lowest temperature at which, under the conditions defined in the test method, a liquid's vapours form a flammable mixture with air.

49 According to the applicant in the main proceedings, by classifying n-propyl bromide as a highly flammable substance, Directive 2004/73 did not follow the methods laid down in Title A.9 of Annex V to Directive 67/548 for determination of the flash point.

50 In that regard, it must be noted that, as recalled in paragraphs 7 and 8 of the present judgment, to determine the flash point of liquids a choice must be made between an equilibrium method in accordance with ISO standards 1516, 3680, 1523 or 3679, and a non-equilibrium method. As the Swedish Government pointed out in its observations, the choice of the most appropriate method depends on the properties of the substance to be analysed.

51 Those methods set criteria for the choice of equipment according to the temperature gradient at which the measurements must be made. There are a number of categories of measuring instruments appropriate to different temperature gradients.

52 It is apparent from the documents before the Court that the Commission, basing its findings on the view of experts in the field contained in the report of the expert group on flammability which met on 4 December 2002 (document No ECBI/59/02; 'the flammability experts' report') took the view that n-propyl bromide was a highly flammable substance on the basis of the results obtained from experiments conducted, inter alia, in accordance with the equilibrium method and ISO standard 1523, with a Pensky-Martens apparatus, which found a flash point at -10 °C.

53 Firstly, with regard to the complaint of the applicant in the main proceedings that the classification of n-propyl bromide as a highly flammable substance rests on the result of a single test carried out in accordance with the specifications referred to above, the flammability experts' report enables that allegation to be rejected.

54 Thus, it is apparent from that document that a number of tests were carried out in accordance with the most widely accepted standards for measuring the flash point and that the majority of those tests did not give a flash point for the substance in question.

55 Nevertheless, as the Swedish Government has pointed out in its written observations, account must be taken of the fact that it is as a general rule difficult to determine the flash point of halogenated hydrocarbons such as n-propyl bromide, the properties of which may mean that results of calculations are inexact or imprecise. As set out in ISO standard 1523 itself, the interpretation of results obtained from solvent mixtures containing halogenated hydrocarbons should be considered with caution, as these mixtures can give anomalous results.

56 That being so, the result obtained by the equilibrium method and by ISO standard 1523 with Pensky-Martens apparatus is not the only one to have shown the existence, for n-propyl bromide, of a flash point lower than 21 °C.

57 In addition to the measurement referred to, the flammability experts' report contains the results of another test carried out using the same apparatus, but by the non-equilibrium method, ASTM D 93-94, which exactly meets the requirements of point 1.6.3.2 of Title A.9 in Annex V to Directive 67/548 and which found a flash point for n-propyl bromide of -4.5 °C. To supplement those tests, a theoretical calculation of the flash point was carried out, which showed that n-propyl bromide may become flammable from -7 °C. On the basis of that information and after discussions, the majority opinion of the expert group was that n-propyl bromide is a highly flammable substance which must be classified as R11.

58 It follows from the foregoing that neither the expert group nor the Commission based their findings on a single test but on a number of scientific factors which enabled a flash

point lower than 21 °C to be found for n-propyl bromide, which permitted them to classify that substance in the category of 'highly flammable' liquids, in accordance with points 2.2.3 to 2.2.5 of Annex VI to Directive 67/548.

59 Secondly, the applicant in the main proceedings alleges that, on its technical specifications, the Pensky-Martens apparatus is more suitable for the determination of a flash point in accordance with ISO standard 1523 in a temperature gradient between 10 °C and 110 °C.

60 In that regard, it must be held that the fact that the measurements were made in a temperature gradient other than that recommended for the measuring instrument is liable to affect the reliability of the classification.

61 Nevertheless, it must be pointed out that, taking account of the safety margin which has to be applied to a result obtained relative to the temperature which determines the classification, that fact is not sufficient of itself to call into question the conclusions of the expert group and of the Commission that n-propyl bromide must be classified as a highly flammable substance.

62 Thus, it is settled case-law that, where a Community authority is called upon, in the performance of its duties, to make complex assessments, its discretion applies also, to a certain extent, to the finding of facts underlying its action (see, to that effect, Case 138/79 *Roquette Frères* v *Council* [1980] ECR 3333, paragraph 25, and Case C-120/97 *Upjohn* [1999] ECR I-223, paragraph 34). Furthermore, in such circumstances, it is the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (Case C-269/90 *Technische Universität München* [1991] ECR I-5469, paragraph 14).

63 It is apparent from the flammability experts' report that, even if the expert group was not unanimous on the question of whether or not n-propyl bromide should be classified as R11, a majority opinion that it should be so classified emerged within the group. It must also be observed that the experts reached a consensus on the fact that n-propyl bromide did indeed have a flash point and an explosive range enabling the view to be taken that, accordingly, it carried an intrinsic risk of flammability.

64 It follows from the foregoing that, in the assessment of the flammability of n-propyl bromide, the Commission followed the opinion of the flammability expert group, which is based on the results of a number of tests carried out using different methods, confirmed by information taken from specialist publications.

65 Accordingly, it is apparent that the exercise of the Commission's discretion as to the classification of n-propyl bromide as a 'highly flammable' substance is not vitiated by manifest error or abuse of power and that the Commission has not manifestly exceeded the limits of its discretion.

— The question of toxicity for human reproduction

66 Since the classification of n-propyl bromide as a substance toxic for human reproduction is based solely on results of tests carried out on animals, which showed marked toxic effects on their reproduction, the applicant in the main proceedings has disputed, before the national court, the fact that it is possible to interpret those results widely in order to deduce from them that the substance in question is harmful to human reproduction.

67 The criteria for classification of a substance as toxic for reproduction are set out in point 4.2.3 of Annex VI to Directive 67/548. In particular, to classify a substance as being of category 2 toxicity on the basis of impaired fertility, there must be clear evidence of impairment of fertility in an animal species, together with either additional evidence as to the mechanism or seat of the effect or as to the existence of a chemical analogy with other known 'anti-fertility' agents, or other information leading to the conclusion that comparable effects are likely to be found in humans.

68 As is apparent from the summary reports of the CMR — Carcinogens, Mutagens, Reproductive Toxicants working group of 14 to 16 May 2003 and of 15 to 17 January 2003 (documents No ECBI/56/03 Rev.2 and No ECBI/30/03 Rev.3; 'CMR working group reports'), the grounds for the classification of n-propyl bromide as category 2 toxic are based on the harmful effects on fertility, found during standard studies on a species of rat, and on the structural similarity between that substance and its isomer, 2-bromopropane, also called iso-bromopropane, classified as category 1 toxic due to both known impairment of human fertility and developmental toxicity to humans.

69 Thus, the fact that n-propyl bromide causes marked harm to the reproductive organs in rats of both sexes on administration of doses which have not given rise to other systematic effects constitutes the most obvious effect resulting from the studies referred to in the CMR working group reports. Furthermore, those studies conclude that the toxic effects are not produced solely on administration of high doses.

70 It is therefore apparent that the experts' opinion was based on the criteria set out in point 4.2.3 of Annex VI to Directive 67/548 and, in particular, in point 4.2.3.3 of that annex and that the Commission, on the basis of that opinion, was thus able validly to classify n-propyl bromide as a substance 'toxic for reproduction in category 2'.

71 Accordingly, it must be held that the Commission's exercise of its discretion in classifying n-propyl bromide as a substance 'toxic for reproduction in category 2' is not vitiated by manifest error or by an abuse of power and that the Commission has not manifestly exceeded the limits of its discretion.

— The questions concerning the precautionary principle and the principle of proportionality

72 Before the Conseil d'État, Enviro Tech submitted that the Commission had applied only the precautionary principle when classifying n-propyl bromide as a highly flammable substance toxic for reproduction, in order to circumvent the criteria laid down in Annexes V and VI to Directive 67/548.

73 In addition, it alleged that the principle of proportionality was not applied in that classification of n-propyl bromide.

74 In that regard, it is sufficient to note that, contrary to the allegations of the applicant in the main proceedings, the Commission did not base its decision classifying n-propyl bromide on the precautionary principle, but based its decision on analyses carried out in accordance with the methods and the criteria laid down in Annexes V and VI to Directive 67/548.

75 As to the alleged breach of the principle of proportionality, the applicant in the main proceedings submits that the Commission based its decision on tests other than those carried out on competing products, in particular chlorine halogens.

76 However, that argument cannot be accepted. As follows from the observations of the Swedish Government, the structure of chlorine halogens is very different from that of bromine halogens.

77 In addition, the applicant in the main proceedings has failed to show that the classification of n-propyl bromide as a 'highly flammable' substance and a substance 'toxic for reproduction in category 2', within the meaning of Directive 67/548, is manifestly unsuited to achieve the objective pursued and that the inconveniences caused by that classification are disproportionate to that objective.

78 It follows from the foregoing considerations that the answer to the national court must be that examination of the first question has shown no factor capable of affecting the validity of Directive 2004/73, in that it classifies n-propyl bromide as a highly flammable substance (R11) and toxic for reproduction in category 2 (R60).

The second question

79 Since the second question was referred only in the event that the Court found that Directive 2004/73 did not comply with Directive 67/548, there is no need to answer that question.

Costs

80 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:

Examination of the questions referred has shown no factor capable of affecting the validity of Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, in that it classifies n-propyl bromide as a highly flammable substance (R11) and toxic for reproduction in category 2 (R60).

[Signatures]