JUDGMENT OF THE COURT (Fourth Chamber)

21 July 2011 *

In Case C-15/10,

REFERENCE for a preliminary ruling under Article 267 TFEU from the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), made by decision of 10 December 2009, received at the Court on 11 January 2010, in the proceedings

Etimine SA

v

Secretary of State for Work and Pensions,

intervener:

Borax Europe Ltd,

* Language of the case: English.

THE COURT (Fourth Chamber),

composed of J.-C. Bonichot, President of the Chamber, K. Schiemann, C. Toader (Rapporteur), A. Prechal and E. Jarašiūnas, Judges,

Advocate General: Y. Bot,
Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 20 January 2011,

after considering the observations submitted on behalf of:

— Etimine SA, by J. Stratford QC, C. Mereu, avocat, V. Wakefield, Barrister, and P. Sellar and C. Buchanan, Solicitors,

— Borax Europe Ltd, by H. Pearson, Solicitor, and K. Nordlander, advokat,

— the United Kingdom Government, by H. Walker, acting as Agent, and J. Coppel, Barrister,

— the Danish Government, by V. Pasternak Jørgensen and C. Vang, acting as Agents,

— the German Government, by B. Klein, acting as Agent,

— the French Government, by G. de Bergues, S. Menez and R. Loosli-Surrans, acting as Agents,

— the Austrian Government, by E. Riedl, acting as Agent,

— the European Commission, by P. Oliver, D. Kukovec and E. Manhaeve, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 24 March 2011,

gives the following

Judgment

1 This reference for a preliminary ruling concerns:

— the validity of the classifications of substances containing borates incorporated into Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ, English Special Edition 1967, p. 234), as amended by Commission Directive 2001/59/EC of 6 August 2001 (OJ 2001 L 225, p. 1) ('Directive 67/548'), by Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Directive 67/548 (OJ 2008 L 246, p. 1; 'the 30th ATP Directive') and

— the validity of those classifications in so far as they were taken from the 30th ATP Directive and incorporated into Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548 and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1; 'the CLP Regulation'), by Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 (OJ 2009 L 235, p. 1; 'the 1st ATP Regulation').

2 The reference has been made in proceedings between Etimine SA ('Etimine') and the Secretary of State for Work and Pensions for judicial review of any measures of the United Kingdom Government to implement the classifications made by the 30th ATP Directive and the 1st ATP Regulation.

Legal context

Legislation on the classification, packaging and labelling of dangerous substances and the assessment of their risks – Directives 67/548 and 93/67/EEC and the CLP Regulation

Directive 67/548 and its 30th adaptation to technical progress by the 30th ATP Directive

3 In the field of chemicals, Directive 67/548 was the first harmonising directive laying down rules relating to the marketing of certain substances and preparations. It contained, in Annex I, a list harmonising the classification and labelling of more than 8 000 substances and groups of substances according to their hazardous properties.

4 Article 2(2)(n) of Directive 67/548 classifies as 'dangerous' and 'toxic for reproduction' substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity.

5 Article 4(1) of Directive 67/548 provides that substances are to be classified on the basis of their intrinsic properties. Article 4(3) states that the list of classified substances is contained in Annex I to the directive and that the decision to place a substance in Annex I together with the harmonised classification and labelling is to be taken in accordance with the procedure laid down in Article 29.

6 Under Articles 28 and 29 of Directive 67/548, the annexes thereto may be adapted to technical progress under the regulatory procedure provided for in Articles 5 and 7 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), as amended by Council Decision 2006/512/EC of 17 July 2006 (OJ 2006 L 200, p. 11) ('Decision 1999/468'). Decision 1999/468 must be read in conjunction with point 1 of Annex III to Council Regulation (EC) No 807/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (OJ 2003 L 122, p. 36).

7 Section 1.1 of Annex VI to Directive 67/548 states inter alia that the object of classification is to identify all the physicochemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling or use.

8 Section 1.4 of Annex VI to Directive 67/548 provides inter alia that the label is to take account of all potential hazards which are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, for example diluted.

9 Section 1.6.1(b) of Annex VI to Directive 67/548 provides that the data required for classification and labelling of the substances which fall within those provisions may be obtained:

'… from a number of different sources, for example:

— the results of previous tests,

— information required by international rules on the transport of dangerous substances,

— information taken from reference works and the literature, or

— information derived from practical experience.

The results of validated structure-activity relationships and expert judgement may also be taken into account where appropriate.'

10 According to section 4.2.3.1 of Annex VI to Directive 67/548, substances classified as toxic to reproduction in category 2 are substances which should be regarded as if they impair fertility in humans, there being sufficient evidence to provide a strong presumption that human exposure to them may result in impaired fertility on the basis of clear evidence in animal studies of impaired fertility or of other relevant information.

11 The third and fourth paragraphs of section 4.2.3.3 of Annex VI to Directive 67/548 state that, whilst the placing of a compound in category 1 for effects on fertility and/or developmental toxicity is done on the basis of epidemiological data, placing a compound in category 2 or 3 for effects on fertility and/or developmental toxicity is done primarily on the basis of animal data. Even when clear effects have been demonstrated in animal studies the relevance for humans may be doubtful because of the doses administered, for example, where effects have been demonstrated only at high doses, or where marked toxicokinetic differences exist, or the route of administration is inappropriate. For these or similar reasons it may be that classification in category 3, or even no classification, will be warranted.

12 Directive 67/548 was amended by the 30th ATP Directive, classifying inter alia certain borate substances (collectively 'the borate substances at issue in the main proceedings') at a high hazard level, which entailed compliance with new labelling and packaging requirements and other legal and commercial consequences. The 30th ATP Directive classified the borate substances at issue in the main proceedings as reprotoxic in category 2.

Directive 93/67/EEC laying down the principles for assessment of risks under the regime laid down by Directive 67/548

13 It is apparent from Article 2(a) of Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548 (OJ 1993 L 227, p. 9), read in

conjunction with Articles 3 to 5 thereof, that assessment of the risks posed by a substance for the purposes of its classification under Directive 67/548 involves, as a first stage, hazard identification, which is defined as being the identification of the adverse effects which a substance has an inherent capacity to cause.

14 It is also apparent from Article 2(d) of Directive 93/67/EEC that risk characterisation consists in estimating the incidence and severity of the adverse effects likely to occur in a human population or environmental compartment due to actual or predicted exposure to a substance, and that that characterisation may include quantification of that likelihood or, in other words, risk estimation.

The CLP Regulation and its first adaptation to technical progress by the 1st ATP Regulation

15 The CLP Regulation adapts Directive 67/548, inasmuch as the latter concerns the classification, labelling and packaging of chemical substances, to the Globally Harmonised System of Classification and Labelling of Chemicals ('the GHS'). The GHS consists of a set of recommendations adopted by the Economic and Social Council of the United Nations, intended to enable dangerous chemicals to be identified and users to be informed of the hazards which they pose by means of standardised symbols and phrases on packaging labels.

16 Recital 53 in the preamble to the CLP Regulation states that, in order to take full account of the work and experience accumulated under Directive 67/548, including the classification and labelling of specific substances listed in Annex I to that directive, all

existing harmonised classifications should be converted into new harmonised classifications using the new criteria.

17 Articles 36 and 37 of the CLP Regulation, which are included in Chapter I (headed 'Establishing harmonised classification and labelling of substances') of Title V, lay down the procedure for the harmonised classification and labelling of substances which fulfil the criteria set out in Annex I to that regulation for hazards such as reproductive toxicity.

18 Article 37 entitles the competent authorities of the Member States and, in more limited circumstances, manufacturers, importers and distributors of substances to submit detailed proposals for harmonised classification and labelling to the European Chemicals Agency (ECHA), which replaced the European Chemicals Bureau from 1 June 2008.

19 Article 53 of the CLP Regulation, headed 'Adaptations to technical and scientific progress', authorises the European Commission to adopt measures intended to adapt Annexes I to VII to the regulation to technical and scientific progress, including 'taking due account of the further development of the GHS', and provides that those measures are to be adopted in accordance with the regulatory procedure with scrutiny laid down in Article 5a(1) to (4) of Decision 1999/468.

20 By virtue of Article 55(2) and (11) of the CLP Regulation, Annex I to Directive 67/548 was deleted and replaced by Part 3 of Annex VI to the regulation from 20 January 2009. Table 3.1 in Annex VI sets out the new classification following that conversion and Table 3.2 reproduces the old classification established under Directive 67/548 as

amended by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Directive 67/548 (OJ 2004 L 152, p. 1; corrigenda at OJ 2004 L 216, p. 3, and OJ 2004 L 236, p. 18).

21 When the CLP Regulation entered into force on 20 January 2009, Annex VI thereto thus did not reflect the classifications at issue, incorporated into Annex I to Directive 67/548 by the 30th ATP Directive.

22 Article 60 of the CLP Regulation provides that Directive 67/548 is to be repealed with effect from 1 June 2015. However, Article 61(3) of the regulation lays down the transitional provision that from 1 December 2010 until 1 June 2015 substances are to be classified in accordance with both Directive 67/548 and the CLP Regulation.

23 Point 1.1.1.3 of Annex I to the CLP Regulation provides in particular that all available information bearing on the determination of the hazard of a substance, such as the results of suitable *in vitro* tests, relevant animal data, information from the application of the category approach (grouping, read-across) or structure-activity relationship results, is considered together.

24 Annex VII to the CLP Regulation contains a table to assist translation of a classification made for a substance under Directive 67/548 into the corresponding classification under the CLP Regulation.

25 On the basis of Article 53 of the CLP Regulation, the 1st ATP Regulation transferred the classifications established by the 30th ATP Directive to Part 3 of Annex VI to the

CLP Regulation and translated them, so that they were included without amendment in Table 3.2 in Annex VI to the CLP Regulation whilst, in Table 3.1 in that annex, they were simply translated into classifications made on the basis of the CLP Regulation, using the translation table in Annex VII thereto. The 1st ATP Regulation entered into force on 25 September 2009.

Legislation on the evaluation and control of the risks of existing substances – Regulation (EEC) No 793/93 and the REACH Regulation

26 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1) ('Regulation No 793/93'), supplemented the system laid down by Directive 67/548 for notification of new substances.

27 It was repealed following the entry into force, on 1 June 2008, of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and corrigendum at OJ 2007 L 136, p. 3; 'the REACH Regulation').

28 Articles 3 and 4 of Regulation No 793/93 obliged manufacturers and importers to submit to the Commission certain relevant data on the substances to be evaluated, depending on the quantity imported or produced, and to make all reasonable efforts to obtain the data. However, in the absence of information, manufacturers and importers were not bound to carry out further tests on animals in order to submit such data.

29 Article 8 of Regulation No 793/93, read in conjunction with Article 15, provided that, on the basis of the information submitted by manufacturers and importers, lists of priority substances requiring immediate attention because of their potential effects on man or the environment were to be adopted in accordance with a comitology procedure with scrutiny.

30 The Commission adopted Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (OJ 1994 L 161, p. 3).

31 It is apparent from the recitals to the REACH Regulation that the current system, managed by ECHA, is intended to ensure a high level of protection of human health and the environment and to enhance the competitiveness of the chemicals sector and innovation. The REACH Regulation obliges undertakings which manufacture and import chemicals to evaluate the hazards and risks resulting from their use and to take the measures necessary to manage any risk identified.

32 According to Article 13 of the REACH Regulation, the information supplied for the purpose of evaluation of chemicals as regards human toxicity in particular must be obtained whenever possible by means other than vertebrate animal tests, through

the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across).

33 Section 1.5 of Annex XI to the REACH Regulation provides for use of the read-across approach in the evaluation of chemicals. It is laid down in particular that substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects in particular may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).

The procedure that led to the classifications at issue

34 On 28 January 1999, the French Republic submitted to the Commission a proposal for classifying boric acid under Directive 67/548 as a reprotoxic substance in category 2 for both fertility and development, that substance not having previously been covered by Annex I to the directive.

35 The Republic of Turkey holds over two thirds of the world's borate reserves.

36 On 10 February 1999, the Kingdom of Denmark submitted a proposal for classifying boric acid and borax decahydrate under Directive 67/548 as reprotoxic substances in category 2 for fertility and category 3 for development.

37 At its meeting held on 15 to 17 November 2000, the Commission's working group on the classification and labelling of dangerous substances ('the CL Working Group') at the European Chemicals Bureau recommended that boric acid should be classified under Directive 67/548 as reprotoxic in category 3 for both fertility and development. In the case of borax decahydrate and anhydrous disodium tetraborate, the CL Working Group recommended classification under Directive 67/548 as toxic for reproduction in category 3.

38 At the request of the Commission's Directorate-General for the Environment, the European Chemicals Bureau called a meeting of specialised experts in order to reconsider the classification of borates under Directive 67/548 with reference to reprotoxicity. At its meeting of 5 and 6 October 2004, the Commission's working group of specialised experts on reprotoxicity ('the Working Group of Specialised Experts') considered various borate substances, including borax pentahydrate, boric oxide, boric acid, borax decahydrate and anhydrous disodium tetraborate, and concluded that they should be classified under Directive 67/548 as reprotoxic in category 2 on the basis of animal studies (document ECBI/132/04 Rev. 2).

39 A meeting took place on 4 April 2005 between the Turkish authorities, Etimine and the Commission, at which the Turkish authorities opposed the proposed classification of the borate substances at issue in the main proceedings as toxic for reproduction in

category 2. In support of their position, the Turkish authorities sent the Directorate-General for the Environment by letter of 18 May 2005 a technical note prepared by Turkish toxicologists, which had been presented orally at the meeting of 4 April 2005, and a report entitled 'Position statement paper of the Turkish Society of Toxicology on the Reproductive Toxicity Category of the Boric Acid and Borates'.

40 By letter to the Directorate-General for the Environment of 8 April 2005, Etimine contested the conclusions of the Working Group of Specialised Experts and asked the Commission to disregard those conclusions.

41 At its meeting of 8 September 2005, the Technical Committee on Classification and Labelling of Dangerous Substances ('the TCCL'), with the participation of representatives of the Turkish authorities, Eti Mine Works General Management and Turkish toxicologists, further discussed the proposed classification under Directive 67/548 of the borate substances at issue in the main proceedings, and decided to follow the opinion of the Working Group of Specialised Experts and to recommend that those substances be classified as reprotoxic in category 2 (document ECBI/43/05 Rev. 1).

42 By letter of 30 September 2005, the Turkish authorities asked the Commission to postpone the decision on the classification under Directive 67/548 of the borate substances at issue in the main proceedings until inter alia several studies being carried out in this regard were completed.

43 By letter to the Directorate-General for the Environment of 17 October 2005, Etimine repeated its request that the borate substances at issue in the main proceedings not be classified as toxic for reproduction in category 2 under the 30th adaptation of Directive 67/548 to technical progress.

44 By letter of 18 November 2005, the Directorate-General for the Environment stated that it had taken due account of Etimine's comments, and replied to certain points raised by Etimine in its letter of 8 April 2005.

45 By letter of 6 February 2006 to the Commission, the Turkish authorities expressed their disagreement with the classification proposed for the borate substances at issue in the main proceedings under Directive 67/548.

46 On 16 February 2007, in response to the recommendation of the CL Working Group and the TCCL, the Committee on Adaptation to Technical Progress ('the ATP Committee') gave an opinion in favour of the proposal for the 30th ATP Directive as a whole (document JM/30ATP/09/2006).

47 After a procedure within the framework of the World Trade Organisation (WTO) where the draft proposal encountered opposition from certain non-member States which produce borates, the Commission, taking the view that that procedure had brought no fresh information to light, adopted the 30th ATP Directive on 21 August 2008. The Member States were required to transpose that directive into national law by 1 June 2009 at the latest.

48 Annex I to Directive 67/548 was repealed on the entry into force of the CLP Regulation on 20 January 2009 and was replaced by Annex VI to the latter, which as at that date contained only the classifications in Annex I to Directive 67/548 as last amended by Directive 2004/73.

49 The content of the 30th ATP Directive was added to Annex VI to the CLP Regulation by the 1st ATP Regulation. The 1st ATP Regulation was adopted on 10 August 2009 on the basis of Article 53 of the CLP Regulation following a proposal of approval adopted unanimously by the ATP Committee on 25 March 2009, and it entered into force on 25 September 2009.

The main proceedings and the questions referred for a preliminary ruling

50 The claimant in the main proceedings, Etimine, a company incorporated under Luxembourg law, is the exclusive sales agent and distributor in the United Kingdom of the borate substances which are produced by its parent company, Eti Mine Works General Management. The latter is wholly owned by the Turkish State and has the exclusive right to mine boron in Turkey.

51 The intervener, Borax Europe Limited ('Borax'), is a company incorporated under the law of England and Wales. It is wholly owned by Rio Tinto plc. Its fellow subsidiary company, U.S. Borax Inc., has borate mining operations in California and Argentina which currently meet almost half of the global demand for borates. Borax carries out the sales and distribution in Europe of U.S. Borax Inc.'s borate substances, those sales accounting for around one third of U.S. Borax Inc.'s global sales.

52 The defendant in the main proceedings, the Secretary of State for Work and Pensions, is the minister in the United Kingdom who has responsibility for the classification of chemical substances.

53 On 19 December 2008, Etimine brought an action against the Secretary of State for Work and Pensions before the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), for judicial review of any measures of the United Kingdom Government to implement the classifications made by the 30th ATP Directive and the 1st ATP Regulation.

54 Etimine contests the validity of the classification in five entries in Annex 1G to the 30th ATP Directive, which were reproduced in Annexes II and V to the 1st ATP Regulation. These entries, which classify certain borate substances as toxic for reproduction in category 2, are the following, namely 005-007-00-2 (boric acid), 005-008-00-8 (diboron trioxide; boric oxide), 005-011-00-4 (disodium tetraborate, anhydrous; boric acid, disodium salt; tetraboron disodium heptaoxide, hydrate; orthoboric acid, sodium salt), 005-011-01-1 (disodium tetraborate decahydrate; borax decahydrate) and 005-011-02-9 (disodium tetraborate pentahydrate; borax pentahydrate) ('the classifications at issue').

55 It is in those circumstances that the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Are the challenged borate classifications in [the 30th ATP Directive] and/or [the 1st ATP Regulation] invalid on one [or] more of the following grounds:

(i) The classifications were included in the 30th ATP [Directive] in breach of essential procedural requirements?

(ii) The classifications were included in the 30th ATP [Directive] in breach of Directive 67/548 … and/or as a result of manifest errors of assessment, in that:

(a) The Commission did not apply or failed properly to apply the "normal handling and use" principle contained in Annex VI to [Directive 67/548]?

(b) There was an unlawful application of risk assessment criteria?

(c) The Commission failed to apply or misapplied the "appropriateness" criterion in breach of [section] 4.2.3.3 of Annex VI to [Directive 67/548]?

(d) The Commission failed to have proper regard to the need for epidemiological/human data? and/or

(e) The Commission unlawfully extrapolated data relating to one of the borate substances for the purposes of classifying the other borate substances and/or gave inadequate reasoning for that extrapolation contrary to Article 253 EC?

(iii) The classifications were included in the 30th ATP [Directive] in breach of the fundamental Community law principle of proportionality?

(2) Are the challenged borate classifications in the 1st ATP [Regulation] invalid, in that:

(i) The 1st ATP [Regulation] was wrongly adopted using the procedure set out in Article 53 [of the CLP Regulation] as its legal basis?

(ii) The criteria for a new harmonised classification under Annex I to [the CLP Regulation] were not applied, and instead Annex VII to the CLP Regulation was wrongly applied?'

Consideration of the questions referred

Admissibility of Question 1

56 In its written observations, the Commission requested that the first question referred for a preliminary ruling be declared inadmissible in so far as it relates to the validity of the 30th ATP Directive, which in its view was repealed when the CLP Regulation entered into force on 20 January 2009. However, at the hearing it withdrew this objection of inadmissibility, taking the view that, in any event, the classifications inserted into Annex VI to the CLP Regulation, by means of the 1st ATP Regulation, merely reproduce the classifications already made in the 30th ATP Directive on the basis of the scientific recommendations put forward by a number of committees of experts within the framework of Directive 67/548.

57 Since there is no reason for the Court to raise other grounds of inadmissibility, it has the task of ruling on the questions referred.

Question 1

58 By its first question, the national court asks the Court whether the classification by the 30th ATP Directive and the 1st ATP Regulation of the borate substances at issue in the main proceedings as reprotoxic substances in category 2 is invalid in that it infringes essential procedural requirements and the principle of proportionality and in that it is vitiated by manifest errors of assessment or a failure to state reasons.

Introductory observations

59 First of all, it should be pointed out that in this complex technical and legal context, which in essence is in a state of flux, Directive 67/548 gives the Commission, in respect of the substance of the assessment, a broad discretion as to the scope of the measures to be taken to adapt the annexes to that directive to technical progress (Case C-425/08 *Enviro Tech (Europe)* [2009] ECR I-10035, paragraph 46).

60 In accordance with settled case-law, where the European Union 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 European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the institutions on which alone the EC Treaty has placed that task (*Enviro Tech (Europe)*, paragraph 47).

Infringement of essential procedural requirements

61 First of all, the national court asks the Court whether the Commission observed the essential procedural requirements referred to in Article 29 of Directive 67/548, read in conjunction with Article 5 of Decision 1999/468.

62 Etimine and Borax submit that, when the proposal for the 30th ATP Directive was considered at the meeting of the ATP Committee on 16 February 2007, the representatives of seven Member States took the view that the borate substances at issue in the main proceedings should be classified as reprotoxic in category 3 rather than category 2.

63 According to those undertakings, since Article 5 of Decision 1999/468 provides that the ATP Committee's opinion must be given by a qualified majority within the meaning of Article 205(2) EC, the ATP Committee should have given an opinion against classification of the borate substances at issue in the main proceedings as substances in category 2. Despite the disagreement, the ATP Committee was asked to give a single opinion on all the classifications proposed within the framework of the 30th ATP Directive (including for the borate substances at issue in the main proceedings) and it

was in this context that the ATP Committee gave a positive opinion by the qualified majority (with one absence and two abstentions) necessary under Article 5 of Decision 1999/468.

64 However, neither Article 29 of Directive 67/548 nor Article 5 of Decision 1999/468 provides that the ATP Committee is obliged to adopt a separate opinion for each classification proposed in the draft measures.

65 Nor, as the Advocate General has observed in point 61 of his Opinion, is there any such requirement under the ATP Committee's Rules of Procedure, in particular under Article 5(2), which does not authorise the members of the ATP Committee to demand a separate vote in circumstances such as those at issue in the main proceedings, even though they are able to demand that the discussion be extended.

66 If the representatives of the seven Member States that had expressed a reservation concerning the classification of the borate substances at issue in the main proceedings as reprotoxic in category 2 had maintained their position, they could, by their vote, have had the entire proposal rejected. However, they did not do so and the proposal was approved.

67 Consequently, it must be found that the Commission did not infringe the essential procedural requirements referred to in Article 29 of Directive 67/548, read in conjunction with Article 5 of Decision 1999/468.

Manifest errors of assessment and failure to state reasons

68 The national court seeks to ascertain next whether, in the context of assessment of the intrinsic properties of the borate substances at issue in the main proceedings, the classifications at issue were adopted following manifest errors of assessment by the Commission relating in particular to five aspects, namely, failure to keep to the normal conditions of handling or use of the substances, risk assessment instead of hazard assessment, the appropriateness of the substances' route of administration when assessing the results of animal testing, the lack of epidemiological data and application of the read-across method, or were adopted in breach of the obligation to state reasons.

— Assessment of the risks during normal handling or use of the substances

69 The national court seeks to ascertain whether the Commission applied properly the 'normal handling and use' principle set out in sections 1.1 and 1.4 of Annex VI to Directive 67/548 in so far as it based its analysis on data collected following oral administration of the borate substances at issue in the main proceedings.

70 Etimine complains that the Commission classified the borate substances at issue in the main proceedings on the basis of their effects when ingested by animals. In Etimine's submission, normal handling and use of those substances involve a potential exposure to their inhalation and perhaps to dermal penetration, but do not involve any risk

of exposure by ingestion. Thus, it contends that there are no normal circumstances in which the substances would be ingested.

71 In this regard, although neither Directive 67/548 nor the CLP Regulation or the REACH Regulation defines 'normal handling or use', it must be accepted, as the Commission has maintained, that this concept includes all handling and uses occurring in normal circumstances, which encompasses, in particular, the need to take account of realistic and foreseeable accidents, as when children ingest certain quantities of substances that are not intended for consumption orally.

72 In any event, it should, first, be recalled that, in defining substances and preparations which are toxic for reproduction, Article 2(2)(n) of Directive 67/548 also mentions the route of oral administration (by ingestion) alongside inhalation and dermal penetration as a possible route of administration of the toxic substances.

73 Second, it must be stated, as the Advocate General has observed in point 79 et seq. of his Opinion, that the criticism advanced by the claimant in the main proceedings rests, essentially, on confusion between assessment of the hazards and that of the risks presented by a substance.

74 As is apparent, in particular, from Article 4 of Directive 67/548, read in conjunction with Articles 2 to 5 of Directive 93/67, the classification and labelling of substances established by Directive 67/548 are based on the transmission of information on the hazards linked to the substances' intrinsic properties. Hazard assessment constitutes the first stage of the process of risk assessment, which is a more specific concept. This

distinction between hazards and risks was moreover maintained in the CLP Regulation and in the REACH Regulation.

75 Thus, an assessment of the hazards linked to the substances' intrinsic properties must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used, the route by which contact with the substance might arise (by ingestion, by inhalation or by dermal penetration) and the possible levels of exposure to the substance.

76 In light of those considerations, it must be found that the Commission did not commit a manifest error of assessment in basing its assessment of the intrinsic properties of the borate substances at issue in the main proceedings on the results of animal testing in which those substances had been administered orally.

— Risk assessment instead of hazard assessment

77 Etimine submits that, despite the fact that Directive 67/548 and any measures adapting it to technical progress are governed by the principle of hazard assessment and not risk assessment, the Commission applied the principles of risk assessment that are laid down by Regulation No 1488/94. This is said to be apparent from point 1.1.5 of the explanatory memorandum to the proposal for the 30th ATP Directive which mentions on several occasions the concept of risks and that of risk identification, as resulting from that regulation.

78 It should be pointed out that, as has been asserted by the United Kingdom, Danish and French Governments, it was the representatives of the industry concerned who sought, in the numerous discussions which preceded the adoption of the 30th ATP Directive, to show by means of risk-based arguments that unfeasibly high levels of exposure would be required for a person to receive a dose liable to cause adverse effects on reproduction.

79 Thus, whilst it is true that the Commission had recourse to risk assessment in point 1.1.5 of the explanatory memorandum, it did so with the aim of responding to the arguments of the representatives of the industry in question concerning failure to observe the principle as to the normal handling and use of substances.

80 Furthermore, having regard to the broad discretion which the system of assessment under Directive 67/548 grants to the Commission, that system does not preclude recourse to risk assessment to confirm the merits of a classification proposal founded on study of the substances' intrinsic properties.

81 Finally, in light of the entire explanatory memorandum to the proposal for the 30th ATP Directive, the reference made to risk assessment by point 1.1.5 alone cannot affect the basis for the assessment of the intrinsic properties of the borate substances at issue in the main proceedings, which rests as a whole on the assessment of the hazards of those substances.

82 Consequently, it is not apparent from point 1.1.5 of the explanatory memorandum to the proposal for the 30th ATP Directive, to which the claimant in the main proceedings refers, that the Commission committed a manifest error of assessment in mentioning there elements of risk assessment that are provided for by Regulation No 1488/94.

— Appropriateness of the substances' route of administration when assessing the results of animal testing

83 The national court asks the Court whether the Commission misapplied the 'appropriateness' criterion in breach of section 4.2.3.3 of Annex VI to Directive 67/548.

84 Etimine contends that the 'appropriateness' criterion under section 4.2.3.3 of Annex VI to Directive 67/548 is not whether a route of administration is one of the three routes referred to in Article 2(2)(n) of the directive (inhalation, ingestion or dermal penetration), but whether the route of administration by which the animal data were obtained is appropriate for humans. For that reason, the Commission should have classified the borate substances at issue in the main proceedings as reprotoxic in category 3 and not category 2.

85 In this regard, it should be pointed out that, in point 1.1.4 of the explanatory memorandum to the proposal for the 30th ATP Directive, the Commission, after indicating that the animal testing had been conducted using an oral route of administration, stated that this route was an appropriate route of administration in accordance with Article 2(2)(n) of Directive 67/548.

86 It necessarily follows that the Commission considered the question of the appropriateness of the route of administration as referred to in section 4.2.3.3 of Annex VI to Directive 67/548 when assessing the intrinsic properties of the borate substances at issue in the main proceedings.

87 Furthermore, with regard to the appropriateness of the oral route of administration on the basis of which the results of the animal testing were gathered, there are no grounds for the conclusion that the Commission committed a manifest error of assessment.

— Lack of sufficient epidemiological data

88 The national court asks the Court whether the Commission accorded sufficient importance to epidemiological or human data.

89 The claimant in the main proceedings submits that the Commission wrongly started from the presumption that the results obtained from animals could be extrapolated to man, before examining the human data, whereas it should have approached the human data without any presumption.

90 It is apparent, however, from document ECBI/132/04 Rev. 2 containing the minutes of the meeting of the Working Group of Specialised Experts on 5 and 6 October 2004 and from point 1.1.4 of the explanatory memorandum to the proposal for the 30th ATP Directive, headed 'Human Data and Toxico-kinetic Information', that those experts and the Commission took the epidemiological data into consideration when classifying the borate substances at issue in the main proceedings and that they looked into the question of the relevance to man of the animal testing carried out.

91 In this context, those experts concluded that the studies already carried out in connection with the occupational exposure of miners to borates were insufficient to demonstrate that the borate substances at issue in the main proceedings had no adverse effect on human fertility.

92 Thus, the lack of sufficient epidemiological data (concerning toxic effects on human reproduction) was taken into account in the sense that the borate substances at issue in the main proceedings were not classified as reprotoxic in category 1, since relevant epidemiological data would have been necessary for classification in that category. Nevertheless, the experts took the view that the toxicokinetic data recorded for laboratory animals did not display major differences from those recorded in humans, so that extrapolation to man of the results recorded in the animal testing was possible and classification of the borate substances at issue in the main proceedings as reprotoxic in category 2 was recommended.

93 It follows that the Commission took account of the existing epidemiological data and did not manifestly exceed the limits of its discretion when assessing the intrinsic properties of the borate substances at issue in the main proceedings.

— Application of the read-across method in the context of assessment of the intrinsic properties of the borate substances at issue in the main proceedings

94 The national court asks the Court whether the Commission exceeded the limits of its discretion in applying the read-across method instead of assessing the intrinsic properties of the borate substances at issue in the main proceedings with the aid of the criteria and data requirements set out in Annex VI to Directive 67/548.

95 Etimine complains that the Commission did not analyse the intrinsic properties of the borate substances at issue in the main proceedings as required in Article 4 of Directive 67/548 and section 1.1 of Annex VI to that directive. It also complains that the Commission applied the read-across method in order to classify those substances despite the lack of data concerning them.

96 The read-across method is one of the valid assessment methods provided for in point 1.1.1.3 of Annex I to the CLP Regulation. It is also described in section 1.5 of Annex XI to the REACH Regulation as a method under which the properties of certain substances may be predicted from existing data relating to reference substances which are structurally similar to them. It avoids the need to test every substance for every endpoint and may, consequently, be used where there are no data concerning the substances subject to risk assessment.

97 Whilst that method is expressly provided for under the REACH Regulation and under the CLP Regulation, it is not mentioned as such in Annex VI to Directive 67/548.

98 The list of sources from which the data required for classification of the borate substances at issue in the main proceedings may be extracted, which is set out in section 1.6.1(b) of Annex VI to Directive 67/548, is merely illustrative, as is apparent from the words 'for example'.

99 Section 1.6.1(b) of Annex VI provides, however, that the results of validated structure-activity relationships and expert judgment may be taken into account when assessing chemical substances.

100 The assessment of substances on the basis of structure-activity relationships is thus, like the read-across method, one of the methods of assessment based on the category approach and represents a process for predicting the activity of a substance from a quantitative assessment of its molecular structure which is similar to that of another substance or of another group of substances whose effects are well-known.

101 Annex VI to Directive 67/548 makes express reference to Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1), under which the read-across method and the method based on structure-activity relationships are encouraged.

102 Also, in 2007, the Joint Research Centre of the Commission published an extensive study relating to the use of read-across within the framework of Directive 67/548 ('A Compendium of Case Studies that helped to shape the REACH Guidance on Chemical Categories and Read Across'). The examples analysed by that study include the classifications of the borate substances at issue in the main proceedings.

103 Thus, whilst it is true that, as the Advocate General has noted in points 121 and 122 of his Opinion, the method based on structure-activity relationships displays certain differences from the read-across method, the fact remains that those two methods are not to be regarded as independent since they are both founded on the principle of extrapolation from existing data on certain substances in order to assess and classify other substances which have a similar structure and on which there are very limited or no data.

104 Furthermore, the read-across method, as a method for assessing substances that is widely recognised by the scientific community, has been used on many occasions when classifying substances in the context of Annex I to Directive 67/548, if only since the entry into force of Commission Directive 91/632/EEC of 28 October 1991 adapting to technical progress for the 15th time Directive 67/548 (OJ 1991 L 338, p. 23).

105 As regards the scientific arguments underlying the classifications at issue, it is apparent from the minutes of the meetings of the CL Working Group, the TCCL and the ATP Committee that the experts agree that the borate substances at issue in the main proceedings have very similar properties. Furthermore, those minutes often contain concomitant use of the terms 'boric acid' and 'borates'.

106 Moreover, in a report on boron, drawn up in 1998 as part of the International Programme on Chemical Safety established jointly by the World Health Organisation, the International Labour Organisation and the United Nations Environment Programme, the experts stated that the chemical and toxicological properties of borax pentahydrate, borax, boric acid, and other borates are expected to be similar on a mol boron/litre equivalent basis when dissolved in water or biological fluids at the same pH and low concentration. They add that boric oxide will exhibit properties identical to those of boric acid, as it is an anhydride that will hydrolyse to give boric acid.

107 The current classification of the borate substances at issue in the main proceedings was therefore decided upon on the basis of the known data relating to borate compounds in the same group.

108 Moreover, the REACH Regulation recognises, in Article 13, the importance of the use of alternative methods, such as the read-across method, in order to evaluate the human toxicity of chemicals by means other than vertebrate animal tests.

109 Finally, it is to be noted that application of the read-across method and the assessment which was made of the physicochemical properties of the borate substances at issue in the main proceedings were the result of a consensus reached at the end of a process that lasted several years by numerous experts sitting on several scientific committees in the presence of representatives of the industry concerned.

110 It follows from the foregoing that, in relying on the judgment of experts who had recourse in particular to the read-across method in order to assess the intrinsic properties of the borate substances at issue in the main proceedings, the Commission did not manifestly exceed the limits of the discretion which it has in this regard.

— Failure to state reasons for the 30th ATP Directive

111 The national court asks the Court whether the 30th ATP Directive is vitiated by a failure to state reasons, in breach of Article 253 EC.

112 Etimine considers that the Commission did not set out the reasons justifying use of the read-across method to extrapolate the data relating to boric acid for the purpose of classifying the other borate substances at issue in the main proceedings.

113 Whilst it is true that the Court has held, first, that the statement of reasons for a European Union measure must appear in that measure and, second, that it must be adopted by the author of the measure (see Case C-378/00 *Commission* v *Parliament and Council* [2003] ECR I-937, paragraph 66 and the case-law cited), the fact remains that the degree of reasoning required varies.

114 Thus, the Court has previously held that the requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations (Case C-333/07 *Régie Networks* [2008] ECR I-10807, paragraph 63 and the case-law cited).

115 It is also clear from settled case-law that the scope of the obligation to state reasons depends on the nature of the measure in question and that, in the case of measures of general application, the statement of reasons may be confined to indicating the general situation which led to the adoption of the measure and the general objectives which it is intended to achieve. In that context, the Court has repeatedly ruled that if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made (see, to this effect, Case C-221/09 *AJD Tuna* [2011] ECR I-1655, paragraph 59 and the case-law cited).

116 Furthermore, as the Advocate General has observed in point 135 of his Opinion, where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed, since they acquire information through their involvement.

117 It is apparent that the contested measure complies with those rules.

118 The 30th ATP Directive is a measure of general application, whose preamble states that the measures provided for in the directive are in accordance with the opinion of the ATP Committee and announces that the pertinent list of substances needs to be updated to include further notified new substances and further existing substances, as well as to adapt certain entries to technical progress.

119 Also, it is undisputed that the 30th ATP Directive falls within a complex technical and legal context which in essence is in a state of flux, making it difficult to state detailed and individual reasons for the classifications made, and the statement of reasons contained in the directive is therefore sufficient in view of the nature of that measure.

120 Finally, it is not disputed that the representatives of the industry concerned were involved in the process for drawing up the directive. Furthermore, the scientific reasoning and the data which substantiated the classifications at issue appeared in a number of documents and of sets of minutes of meetings of experts which were disclosed to the public before the 30th ATP Directive was adopted.

121 Accordingly, it is to be concluded, in this context, that the 30th ATP Directive is not vitiated by a failure to state reasons contrary to Article 253 EC.

Infringement of the principle of proportionality

122 The national court asks the Court whether the Commission observed the principle of proportionality when adopting the classifications at issue.

123 Etimine contends that, pending receipt of the further epidemiological data, the Commission should either have proposed no classification or proposed classification in category 3.

124 It is to be recalled first of all that, according to settled case-law, the principle of proportionality, which is one of the general principles of Community law, requires that measures adopted by Community institutions 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 Case C-343/09 *Afton Chemical* [2010] ECR I-7027, paragraph 45 and the case-law cited).

125 With regard to judicial review of the conditions referred to in the previous paragraph, in so far as adoption by the Commission of a directive or a regulation entails political, economic and social choices on its part, in which it is called upon to undertake complex assessments, it must be stated that the Commission has a broad discretion in that respect, so that judicial review of the legality of those acts is necessarily limited. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the Commission is seeking to pursue (see, to this effect, *Afton Chemical*, paragraph 46 and the case-law cited).

126 In that regard, it is to be noted at the outset that, as the Court has already stated in *Enviro Tech (Europe)*, paragraph 46, classification measures under Directive 67/548 are adopted within a complex technical and legal framework and in essence are liable to evolve. In this context, classifications adopted by adaptations to technical progress, such as the 30th ATP Directive and the 1st ATP Regulation, are based on scientific and technical knowledge as it stands at a given moment, which subsequent matters are liable to affect.

127 Here, in this complex framework that is in a state of flux, the Commission decided to adopt the classifications at issue at the end of a procedure covering the period from 1999 to 2008 and after numerous discussions by several committees of experts, in which the representatives of the industry concerned participated.

128 Accordingly, an argument which is intended to demonstrate that the principle of proportionality requires such measures to be postponed for the sole reason that studies liable to call into question the classifications adopted are ongoing cannot be upheld.

129 Moreover, observance of the precautionary principle applicable in the sensitive field of protection of human health and of the environment, as is apparent from Article 95(3) EC read in conjunction with Article 174(1) and (2) EC, likewise means that such an argument lacks any merit.

130 In view of these factors, it has not been established that the principle of proportionality was infringed when the borate substances at issue in the main proceedings were classified as reprotoxic in category 2.

131 In light of all the foregoing considerations, it must be held that examination of the first question has disclosed no factor of such a kind as to affect the validity of the 30th ATP Directive and, consequently, that of the 1st ATP Regulation, in so far as they classified the borate substances at issue in the main proceedings as reprotoxic in category 2.

Question 2

132 By its second question, the national court raises with the Court the validity of the first ATP Regulation, which incorporates into Tables 3.1 and 3.2 in Part 3 of Annex VI to the CLP Regulation the amendments which were made to Annex I to Directive 67/548 by the 30th ATP Directive.

133 The national court asks, more specifically, first, whether the choice of legal basis for the 1st ATP Regulation is sound and, second, whether the classifications set out in Table 3.1 in Part 3 of Annex VI to the CLP Regulation are lawful.

Choice of legal basis for the 1st ATP Regulation

134 The national court seeks to ascertain whether the validity of the 1st ATP Regulation is affected by the fact that, in adopting it, the Commission had recourse to Article 53, rather than Article 37, of the CLP Regulation as its legal basis.

135 The claimant in the main proceedings complains that the Commission used the procedure for adaptation to technical progress that is provided for in Article 53 of the CLP Regulation, inasmuch as it chose an almost automatic method for adaptation of that regulation to technical progress without passing through the procedure, provided for in Article 37 of that regulation, for complex and detailed assessment of the intrinsic properties of the substances at issue in the main proceedings.

136 As regards this first criticism, Article 37 forms part of Chapter 1 of Title V of the CLP Regulation, a chapter which is headed 'Establishing harmonised classification and labelling of substances'.

137 The use of the word 'establishing' in this context indicates that the procedure provided for in Article 37 of the CLP Regulation should be used only when adopting new classifications. On the other hand, under the procedure provided for in Article 53 of the CLP Regulation, 'the Commission may adjust and adapt … Annexes I to VII [to that regulation] to technical and scientific progress'.

138 In the present instance, the 1st ATP Regulation merely incorporates into the CLP Regulation the classifications at issue, which had already been adopted on the basis of criteria and principles laid down within the framework of Directive 67/548.

139 It follows that Article 53 of the CLP Regulation could legitimately constitute the legal basis for adopting the 1st ATP Regulation.

Legality of the classifications set out in Table 3.1 in Part 3 of Annex VI to the CLP Regulation

140 The national court asks the Court whether, in adopting the classifications at issue in Table 3.1 in Part 3 of Annex VI to the CLP Regulation, the Commission erred by using the translation table in Annex VII to that regulation rather than considering the criteria in Annex I thereto.

141 According to the claimant in the main proceedings, the Commission should have taken up again the process of assessing the intrinsic properties of the borate substances at issue in the main proceedings by applying the criteria set out in Annex I to the CLP Regulation.

142 As has been stated in paragraph 138 of the present judgment, a repetition of that assessment process was not necessary in view of the fact that the 1st ATP Regulation merely incorporates into the CLP Regulation the same classifications as those which had undergone the complex assessment procedure applicable within the framework of Directive 67/548.

143 As regards the translation table in Annex VII to the CLP Regulation, it is to be recalled that, as provided in Article 61(3) of that regulation, all substances must be classified in both the old and the new system until 1 June 2015. It follows that all the classifications established under Directive 67/548 must be translated, with the aid of the translation table set out in Annex VII, into the corresponding classifications under the CLP Regulation.

144 Accordingly, the Commission was right in deciding to incorporate the classifications at issue into Table 3.1 in Part 3 of Annex VI to the CLP Regulation with the aid of the translation table contained in Annex VII to that regulation.

145 In light of all the foregoing considerations, it must be held that examination of the second question has disclosed no factor of such a kind as to affect the validity of the 1st ATP Regulation, in so far as that regulation classified the borate substances at issue in the main proceedings as reprotoxic in category 2.

Costs

146 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 (Fourth Chamber) hereby rules:

Examination of the questions referred for a preliminary ruling has disclosed no factor of such a kind as to affect the validity, first, of Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th 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 and, second, of Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for

the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, in so far as that directive and that regulation classified certain borate substances as reprotoxic in category 2.

[Signatures]