ORDER OF THE GENERAL COURT (Grand Chamber)

7 September 2010 *

In Case T-539/08,

Etimine SA, established in Bettembourg (Luxembourg),

Ab Etiproducts Oy, established in Espoo (Finland),

represented by C. Mereu and K. Van Maldegem, lawyers,

applicants,

supported by

* Language of the case: English.

Borax Europe Ltd, established in London (United Kingdom), represented by K. Nordlander, lawyer, and S. Kinsella, Solicitor,

intervener,

v

European Commission, represented by P. Oliver and D. Kukovec, acting as Agents,

defendant,

supported by

Kingdom of Denmark, represented by B. Weis Fogh, acting as Agent,

intervener,

APPLICATION for the partial annulment 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 (OJ 2008 L 246, p. 1) and 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 (OJ 2009 L 235, p. 1), in so far as they amend the classification of certain borates,

THE GENERAL COURT (Grand Chamber),

composed of M. Jaeger, President, J. Azizi (Rapporteur), A.W.H. Meij, M. Vilaras, N.J. Forwood, M.E. Martins Ribeiro, O. Czúcz, I. Wiszniewska-Białecka, I. Pelikánová, E. Cremona, I. Labucka, S. Frimodt Nielsen and K. O'Higgins, Judges,

Registrar: E. Coulon,

makes the following

Order

1 By this action the applicants Etimine SA ('Etimine') and Ab Etiproducts Oy ('Etiproducts') challenge the lawfulness of the classification of certain borates as dangerous

substances ('the contested classifications'), which appeared first in 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) and then in 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).

2 The contested classifications were introduced 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 contested directive') and were repeated with effect from 25 September 2009 in 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 contested regulation') (referred to together as 'the contested acts').

Legal context

Provisions of the EC and FEU Treaties

3 In accordance with the fourth paragraph of Article 230 EC:

'Any natural or legal person may, under the same conditions, institute proceedings against a decision addressed to that person or against a decision which, although in

the form of a regulation or a decision addressed to another person, is of direct and individual concern to the former.'

4 In accordance with the fourth paragraph of Article 263 TFEU:

'Any natural or legal person may, under the conditions laid down in the first and second paragraphs, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.'

Directive 67/548

5 Directive 67/548, as amended inter alia by Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548 (OJ 1992 L 154, p. 1) and by Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Directive 67/548 in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (OJ 2006 L 396, p. 850), lays down rules on the marketing of certain 'substances', defined as 'chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.

6 For that purpose Directive 67/548, in accordance with Article 4(1), classifies substances on the basis of their intrinsic properties according to the categories laid down in Article 2(2). Classification of a substance as 'dangerous' in Annex I to that directive means that, as a condition prior to its being placed on the market, its packaging must be provided with mandatory labelling including in particular symbols for the dangers arising from use of the substance and standard phrases indicating the special risks arising from the dangers involved in using the substance and relating to the safe use of the substance.

7 Under Article 4(3) of Directive 67/548, in the version in force before that resulting from Article 55(2) of Regulation No 1272/2008:

'Annex I … contains the list of substances classified in accordance with the principles outlined in paragraphs 1 and 2, together with their harmonised classification and labelling. The decision to place a substance in Annex I together with the harmonised classification and labelling shall be taken in accordance with the procedure laid down in Article 29 [of that directive].'

8 Article 4(2) of Directive 67/548 provides that '[t]he general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI … save where contrary requirements for dangerous preparations are specified in separate Directives.'

9 Point 1.2 of Annex VI to Directive 67/548 states:

'This Annex sets out the general principles governing the classification and labelling of substances and preparations referred to in Article 4 of this Directive …

It is addressed to all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations.'

10 Point 4.1.2 of Annex VI to Directive 67/548 provides:

'If a manufacturer, distributor or importer has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in section 4.2.1, 4.2.2 or 4.2.3, he shall provisionally label the substance in accordance with these criteria, on the basis of the assessment of the evidence by a competent person.'

11 Under point 4.1.3 of Annex VI to Directive 67/548, '[t]he manufacturer, distributor or importer shall submit as soon as possible a document summarising all relevant information to one Member State in which the substance is placed on the market …'.

12 Point 4.1.4 of Annex VI to Directive 67/548 provides:

'Furthermore, a manufacturer, distributor or importer who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria given in section 4.2.1, 4.2.2 or 4.2.3 shall submit this data as soon as possible to one Member State in which the substance is placed on the market.'

13 Point 4.1.5 of Annex VI to Directive 67/548 reads:

'To obtain as quickly as possible a harmonised classification for the Community by the procedure defined in Article 28 of this Directive, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information, together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

…'

Procedure for adapting Directive 67/548 to technical progress

14 Under Article 28 of Directive 67/548, the amendments necessary for adapting the annexes to technical progress are to be adopted in accordance with the procedure laid down in Article 29 of the directive. In the context of that procedure, under Article 5(1) 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) in conjunction with point 1 of Annex III to Council Regulation (EC) No 807/2003 of 14 April 2003 adapting to Decision 1999/468 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 (unanimity) (OJ 2003 L 122, p. 36), the European Commission is to be assisted by a committee composed of representatives of the Member States and chaired by a representative of the Commission. Under Article 5(3) of that decision, the Commission is to adopt the measures envisaged if they are in accordance with the opinion of the committee. Article 5(4) of the decision provides, on the other hand, that if the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the matter is to be submitted to the Council of the European Union and the European Parliament informed.

Partial repeal, amendment and replacement of Directive 67/548 by Regulation No 1272/2008

15 With effect from 20 January 2009, Directive 67/548 was partially repealed, amended and replaced by Regulation No 1272/2008. That regulation is intended in particular to implement the Globally Harmonised System of Classification and Labelling of Chemicals developed within the United Nations (recitals 5 to 8 in the preamble to Regulation No 1272/2008).

16 Even though Article 55(11) of Regulation No 1272/2008 provides that 'Annex I [to Directive 67/548] shall be deleted', Annex VI to that regulation did not, at the time of its entry into force, contain the contested classifications, the procedure for the adoption of which had been considerably delayed, but only the classifications introduced in connection with the earlier adaptations of Directive 67/548 to technical progress, including those prescribed 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, corrigendum OJ 2004 L 216, p. 3).

17 In this respect, recital 53 in the preamble to Regulation No 1272/2008 states as follows:

'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] Directive 67/548 …, all existing harmonised classifications should be converted into new harmonised classifications using the new criteria. Moreover, as the applicability of this Regulation is deferred and the harmonised classifications in accordance with the criteria of Directive 67/548 … are relevant for the classification of substances and mixtures during the ensuing transition period, all existing harmonised classifications should also be placed unchanged in an annex to this Regulation. By subjecting all future harmonisations of classifications to this Regulation, inconsistencies in harmonised classifications of the same substance under the existing and the new criteria should be avoided.'

18 Article 36 of Regulation No 1272/2008, 'Harmonisation of classification and labelling of substances', provides inter alia:

'1. A substance that fulfils the criteria set out in Annex I for the following shall normally be subject to harmonised classification and labelling in accordance with Article 37:

(a) respiratory sensitisation, category 1 (Annex I, section 3.4);

(b) germ cell mutagenicity, category 1A, 1B or 2 (Annex I, section 3.5);

(c) carcinogenicity, category 1A, 1B or 2 (Annex I, section 3.6);

(d) reproductive toxicity, category 1A, 1B or 2 (Annex I, section 3.7).

...'

19 Under Article 37 of Regulation No 1272/2008, 'Procedure for harmonisation of classification and labelling of substances':

'1. A competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof.

…

2. A manufacturer, importer or downstream user of a substance may submit to the Agency a proposal for harmonised classification and labelling of that substance and, where appropriate, specific concentration limits or M-factors, provided that there is no entry in Part 3 of Annex VI for such a substance in relation to the hazard class or differentiation covered by that proposal.

…

4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission.

5. Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay, submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, where appropriate, the specific concentration limits or M-factors.

A corresponding entry shall be included in Table 3.2 of Part 3 of Annex VI subject to the same conditions, until 31 May 2015.

That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3). …

6. Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal … to the competent authority in one of the Member States in which the substance is placed on the market.'

20 Under Article 53 of Regulation No 1272/2008, 'Adaptations to technical and scientific progress':

'1. The Commission may adjust and adapt … Annexes I to VII to technical and scientific progress, including taking due account of the further development of the [Globally Harmonised System of Classification and Labelling of Chemicals] … Those measures, designed to amend non-essential elements of this Regulation, shall be

adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3). …'

21 Under Article 54 of Regulation No 1272/2008, 'Committee procedure':

'1. The Commission shall be assisted by the Committee instituted by Article 133 of Regulation (EC) No 1907/2006.

…

3. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468 … shall apply, having regard to the provisions of Article 8 thereof.

…'

22 Article 5a of Decision 1999/468, as amended by Council Decision 2006/512/EC of 17 July 2006 (OJ 2006 L 200, p. 11), governs the 'regulatory procedure with scrutiny', in which, in accordance with Article 5a(1), '[t]he Commission shall be assisted by a Regulatory Procedure with Scrutiny Committee composed of the representatives of the Member States and chaired by the representative of the Commission'. Under Article 5a(3), if the measures envisaged are in accordance with the opinion of the committee, the Commission must without delay submit the draft measures for scrutiny by the European Parliament and the Council, and can adopt them only if, on expiry of a period of three months, neither the European Parliament nor the Council has opposed the draft measures. Article 5a(4) of the decision provides that, if the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission must without delay submit to the Council a

proposal relating to the measures to be taken, and forward it to the European Parliament at the same time.

Regulation (EEC) No 793/93 and Regulation (EC) No 1907/2006

23 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, provides, as stated in the fourth recital in the preamble, for a sharing and coordination of responsibilities between Member States, the Commission and industrialists concerning the evaluation of the risks of substances produced, imported and/or used by those industrialists. Articles 3 and 4 of the regulation lay down an obligation for manufacturers and importers of those substances to report certain relevant data depending on the volume of production and import.

24 In accordance with Article 8(1) of Regulation No 793/93, the Commission is to draw up lists of substances requiring a priority risk evaluation. For each of those substances, the competent authority of a Member State is to be designated as a rapporteur for the purpose of evaluating the risk to man and the environment (Article 10(1) to (3) of Regulation No 793/93).

25 Articles 9, 10(2) and 12 of Regulation No 793/93 lay down an obligation for manufacturers and importers, where appropriate, to provide further information or carry out tests to obtain any missing data that are needed for the evaluation of risks. In the circumstances provided for in Article 12(3) of the regulation, the tests may be performed by one or more manufacturers or importers acting on behalf of other manufacturers or importers concerned. In addition, under Article 9(3) of the regulation,

manufacturers and importers may request of the rapporteur, with justification being provided, that they be exempted from some or all of the additional testing on the grounds that a given piece of information is either unnecessary for risk evaluation or impossible to obtain. They may also request a longer period where circumstances so require.

26 Following its risk evaluation, the rapporteur may, where appropriate, suggest a strategy and measures for limiting the risks identified (Article 10(3) of Regulation No 793/93). On the basis of the risk evaluation and the strategy recommended by the rapporteur, the Commission is to submit a proposal concerning the results of the risk evaluation of the priority substances, and, if necessary, a recommendation for an appropriate strategy for limiting those risks, for adoption in accordance with the committee procedure referred to in Article 15 of Regulation No 793/93. On the basis of the risk evaluation and the recommended strategy thus adopted, the Commission is to decide, where necessary, to propose Community measures within the framework of Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201), as amended, or within the framework of other relevant existing Community instruments (Article 11(1) to (3) of Regulation No 793/93).

27 Regulation No 793/93 was repealed and replaced by 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 and repealing Regulation No 793/93 and Commission Regulation (EC) No 1488/94 as well as

Directive 76/769 and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, corrigendum OJ 2007 L 136, p. 3; 'the REACH regulation').

28 In accordance with Article 1(1) of the REACH regulation, the purpose of the regulation is in particular to ensure a high level of protection of human health and the environment. To that end, it lays down provisions on substances and preparations within the meaning of Article 3 which are to apply to the manufacture, placing on the market or use of such substances on their own, in preparations or in articles and to the placing on the market of preparations (Article 1(2) of the REACH regulation). According to Article 1(3), the REACH regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment, and on the precautionary principle.

29 In accordance with the 'no data, no market' principle set out in Article 5 of the REACH regulation and the obligations laid down in Articles 6 and 7, manufacturers and importers whose production or importation of the substance in question exceeds one tonne per year are required to notify and submit a registration of that substance to the European Chemicals Agency (ECHA). Pursuant to Articles 10 and 13 of the REACH regulation, they must produce a detailed technical dossier containing information on the substance in question, including its manufacture and uses, classification and intrinsic properties, which must if necessary be demonstrated by appropriate tests or the results of relevant studies.

Facts of the dispute

Applicants and substances concerned

30 One of the applicants, Etimine, is a company governed by Luxembourg law. The other applicant, Etiproducts, is a company governed by Finnish law. They import into the European Union borate substances from the boron mines of Emet, Kestelek, Bigadic and Kirka (Turkey) which are operated by their parent company Eti Mine Works General Management ('Eti Mine Works'), a company governed by Turkish law and wholly controlled by the State.

31 Etimine is the exclusive distributor of those substances in 15 Member States, namely the Kingdom of Belgium, the Czech Republic, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, the Grand Duchy of Luxembourg, the Republic of Hungary, the Kingdom of the Netherlands, the Republic of Austria, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic and the United Kingdom of Great Britain and Northern Ireland. Etiproducts is the exclusive distributor of those substances in seven other Member States, namely the Kingdom of Denmark, the Republic of Estonia, the Republic of Latvia, the Republic of Lithuania, the Republic of Poland, the Republic of Finland and the Kingdom of Sweden.

32 The Republic of Turkey has substantial reserves of boron and is the world's second largest producer of boric acid, after the United States of America. Eti Mine Works, the world's largest boron mining company, holds the exclusive operating rights for the mines listed in paragraph 30 above. Those operating rights were granted on the

basis of Articles 6 and 24 of the Turkish Law on mining, No 3213 of 15 June 1985 (*T.C. Resmi Gazete* No 18785, 15 June 1985).

33 In 2007 Etimine imported into the European Union, on the basis of an exclusive distribution contract between it and Eti Mine Works, approximately 245 500 t of borates, namely approximately 44 000 t of boric acid, 189 000 t of borax pentahydrate and 12 500 t of borax decahydrate. In the same period Etiproducts imported, on the basis of a similar distribution contract, approximately 85 700 t of borates into the European Union. Those imports represent the majority of imports of boric acid, borax decahydrate and borax pentahydrate into the European Union in 2007.

Procedure leading to the contested classifications

34 On 28 January 1999 the French Republic submitted to the Commission a proposal for classifying boric acid under Directive 67/548 as category 2 for reproductive toxicity and developmental toxicity, to which the phrases R 60 ('May impair fertility') and R 61 ('May cause harm to the unborn child') relate, that substance not having previously been covered by Annex I to Directive 67/548.

35 On 10 February 1999 the Kingdom of Denmark submitted a proposal, prepared by the Danish Environmental Protection Agency, for classifying boric acid and borax decahydrate under Directive 67/548 as category 2 for reproductive toxicity, to which

the phrase R 60 ('May impair fertility') relates, and category 3 for developmental toxicity, to which the phrase R 63 ('Possible risk of harm to the unborn child') relates.

36 At its meeting of 15 to 17 November 2000, the Commission's working group on the classification and labelling of dangerous substances at the European Chemicals Bureau ('the C&L working group') recommended that boric acid should be classified under Directive 67/548 as toxic to reproduction category 3 for both fertility and development. For borax decahydrate and anhydrous disodium tetraborate, the C&L working group recommended classification under Directive 67/548 as toxic to reproduction category 3.

37 At the request of the Commission's Directorate-General (DG) for the Environment, the European Chemicals Bureau called a meeting of specialised experts in order to reconsider the classification of the borates under Directive 67/548 with reference to reproductive toxicity. At its meeting of 5 and 6 October 2004, the Commission's working group of specialised experts on reproductive toxicity 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 toxic to reproduction category 2 on the basis of animal studies.

38 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 as toxic to reproduction category 2. In support of their position, the Turkish authorities by letter of 18 May 2005 sent the Environment DG 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'.

39 By letter to the Environment DG of 8 April 2005, Etimine objected to the conclusions of the working group of specialised experts and asked the Commission to disregard those conclusions.

40 At its meeting of 8 September 2005, the C&L working group, with the participation of representatives of the Turkish authorities, Eti Mine Works and Turkish toxicologists, further discussed the proposed classification of the borate substances under Directive 67/548, and decided to follow the opinion of the working group of specialised experts and recommend that those substances be classified as toxic to reproduction category 2.

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

42 By letter to the Environment DG of 17 October 2005, Etimine repeated its request that the borate substances should not be classified as toxic to reproduction category 2 under the 30th adaptation to technical progress of Directive 67/548.

43 By letter of 18 November 2005, the Environment DG 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.

44 By letter of 6 February 2006 to the Commission, the Turkish authorities expressed their disagreement with the proposed classification of the borate substances under Directive 67/548.

45 On 16 February 2007 the committee within the meaning of Article 29 of Directive 67/548 in conjunction with Article 5(1) of Decision 1999/468 and point 1 of Annex III to Regulation No 807/2003 (see paragraph 14 above) decided in favour of the proposal for a directive amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548, which incorporated the proposed classification of the borate substances.

46 On 21 August 2008 the Commission adopted the contested directive.

47 The contested classifications, as set out in Annex 1G to the contested directive, are essentially as follows:

'Index No	Chemical name	Classification	Labelling
…	…	…	…
005-007-00-2	boric acid; … boric acid, crude natural, containing not more than 85 per cent of H_3BO_3 calculated on the dry weight …	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45

005-008-00-8	diboron trioxide; boric oxide	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-00-4	disodium tetraborate, anhydrous; boric acid, disodium salt; … tetraboron disodium heptaoxide, hydrate; … orthoboric acid, sodium salt …	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-01-1	disodium tetraborate decahydrate; borax decahydrate	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-02-9	disodium tetraborate pentahydrate; borax pentahydrate	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
…	…	…	…’

48 On 10 August 2009 the Commission adopted the contested regulation on the basis in particular of Article 53 of Regulation No 1272/2008.

49 By the contested regulation, the contested classifications were inserted into Annex VI to Regulation No 1272/2008 with effect from 25 September 2009.

50 Recitals 1 to 3 in the preamble to the contested regulation state as follows:

'(1) Part 3 of Annex VI to Regulation … No 1272/2008 contains two lists of harmonised classification and labelling of hazardous substances. Table 3.1 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Parts 2 to 5 of Annex I to Regulation … No 1272/2008. Table 3.2 lists the harmonised classification and labelling of hazardous substances based on the criteria set out in Annex VI to … Directive 67/548 … These two lists need to be amended to include updated classifications for substances already subject to harmonised classification and to include new harmonised classifications. In addition, it is necessary to delete entries for certain substances.

(2) It is necessary to amend Annex VI to Regulation … No 1272/2008 in order to reflect the recently adopted amendments to Annex I to Directive 67/548 … introduced by [the contested directive] … and by Commission Directive 2009/2/EC of 15 January 2009 amending for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548 … Those measures constitute adaptations to technical and scientific progress within the meaning of Article 53 of Regulation … No 1272/2008.

(3) Recital (53) of Regulation … No 1272/2008 underlines the fact that full account should be taken 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.'

51 Article 1 of the contested regulation provides in particular:

‘Part 3 of Annex VI to Regulation … No 1272/2008 is amended as follows:

(1) Table 3.1 is amended as follows:

(a) The entries corresponding to the entries set out in Annex I are replaced by the entries set out in that Annex;

(b) The entries set out in Annex II are inserted in accordance with the order of the entries set out in Table 3.1;

…

(2) Table 3.2 is amended as follows:

(a) The entries corresponding to the entries set out in Annex IV are replaced by the entries set out in that Annex;

(b) The entries set out in Annex V are inserted in accordance with the order of the entries set out in Table 3.2;

…'

52 In accordance with Article 2 of the contested regulation:

'1. This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2. Article 1 shall apply from 1 December 2010.

3. The harmonised classifications set out in Part 3 of Annex VI to Regulation … No 1272/2008, as amended by this Regulation, may be applied before 1 December 2010.'

53 The contested classifications, as set out in Annexes II and V to the contested regulation, are essentially the following:

'Annex II

Index No	International Chemical Identification	Classification		Labelling	
		Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)
…	…	…	…	…	…
005-007-00-2	boric acid; … boric acid, crude natural, containing not more than 85 per cent of H_3BO_3 calculated on the dry weight …	Repr. 1B	H360FD	GHS08 Dgr	H360FD
005-008-00-8	diboron trioxide; boric oxide	Repr. 1B	H360FD	GHS08 Dgr	H360FD
005-011-00-4	disodium tetraborate, anhydrous; boric acid, disodium salt; … tetraboron disodium heptaoxide, hydrate; … orthoboric acid, sodium salt …	Repr. 1B	H360FD	GHS08 Dgr	H360FD
005-011-01-1	disodium tetraborate decahydrate; borax decahydrate	Repr. 1B	H360FD	GHS08 Dgr	H360FD
005-011-02-9	disodium tetraborate pentahydrate; borax pentahydrate	Repr. 1B	H360FD	GHS08 Dgr	H360FD
…	…	…	…	…	…'

'Annex V

Index No	International Chemical Identification	Classification	Labelling
…	…	…	…
005-007-00-2	boric acid; … boric acid, crude natural, containing not more than 85 per cent of H_3BO_3 calculated on the dry weight …	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-008-00-8	diboron trioxide; boric oxide	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-00-4	disodium tetraborate, anhydrous; boric acid, disodium salt; … tetraboron disodium heptaoxide, hydrate; … orthoboric acid, sodium salt …	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-01-1	disodium tetraborate decahydrate; borax decahydrate	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
005-011-02-9	disodium tetraborate pentahydrate; borax pentahydrate	Repr. Cat. 2; R60-61	T R: 60-61 S: 53-45
…	…	…	…'

Procedure and forms of order sought

54 By application lodged at the Registry of the Court on 5 December 2008, the applicants brought the present action.

55 By document lodged at the Registry of the Court on 6 April 2009, the Kingdom of Denmark applied for leave to intervene in the proceedings in support of the form of order sought by the Commission. By order of 7 July 2009, the President of the Third Chamber of the Court granted leave to intervene.

56 By document lodged at the Registry of the Court on 9 April 2009, Borax Europe Ltd ('Borax'), a company governed by English law which produces and markets borates, applied for leave to intervene in the proceedings in support of the form of order sought by the applicants. By order of 7 July 2009, the President of the Third Chamber of the Court granted leave to intervene.

57 By separate document lodged at the Registry of the Court on 11 March 2009, the Commission raised a plea of inadmissibility under Article 114 of the Court's Rules of Procedure and applied for a declaration of no need to adjudicate under Article 113 of the Rules of Procedure. The applicants submitted their observations on that plea and application on 30 April 2009. Borax filed a statement in intervention limited to the question of admissibility on 24 August 2009.

58 In their application and their observations on the plea of inadmissibility, the applicants, supported by Borax, claim that the Court should:

— dismiss the plea of inadmissibility and declare the action admissible;

— annul the entries in the table in Annex 1G to the contested directive relating to the following substances:

— boric acid and boric acid, crude natural (index number 005-007-00-2);

— diboron trioxide and boric oxide (index number 005-008-00-8);

— disodium tetraborate, anhydrous; boric acid, disodium salt; tetraboron disodium heptaoxide, hydrate; and orthoboric acid, sodium salt (index number 005-011-00-4);

— disodium tetraborate decahydrate and borax decahydrate (index number 005-011-01-1);

— disodium tetraborate pentahydrate and borax pentahydrate (index number 005-011-02-9);

— in the alternative, annul the entries in the table in Annex 1G to the contested directive relating to the following substances:

— diboron trioxide and boric oxide (index number 005-008-00-8);

— disodium tetraborate, anhydrous; boric acid, disodium salt; tetraboron disodium heptaoxide, hydrate; and orthoboric acid, sodium salt (index number 005-011-00-4);

— disodium tetraborate decahydrate and borax decahydrate (index number 005-011-01-1);

— disodium tetraborate pentahydrate and borax pentahydrate (index number 005-011-02-9);

— order the Commission to pay the costs.

59 In its plea of inadmissibility, the Commission contends that the Court should:

— dismiss the application as being devoid of purpose;

— in the alternative, declare the application manifestly inadmissible;

— order the applicants to pay the costs.

60 By separate documents lodged at the Registry of the Court on 6 and 30 November and 8 December 2009, the applicants applied, in response to a written question put by the Court, for leave to amend their form of order and pleas in law seeking annulment so as to extend also to the contested classifications as set out in the contested regulation.

61 In their application to amend the form of order and pleas in law, the applicants, supported by Borax, claim essentially that the Court should:

— declare the application in its amended form admissible and well founded;

— allow their application to amend the form of order and pleas in law seeking annulment so as to extend also to the entries in the tables in Annexes II and V to the contested regulation corresponding to the contested classifications;

— order the Commission to pay the costs.

62 By document lodged at the Registry of the Court on 9 November 2009, the Commission stated that it did not oppose the amendment to the form of order and pleas in law, on the assumption that the application to amend had been made before the expiry of the period for bringing proceedings against the contested regulation.

63 By letter of 19 December 2009, the President of the Third Chamber of the Court informed the applicants of his decision to allow them to amend their form of order and pleas in law.

64 By document lodged at the Registry of the Court on 21 December 2009, the applicants, supported by Borax, submitted, in reply to a written question put by the Court, that their application was admissible in any event because of the entry into force on 1 December 2009 of the fourth paragraph of Article 263 TFEU. By document lodged on the same date, the Commission disputed that position.

65 Pursuant to Article 14 of the Rules of Procedure and on a proposal of the President of the Court, the Court decided on 14 January 2010, after hearing the parties in accordance with Article 51 of the Rules of Procedure, to refer the case to a formation composed of a greater number of judges (the Grand Chamber) to rule on the plea of inadmissibility.

Law

66 Under Article 114(1) of the Rules of Procedure, on the application of a party, the Court can rule on admissibility without going to the substance of the case. In accordance with Article 114(3), the remainder of the proceedings is to be oral, unless the Court decides otherwise.

67 In the present case, the Court takes the view that it has sufficient information from the documents in the file, and decides to rule by reasoned order without opening the oral procedure.

Applicability of the fourth paragraph of Article 263 TFEU

Arguments of the parties

68 The Commission submits that the last phrase of the fourth paragraph of Article 263 TFEU is not applicable in the present case.

69 It is settled case-law that the admissibility of an action must be judged by reference to the situation prevailing when the application is lodged. Moreover, the application of the last phrase of the fourth paragraph of Article 263 TFEU to applications brought before 1 December 2009 would lead to arbitrary consequences, depending on whether the Court gave judgment before or after that date.

70 The Commission concludes that the fourth paragraph of Article 263 TFEU applies only to actions brought after 30 November 2009. In the present case, since the original application was made on 5 December 2008 and the application for leave to amend the form of order and pleas in law was made before 1 December 2009, Article 263 TFEU has no relevance for these proceedings.

71 The applicants, supported by Borax, submit that the changes made by the Treaty of Lisbon apply to the present proceedings. That follows from Article 1 in conjunction with Article 19(1) and (3)(a) TEU. No provision of the Treaty of Lisbon provides that the rules of the EC Treaty are to continue to apply for a transitional period after 1 December 2009. The European Union judicature is therefore bound to apply the fourth paragraph of Article 263 TFEU, including the conditions of admissibility of an action contesting the lawfulness of a regulatory act, to actions pending on 1 December 2009.

72 Consequently, following the entry into force of the fourth paragraph of Article 263 TFEU, the applicants' claim for partial annulment of the contested acts is admissible, without their having to show that they are individually concerned.

Findings of the Court

73 In the case of the contested regulation, the period for instituting proceedings in accordance with the fifth paragraph of Article 230 EC expired on 30 November 2009, when the EC Treaty was in force, and the applicants made their application for leave to amend their form of order and pleas in law before that date. On the date of the entry into force of Article 263 TFEU, 1 December 2009, any application for annulment of

the contested regulation would therefore have been inadmissible in any event on the ground of failure to comply with the time-limit for bringing proceedings laid down in the sixth paragraph of that article, which repeats the wording of the fifth paragraph of Article 230 EC. That applies all the more so, *mutatis mutandis*, to the application made on 5 December 2008 for partial annulment of the contested directive.

74 The parties differ on the point of whether the fourth paragraph of Article 263 TFEU, in particular the last phrase of the paragraph, applies to the present case *ratione temporis*. In particular, the applicants, supported by Borax, argue that the amended conditions of admissibility laid down there with respect to regulatory acts are of immediate application, and therefore make their action for the partial annulment of the contested acts admissible without their having to show that they are individually concerned by the contested classifications. The Commission, on the other hand, argues that that provision does not apply to the present proceedings, since the admissibility of the applications must be assessed by reference to the conditions of admissibility in force at the time when they were brought.

75 On this point, it must be noted that the FEU Treaty does not lay down any specific transitional provisions on whether the fourth paragraph of Article 263 TFEU is to apply to judicial proceedings pending on 1 December 2009.

76 As regards specifically the question of the temporal application of the rules determining the conditions of admissibility of an action for annulment brought by an individual before the European Union judicature, it is settled case-law, first, that in accordance with the maxim *tempus regit actum* (see, to that effect, Case 12/71 *Henck* [1971] ECR 743, paragraph 5) the question of the admissibility of an application must be resolved on the basis of the rules in force at the date on which it was submitted (Case 60/72 *Campogrande* v *Commission* [1973] ECR 489, paragraph 4; see also, to that effect and

by analogy, order of the President of 22 February 2008 in Case C-66/08 *Kozlowski*, not published in the ECR, paragraph 7) and, second, that the conditions of admissibility of an action are judged at the time of bringing the action, that is, the lodging of the application (Joined Cases C-61/96, C-132/97, C-45/98, C-27/99, C-81/00 and C-22/01 *Spain* v *Council* [2002] ECR I-3439, paragraph 23; Case T-131/99 *Shaw and Falla* v *Commission* [2002] ECR II-2023, paragraph 29; and Case T-301/01 *Alitalia* v *Commission* [2008] ECR II-1753, paragraph 37), a defect in which can be rectified only before the expiry of the period for bringing proceedings (Case 50/84 *Bensider and Others* v *Commission* [1984] ECR 3991, paragraph 8).

77 The contrary view would moreover lead to the danger of arbitrariness in the administration of justice, since the admissibility of an application would then depend on the — uncertain — date of delivery of the decision of the Court putting an end to the proceedings (see, to that effect and by analogy, Joined Cases 212/80 to 217/80 *Salumi and Others* [1981] ECR 2735, paragraph 14).

78 In the present case, at the time of bringing the action, namely both the lodging of the original application and the lodging of the application for leave to amend the form of order and pleas in law, the conditions of its admissibility were governed by Article 230 EC. Consequently, having regard to the case-law cited in paragraph 76 above, the question of the applicants' standing to bring proceedings for the annulment of the contested acts must be resolved on the basis of that article. Moreover, even if the fourth paragraph of Article 263 TFEU, in particular the last phrase of the paragraph, could in the present case confer on the applicants a *locus standi* which they did not have under the fourth paragraph of Article 230 EC, that standing could not be taken into account for the purposes of assessing the admissibility of the present action, since the period for bringing proceedings within the meaning both of the fifth paragraph

of Article 230 EC and of the sixth paragraph of Article 263 TFEU had already expired when Article 263 TFEU entered into force on 1 December 2009.

79 That conclusion is not affected by the argument that Article 263 TFEU forms part of the procedural rules with respect to which the case-law has held that, unlike substantive rules, they are generally taken to apply to all proceedings pending at the time when they enter into force (*Salumi and Others*, cited in paragraph 77 above, paragraph 9; Case C-293/04 *Beemsterboer Coldstore Services* [2006] ECR I-2263, paragraph 19; and Case C-467/05 *Dell'Orto* [2007] ECR I-5557, paragraph 48). Even if it were considered that jurisdictional questions are within the field of procedural rules (see, to that effect, *Dell'Orto*, paragraph 49), it is clear that, as follows from the case-law cited in paragraphs 76 and 77 above, for the purposes of determining the applicable provisions by reference to which the admissibility of an action for the annulment of a European Union act must be assessed, the maxim *tempus regit actum* must be applied.

80 It follows that the fourth paragraph of Article 263 TFEU does not apply to the present action.

81 It must therefore be examined whether the applicants have shown that they have standing to bring proceedings for the annulment of the contested acts under the fourth paragraph of Article 230 EC.

Admissibility of the action

Arguments of the parties

82 In support of the plea of inadmissibility and the application for a declaration that there is no need to adjudicate under Articles 113 and 114 of the Rules of Procedure, the Commission submits that Annex I to Directive 67/548, including the contested classifications as introduced by the contested directive, was repealed from 20 January 2009 by Article 55(11) of Regulation No 1272/2008, with the automatic consequence that the contested directive amending that annex was repealed from the same date and no longer has legal effects. The application for the partial annulment of the contested directive therefore became devoid of purpose within the meaning of Article 113 of the Rules of Procedure.

83 Even if that were not the case, the Commission argues that the contested classifications laid down by the contested acts are neither of direct nor of individual concern to the applicants within the meaning of the fourth paragraph of Article 230 EC.

84 The applicants, supported by Borax, submit that they are directly and individually concerned within the meaning of the fourth paragraph of Article 230 EC by the contested classifications laid down by the contested acts.

85 As regards the criterion of individual concern, the applicants argue that the contested acts concern them individually by reason of certain attributes peculiar to them or by reason of a factual situation which differentiates them from all other persons and thereby distinguishes them individually in the same way as the addressee. A number

of factors capable of showing that they are individually distinguished in that way should be taken into account.

86 First, the applicants hold exclusive rights affected by the contested classifications relating to boron mining in Turkey. Second, Etimine is the largest importer of borate substances in the European Union. The applicants import the majority of the borate substances used in the European Union and their activities in the internal market depend on the import and sale of those substances. Third, the applicants played an active part in the procedure which led to the adoption of the contested classifications. Fourth, they are identifiable in recital 2 in the preamble to the contested directive. Fifth, the Commission based the contested classifications on a provisional risk evaluation under Regulation No 793/93, by virtue of which the applicants enjoy procedural guarantees.

87 In the first place, as regards the exclusive rights, the applicants point out that they are the only operators in the European Union authorised to import and market in the internal market the borate substances mined in Turkey. Those exclusive rights were granted to them before the adoption of the contested directive, and thus differentiate them from all other operators. Those rights are affected by the obligation to label borate products with the skull and crossbones symbol and the phrases R 60 ('May impair fertility') and R 61 ('May cause harm to the unborn child'), which is equivalent to imposing a technical specification on the applicants. Moreover, the classification of the borate substances under Directive 67/548 as toxic to reproduction category 2 will have the effect that the products concerned can no longer be sold to the general public.

88 The applicants contest the Commission's argument that those exclusive rights are of no concern to the European Union. The Commission fails to take account of the

special relationship between the European Union and the Republic of Turkey which has existed since the Agreement establishing an Association between the European Economic Community and Turkey signed on 12 September 1963 in Ankara, by virtue of which the strengthening of trade and economic relations with the Republic of Turkey is a key aim of the European Union. Moreover, the exclusive mining rights enjoyed by the applicants are similar to those which are granted by the Member States in similar circumstances and form part of their common tradition.

89 Similarly, according to the applicants and Borax, the argument that those exclusive rights are not capable, together with the other distinguishing factors, of distinguishing them individually from all other operators is wrong. It has been held that, where the contested measure affects a group of persons who were identified or identifiable when that measure was adopted by reason of criteria specific to the members of the group, those persons may be individually concerned by that measure inasmuch as they form part of a limited class of operators. That may be the case in particular when the measure alters rights, such as exclusive television broadcasting rights, acquired by those persons prior to its adoption (Case C-125/06 P *Commission* v *Infront WM* [2008] ECR I-1451, paragraphs 71, 72, 75 and 76). In the same way, in the present case, the applicants' exclusive rights to mine and market borates in Turkey existed before the adoption of the contested directive, and the contested classifications subjected those rights to new restrictions which did not exist at the time when the applicants acquired the rights and which render the exercise of the rights more difficult. Such exclusive rights are therefore sufficient to identify them as forming part of the class of 29 companies holding borate mining rights affected by the contested directive.

90 In the second place, Etimine is the largest importer of borate substances in the European Union (see paragraph 33 above), with an estimated volume of 56 % of total imports of borate substances in 2007. Etimine and Etiproducts derived 72 % and 53 % respectively of their turnover for that year from the sale of boric acid, borax decahydrate and borax pentahydrate in the European Union. Moreover, the applicants are

among the three companies which together own 61 % of world borates production capacity. In view of the fact that their commercial activities depend on those substances, the applicants must be regarded as the operators most affected by the contested classifications, in the sense of Case C-358/89 *Extramet Industrie* v *Council* [1991] ECR I-2501, paragraph 17, the principles of which do not apply only to anti-dumping cases (Case T-289/03 *BUPA and Others* v *Commission* [2008] ECR II-81, paragraph 79). Consequently, they are in a specific situation which differentiates them from all other economic operators.

91 In the third place, even though the applicants did not have procedural guarantees in this connection, they participated actively, through Eti Mine Works and the Turkish State, in the procedure which led to the adoption of the contested classifications, in particular by providing the Commission with several studies and a large amount of data and attending several meetings with the Commission and meetings of the C&L working group. While that active participation is not in itself capable of distinguishing the applicants individually, it is an attribute peculiar to them which, together with other specific factors, differentiates them from all other operators affected by the contested directive. Since Eti Mine Works is wholly controlled by the Turkish State, and since it in turn controls 100 % of the capital of the applicants, the active participation of Eti Mine Works and the Turkish authorities in the procedure in question is to be attributed entirely to the applicants.

92 In the fourth place, recital 2 in the preamble to the contested directive refers to information produced by the applicants, namely a study by M.K. entitled 'Estimation of human daily boron exposure in a boron-rich area'. The Turkish authorities submitted that study to the Commission on behalf of the applicants on 3 July 2007, in connection with their comments on the notification by the Commission to the Committee on Technical Barriers to Trade of the World Trade Organisation (WTO) of the draft of the

30th adaptation to technical progress of Directive 67/548. Moreover, recital 2 in the preamble to the contested directive refers to epidemiological studies in progress, including one relating to Eti Mine Works' Bandirma (Turkey) site, the results of which — to be produced inter alia by the applicants — could, as the recital itself said, alter the contested classifications. The applicants and Borax do not accept that the recital refers only to one study carried out in China. They state that, unlike the contested directive, the previous adaptations of Directive 67/548 to technical progress did not refer to the involvement of the industrial sector. Finally, those references show that the information provided by the applicants was taken into account in the decision-making process which resulted in the contested classifications, and that other information which was to be provided by the industrial sector, including the applicants, would receive particular attention when the classification was next revised. The applicants are therefore identified as members of a limited class constituted by the members of the industrial sector who submitted relevant information on the borate substances. They are thus in a specific situation which differentiates them from all other persons.

93 In the fifth place, the applicants submit that the contested classifications are based on a provisional risk evaluation under Regulation No 793/93, in which they supplied information and enjoyed procedural rights. In this connection, the applicants, as importers and manufacturers concerned by the risk evaluation procedure laid down by that regulation, presented and signed, together with other companies, on 26 March 2004 a declaration of intent concerning the risks of the priority substances boric acid and disodium tetraborate ('the declaration of intent'). Only four companies which signed the declaration of intent, one of which was Eti Mine Works, were concerned by that risk evaluation. The declaration was made in connection with the first stage of the risk evaluation, which is hazard identification within the meaning of Articles 4 and 5 of Commission 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 Regulation No 793/93 (OJ 1994 L 161, p. 3). It provided information on the risk evaluation of the substances concerned as regards human health, for the purposes of a preliminary risk evaluation by the rapporteur Member State, the Republic of Austria, which had also signed the declaration.

94 The applicants conclude that the contested classifications will have a significant effect on the risk evaluation launched by the declaration of intent. In that evaluation the Austrian rapporteur will have to take account of the identification of a reproductive toxicity hazard, and the identification will therefore have a direct effect on the risk evaluation for boric acid and disodium tetraborate. The contested directive thus affects the applicants' participation in that risk evaluation and their expectations as to how it will be conducted. Furthermore, the Commission conducted its own provisional risk evaluation in accordance with the principles laid down by Regulation No 1488/94 in the course of its examination of the normal handling and use criterion under Directive 67/548. That provisional evaluation thus pre-empted the risk evaluation under Regulation No 793/93 to be undertaken by the Austrian rapporteur on the basis of the declaration of intent. The applicants conclude that the Commission substituted its assessment for that of the Austrian rapporteur, whose assessment is still ongoing, and that the contested directive is capable of having an adverse effect on it.

95 It follows that the applicants are in a specific situation distinguishing them in the same way as an addressee, since, first, through Eti Mine Works they form part of a group of four operators concerned by the risk evaluation under Regulation No 793/93 and, second, the contested classifications affect that risk evaluation, since it was pre-empted by that already carried out by the Commission.

96 Finally, the applicants, supported by Borax, do not agree that their action has become devoid of purpose as a result of the repeal of Annex I to Directive 67/548.

Findings of the Court

97 It must first be examined whether the applicants are individually concerned within the meaning of the fourth paragraph of Article 230 EC by the contested classifications in the contested acts.

98 The contested acts, including the contested classifications, are of general application in that they apply to objectively determined situations and produce legal effects with respect to a category of persons viewed generally and in the abstract, namely all natural or legal persons producing and/or marketing the substances concerned. However, the fact that an act is, by its nature and scope, an act of general application in that it applies to the economic operators concerned in general does not prevent it from being of individual concern to some of them (Case C-362/06 P *Sahlstedt and Others* v *Commission* [2009] ECR I-2903, paragraph 29; order in Case T-223/01 *Japan Tobacco and JT International* v *Parliament and Council* [2009] ECR II-3259, paragraph 29; and order in Case T-154/02 *Villiger Söhne* v *Council* [2003] ECR II-1921, paragraph 40; see also, to that effect, Case C-309/89 *Codorníu* v *Council* [1994] ECR I-1853, paragraph 19).

99 It should be recalled that persons other than those to whom an act is addressed can claim to be individually concerned within the meaning of the fourth paragraph of Article 230 EC only if the act affects them by reason of certain attributes peculiar to them or by reason of a factual situation which differentiates them from all other

persons and thereby distinguishes them individually in the same way as the addressee (Case 25/62 *Plaumann* v *Commission* [1963] ECR 95, 107, and order in eCase C-444/08 P *Região autónoma dos Açores* v *Council* [2009] not published in the ECR, paragraph 36).

100 Moreover, where a decision affects a group of persons who were identified or identifiable when that act was adopted by reason of criteria specific to the members of the group, those persons may be individually concerned by that act inasmuch as they form part of a limited class of economic operators (Joined Cases C-182/03 and C-217/03 *Belgium and Forum 187* v *Commission* [2006] ECR I-5479, paragraph 60; *Commission* v *Infront WM*, cited in paragraph 89 above, paragraph 71; and *Sahlstedt and Others* v *Commission*, cited in paragraph 89 above, paragraph 30).

101 However, the fact that it is possible to determine more or less precisely the number, or even the identity, of the persons to whom a measure applies by no means implies that that measure must be regarded as being of individual concern to those persons where it is established that that application takes effect by virtue of an objective legal or factual situation defined by the act in question (*Sahlstedt and Others* v *Commission*, cited in paragraph 98 above, paragraph 31, and order in Case C-503/07 P *Saint-Gobain Glass Deutschland* v *Commission* [2008] ECR I-2217, paragraph 70).

102 It is in the light of those principles that the admissibility of the present action must be considered.

103 The applicants take the view that they are individually concerned by the contested classifications within the meaning of the fourth paragraph of Article 230 EC by reason of a series of attributes peculiar to them, which should be taken into account cumulatively. First, they submit that the contested classifications affect the scope and exercise of their exclusive rights to import and market in the European Union the borates from the Turkish mines operated by Eti Mine Works. As holders of those rights, they

form part of a limited class of operators who are particularly affected, since the contested classifications subject those rights to new restrictions which make their exercise more difficult. Second, Etimine is the largest importer of borate substances in the European Union. Third, through the Turkish authorities and Eti Mine Works, whose actions may be attributed to them, the applicants actively participated in the procedure for adapting Directive 67/548 to technical progress which led to the contested classifications. Fourth, recital 2 in the preamble to the contested directive refers to information produced by the applicants, namely a study by M.K. Fifth, the contested classifications are based on a provisional risk evaluation under Regulation No 793/93, in which the applicants supplied information and enjoyed procedural rights.

104 In the first place, with respect to the exclusive rights relied on by the applicants, it must be stated that the existence of an actual or individual right, including that conferred by a provision of general application, whose scope or exercise is potentially affected by the contested measure is not as such capable of distinguishing the rightholder individually, in particular where other operators may enjoy similar rights and hence be in the same situation as that rightholder (see, to that effect, *Sahlstedt and Others* v *Commission*, cited in paragraph 98 above, paragraphs 32 and 34; order in Case T-94/04 *EEB and Others* v *Commission* [2005] ECR II-4919, paragraphs 53 to 55; and order of 11 September 2007 in Case T-28/07 *Fels-Werke and Others* v *Commission*, not published in the ECR, paragraph 63).

105 In the present case, apart from their general assertion that there are a total of 29 operators holding borate mining rights affected by the contested classifications (see paragraph 89 above), the applicants have neither identified those operators nor specified the reasons why, having regard to the attributes peculiar to them, they could form a limited class as defined in the case-law cited in paragraph 100 above, which can no longer be extended after the entry into force of the contested classifications (see, to that effect, Case C-152/88 *Sofrimport* v *Commission* [1990] ECR I-2477,

paragraph 11, and order in Case T-213/02 *SNF* v *Commission* [2004] ECR II-3047, paragraphs 62 and 63). A fortiori, the applicants have also not shown that, within that class of operators, they were particularly affected as a result of the restriction placed on their exclusive rights to import and market borate substances in the European Union, since other operators in that class could hold similar rights relating to the import and marketing of such substances originating in other non-member countries and suffering the same consequences.

106 The applicants have likewise failed to show that the contested classifications had the purpose or consequence of affecting the scope of the exclusive rights relied on, or even of preventing them from being exercised, as in Case 11/82 *Piraiki-Patraiki and Others* v *Commission* [1985] ECR 207, paragraph 31, and *Codorníu* v *Council*, cited in paragraph 98 above, paragraphs 21 and 22 (see, to that effect, order of 21 November 2005 in Case C-482/04 P *SNF* v *Commission*, not published in the ECR, paragraphs 40 and 41, and order in Case C-483/07 P *Galileo Lebensmittel* v *Commission* [2009] ECR I-959, paragraphs 44 to 46). It should be pointed out that the contested classifications do not interfere with the applicants' exclusive rights to import and market in the European Union the borate substances from the Turkish mines operated by Eti Mine Works. The mere fact that the classifications may make the exercise of those exclusive rights more difficult is not sufficient to distinguish the applicants individually within the meaning of the fourth paragraph of Article 230 EC, since a priori they affect in the same way all operators who carry on or may carry on activities involving the import and/or marketing of borate substances in the European Union, whether or not they enjoy exclusive rights to do so (see, to that effect, *Sahlstedt and Others* v *Commission*, cited in paragraph 98 above, paragraphs 32 and 34; see also the contrary view of Advocate General Bot in his Opinion in that case, [2009] ECR I-2906, points 116 to 119). It should be noted that the possibility that the applicants will suffer an economic disadvantage — even a serious one — as a result of the contested classifications is not enough to show that those classifications distinguish them individually from all other operators who might be exposed to similar consequences (see, to that effect, order of

29 June 2006 in Case T-311/03 *Nürburgring* v *Parliament and Council*, not published in the ECR, paragraphs 65 and 66).

107 In the second place, even if Etimine is the largest importer of borates in the European Union, the fact remains that it is only one operator among several who are affected by the contested acts in their objective capacity of importers of borates and are in a comparable situation with respect to the contested classifications. A smaller operator with similar distribution rights will be exposed to comparable economic difficulties, since the classifications affect all operators in that capacity and in proportion to their size and the extent of their commercial activities in connection with borates (see, to that effect and by analogy, Case T-16/04 *Arcelor* v *Parliament and Council* [2010] ECR II-211, paragraph 111). In any event, the figures, in absolute and percentage terms, put forward by the applicants (see paragraph 90 above) are not sufficiently comparable with those of other operators such as Borax, which, according to its own statement, also imports a considerable volume of borates, from the United States of America, into the European Union. Consequently, the applicants have not shown to the requisite legal standard that Etimine's alleged status of the largest importer of borates in the European Union was capable of distinguishing it individually, like the applicants in *Extramet Industrie* v *Council*, cited in paragraph 90 above, paragraph 17, and *BUPA and Others* v *Commission*, cited in paragraph 90 above, paragraphs 78 and 79, from all other operators carrying on similar economic activities.

108 In the third place, it must be assessed whether the applicants can validly claim to be individually concerned by reason of their active participation, such as that of Eti Mine Works and the Turkish authorities, in the procedure which led to the contested classifications and of their procedural status in connection with the risk evaluation procedure under Regulation No 793/93.

109 It must be recalled, to begin with, that the fact that a person participates in the process by which a European Union measure is adopted does not distinguish him individually with regard to the measure in question unless provision has been made under the European Union rules for procedural guarantees in his favour. Thus, where a provision of European Union law requires that, for the purposes of adopting a decision, a procedure must be followed in respect of which a natural or legal person may assert rights, such as the right to be heard, the special legal position which that person enjoys has the effect of distinguishing him individually within the meaning of the fourth paragraph of Article 230 EC (see order in *Galileo Lebensmittel* v *Commission*, cited in paragraph 106 above, paragraph 53 and the case-law cited).

110 It must be stated, next, that a person is, however, only recognised as being distinguished individually in such a way if the procedural guarantees relied on are those provided for in the applicable legislation (see, to that effect, Case C-263/02 P *Commission* v *Jégo-Quéré* [2004] ECR I-3425, paragraph 47; order of 8 December 2006 in Case C-368/05 P *Polyelectrolyte Producers Group* v *Commission and Council*, not published in the ECR, paragraph 58; order in *Galileo Lebensmittel* v *Commission*, cited in paragraph 106 above, paragraphs 46 and 54; Case T-13/99 *Pfizer Animal Health* v *Council* [2002] ECR II-3305, paragraph 101; and Case T-70/99 *Alpharma* v *Council* [2002] ECR II-3495, paragraph 93). It thus follows from the case-law that the applicant's active participation in a procedure, especially where it is directed at the adoption of acts of general application, is capable of distinguishing him individually only if that participation is based on such procedural guarantees (see, to that effect, order in Case T-215/00 *La Conqueste* v *Commission* [2001] ECR II-181, paragraphs 42 and 43 and the case-law cited, and order in Case T-369/03 *Arizona Chemical and Others* v *Commission* [2005] ECR II-5839, paragraph 73).

111 The applicants themselves concede, however, that they do not enjoy such procedural guarantees under Directive 67/548 or Regulation No 1272/2008.

112 As regards the contested directive, it need only be pointed out that the relevant procedural rules defining the process of its adoption, in particular points 4.1.2 to 4.1.5 of Annex VI to Directive 67/548, do not lay down such procedural guarantees for the benefit of operators who might be affected by the outcome of a procedure for adapting Directive 67/548 to technical progress (see, to that effect, order in *Arizona Chemical and Others* v *Commission*, cited in paragraph 110 above, paragraphs 72 to 80 and the case-law cited).

113 The same is true of the provisions of Regulation No 1272/2008, in particular Articles 53(1) and 54(3) in conjunction with Article 5a(1) to (4) of Decision 1999/468 (see paragraphs 20 to 22 above), which govern the adoption of the contested regulation. That conclusion is not affected by the fact that Article 37 of Regulation No 1272/2008 (see paragraph 19 above) provides in paragraphs 2 to 4 for a right of manufacturers, importers or downstream users to submit to the ECHA a proposal for harmonised classification and labelling of a substance and, possibly after submitting comments, to obtain an opinion from the ECHA Committee for Risk Assessment. Any procedural guarantees provided for in Article 37 of Regulation No 1272/2008 would apply only in the event of a national authority or a manufacturer, importer or downstream user submitting such a proposal, which was not the case here.

114 In so far as the applicants rely on their procedural status under Regulation No 793/93, it must be observed that that regulation does indeed provide in Articles 6 to 10, as specific procedural rights and obligations (see paragraphs 23 to 26 above), for the active participation of the operators concerned in the risk evaluation procedure for the purposes of drawing up a priority list of the substances concerned and possibly suggesting strategies and measures inter alia for limiting the risks identified. However, it is clear, first, that the provisions of Regulation No 793/93 do not apply to the procedure for the classification of a substance as a dangerous substance and, second, that the risk evaluation procedure for the borates — which, as the applicants themselves

concede, had not yet been completed for the purposes of Article 11(2) of that regulation at the time of adoption of the contested classifications — is a separate procedure from that which led to the contested classifications. That is confirmed by Article 11(1) to (3) of Regulation No 793/93, under which it is only on the basis of the finalised risk evaluation and any strategy recommended by the rapporteur that the Commission can, if necessary, propose Community measures within the framework of Directive 76/769 or other relevant existing Community instruments (see paragraph 26 above). Those provisions do not in any way specify the conditions under which the results of the risk evaluation may give rise to a proposal to classify the substance concerned under Directive 67/548 or Regulation No 1272/208, which shows that the risk evaluation procedure is independent of the procedure for classifying a substance as a dangerous substance.

115 Those provisions of Regulation No 793/93 do not therefore lay down any procedural guarantees applicable for the purposes of the classification of a substance as a dangerous substance under Directive 67/548 or Regulation No 1272/2008. Nor do they create a link between the risk evaluation procedure for a substance on the one hand and the procedure for such a classification as a dangerous substance on the other from which it could be concluded that the procedural guarantees accorded by Regulation No 793/93 are applicable in the latter procedure.

116 Consequently, the argument that those procedural guarantees and their exercise during the risk evaluation procedure can distinguish the applicants individually with respect to the contested classifications must be rejected, since those classifications are the result not of the risk evaluation procedure under Regulation No 793/93 but of the separate procedures for adapting Directive 67/548 and Regulation No 1272/2008

respectively to technical progress, in the context of which the applicants have no such guarantees.

117 Moreover, in the absence of procedural guarantees in connection with the latter procedures, it is not possible to accept the argument that the applicants are distinguished individually on the ground that they took an active part in the procedures which led to the contested classifications. It is therefore unnecessary to decide whether the participation of Eti Mine Works and the Turkish authorities in those procedures may be taken into account for assessing the admissibility of the present action.

118 In the fourth place, the argument that recital 2 in the preamble to the contested directive expressly refers to information supplied by the Turkish authorities, in particular the study by M.K., must also be rejected. It suffices to state that, apart from a reference to an ongoing study in China, that recital is very indefinite and does not specify the identity or the source of the information taken into account during the procedure for adapting Directive 67/548 to technical progress. In any event, regardless of whether the applicants, as subsidiaries of Eti Mine Works, a company controlled by the Turkish State, can rely on that argument, it has not been shown that that information includes the study by M.K. or that the information is precisely that which the Turkish authorities submitted during the procedure in question.

119 In those circumstances, the conclusion must be that the applicants have not shown that, by reason of a series of characteristics peculiar to them, they were individually concerned within the meaning of the fourth paragraph of Article 230 EC by the contested classifications in the contested acts.

120 The application for the partial annulment of the contested acts must therefore be dismissed as inadmissible with regard to the fourth paragraph of Article 230 EC.

121 In the light of all the above considerations, without there being any need to rule on the application for a declaration that there is no need to adjudicate on the application in so far as it relates to the partial annulment of the contested directive, the application must be dismissed as inadmissible in its entirety.

Costs

122 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicants have been unsuccessful, they must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

123 Under the first subparagraph of Article 87(4) of the Rules of Procedure, Member States which have intervened in the proceedings are to bear their own costs. The Kingdom of Denmark is therefore to bear its own costs.

124 Under the third subparagraph of Article 87(4) of the Rules of Procedure, the Court may order an intervener to bear his own costs. In the present case, Borax, which intervened in support of the form of order sought by the applicants, is to bear its own costs.

On those grounds,

THE GENERAL COURT (Grand Chamber)

hereby orders:

1. **The application is dismissed as inadmissible.**

2. **Etimine SA and Ab Etiproducts Oy are to bear their own costs and to pay the costs of the European Commission.**

3. **The Kingdom of Denmark and Borax Europe Ltd are to bear their own costs.**

Luxembourg, 7 September 2010.

E. Coulon
Registrar

M. Jaeger
President

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