ORDER OF THE GENERAL COURT (Grand Chamber)

7 September 2010 *

In Case T-532/08,

Norilsk Nickel Harjavalta Oy, established in Espoo (Finland),

Umicore SA/NV, established in Brussels (Belgium),

represented by K. Nordlander, lawyer,

applicants,

supported by

Nickel Institute, established in Toronto (Canada), represented by K. Nordlander, lawyer, D. Anderson QC, S. Kinsella and H. Pearson, Solicitors,

intervener,

* Language of the case: English.

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 nickel carbonate compounds,

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 Norilsk Nickel Harjavalta Oy (formerly OMG Harjavalta Oy, 'Norilsk Nickel') and Umicore SA/NV challenge the lawfulness of the classification of certain nickel carbonate compounds 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 of 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 is 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, Norilsk Nickel, is a company governed by Finnish law which produces nickel hydroxycarbonate and nickel-based intermediate and finished products such as cathodes, briquettes and salts. It is controlled by OJSC Mining and Metallurgical Company Norilsk Nickel, a company governed by Russian law which is one of the leading world producers of nickel. The other applicant, Umicore, is a company governed by Belgian law which imports nickel-derived products including nickel hydroxycarbonate into Belgium from non-member countries.

31 The contested classifications concern a group of four nickel carbonate related compounds, namely nickel hydroxycarbonate, pure nickel carbonate and two other compounds, each being a salt of nickel ('the nickel carbonates'). The substance principally sold commercially is nickel hydroxycarbonate, also known as basic nickel carbonate or nickel carbonate hydroxide.

Risk evaluation procedure for the nickel carbonates

32 In 2000 the Commission included pure nickel carbonate in the fourth list of priority substances when it adopted Regulation (EC) No 2364/2000 of 25 October 2000

concerning the fourth list of priority substances as foreseen under Regulation No 793/93 (OJ 2000 L 273, p. 5). The Danish Environmental Protection Agency (DEPA) was designated as rapporteur for the evaluation of the risks of that substance. After discussion, the risk evaluation of pure nickel carbonate was extended to four compounds in the nickel carbonates group. At that time the main producers of nickel carbonates in Europe were OMG Harjavalta ('OMG'), whose activities in the nickel sector have since been acquired by one of the applicants, Norilsk Nickel; Pharmacie centrale de France SA ('PCF'); and Königswarter & Ebell GmbH ('Königswarter'). In addition, the other applicant, Umicore, imported nickel carbonates into Belgium. OMG was responsible for communicating with DEPA on behalf of the other companies for the purpose of the risk evaluation of the nickel carbonates in accordance with the relevant provisions of Regulation No 793/93.

33 On 20 November 2002 OMG informed DEPA that no human toxicological data for nickel hydroxycarbonate existed and that it intended to request a derogation under Article 9(3) of Regulation No 793/03 (see paragraph 25 above).

34 By a document submitted to DEPA on 27 May 2003, OMG, PCF, Königswarter and Umicore made a request, on the basis of Article 9(3) of Regulation No 793/93, to be exempted from the obligation to perform certain tests and to communicate data on the toxicity of nickel hydroxycarbonate for human health and the environment ('the derogation statement').

Procedure leading to the contested classifications

35 On 16 April 2004 DEPA submitted to the European Chemicals Bureau (ECB) — a Commission body based in Ispra (Italy) which was replaced by the ECHA — and the Technical Committee on Classification and Labelling of Dangerous Substances (TCCL) a formal proposal for a revised classification of the nickel carbonates under Directive 67/548.

36 At a meeting held on 20 and 21 April 2004, the working party of specialised experts on carcinogenicity, mutagenicity and reproductive toxicity discussed the proposed carcinogenicity and mutagenicity classifications.

37 The TCCL discussed the proposed classification at its meetings of 12 to 14 May and 21 to 24 September 2004. At the meeting of 21 to 24 September 2004 it was decided to recommend the proposed revised classification for the nickel carbonates and to include it in the draft proposal for the directive adapting Directive 67/548 to technical progress for the 30th time which was to be sent to the Commission.

38 In November 2005 DEPA repeated the proposal for the revised classification of the nickel carbonates under Directive 67/548 in a draft risk evaluation report on the nickel carbonates, and also in a draft report on the risk evaluation of nickel and nickel compounds which stated in particular that the classification of the nickel carbonates

as category 3 mutagens (phrase R 68) was 'justified on the basis of the … derogation statement'.

39 On the basis of the TCCL's recommendation of September 2004, 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, at its meeting of 16 February 2007, in favour of the proposal for the directive adapting Directive 67/548 to technical progress for the 30th time, which took up the proposed revised classification of the nickel carbonates.

40 In March 2007 that draft proposal was notified to the Committee on Technical Barriers to Trade ('the TBT Committee') of the World Trade Organisation (WTO). On 7 November 2007 the Commission replied in writing to the comments submitted by non-member countries. Following a discussion at a meeting of the TBT Committee on 9 November 2007, the Commission decided to postpone the adoption of the contested directive, so that further written comments could be submitted to it and a second discussion of the draft proposal held within the TBT Committee. On 12 March 2008 the Commission replied in writing to a second round of written comments, and the draft proposal was reconsidered at the meeting of the TBT Committee of 19 March 2008.

41 On 21 August 2008 the Commission adopted the contested directive, in particular the proposed revised classification of the nickel carbonates, pursuant to the procedure laid down in Articles 28 and 29 of Directive 67/548 in conjunction with Article 5 of Decision 1999/468 and point 1 of Annex III to Regulation No 807/2003 (see paragraph 14 above).

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

'Index No	Chemical name	Classification	Labelling
…	…	…	…
028-010-00-0	nickel carbonate; basic nickel carbonate; carbonic acid, nickel (2+) salt; … carbonic acid, nickel salt; … [μ-[carbonato(2-)-*O*:*O*']] dihydroxy trinickel; … [carbonato(2-)] tetrahydroxytrinickel; …	Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R48/23 Xn; R20/22 Xi; R38 R42/43 N; R50-53	T; N R: 49-61-20/22-38-42/43-48/23-68-50/53 S: 53-45-60-61
…	…	…	…'

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

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

45 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.'

46 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;

…’

47 In accordance with Article 2 of the contested regulation:

'1. This Regulation shall enter into force on the twentieth 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.'

48 The contested classifications, as set out in Annexes I and IV to the contested regulation, are essentially the following:

'*ANNEX I*

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)
…	…	…	…	…	…

028-010-00-0	nickel carbonate; basic nickel carbonate; carbonic acid, nickel (2+) salt; … carbonic acid, nickel salt; … [μ-[carbonato(2-)-*O*:*O*']] dihydroxy trinickel; … [carbonato(2-)] tetrahydroxytrinickel; …	Carc. 1A Muta. 2 Repr. 1B STOT RE 1 Acute Tox 4 * Acute Tox. 4 * Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D*** H372** H332 H302 H315 H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H350i H341 H360D*** H372** H332 H302 H315 H334 H317 H410
…	…	…	…	…	…'

'*ANNEX IV*

Index No	International Chemical Identification	Classification	Labelling
…	…	…	…

028-010-00-0	nickel carbonate; basic nickel carbonate; carbonic acid, nickel (2+) salt; … carbonic acid, nickel salt; … [μ-[carbonato(2-)-*O*:*O*']] dihydroxy trinickel; … [carbonato(2-)] tetrahydroxytrinickel; …	Carc. Cat. 1; R49 Muta. Cat. 3; R68 Repr. Cat. 2; R61 T; R48/23 Xn; R20/22 Xi; R38 R42/43 N; R50-53	T; N R: 49-61-20/22-38-42/43-48/23-68-50/53 S: 53-45-60-61
…	…	…	…'

Procedure and forms of order sought

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

50 By document lodged at the Registry of the Court on 18 December 2008, the Nickel Institute, an association representing the interests of 24 nickel producers in Europe and in the world, applied for leave to intervene in the proceedings in support of the form of order sought by the applicants. By order of 1 April 2009, the President of the Third Chamber of the Court granted leave to intervene.

51 By separate document lodged at the Registry of the Court on 13 March 2009, the Commission raised a plea of inadmissibility under Article 114 of the Court's Rules of Procedure and applied for a declaration under Article 113 of the Rules of Procedure that there was no need to adjudicate on the matter. The applicants submitted their observations on that plea and application on 29 April 2009. The Nickel Institute filed a statement in intervention limited to the question of admissibility on 13 May 2009.

52 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 17 June 2009, the President of the Third Chamber of the Court granted leave to intervene.

53 In their application and their observations on the plea of inadmissibility, the applicants, supported by the Nickel Institute, claim that the Court should:

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

— annul the entry in the table in Annex 1F to the contested directive corresponding to the contested classifications (index number 028-010-00-0);

— annul the Commission's 'decision' to base the contested classifications on the derogation statement;

— order the Commission to pay the costs.

54 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.

55 By separate document lodged at the Registry of the Court on 3 November 2009, the applicants, in response to a written question by the Court, applied 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.

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

— allow their application to a mend the form of order and pleas in law seeking annulment so as to extend also to the entries in the tables in Annexes I and IV to the contested regulation corresponding to the contested classifications (index number 028-010-00-0);

— dismiss the plea of inadmissibility;

— order the Commission to pay the costs.

57 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.

58 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.

59 By document lodged at the Registry of the Court on 21 December 2009, the applicants, supported by the Nickel Institute, in reply to a written question put by the Court, submitted 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 contention.

60 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

61 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.

62 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

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

64 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 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.

65 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.

66 The applicants, supported by the Nickel Institute, submit that the conditions of admissibility in the fourth paragraph of Article 263 TFEU apply to all actions pending before the Court on the date of the entry into force of the Treaty of Lisbon, 1 December 2009.

Findings of the Court

67 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 applications made on 5 December 2008 for the annulment of the contested directive and of the supposed 'decision' to base the contested classifications on the derogation statement.

68 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 the Nickel Institute, 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.

69 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.

70 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 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).

71 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).

72 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 70 above, the question of the admissibility of the present action 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.

73 That conclusion is not affected by the argument that Article 263 TFEU forms part of the procedural rules in respect of 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 71 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 70 and 71 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.

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

75 The admissibility of the action must therefore be examined by reference to the fourth paragraph of Article 230 EC.

Admissibility of the action

Arguments of the parties

76 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 has therefore become devoid of purpose within the meaning of Article 113 of the Rules of Procedure.

77 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.

78 Finally, the application for annulment of the supposed 'decision' of the Commission to base the contested classifications on the derogation statement is manifestly inadmissible, as no such 'decision' exists. Even if it did exist, the 'decision' would be an integral part of the contested directive and the procedure leading up to its adoption, in which the Commission conducted its own risk evaluation.

79 The applicants, supported by the Nickel Institute, 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.

80 As regards the criterion of individual concern, the applicants argue that despite their general application the contested classifications concern them individually by reason of a factual situation which differentiates them from all other persons.

81 First, like the two other companies which signed the derogation statement, the applicants were clearly identifiable at the time of the adoption of the contested acts, and thus constituted a limited class of operators as defined in the case-law. That is because the applicants took part in the risk evaluation of the nickel carbonates on which the contested classifications were based. More particularly, they are distinguished

individually as a consequence of the four companies' agreement to the derogation statement which the Commission made use of for that purpose.

82 Second, in the risk evaluation procedure, as producers and importers of the substances concerned, the applicants enjoyed specific procedural guarantees, namely those conferred by Article 10(1) of Regulation No 793/93. In accordance with Articles 9(1) and 12 of that regulation, the applicants were obliged to take part in that procedure, as they had previously stated that they had produced and imported nickel carbonates. It is acknowledged that a person is individually concerned by an act if he was involved in the procedure leading to its adoption and the applicable legislation grants him certain procedural guarantees. By virtue of those procedural guarantees, the applicants had a right to be consulted by the rapporteur before it decided whether information or tests would be necessary for the risk evaluation of the nickel carbonates.

83 According to the applicants, those procedural guarantees apply not only to the risk evaluation procedure but also *de facto* to the procedure leading up to the adoption of the contested directive, given that the contested classifications were based on that risk evaluation, in particular on the derogation statement. Under Article 11(3) of Regulation No 793/93 (see paragraph 26 above), the Commission is obliged to consult the rapporteur before taking a decision to introduce measures to manage the risks disclosed, which may include a proposal to amend the classification. The rapporteur for its part must consult the operators concerned, under Article 10(1) of that regulation. The applicants' procedural guarantees in the risk assessment procedure were therefore an integral part of the process leading to a classification decision, such as that underlying the contested directive, which had the consequence of distinguishing them individually with respect to the contested acts. The applicants explain that they are not relying on specific procedural guarantees under Directive 67/548, so that

the Commission's reference to the order in Case T-369/03 *Arizona Chemical and Others* v *Commission* [2005] ECR II-5839, paragraph 76, is irrelevant. Moreover, because of their deep involvement in the risk evaluation procedure under Articles 10(1) and 11(3) of Regulation No 793/93, their position is very different from that of the applicants in the *Arizona Chemical* case.

84 Third, the applicants are individually concerned by the contested classifications in that, in adopting those classifications, the Commission infringed their procedural rights not to have the information they provided used for purposes other than those for which it was provided. The derogation statement was drawn up in the specific context of the risk assessment of the nickel carbonates under Regulation No 793/93, and not for the purpose of their classification as dangerous substances. In particular, in that statement, the applicants did not accept that there was any scientific basis for the application of the 'worst case' scenario to nickel sulphate. The Commission was therefore obliged to consult or at least hear the applicants before using the derogation statement for purposes other than those for which it had been drawn up.

85 Fourth, the contested acts affect the position of Norilsk Nickel in its capacity of representative of the nickel carbonates industry in the discussions with the rapporteur, DEPA, and the Commission. Norilsk Nickel's predecessor OMG, as the largest producer, was the company which represented the nickel carbonates industry in the negotiations inter alia with DEPA and the ECB in connection with the risk evaluation under Regulation No 793/93, submitting written observations including the derogation statement and keeping in close contact with those bodies. It follows that Norilsk Nickel is also individually concerned by the contested acts in its capacity of representative of the nickel carbonates industry and interlocutor of DEPA and the Commission. The applicants, supported by the Nickel Institute, dispute the Commission's argument that Norilsk Nickel cannot rely on the judgments in Joined Cases 67/85,

68/85 and 70/85 *Kwekerij van der Kooy and Others* v *Commission* [1988] ECR 219, paragraphs 20 to 24, and Case C-313/90 *CIRFS and Others* v *Commission* [1993] ECR I-1125, paragraphs 29 and 30, because it is not a trade association, since those judgments focused on the role of negotiator of the organisation concerned rather than its legal form. In this respect, the Nickel Institute adds that it could not have represented the industry in connection with the risk evaluation of the nickel carbonates, as Regulation No 793/93 requires that it is the manufacturers and importers of the substances concerned who take part in the evaluation.

86 Fifth, the applicants are individually concerned by the contested classifications because they were closely involved in the nickel carbonates risk evaluation procedure that led directly, by virtue of the contested acts, to the contested classifications. Those classifications are comparable to implementing measures concerning competition, dumping or State aid, which are open to challenge by an operator who has played an active part in the procedure leading to their adoption. Like those measures, the classification of a substance under Directive 67/548 does not depend on a decision of pure policy, in which the institutions have a wide discretion, but has to be decided largely on the basis of defined and objective criteria, with regard in particular to the criteria and detailed scientific data specified in Annex VI to that directive. Moreover, in the present case, the applicants' position was comparable to that of a producer who participated in the investigation leading to the adoption of an anti-dumping regulation, in that they took an active part in the procedure which led to the contested classifications, which were based in particular on the derogation statement.

87 Finally, the applicants state that the considerations in paragraphs 80 to 86 above apply *mutatis mutandis* to the contested classifications as they appear in the contested regulation, given that they are the result of a 'mechanical transfer' in identical terms of those laid down in the contested directive.

88 As regards the claim for annulment of the 'decision' to base the contested classifications on the derogation statement, the applicants, supported by the Nickel Institute, submit that it is the substance of a measure rather than its form that determines whether it has legal effects which can be the subject of an action. It is clear that at a given point in time the Commission decided to classify the nickel carbonates on the sole basis of the derogation statement. The Commission did not, in support of the contested classifications, present any data or evidence relating to its own evaluation of the risks attached to the intrinsic properties of the nickel carbonates, the only data relevant in this respect, namely the study of acute oral toxicity, having already been used for the previous classification of pure nickel carbonate.

89 Moreover, by making use of the derogation statement for that purpose, the Commission infringed the principle of the protection of legitimate expectations. The applicants had a legitimate expectation that the information they provided under Regulation No 793/93 would not be used for worst-case classifications under Directive 67/548 and that, in order to classify the nickel carbonates, the Commission would carry out its own scientific assessment of the risks of the intrinsic properties of those substances in accordance with Article 4 of and Annex VI to that directive.

90 Finally, in the applicants' view, the contested 'decision' is not a mere integral part of the contested directive but has autonomous legal effects. It is possible that third parties such as nickel carbonate users might attempt to hold the applicants liable for the negative effects of the derogation statement, including the effects on subsequent classifications of other sparingly soluble nickel compounds.

91 On this point, the Nickel Institute states essentially that the derogation statement has had, and continues to have, serious consequences for its member undertakings,

in that its use affects many other nickel substances produced, imported and used by them. Thus, largely because of that statement and the contested classifications, in Commission Directive 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st time, Directive 67/548 (OJ 2009 L 11, p. 6) nickel hydroxycarbonate, nickel dihydroxide and a further 16 sparingly soluble nickel substances were classified as 'proven human carcinogens' without an independent evaluation of their intrinsic properties or their ability to cause cancer or other relevant effects on human health.

92 Finally, the applicants, supported by the Nickel Institute, deny that their application has become devoid of purpose as a result of the repeal of Annex I to Directive 67/548 by Article 55(11) of Regulation No 1272/2008.

Findings of the Court

— Admissibility of the application for annulment of the alleged 'decision' to base the contested classifications on the derogation statement

93 As regards the admissibility of the application in so far as it is directed against the alleged 'decision' tonstitute an intermediate stage or a preparatory act in the procedure for the adaptation to technical progress of Directive 67/548 which resulted in those classifications. Such an act could not as such be the target of an action for annulment

within the meaning of Article 230 EC, since it would not have binding legal effects capable of affecting the interests of the applicants by bringing about a distinct change in their legal position (see, to that effect, order of 17 March 2009 in Case C-251/08 P *Ayyanarsamy* v *Commission and Germany*, not published in the ECR, paragraph 14 and the case-law cited, and order in *Arizona Chemical and Others*, cited in paragraph 83 above, paragraph 55 et seq.).

94 Any unlawful features vitiating such a preparatory act must be relied on in an action directed against the definitive act for which it represents a preparatory step (see, to that effect, Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 12). The lawfulness of that 'decision' can therefore be challenged only indirectly, in support of an action directed against the acts which closed the procedure (see, to that effect, judgment of 8 June 2009 in Case T-498/07 P *Krcova* v *Court of Justice*, not yet published in the ECR-SC, paragraphs 55 and 56), namely, in the present case, the contested acts.

95 It must therefore 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.

— Admissibility of the application for partial annulment of the contested acts

96 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).

97 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 Case C-444/08 P *Região autónoma dos Açores* v *Council* [2009] not published in the ECR, paragraph 36).

98 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; Case C-125/06 P *Commission* v *Infront WM* [2008] ECR I-1451, paragraph 71; and *Sahlstedt and Others* v *Commission*, cited in paragraph 96 above, paragraph 30).

99 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 96 above, paragraph 31, and order in Case C-503/07 P *Saint-Gobain Glass Deutschland* v *Commission* [2008] ECR I-2217, paragraph 70).

100 It is in the light of those principles that the admissibility of the application for the annulment of the contested acts must be examined.

101 In support of their argument that they are individually concerned by the contested classifications, the applicants submit in essence, first, that they, together with two other companies marketing nickel carbonates, form a limited class of operators who jointly, on the basis of a common agreement, in the risk evaluation procedure in accordance with Regulation No 793/93, submitted the derogation statement, whose content the Commission unlawfully used for the purposes of the contested classifications. Second, the applicants have specific procedural guarantees under that regulation which apply *de facto* to the procedure leading to the adoption of the contested directive. Third, the Commission infringed the applicants' procedural rights, in particular their right to be heard, by failing to consult them before making use of the derogation statement for purposes other than those for which it had been drawn up. Fourth, Norilsk Nickel is distinguished individually in its capacity of representative of the nickel carbonates industry in the negotiations with DEPA and the ECB relating to the risk evaluation of those substances under Regulation No 793/93. Fifth, the applicants are individually concerned by the contested classifications because of their close involvement in that risk evaluation procedure which led directly to those classifications.

102 In the first place, it should be examined whether the applicants enjoyed expressly guaranteed procedural rights in the procedure leading to the adoption of the contested classifications which were capable of distinguishing them individually in the same way as the addressees, since that point is at the heart of their argument.

103 It must be recalled, first of all, 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 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 Case C-483/07 P *Galileo Lebensmittel* v *Commission* [2009] ECR I-959, paragraph 53 and the case-law cited).

104 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 103 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 *Arizona Chemical and Others* v *Commission*, cited in paragraph 83 above, paragraph 73).

105 The applicants themselves concede, however, that they do not enjoy such procedural guarantees under Directive 67/548 or Regulation No 1272/2008 which could make their application admissible.

106 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 83 above, paragraphs 72 to 80 and the case-law cited).

107 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.

108 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 28 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 nickel carbonates, a separate procedure from that which led to the contested classifications, ended, in accordance with Article 11(2) of that regulation, with the inclusion of those substances in the fourth list of priority substances by Regulation No 2364/2000 (see paragraph 32 above). 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 recommended strategy adopted in accordance with the committee procedure referred to in Article 15 of that regulation that the Commission can decide, if necessary, to 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 or any strategy recommendation may give rise to a proposal to classify the substance concerned under Directive 67/548 or Regulation No 1272/2008, which shows that the risk evaluation procedure is independent of the procedure for classifying a substance as a dangerous substance.

109 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, even if only *de facto*, as the applicants claim, in the latter procedure.

110 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.

111 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 risk evaluation procedure for the nickel carbonates. Nor can the argument be accepted that the procedures for adaptation to technical progress are comparable to other administrative procedures such as those concerning competition, State aid or dumping, in which certain rights of the defence laid down by express provisions must be guaranteed and respected for the adoption of an act of individual or general application (see, to that effect, order in *Arizona Chemical and Others* v *Commission*, cited in paragraph 83 above, paragraphs 58 and 74 and the case-law cited), which is precisely not the case here.

112 In the second place, the applicants do not claim that in the procedures which led to the adoption of the contested acts Norilsk Nickel played the part of representative and main negotiator of the nickel industry in the way that it did in the risk assessment procedure under Regulation No 793/93. Moreover, it follows from the considerations in paragraphs 105 to 111 above that such a status in the latter procedure — even if it were shown to exist — does not necessarily extend to the procedures for adapting

Directive 67/548 and Regulation No 1272/2008 to technical progress. Nickel Norilsk cannot therefore be regarded as distinguished individually by reason of that status with respect to the contested classifications, and there is no need to consider whether, as regards its participation in the risk evaluation procedure alone, it was capable of satisfying the criteria for being distinguished individually recognised in *Kwekerij van der Kooy and Others* v *Commission*, cited in paragraph 85 above, paragraphs 20 to 24, and *CIRFS and Others* v *Commission*, cited in paragraph 85 above, paragraphs 29 and 30.

113 In the third place, the applicants have failed to show the existence of a right to be heard that was allegedly infringed by the Commission because it did not consult them before making use of the derogation statement outside the risk evaluation procedure and/or for other purposes (see paragraph 84 above). Neither Article 9(1) and (3) nor Article 10(1) nor Article 11(1) to (3) of Regulation No 793/93 provide for such a right following the submission and acceptance of a request by the manufacturers and importers to be exempted from some or all of the additional tests. Moreover, the applicants have not submitted that the derogation statement contained confidential material within the meaning of Article 16(1) of that regulation which the Commission was required to protect. It may also be noted that, in principle, neither the process of drawing up acts of general application nor the nature of those acts themselves requires, in accordance with the general principle of European Union law such as the right to be heard, that the persons affected should take part, since their interests are deemed to be represented by the political bodies called on to adopt those acts (see order in *Arizona Chemical and Others* v *Commission*, cited in paragraph 83 above, paragraph 73 and the case-law cited). In any event, even if, in the procedure leading to the contested classifications, the Commission did have recourse to the derogation statement as claimed by the applicants, it follows from the case-law cited in paragraphs 103 and 104 above that, in view of the fact that the procedure for the classification of dangerous substances is independent of the risk evaluation procedure for certain substances and in the absence of any procedural right expressly guaranteed by the legislation applicable in the present case, the applicants cannot rely, in support of

their capacity to bring proceedings against the contested classifications, on a procedural guarantee linked solely to the risk evaluation procedure.

114 In the fourth place, it must be examined whether the agreement between the applicants, PCF and Königswarter on the derogation statement, and the existence of that statement and its use by the Commission, are capable of distinguishing them individually as operators forming part of a limited class within the meaning of the case-law cited in paragraph 98 above.

115 It must be observed here, to begin with, that the applicants have not claimed to be the only operators to produce and market the nickel carbonates affected by the contested classifications.

116 Next, it is indeed common ground that the applicants and the other two operators who signed the derogation statement were the only ones who took an active part in the risk evaluation procedure for the nickel carbonates, and that DEPA used that statement in support of its later proposal to classify the nickel carbonates as dangerous substances under Directive 67/548. Furthermore, unlike other operators in the nickel sector potentially affected, those four operators were clearly identifiable or even identified by the authorities responsible for examining and discussing that proposed classification and taking a final decision on it.

117 Nevertheless, those factors are not sufficient to distinguish the applicants individually with respect to the contested classifications.

118 The joint submission of a derogation statement does not create an actual or individual right for those operators, since that statement is no more than a request on their part, in accordance with Article 9(3) of Regulation No 793/93, to be exempted from certain additional testing for the purposes of the risk evaluation of the substance concerned. That circumstance is not therefore a characteristic specific to those operators which could be compared to the status of holder of an existing exclusive television broadcasting right for a sporting event of major importance for society, such as that at issue in *Commission* v *Infront WM*, cited in paragraph 98 above, paragraphs 73 to 77; the status of party to a contract entered into before the adoption of the contested act, such as that at issue in Case 11/82 *Piraiki-Patraiki and Others* v *Commission* [1985] ECR 207, paragraph 31; or the status of person entitled to a special tax regime by virtue of State authorisation granted on the basis of an aid scheme, such as that at issue in *Belgium and Forum 187* v *Commission*, cited in paragraph 98 above, paragraphs 59 to 63.

119 Furthermore, it is only exceptionally that the case-law has accepted such a specific status as distinguishing a person individually on the ground that the object of the contested measures was precisely to interfere with the scope and exercise of those existing rights, whose existence the competent institution was already aware of or whose holders could easily be identified at the time (see, to that effect, *Piraiki-Patraiki and Others* v *Commission*, cited in paragraph 118 above, paragraph 31; *Belgium and Forum 187* v *Commission*, cited in paragraph 98 above, paragraph 63; *Commission* v *Infront WM*, cited in paragraph 98 above, paragraphs 72 and 76; order in *Galileo Lebensmittel* v *Commission*, cited in paragraph 103 above, paragraph 46; and order in Case T-213/02 *SNF* v *Commission* [2004] ECR II-3047, paragraphs 68 to 70).

120 In the present case, the applicants cannot rely on existing rights which could be affected by the contested classifications and hence claim to be affected in a particular way compared to all other operators potentially concerned, since the derogation statement cannot be equated to such a right. The mere possibility of determining, at the time of adoption of the contested acts, by recourse to the derogation statement,

the number and the identity of some of the operators to which they apply does not imply that those acts must be regarded as being of individual concern to those operators, since that application takes effect by virtue of an objective legal or factual situation defined by those acts (see paragraph 99 above), namely their status of producers or distributors of nickel carbonates. Consequently, even with respect to that statement, the applicants are concerned by the contested acts on the same basis as any other operator actually or potentially in the same situation, namely that of producing and/or marketing nickel carbonates.

121 It follows that the applicants are wrong to claim that they are individually concerned by the contested classifications.

122 The application for the partial annulment of the contested acts must therefore be dismissed as inadmissible.

123 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

124 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.

125 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.

126 Under the third subparagraph of Article 87(4) of the Rules of Procedure, the Court can order an intervener to bear its own costs. In the present case, the Nickel Institute, 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. Norilsk Nickel Harjavalta Oy and Umicore SA/NV are to bear their own costs and to pay the costs of the European Commission.

3. The Kingdom of Denmark and the Nickel Institute are to bear their own costs.

Luxembourg, 7 September 2010.

E. Coulon
Registrar

M. Jaeger
President

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