OPINION OF ADVOCATE GENERAL
BOT
delivered on 24 March 2011 [1]

1. This reference for a preliminary ruling concerns the validity of the classifications under European Union law of certain nickel substances as dangerous substances.

2. Two regulatory frameworks are relevant here. The first is laid down in 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. [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, [3] and 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. [4]

3. The second regulatory framework is established by Regulation (EC) No 1272/2008 [5] which partially repeals, amends and replaces Directive 67/548 in order to implement the Globally Harmonised System of Classification and Labelling of Chemicals developed within the United Nations ('the GHS'). Bearing in mind that the classifications harmonised on the basis of Directive 67/548 were still relevant, the European Commission decided to include those classifications in that new regulatory framework. Thus, the contested classifications were reproduced 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. [6]

4. By its questions, the High Court of Justice (England and Wales), Queen's Bench Division

1 — Original language: French.

2 — OJ, English Special Edition, 1967, p. 234, as amended by Council Directive 92/32/EEC of 30 April 1992 (OJ 1992 L 154, p. 1, 'Directive 67/548').

3 — OJ 2008 L 246, p. 1, 'the 30th ATP Directive'.

4 — OJ 2009 L 11, p. 6, 'the 31st ATP Directive'.

5 — Regulation 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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

6 — OJ 2009 L 235, p. 1, 'the 1st ATP Regulation'.

(Administrative Court) is essentially asking the Court whether the 30th and 31st ATP Directives and the 1st ATP Regulation are valid. In particular, the referring court entertains doubts as to whether, in classifying the nickel carbonates in the 30th ATP Directive,[7] and in classifying nickel hydroxide, nickel dihydroxide and the group of nickel substances in the 31st ATP Directive,[8] the Commission complied with the substantive and procedural rules laid down, inter alia, by Directive 67/548 and Regulation No 1272/2008.

5. It should be noted that this reference for a preliminary ruling raises certain issues that are identical to, or closely connected with, those raised in the *Étimine* case (C-15/10), currently pending before the Court, in connection with which I shall also deliver an Opinion.

7 — Under entry 028-010-00-0 in Annex 1F to the 30th ATP Directive, the Commission classified nickel carbonates as 'carcinogenic, category 1' (R 49), 'mutagenic, category 3' (R 68), 'toxic for reproduction, category 2' (R 61), 'toxic' (R 48/23), 'harmful' (R 20), 'skin irritant' (R 38) and 'sensitising' (R 42).

8 — The contested classifications are set out in entries 028-013-00-7 to 028-052-002 in Annex 1B to the 31st ATP Directive and in Annexes II and V to the 1st ATP Regulation respectively.

I — European Union law

A — *Legislation on the classification, labelling and packaging of dangerous substances*

1. Directive 67/548

6. The object of classification is to identify all the physicochemical, toxicological and ecotoxicological properties of substances which may constitute a risk during normal handling or use. Once hazardous properties have been identified, the substance or preparation must be labelled to indicate the hazard(s) in order to protect the user, the general public and the environment. Annex I to Directive 67/548 therefore contains a list harmonising the classification and labelling of over 8 000 substances and groups of substances.

2. Procedure for adapting Directive 67/548 to technical progress

7. Under Articles 28 and 29 of Directive 67/548, the Commission may adapt the annexes to the directive to technical progress by having recourse to the regulatory procedure

with scrutiny. That procedure is laid down in Article 5a(1) to (4) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. [9]

8. Under that procedure, the Commission is to be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission. 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 may adopt them only if, on expiry of a three-month period, neither the Parliament nor the Council has opposed the draft measures. However, 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 a proposal relating to the measures to be taken to the Council and forward it to the Parliament at the same time.

9 — OJ 1999 L 184, p. 23, as amended by Council Decision 2006/512/EC of 17 July 2006 (OJ 2006 L 200, p. 11, 'Decision 1999/468'). That provision must be read in conjunction with paragraph 1 of Annex III to Council Regulation (EC) No 807/2003 of 14 April 2003 adapting to Decision 1999/468/EC 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).

9. Annex I to Directive 67/548 was most recently amended by the 30th and 31st ATP Directives.

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

10. With effect from 20 January 2009, Directive 67/548 was partially repealed, amended and replaced by Regulation No 1272/2008. One of the aims of that regulation is to implement the GHS. [10]

11. As is apparent from recital 53 in the preamble to Regulation No 1272/2008, all existing harmonised classifications were converted into new harmonised classifications based on the new criteria laid down by that regulation. For that purpose, a conversion table is included in Annex VII to the regulation.

12. Those new classifications are set out in Annex VI, Part 3, to Regulation No 1272/2008, in particular in Table 3.1.

13. Furthermore, Article 55(11) of Regulation No 1272/2008 provides that Annex I to Directive 67/548, containing the list of

10 — See recitals 5 to 8 in the preamble to that regulation.

harmonised classifications, is to be deleted. Since application of that regulation is deferred, the classifications harmonised in accordance with the criteria established in Directive 67/548 are still relevant. They are therefore now set out in Table 3.2 in Part 3 of Annex VI to Regulation No 1272/2008.

14. However, it should be pointed out that when that regulation entered into force, Annex VI thereto contained all the classifications from Annex I to Directive 67/548, as amended by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the twenty-ninth time Directive 67/548. [11] That annex therefore did not contain the contested classifications incorporated by the 30th and 31st ATP Directives.

15. The content of those directives was therefore added to Annex VI to Regulation No 1272/2008 when the 1st ATP Regulation was adopted.

16. For the purpose of incorporating the content of those directives, the Commission relied on Articles 53 and 54(3) of Regulation No 1272/2008. Under those provisions, Annexes I to VII to that regulation may be adjusted and adapted to technical and scientific progress in accordance with the regulatory procedure with scrutiny referred to in Article 5a(1) to (4) of Decision 1999/468.

B — *Evaluation and control of the risks of existing substances*

17. Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances [12] provides, as set out in the fourth recital in the preamble thereto, for the sharing and coordination of responsibilities between Member States, the Commission and industrial operators in assessing the risks of substances produced, imported and/or used by those operators. Accordingly, Articles 3 and 4 of the regulation require manufacturers and importers of those substances to report certain relevant information, depending on the volume of production and import.

18. Under Article 8(1) of Regulation No 793/93, the Commission is to draw up lists of substances requiring priority risk evaluation. For each of those substances, the competent authority of a Member State is to

11 — OJ 2004 L 152, p. 1, and Corrigendum, OJ 2004 L 216, p. 3.

12 — OJ 1993 L 84, p. 1, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1, 'Regulation No 793/93').

be designated as rapporteur, in accordance with Article 10(1) of the regulation.

19. Articles 9, 10(2) and 12 of Regulation No 793/93 require manufacturers and importers to forward, where necessary, further information or carry out testing to obtain any missing information that is lacking and is needed for evaluating the risks. In that regard, manufacturers and importers may request of the rapporteur, giving reasons, 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.

20. Following the risk evaluation, the rapporteur may, where appropriate, suggest a strategy and control 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 required 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.

21. That regulatory framework was updated by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH). [13]

22. REACH is an integrated system for registration, evaluation, authorisation and restriction of chemicals, managed by the European Chemicals Agency (ECHA). One of the objectives of the REACH Regulation, [14] laid down in Article 13 thereof, is to promote the development of alternative methods for the assessment of hazards associated with chemical substances.

23. In accordance with the obligations laid down in Articles 6 and 7 of the REACH Regulation, 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 for that substance to the ECHA. To that end, pursuant to Articles 10 and 13 of the REACH Regulation, they must draw up a detailed

13 — Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and Corrigendum, OJ 2007 L 136, p. 3, 'the REACH Regulation').

14 — Recital 1 in the preamble to the REACH Regulation.

technical dossier containing information on the substance in question, including information on its manufacture and uses, its classifications and intrinsic properties, which must, where necessary, be demonstrated by appropriate tests or the results of relevant studies.

II — Facts and the main proceedings

A — *Risk evaluation procedure for nickel carbonates*

24. In October 2000, the Commission, in accordance with Article 8 of Regulation No 793/93, included pure nickel carbonate in the fourth list of priority substances. [15]

25. The Danish Environmental Protection Agency ('the DEPA') was designated as rapporteur for evaluating the risks of that substance. [16] After discussion, the risk evaluation concerning pure nickel carbonate was extended to four compounds in the nickel carbonates group. OMG Harjavalta, one of the main producers of nickel carbonates in Europe, was given responsibility for communicating with the DEPA on behalf of the other producers for the purpose of evaluating the risks of the nickel carbonates in accordance with the relevant provisions of Regulation No 793/93.

26. OMG Harjavalta informed the DEPA that no human toxicological data for nickel hydroxycarbonate existed and, on 27 May 2003, submitted a request, on the basis of Article 9(3) of Regulation No 793/93, to be exempted from the requirement to carry out certain tests and to provide data on the toxicity of nickel hydroxycarbonate as regards

15 — The Commission adopted Commission Regulation (EC) No 2364/2000 of 25 October 2000 concerning the fourth list of priority substances as foreseen under Council Regulation (EEC) No 793/93 (OJ 2000 L 273, p. 5).

16 — Under Article 10(1) of Regulation No 793/93, for each substance on the priority lists, a Member State is given responsibility for its evaluation in accordance with the procedure laid down in Article 15 of that regulation, whilst ensuring fair burden sharing between Member States. The Member State is to designate a rapporteur for that substance from among the competent authorities referred to in Article 13 of the regulation. The rapporteur is to be responsible for evaluating the information submitted by the manufacturer(s) or importer(s) in conformity with the requirements of Articles 3, 4, 7 and 9 of Regulation No 793/93 and any other available information, and for identifying, after consultation of the producers or importers concerned, whether, for the purpose of the risk evaluation, it is necessary to require the manufacturers or importers of priority substances to submit further information and/or to carry out further testing.

human health and the environment ('the derogation statement').

B — *Procedure leading to the contested classifications*

27. In accordance with the final paragraph of Article 10(3) of Regulation No 793/93, the DEPA forwarded the recommended risk evaluation and strategy to the Commission. On 16 April 2004 it submitted to the European Chemicals Bureau (which was replaced by the ECHA) and to the Technical Committee on Classification and Labelling of Dangerous Substances ('the TCCL') a formal proposal for a revised classification of the nickel carbonates under Directive 67/548.

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

29. The TCCL discussed the proposed classification at its meetings of 12 to 14 May 2004 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 30th ATP Directive which was to be sent to the Commission.

30. In November 2005, the 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 risk evaluation report on nickel and the nickel compounds, which stated inter alia that the classification of the nickel carbonates as category 3 mutagens (phrase R 68) was 'justified on the basis of the … derogation statement'.

31. On the basis of the TCCL's recommendation of September 2004, the Committee for Adaptation to Technical Progress of Directive 67/548 [17] decided, at its meeting of 16 February 2007, in favour of the proposal for the 30th ATP Directive, which reproduced the proposed revised classification of the nickel carbonates.

32. In March 2007, that draft proposal was notified to the Committee on Technical Barriers to Trade of the World Trade Organisation (WTO) ('the TBT Committee'). On

17 — See Article 29 of Directive 67/548, read in conjunction with Article 5(1) of Decision 1999/468 and with paragraph 1 of Annex III to Regulation No 807/2003.

7 November 2007, the Commission replied in writing to the comments submitted by non-member States. Following a discussion at the TBT Committee meeting held on 9 November 2007, the Commission decided to postpone the adoption of the 30th ATP Directive, so that further written comments could be submitted to it and a second discussion of the draft proposal take place within that 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 TBT Committee meeting of 19 March 2008.

33. On 21 August 2008, the Commission adopted the 30th ATP Directive and, in particular, the proposed revised classification of the nickel carbonates. On 15 January 2009, the Commission adopted the 31st ATP Directive, in particular the proposed classification of nickel hydroxide, nickel dihydroxide and the group of nickel substances. Those two directives were adopted in accordance with the regulatory procedure with scrutiny referred to in Articles 28 and 29 of Directive 67/548.

34. Finally, on 10 August 2009, the Commission adopted the 1st ATP Regulation on the basis of Article 53 of Regulation No 1272/2008. The contested classifications were therefore inserted into Annex VI to that regulation with effect from 25 September 2009.

III — The reference for a preliminary ruling

35. The High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) decided to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'1. Are [the 30th ATP Directive] and/or [the 1st ATP Regulation], to the extent that they purport to classify or reclassify the nickel carbonates for the relevant endpoints, invalid in that:

(a) the classifications were arrived at without adequate assessment of the intrinsic properties of the nickel carbonates in accordance with the criteria and data requirements set out in Annex VI to [Directive 67/548];

(b) there was no adequate consideration of whether the intrinsic properties of the nickel carbonates may present a risk during normal handling and use, as required by sections 1.1 and 1.4 of Annex VI to [Directive 67/548];

(c) the conditions for the use of the procedure in Article 28 of [Directive 67/548] were not made out;

(d) the classifications were impermissibly based on a derogation statement prepared for the purposes of a risk assessment carried out by a competent authority pursuant to Regulation … No 793/93; and/or

(e) the reasons for adopting the classifications were not given as required by Article 253 EC?

2. Are [the 31st ATP Directive] and/or the 1st ATP Regulation invalid, to the extent that they purport to classify or reclassify the nickel hydroxides and the grouped nickel substances … in the specified respects, in that:

(a) the classifications were arrived at without adequate assessment of the intrinsic properties of the contested nickel substances in accordance with the criteria and data requirements set out in Annex VI to [Directive 67/548], but rather on the basis of certain read-across methods;

(b) there was no adequate consideration of whether the intrinsic properties of the contested nickel substances may present a risk during normal handling and use, as required by sections 1.1 and 1.4 of Annex VI to [Directive 67/548]; and/or

(c) the conditions for the use of the procedure in Article 28 of [Directive 67/548] were not made out?

3. Is the 1st ATP Regulation invalid, so far as it concerns the nickel carbonates and the contested nickel substances, in that:

(a) the conditions for the use of the procedure in Article 53 of Regulation … No 1272/2008 … were not made out; and/or

(b) the classifications for Table 3.1 of Annex VI to [Regulation No 1272/2008] were arrived at without adequate assessment of the properties of the nickel carbonates and the contested nickel substances in ac-

cordance with the criteria and data requirements set out in Annex I to [that] regulation, but rather on the application of Annex VII to [that] regulation?'

36. Observations have been submitted by the parties to the main proceedings as well as the Austrian, Danish, German and United Kingdom Governments and the Commission.

IV — My analysis

A — *Whether the first and second questions are admissible*

37. At the hearing, the Commission stated that it was withdrawing the plea of inadmissibility that it had raised in relation to the first and second questions. Since that issue is raised in the written pleadings, I should nevertheless like to refer to it.

38. The Commission argued that the first and second questions are inadmissible in so far as they concern the validity of the 30th and 31st ATP Directives, claiming that those directives were repealed by the 1st ATP Regulation with effect from 20 January 2009, that is to say, some months before this reference for a preliminary ruling was made. It also stated that the United Kingdom of Great Britain and Northern Ireland failed to transpose those directives into domestic law and has inferred from this that the answers given by the Court would not be capable of influencing the outcome of the case.

39. That line of argument is irrelevant in my view.

40. In particular, I do not share the Commission's view that the European Union legislature repealed the 30th and 31st ATP Directives by deleting Annex I to Directive 67/548 under Regulation No 1272/2008.

41. While the sole purpose of the 30th and 31st ATP Directives was to amend Annex I to Directive 67/548, [18] that does not allow such a conclusion to be drawn. Indeed, those directives entail legal effects for the Member States and their repeal can be effected, to my mind, only by means of a formal repeal. [19] That is justified by the principle of

18 — See the first recital in the preamble to the 30th ATP Directive and the second recital in the preamble to the 31st ATP Directive.

19 — See, in this context, Objective Four, Action A, entitled 'Clarifying which legislation is in force', of the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, 'Updating and simplifying the Community acquis' of 11 February 2003 (COM(2003) 71 final).

legal certainty. Although the directives concerned have now become obsolete, the fact remains that they were not expressly repealed under Regulation No 1272/2008, as amended by the 1st ATP Regulation.

42. In addition, the 30th and 31st ATP Directives are instruments amending Directive 67/548. Consequently, their fate is closely connected to the fate of that directive. The European Union legislature expressly provided in Article 60 of Regulation No 1272/2008, as amended by the 1st ATP Regulation, that 'Directive 67/548 … shall be repealed with effect from 1 June 2015'. The reference to 'Directive 67/548' includes, *a fortiori*, all the amending directives adopted since 27 June 1967, including the 30th and 31st ATP Directives. The 1st ATP Regulation and Directive 67/548 have coexisted since entry into force of Regulation No 1272/2008 and will continue to coexist until 1 June 2015. The classifications adopted in accordance with the harmonised criteria laid down by Directive 67/548 continue to be relevant and are included, as they stand, in Table 3.2 in Annex VI to Regulation No 1272/2008, Table 3.1 in that annex setting out the new classification established in accordance with the GHS. [20]

43. Lastly, the Commission made an error of assessment in maintaining that the 30th and 31st ATP Directives were repealed with effect from 20 January 2009.

44. That date is incorrect: it corresponds to the date of entry into force of Regulation No 1272/2008. In accordance with Article 55(11) thereof, that regulation deletes Annex I to Directive 67/548 with immediate effect. [21] That is Annex I as amended by Directive 2004/73, which, it should be recalled, adapts Directive 67/548 for the twenty-ninth time to technical progress. As the Commission pointed out in its observations, the European Union legislature could not take account of the amendments made to that annex by the 30th and 31st ATP Directives as the text of Regulation No 1272/2008 had been 'frozen', when those directives were adopted, in the course of the codecision procedure.

45. Those amendments were therefore incorporated by the Commission on 10 August 2009 under the 1st ATP Regulation. [22] As is apparent from recital 2 in the preamble to that regulation, the Commission took the view that '[i]t [was] necessary to amend Annex VI to Regulation … No 1272/2008 *in*

20 — Under Article 61(1) to (3) of Regulation No 1272/2008, substances are therefore to be classified in accordance with Directive 67/548 until 1 December 2010. Then, from 1 December 2010 until 1 June 2015, 'substances shall be classified in accordance with both Directive 67/548 … and … Regulation [No 1272/2008]'.

21 — The French version of that provision expressly provides that '[l]'annexe I est supprimée', and the English version that 'Annex I shall be deleted'.

22 — The Commission relied on Article 53 of Regulation No 1272/2008, which provides, inter alia, for the adaptation of Annex VI thereto to technical progress.

order to reflect the recently adopted amendments to Annex I to Directive 67/548 … introduced by [the 30th ATP Directive] and by [the 31st ATP Directive].' [23] It is therefore clear that, prior to entry into force of the 1st ATP Regulation on 10 August 2009, the 30th and 31st ATP Directives were in force.

46. In the light of those factors, I therefore take the view that the 30th and 31st ATP Directives were in force on the date on which the referring court made this reference for a preliminary ruling.

47. Contrary to the Commission's submission, I do not consider that an assessment of the validity of those directives is manifestly irrelevant to the outcome of the main proceedings. As I have stated, in Table 3.2 in Part 3 of Annex VI to Regulation No 1272/2008 that regulation, as amended by the 1st ATP Regulation, reproduces the classification established in accordance with Directive 67/548, as amended most recently by the 30th and 31st ATP Directives. Consequently, assessment of the validity of Regulation No 1272/2008 cannot be dissociated from assessment of the validity of those directives.

23 — My emphasis.

48. In the light of those factors, I am of the view that the first and second questions are admissible in so far as they concern the validity of the 30th and 31st ATP Directives.

B — *The first and second questions*

49. The first and second questions should, to my mind, be addressed together since they raise identical issues.

50. First, the referring court entertains doubt as to the legality of the methods chosen by the Commission for the purpose of assessing the intrinsic properties of the substances at issue in the context of the 30th and 31st ATP Directives. In that regard, it asks the Court, first, whether the read-across method is consistent with the principles laid down in Annex VI to Directive 67/548 and, second, whether the Commission was required to consider the risks associated with normal handling or use of the substances at issue for the purposes of classification. Secondly, the referring court is uncertain whether Article 28 of Directive 67/548 constitutes the appropriate legal basis for the adoption of the 30th and 31st ATP Directives. Thirdly, it asks

the Court whether the validity of the 30th ATP Directive is vitiated by a failure to state reasons, contrary to Article 253 EC.

1. Preliminary observations on the Commission's discretion

51. In order to answer the questions referred by the national court, it is appropriate at the outset to note that, in accordance with settled case-law, [24] the European Union judicature confers on the Commission a broad discretion, in particular as to the assessment of highly complex scientific and technical facts, in order to determine, with full knowledge of the facts, the measures that are necessary and appropriate for the protection of public health. That approach is necessary where action by the Commission is in an area of evolving and complex technology such as that in the main proceedings, and where the matter involves a dangerous substance such as nickel, the classification and labelling of which raise delicate and controversial issues from a scientific viewpoint. Directive 67/548 thus grants the Commission considerable discretion, as to the substance, concerning the extent of the measures to be taken in order to adapt the annexes to that directive to technical progress.

52. Review by the European Union judicature must be confined to verifying whether the exercise of such powers has been vitiated by a manifest error of assessment or a misuse of powers, or whether the legislature has manifestly exceeded the bounds of its discretion. In such a context, the Court has ruled that it cannot substitute its assessment of scientific and technical facts for that of the legislature on which the EC Treaty conferred that task. [25]

2. The assessment of the intrinsic properties of the nickel carbonates

53. In accordance with Article 4(1) of Directive 67/548, substances are to be classified on the basis of their intrinsic properties (extremely flammable, toxic, carcinogenic, etc.). The general principles governing the classification of those substances are set out in Annex VI to the directive.

54. Section 1.1 of Annex VI states that '[t]he object of classification is to identify all the physicochemical, toxicological and ecotoxicological properties of substances … which

24 — Case C-448/06 *cp-Pharma* [2008] ECR I-5685, paragraph 27 and cited case-law, and Case C-343/09 *Afton Chemical* [2010] ECR I-7027, paragraph 28.

25 — *Afton Chemical*, paragraph 28 and case-law cited.

may constitute a risk during normal handling or use'.

55. In particular, section 1.6.1(b) of that annex [26] states that the data required for classification of the substances in question may, if necessary, be obtained from a number of different sources, including not only the results of previous tests, information taken from reference works and the literature and information derived from practical experience but also the results of validated structure-activity relationships and expert judgment.

56. According to the applicant in the main proceedings, by carrying out the contested classifications in the 30th and 31st ATP Directives, the Commission failed to comply with the general principles of classification set out in Annex VI to Directive 67/548. First, the applicant claims that the competent authorities based their assessment on the read-across method rather than on an evaluation of the intrinsic properties of the substances at issue. Secondly, it complains that the Commission failed to consider the risks posed by the substances concerned during normal handling or use.

26 — That provision applies to existing substances, listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), while section 1.6.1(a) of Annex VI to Directive 67/548 applies to new substances.

(a) Use of the read-across method [Questions 1(a) and 2(a)]

57. Unlike the applicant in the main proceedings, I take the view that the Commission did not exceed the bounds of its discretion in using the read-across method for the purposes of its analysis.

58. First, the Commission did not, to my mind, deviate from the principles laid down in section 1.6.1(b) of Annex VI to Directive 67/548 by using the read-across method for the purposes of the contested classification.

59. While use of that method is expressly provided for under the REACH Regulation, its use is also valid under Directive 67/548, a fact which is, moreover, recognised across the scientific community. In 2007, the Commission therefore produced a lengthy study on the use of the read-across method in the context of that directive, referring, by way of illustration, to many examples of classifications based on that method. Those examples include the classifications for the nickel and

borate substances. [27] Also, in 2007, the OECD (Organisation for Economic Cooperation and Development) referred expressly to that method as a method provided for in Directive 67/548 for assessing the intrinsic properties of substances. [28] Lastly, use of the read-across method in the classification and labelling of dangerous substances has been the subject of many reports by legal commentators, including a study on the classification of the nickel substances. [29]

60. Clearly, therefore, use of the read-across method is broadly accepted and widely publicised in the scientific community.

61. That method is one of prediction, based on the similarity of the chemical molecules. Scientists make use of the available data on substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern due to their structural similarity (the substances may be regarded as a group or 'category' of substances). [30] Endpoint information relating to one chemical substance is therefore used to predict the same endpoint for another chemical substance which is regarded as similar. [31] Thus, that method avoids the need to test every substance for every hazard endpoint.

62. The Danish Government maintains that the read-across method is the same as the method of drawing on data from the structure-activity relationships referred to in section 1.6.1(b) of Annex VI to Directive 67/548.

27 — See the document of the Commission's Joint Research Centre, 'A Compendium of Case Studies that helped to shape the REACH Guidance on Chemical Categories and Read Across', 2007, available at: http://ecb.jrc.ec.europa.eu/documents/QSAR/EUR_22481_EN.pdf. See, in particular, Gallegos, A., Langezaal, I., and Worth, A., 'Summary of Discussions on the Use of QSARs, Read-Across and Grouping in the Technical Committee for Classification and Labelling (TC C&L)', 28 February 2007, at p. 67 of the Commission document.

28 — See 'Report on the regulatory uses and applications in OECD member countries of (quantitative) structure-activity relationship [(Q)SAR] models in the assessment of new and existing chemicals', available at: http://www.oecd.org/dataoecd/55/22/38131728.pdf.

29 — See, for example, Hart, J., 'Nickel compounds – a category approach for metals in EU legislation', a report to the Danish Environmental Protection Agency, January 2008, available at: http://cms.mim.dk/NR/rdonlyres/07DB028E-134E-4796-BF6D-97B9AD5F9E82/0/Nikkel.pdf; Hart, J., and Veith, G.D., 'Applying Chemical Categories to Classification & Labelling: A Case Study of Volatile Aliphatic Ethers', a report to the Danish Environmental Protection Agency, January 2007, available at: http://www.qsari.org/documents/aliphaticethers.pdf, and Comber, M., and Simpson, B., 'Grouping of Petroleum Substances', September 2006, at p. 113 of the Commission document cited in footnote 27.

30 — Application of the group concept requires it to be possible for physicochemical properties, the effects on human health and environmental effects or environmental fate to be predicted from data for a reference substance or substances within the group by interpolation from other substances in the group. Ideally, a category should include all potential elements of similar substances.

31 — See paragraph 2.1 of 'Practical guide 6: How to report read-across and categories' and paragraph 3.1.2.4 of the 'Evaluation under REACH – Progress Report 2009', available on the ECHA website.

The United Kingdom Government submits that, by authorising the use of 'the results of previous tests' and data from structure-activity relationships, the European Union legislature implicitly authorised, in that section, the use of that method for the purposes of classifying a substance.

63. Unlike the Danish Government, I am not persuaded that the read-across method is the same as the model based on the structure-activity relationship. Nevertheless, those methods must not, to my mind, be regarded as separate and mutually independent. Based on common principles, they form part of the same overall scheme and I am therefore inclined to the view that reference to one of them does not preclude recourse to the other.

64. The structure-activity relationship model seeks to predict the intrinsic properties of chemicals by using various databases and theoretical models, instead of conducting tests. Based on knowledge of chemical structure, that model relates characteristics of the chemical to a measure of a particular activity. It allows qualitative conclusions to be drawn concerning the presence or absence of a property of a substance, based on a structural feature of the substance. [32]

65. Therefore, provided that data exist relating to a validated structure-activity relationship of a substance that has already been classified, an expert can extrapolate from those data to classify a substance with similar structures and properties. As pointed out by the United Kingdom Government, the read-across method always involves the use of data relating to other substances.

66. I therefore consider that the principles laid down in section 1.6.1(b) of Annex VI to Directive 67/548 do not preclude the Commission from having recourse to the read-across method for the purposes of its assessment.

67. Secondly, the REACH Regulation promotes the use of that technique [33] to avoid recourse to further tests on animals.

68. In accordance with Article 13 of that regulation, information on intrinsic properties of chemicals, in particular on their human toxicity, is to be generated whenever possible by means other than vertebrate animal tests,

32 — See paragraph 3.1.2.2 of the 'Evaluation under REACH – Progress Report 2009'.

33 — See also Article 10(5) of Regulation No 793/93.

through the use of alternative methods, for example, qualitative or quantitative structure-activity relationship models or information from structurally related substances (grouping or read-across). As the European Union legislature states at section 1.3 of Annex XI to that regulation, *the results of those assessments are adequate for the purpose of classification and labelling*[34] and/or for the risk assessment of those substances.

69. Moreover, that method, like the method based on the structure-activity relationship, is promoted in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes,[35] to which Annex VI to Directive 67/548 expressly refers.

70. Lastly, predictions made using the read-across method are currently expressly permitted under Regulation No 1272/2008. Section 1.1.1.3 of Annex I to that regulation points out inter alia that all available information bearing on the determination of hazard, such as information from the application of the category approach (grouping, read-across), must be considered in order to determine the weight of evidence.

71. Thirdly, account must be taken of the fact that use of the read-across method has, in the present case, been scrutinised by experts.

72. Whether or not use of that method is justified from a scientific point of view is, to my mind, a matter for expert scientific opinion; it is not for the Court to assess its merits.

73. None the less, I note that a broad range of scientific experts, meeting in working parties and committees,[36] as well as representatives from the nickel sector, were brought together over several years for the purpose of the assessments at issue. Those assessments were based on epidemiological studies carried out on workers exposed to nickel compounds and experimental carcinogenicity studies carried out on laboratory animals. They were

34 — My emphasis. See also section 1.5 of that annex.

35 — OJ 1986 L 358, p. 1.

36 — See points 27 to 32 of this Opinion.

also based on information from specialist publications. [37]

74. In the studies carried out by the various groups, it was found that the toxicity risk assessment for the nickel carbonates should be based on the toxicity of the nickel ion, which the nickel substances are composed of. As is apparent from the Opinion on the Risk Assessment Report delivered on 4 May 2006 by the Scientific Committee on Health and Environmental Risks, [38] the actual release of that ion or its bioavailability is responsible for the genotoxic and carcinogenic effects of those substances. The nickel compounds were therefore considered to belong to the same group. Since the bioavailability of that ion was assessed by reference to its solubility, the experts took the view that where the water solubility of a given nickel compound is sufficiently similar to that of another nickel compound for which toxicological data are available, those factors could justify the same classification.

75. Consequently, it seems to me that the physicochemical properties and the effects on human health of the nickel carbonates were predicted on the basis of data for nickel compounds from the same group, after expert studies and consultations based on a great many scientific works had been carried out, ultimately arriving at a consensus.

76. In assessing the carcinogenicity and toxicity of the nickel carbonates, the Commission followed the opinion of those groups of experts.

77. Therefore, in the light of the foregoing considerations, it seems to me that the Commission did not manifestly exceed the bounds of its discretion in using the read-across method for the purposes of assessing the intrinsic properties of the substances in question.

(b) Assessment of the risks during normal handling or use of the substances [Questions 1(b) and 2(b)]

78. As I have pointed out, the object of classification is, in accordance with sections 1.1 and 1.7 of Annex VI to Directive 67/548, to identify all the physicochemical, toxicological and ecotoxicological properties of substances *which may constitute a risk during*

37 — See the document of the World Health Organisation, International Agency for Research on Cancer, 'Chromium, Nickel and Welding, Summary of Data Reported and Evaluation', *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, vol. 49, 5 November 1997, included in Annex I to the Commission's observations.

38 — Available in English on the website of the European Commission, Directorate-General for Health and Consumers (see, in particular, p. 4 et seq.).

their normal handling or use. [39] In that regard and in accordance with section 1.4 of that annex, the label must take account of all potential hazards which are likely to be faced in such handling or use.

79. In this case, the applicant in the main proceedings submits that the Commission failed to take account of the risks entailed in the normal handling or use of the substances at issue for the purposes of the contested classification. It points, in particular, to the fact that three of the four nickel carbonates are never handled or used outside a laboratory.

80. I do not consider that criticism valid or that it can invalidate the contested classifications. That criticism, to my mind, confuses assessment of the hazards associated with a substance with assessment of the risks of the substance.

81. The system for classifying and labelling substances established by Directive 67/548 and reproduced in Regulation No 1272/2008 is based on the reporting of information relating to the hazards associated with substances.

82. This is stated expressly in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548. [40] Under Article 2(2) of Directive 93/67, '"hazard identification [of a substance]"' is defined as 'the identification of the adverse effects which [that] substance has an inherent capacity to cause'.

83. Assessment of the hazards associated with a substance must therefore not be confused with assessment of its risks.

84. Risk assessment is concerned with the likelihood that one of the hazards associated with a substance will occur as a result of human or environmental exposure to that substance. Classification and labelling based on risk are therefore linked to specific use and specific conditions of exposure. They therefore do not reflect the actual exposure situation; nor do they make it possible to adopt risk management measures.

85. Classification and labelling based on the hazards associated with normal handling or use of a substance make it possible for the same information to be provided in an appropriate manner to all users of chemicals, irrespective of the location and methods of use. That information thus enables the competent authorities to adopt independent decisions on the risk management measures to be taken, which may vary considerably depend-

39 — My emphasis.

40 — OJ 1993 L 227, p. 9, that directive having been repealed.

ing on the conditions and types of use. Hazards must therefore be classified independently of the manner or location in which the substance is used – whether in a laboratory or outside a laboratory – independently of the means by which exposure occurs, whether orally, by dermal exposure or by inhalation, and of the levels of exposure to the substance. Such classification must not be limited by consideration of specific uses.

86. Consequently, it cannot be established to my mind on the basis of the argument put forward by the applicant in the main proceedings that the Commission manifestly exceeded the bounds of its discretion or that it made a manifest error in exercising that discretion by failing to take account of the fact that some nickel carbonates are never handled or used outside a laboratory.

(c) Use of the derogation statement issued by the nickel manufacturers and importers [Question 1(d)]

87. By Question 1(d), the referring court asks the Court, in essence, whether the validity of the 30th ATP Directive and of the 1st ATP Regulation is affected in so far as the Commission relied on the risk assessment carried out by the DEPA, in particular the derogation statement issued under Regulation No 793/93, for the purposes of the contested classifications.

88. It is apparent from the information submitted to the Court that the Commission, assisted by a committee composed of representatives of the Member States, decided, in accordance with Article 8 of Regulation No 793/93, to include the nickel carbonates in a list of priority substances for the purpose of assessing the risks they pose to human health and the environment.

89. In assessing the risks associated with the nickel carbonates, manufacturers and importers were required to submit all relevant information available to them and carry out additional testing. [41] However, as is apparent from Article 9(3) of that regulation, manufacturers and importers may be exempted from some or all of that testing on the grounds that a given piece of information is either unnecessary for risk assessment or is impossible to obtain. In the action in the main proceedings, having informed the DEPA that no human toxicological data for nickel hydroxycarbonate existed,

41 — See, inter alia, Article 9 of that regulation.

OMG Harjavalta requested on 27 May 2003 that it be exempted from the requirement to carry out tests and report information on the toxicity of nickel hydroxycarbonate for human health and the environment. The DEPA granted that request.

90. The applicant in the main proceedings claims that the Commission made the contested classification on the basis of the derogation statement. In its view, the Commission therefore disregarded the classification criteria set out in Annex VI to Directive 67/548 and thus misused its powers, rendering the 30th ATP Directive unlawful.

91. Those criticisms are clearly unfounded.

92. First, contrary to what the applicant in the main proceedings appears to be claiming, the Commission did not base its classification decision on the derogation statement. In particular, as has been seen, a broad range of experts were brought together, alongside the Commission, for the assessment of the intrinsic properties of the nickel carbonates, taking as their basis for the assessment a great many scientific works and prediction methods consistent with the methods and criteria laid down in Annex VI to Directive 67/548. Therefore, as the Danish and United Kingdom Governments state in their observations, the contested classifications were made on a scientific basis, independently of the request by the manufacturers and importers to be exempted from further testing and from reporting additional information.

93. Secondly, the applicant in the main proceedings has failed to show, in my view, that the Commission in fact relied on that derogation statement for the purposes of the contested classifications. Indeed, the first measure on which the applicant relies in support of its argument is the proposal for a revised classification of the nickel carbonates under Directive 67/548 submitted by the DEPA. The second measure is the minutes of the meeting held between the representatives of the European Chemicals Bureau and the experts from the TCCL. The conclusions reached in that document in 2004 were then redrafted to a considerable degree in the various expert reports.

94. In the light of those considerations, I find it difficult to conclude that the Commission could have manifestly exceeded the bounds of the discretion which it enjoys in this area.

3. Whether the legal basis for the 30th and 31st ATP Directives is valid [Questions 1(c) and 2(c)]

95. By Questions 1(c) and 2(c), the referring court asks the Court whether Article 28 of Directive 67/548 constituted an appropriate legal basis for the adoption of the 30th and 31st ATP Directives.

96. Article 28 of Directive 67/548 is entitled 'Adaptation to technical progress'. It provides that the amendments necessary for adapting the annexes to technical progress are to be adopted in accordance with the regulatory procedure with scrutiny laid down in Article 5a(1) to (4) of Decision 1999/468. As I have stated, Article 5a provides that the Commission is to be assisted by a committee composed of the representatives of the Member States responsible for delivering an opinion on the draft adaptation proposed by the Commission. It also provides for a vote in the Council if the measures envisaged by the Commission are not in accordance with the opinion of the committee.

97. The applicant in the main proceedings submits that the conditions under which the Commission may have recourse to the procedure under Article 28 of Directive 67/548 were not met in so far as, since no technical or scientific data existed, there could not be said to be any technical progress concerning the substances at issue.

98. Like all the governments of the Member States which have submitted observations and the Commission, I consider that Article 28 of Directive 67/548 constitutes a permissible legal basis for the measures contained in the 30th and 31st ATP Directives.

99. First, the applicant's premiss that there could not be said to be any technical progress as no technical or scientific data existed is incorrect. Indeed, I have shown above that the adaptations of Directive 67/548 were adopted when wide-ranging consultations took place and a large number of expert reports produced after the Commission's inclusion, in October 2000, of the pure nickel carbonates in the fourth list of priority substances. I have also taken the view that the intrinsic properties of the substances at issue were assessed on the basis of data collected in the course of scientific and experimental studies, data which emerged, inter alia, from prediction methods, all those works requiring the involvement of a broad range of experts and their consensus.

100. Secondly, the question whether those data were sufficient to show that technical progress exists within the meaning of Article 28 of Directive 67/548 and to justify adapting the classification and labelling procedures of the substances at issue is, to my mind, a matter for the Commission's assessment in this area.

101. In the *Enviro Tech (Europe)* judgment, [42] the Court observed that the Commission has a broad discretion as to complex scientific and technical facts, such as those relating to the evaluation of the intrinsic properties of the substances at issue, for the purpose of determining the nature and scope of the measures to be adopted in order to adapt the annexes to Directive 67/548. [43] Accordingly, the Commission's decision to adapt the classification and labelling of the substances at issue can be subject to only limited review by the court.

102. In this instance, I take the view that the Commission clearly did not exceed the bounds of its discretion or vitiate its decision by committing a manifest error or misusing its powers in considering that, given the current state of scientific knowledge and in the light of the conclusions reached by the various technical committees, there was sufficient technical progress to justify adapting Directive 67/548.

4. The question alleging a failure to state reasons for the 30th ATP Directive [Question 1(e)]

103. The referring court has asked the Court whether the validity of the 30th ATP Directive is vitiated by a failure to state reasons, contrary to Article 253 EC. The applicant in the main proceedings complains that the Commission has failed to set out the facts and legal considerations justifying the adoption of the contested classifications in the 30th ATP Directive.

104. In accordance with Article 253 EC, regulations and directives must state the reasons on which they are based. It has been consistently held that the statement of reasons must show clearly and unequivocally the reasoning of the institution which adopted the measure. It must, on the one hand, enable the persons concerned to understand the full significance of and the reasons for the measure at issue in order to enable them to safeguard their rights and, on the other hand, enable the European Union judicature to exercise its powers of review of legality. [44]

42 — Case C-425/08 [2009] ECR I-10035.

43 — Paragraphs 46 and 47 of that judgment and the case-law cited.

44 — See Case C-380/03 *Germany* v *Parliament and Council* [2006] ECR I-11573, paragraph 107 and case-law cited.

105. However, the degree of reasoning required may vary. Thus, the scope of the obligation to state reasons depends on the nature of the measure and all the documents in the case. It must also be assessed with reference to the wording of the measure, the context and the procedure under which it was adopted, and to the whole body of legal rules governing the matter in question. [45]

106. Thus, as regards regulations forming part of legislation that is complex in content, the Court has held that 'the statement of the reasons on which regulations are based is not required to specify the often very numerous and complex matters of fact or of law dealt with in the regulations, provided that the latter fall within the general scheme of the body of measures of which they form part. Consequently, if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for each of the technical choices made by the institution.' [46]

107. Furthermore, the Court has stated that the requirement of a statement of reasons must be viewed in the context of the interest which the addressee may have in obtaining explanations, [47] that is to say, the opportunities available to addressees for obtaining information. Accordingly, the Court accepts that a decision addressed to a Member State might not contain a detailed statement of reasons since the Government concerned was closely involved in the process by which that decision came about. [48] Consequently, where the persons concerned are involved in the process by which a measure came about, the requirement to state reasons may be circumscribed, since they acquire information through their involvement. [49]

108. In the preamble to the 30th ATP Directive reference is made to the need to update Annex I to Directive 67/548 to include further existing substances and to adapt existing entries if new scientific knowledge becomes available. As regards the nickel substances, the Commission points out that recent preliminary and partial information was submitted by industry. It notes, however, that, since that information had not yet been peer-reviewed, special attention was to be paid to the outcome of the discussion within the International Agency for Research on Cancer (IARC) on the classification of nickel substances and any new relevant scientific findings or interpretations given to the data used to establish the current proposals for the nickel compounds concerned by the 30th ATP Directive. Finally, the Commission points out that the measures adopted un-

45 — Ibid., paragraph 108 and case-law cited.

46 — Case 250/84 *Eridania zuccherifici nazionali and Others* [1986] ECR 117, paragraph 38. See also Case 167/88 *AGPB* [1989] ECR 1653, paragraph 34.

47 — Case C-303/88 *Italy* v *Commission* [1991] ECR I-1433, paragraph 52 and case-law cited.

48 — Case 819/79 *Germany* v *Commission* [1981] ECR 21.

49 — Case T-504/93 *Tiercé Ladbroke* v *Commission* [1997] ECR II-923, paragraphs 52 to 55.

der that directive are in accordance with the opinion of the Committee on the Adaptation to Technical Progress.

109. In the specific context of establishing the adaptations of Directive 67/548 to technical progress, the reasoning in the 30th ATP Directive is in my view adequate.

110. First, as has been seen, the enactment of the 30th ATP Directive forms part of a complex evolving legal process and calls for high-level scientific and technical assessments. In my view, the Commission was not therefore required to specify all the technical and scientific evidence on which it relied for the purposes of the contested classifications.

111. Secondly, as has been seen, following the inclusion of the pure nickel carbonates in the list of priority substances in October 2000, the Member States and the nickel producers were closely involved in the process by which the 30th ATP Directive came about, the former via attendance at the meetings of specialist experts brought together inter alia within the TCCL and the Committee on the Adaptation to Technical Progress, and the latter in view of their obligations to report information under Regulation No 793/93. In this regard, it is apparent from the documents in the case that the applicant in the main proceedings was able to raise objections regarding the evaluation methods contemplated by the Commission during the administrative procedure. [50]

112. Moreover, it is apparent from the information submitted to the Court by the Commission and the United Kingdom Government that the meetings of those experts were minuted and those minutes were available to the parties concerned prior to the adoption of the 30th ATP Directive. [51] Consultation of the website of the Commission Directorate-General for Health and Consumers and of the many annexes attached by the applicant in the main proceedings to its observations [52] in fact illustrates the public nature of those documents. Furthermore, specific studies describing in detail the discussions which led to the adoption of such an approach were published. [53] The applicant in the main proceedings, in view of its involvement in the procedure and the accessibility of the Commission's documents, was fully apprised, to my mind, of the Commission's reasoning. Clearly, the applicant is now in a position to

50 — See PowerPoint presentation given by the applicant in the main proceedings in Brussels on 29 September 2008, contained in Annex 3 to the Commission's observations.

51 — See, for example, final risk assessment report on nickel carbonates, published by the DEPA, available on the website of the Danish Environment Ministry (the Kingdom of Denmark was designated as rapporteur under Regulation No 793/93) at the following address: http://www.mst.dk/NR/rdonlyres/2929A8CB-8A5B-43C9-BB67-506D847E960E/0/Ni_carbonate_EU_RAR_HH_March_2008_finaldraft.pdf.

52 — See 'Background documentation to nickel-entries in ATP 30' and 'Background documentation to nickel-entries in ATP 31', available on the Commission website at the following address: http://tcsweb3.jrc.it/home.php?CONTENU=/DOCUMENTS/Classification-Labelling/.

53 — See Commission document cited in footnote 27, and Hart, J., op. cit.

bring its action before the national court in full knowledge of the facts. As to the European Union judicature, I take the view that it is likewise in a position to exercise its power of review.

113. In the light of those considerations, I therefore take the view that the 30th ATP Directive is not vitiated by a failure to state reasons.

114. It follows from all the foregoing considerations that consideration of the first and second questions has disclosed nothing to affect the validity of the 30th or 31st ATP Directives or, consequently, the validity of the 1st ATP Regulation, in so far as concerns the Commission's classification of the nickel carbonates, nickel hydroxide and nickel dihydroxide and the group of nickel substances.

C — *The third question*

115. By its third question, the referring court asks the Court to assess the validity of the 1st ATP Regulation, which, it will be recalled, adapted Regulation No 1272/2008 for the first time to technical progress.

116. As is apparent from recital 53 in the preamble to Regulation No 1272/2008, all existing harmonised classifications were converted into new harmonised classifications using the new criteria laid down by that regulation. Moreover, as the application of that regulation is deferred and the classifications harmonised in accordance with the criteria laid down in Directive 67/548 are relevant for the classification of substances during the ensuing transition period, all existing harmonised classifications are also set out in an annex to Regulation No 1272/2008.

117. Thus, Part 3 of Annex VI to that regulation contains two lists of hazardous substances subject to harmonised classification and labelling. Table 3.1 of that annex lists the hazardous substances subject to harmonised classification and labelling based on the criteria set out in that regulation. Table 3.2 of that annex lists the hazardous substances subject to harmonised classification and labelling based on the criteria set out in Annex VI to Directive 67/548. [54]

118. The referring court is uncertain inter alia whether the legal basis of the 1st ATP

54 — See recital 1 in the preamble to the 1st ATP Regulation.

Regulation is valid and whether the classifications in Table 3.1 in Part 3 of Annex VI to Regulation No 1272/2008 are lawful.

1. Whether the legal basis of the 1st ATP Regulation is valid [Question 3(a)]

119. In the first part of its question the referring court asks the Court whether the Commission could legitimately rely on Article 53 of Regulation No 1272/2008 for the purpose of adopting the 1st ATP Regulation.

120. As is apparent from recital 2 in the preamble to the 1st ATP Regulation, the Commission considered it '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 30th and 31st ATP Directives]'. The Commission also considered that '[t]hose measures constitute[d] adaptations to technical and scientific progress within the meaning of Article 53 of Regulation … No 1272/2008'.

121. The applicant in the main proceedings maintains that the only permissible legal basis for the measures contained in the 1st ATP Regulation is to be found not in Article 53 but in Article 37 of Regulation No 1272/2008. What the applicant is in fact seeking is a new assessment by the competent authorities of the intrinsic properties of the substances at issue.

122. Contrary to what is claimed by the applicant in the main proceedings, I take the view that Article 37 of Regulation No 1272/2008 does not apply in this instance, in view of the purpose of that provision.

123. That provision forms part of Chapter I under Title V of that regulation, entitled '*Establishing*[55] harmonised classification and labelling of substances'. Under that provision, Member States and representatives of industry in the sector may submit to the ECHA a proposal for harmonised classification and labelling of substances in accordance with the principles established in that regulation. The proposal is first examined by the ECHA Committee for Risk Assessment and subsequently by the Commission, which must then submit a draft decision concerning the inclusion of that substance together with the

55 — My emphasis.

relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI to Regulation No 1272/2008. [56]

124. In my view, Article 37 of that regulation establishes the procedure to be followed where a proposal is submitted to adopt, for the first time, harmonised classification or labelling of a substance on the basis solely of the criteria established in Annex I to that regulation. It is therefore not possible under that procedure for the harmonised classification and labelling of substances in respect of which a decision has already been taken on the basis of the principles laid down in Directive 67/548 to be incorporated.

125. On the other hand, that is, to my mind, entirely possible if Article 53 of Regulation No 1272/2008 is taken as the basis. As shown by its title, that provision establishes the procedure for '[a]daptations to technical and scientific progress' of that regulation. Under that provision, '[t]he Commission may adjust and adapt … Annexes I to VII [to that regulation] to technical and scientific progress'. [57] It seems clear to me that, in adopting the 1st ATP Regulation, the Commission 'adjusted and adapted' Regulation No 1272/2008 to the latest amendments to Directive 67/548 introduced by the 30th and 31st ATP Directives. It will be recalled that those amendments could not be included in the first version of Regulation No 1272/2008 as the text of the regulation was 'frozen' during the codecision procedure. It should also be recalled that those amendments were, to my mind, justified since there was technical progress within the meaning of Article 28 of Directive 67/548.

126. In the light of those factors, I therefore consider that Article 53 of Regulation No 1272/2008 constitutes a permissible legal basis for the measures contained in the 1st ATP Directive.

2. Whether the classifications in Table 3.1 in Part 3 of Annex VI to Regulation No 1272/2008 are lawful [Question 3(b)]

127. This question concerns the classification of the substances at issue in Table 3.1 in Part 3 of Annex VI to Regulation No 1272/2008. The referring court asks the Court whether the Commission was entitled to rely on Annex VII to that regulation in order to arrive at that classification. The applicant in the main proceedings maintains that the Commission should have carried out a new assessment of the intrinsic properties of the nickel carbonates and the nickel substances on the

56 — That measure is adopted in accordance with the regulatory procedure with scrutiny laid down in Article 5a(1) to (4) of Decision 1999/468.

57 — Ibid.

basis of the criteria laid down in Annex I to that regulation.

128. In my view, the Commission did not, in this regard, commit any manifest error of assessment or misuse its powers in such a way as to affect the validity of the 1st ATP Regulation. I have indeed pointed out that, in line with the intention of the European Union legislature, all existing harmonised classifications were to be converted into new harmonised classifications using the new criteria laid down in Regulation No 1272/2008. To that end, Annex VII to that regulation contains a table specifically designed to facilitate the conversion of the classification of a substance established under Directive 67/548 into the corresponding classification established under Regulation No 1272/2008. The Commission was therefore perfectly entitled to rely on that annex.

129. It follows from all of the foregoing that consideration of the third question has disclosed nothing to affect the validity of the 1st ATP Regulation adapting, for the first time, Regulation No 1272/2008 to technical progress, in so far as concerns the Commission's classification of the nickel carbonates, nickel hydroxide and nickel dihydroxide and the group of nickel substances.

V — Conclusion

130. In the light of the foregoing considerations, I propose that the Court should answer the questions referred by the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) for a preliminary ruling as follows:

Consideration of the questions referred for a preliminary ruling has disclosed nothing to affect the validity of: (i) 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; (ii) 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/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; or (iii) 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.