JUDGMENT OF THE COURT (Fourth Chamber)

21 July 2011 *

In Case C-14/10,

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

Nickel Institute

v

Secretary of State for Work and Pensions,

THE COURT (Fourth Chamber),

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

* Language of the case: English.

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

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

after considering the observations submitted on behalf of:

— the Nickel Institute, by D. Anderson QC, K. Nordlander, advokat, and H. Pearson, Solicitor,

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

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

— the German Government, by J. Möller and B. Klein, acting as Agents,

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

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

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

gives the following

Judgment

1 This reference for a preliminary ruling concerns:

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

— the validity of the classifications of nickel hydroxides and other grouped nickel substances incorporated into Annex I to Directive 67/548 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 (OJ 2009 L 11, p. 6, 'the 31st ATP Directive'); and

— the validity of those classifications in so far as they were taken from the 30th and 31st ATP Directives and incorporated into Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548 and 1999/45/EC, and amending Regulation

(EC) No 1907/2006 (OJ 2008 L 353, p. 1; 'the CLP Regulation'), by Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 (OJ 2009 L 235, p. 1; 'the 1st ATP Regulation').

2 The reference has been made in proceedings between the Nickel Institute and the Secretary of State for Work and Pensions for judicial review of any measures of the United Kingdom Government to implement the classifications made by the 30th and 31st ATP Directives and the 1st ATP Regulation.

Legal context

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

Directive 67/548 and its 30th and 31st adaptation to technical progress by the 30th and 31st ATP Directives

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

4 Article 2(2)(l), (m) and (n) of Directive 67/548 classifies as 'dangerous' within the meaning of the directive inter alia substances which are 'carcinogenic', 'mutagenic' or 'toxic for reproduction'.

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

6 Under Articles 28 and 29 of Directive 67/548, the annexes thereto may be adapted to technical progress under the regulatory procedure provided for in Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23), as amended by Council Decision 2006/512/EC of 17 July 2006 (OJ 2006 L 200, p. 11) ('Decision 1999/468'). Decision 1999/468 must be read in conjunction with point 1 of Annex III to Council Regulation (EC) No 807/2003 of 14 April 2003 adapting to Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in Council instruments adopted in accordance with the consultation procedure (OJ 2003 L 122, p. 36).

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

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

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

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

— the results of previous tests,

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

— information taken from reference works and the literature, or

— information derived from practical experience.

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

10 Directive 67/548 was last amended by the 30th and 31st ATP Directives, classifying inter alia certain nickel carbonates, nickel hydroxides, and other grouped nickel substances at issue in the main proceedings (collectively 'the nickel substances at issue in the main proceedings') at a high hazard level, which entailed compliance with new labelling and packaging requirements and other legal and commercial consequences. Those ATP Directives classified the nickel substances at issue in the main proceedings as carcinogenic in category 1 and some of them also as mutagenic in category 3 and/or reprotoxic in category 2.

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

11 It is apparent from Article 2(a) of Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Directive 67/548 (OJ 1993 L 227, p. 9), read in conjunction with Articles 3 to 5 thereof, that assessment of the risks posed by a substance for the purposes of its classification under Directive 67/548 involves, as a first stage, hazard identification, which is defined as being the identification of the adverse effects which a substance has an inherent capacity to cause.

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

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

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

14 Recital 53 in the preamble to the CLP Regulation states that, in order to take full account of the work and experience accumulated under Directive 67/548, including the classification and labelling of specific substances listed in Annex I to that directive, all existing harmonised classifications should be converted into new harmonised classifications using the new criteria.

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

16 Article 37 entitles the competent authorities of the Member States and, in more limited circumstances, manufacturers, importers and distributors of substances to submit detailed proposals for harmonised classification and labelling to the European

Chemicals Agency (ECHA), which replaced the European Chemicals Bureau from 1 June 2008.

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

18 By virtue of Article 55(2) and (11) of the CLP Regulation, Annex I to Directive 67/548 was deleted and replaced by Part 3 of Annex VI to the regulation from 20 January 2009. Table 3.1 in Annex VI sets out the new classification following that conversion and Table 3.2 reproduces the old classification established under Directive 67/548 as amended by Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Directive 67/548 (OJ 2004 L 152, p. 1; corrigenda at OJ 2004 L 216, p. 3, and OJ 2004 L 236, p. 18).

19 When the CLP Regulation entered into force on 20 January 2009, Annex VI thereto thus did not reflect the classifications at issue, incorporated into Annex I to Directive 67/548 by the 30th and 31st ATP Directives.

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

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

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

23 On the basis of Article 53 of the CLP Regulation, the 1st ATP Regulation transferred the classifications established by the 30th and 31st ATP Directives to Part 3 of Annex VI to the CLP Regulation and translated them, so that they were included without amendment in Table 3.2 in Annex VI to the CLP Regulation whilst, in Table 3.1 in that annex, they were simply translated into classifications made on the basis of the CLP Regulation, using the translation table in Annex VII thereto. The 1st ATP Regulation entered into force on 25 September 2009.

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

24 Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003

(OJ 2003 L 284, p. 1) ('Regulation No 793/93'), supplemented the system laid down by Directive 67/548 for notification of new substances.

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

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

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

28 Under Article 9 of Regulation No 793/93, headed 'Data to be supplied for substances appearing on the priority lists', manufacturers and importers were obliged to provide all available information and corresponding study reports for risk assessment of the substances concerned and, if necessary, to carry out the testing necessary to obtain missing data. By way of derogation from that rule, manufacturers and importers could submit a reasoned request to the Member State authority designated as rapporteur in accordance with Article 10 of the regulation for exemption from some or all of the additional testing on the grounds that a given piece of information was either unnecessary for risk assessment or was impossible to obtain.

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

30 According to Article 13 of the REACH Regulation, the information supplied for the purpose of evaluation of chemicals as regards human toxicity in particular must be obtained whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across).

31 Section 1.5 of Annex XI to the REACH Regulation provides for use of the read-across approach in the evaluation of chemicals. It is laid down in particular that substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be

considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects in particular may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).

The procedure that led to the classifications at issue

32 By 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 Commission included pure nickel carbonate in the priority list provided for in Article 8 of Regulation No 793/93 and designated the Kingdom of Denmark as the Member State responsible for its evaluation.

33 The Kingdom of Denmark designated the Danish Environmental Protection Agency ('the DEPA') as the authority responsible for the report on the evaluation of that substance and of four other nickel substances (nickel metal, nickel sulphate, nickel chloride and nickel dinitrate).

34 In the course of the DEPA evaluation procedure, the three manufacturers and the importer of nickel carbonates which were required to provide data on those substances ('the companies concerned'), represented by the company OMG Harjavalta, submitted on 27 May 2003, on the basis of Article 9(3) of Regulation No 793/93, a request for derogation from the requirement to carry out certain tests ('the derogation

statement'), since they took the view that there were no human toxicological data in respect of nickel hydroxycarbonate. The companies concerned also stated that, in the absence of such data, the classification of that substance, using the classifications derived for water-soluble nickel compounds, should follow the worst case scenario.

35 According to the companies concerned, nickel hydroxycarbonate was the only nickel carbonate having a commercial use, the three other nickel carbonates not being used outside the laboratory.

36 After the DEPA disclosed the results of its evaluation, on 16 April 2004 the Commission forwarded a formal proposal for a revised classification of the nickel carbonates under Directive 67/548 to the European Chemicals Bureau and the Technical Committee on Classification and Labelling of Dangerous Substances ('the TCCL').

37 The proposed classifications were also discussed by a Commission working group on the classification and labelling of dangerous substances including specialised experts in the fields of carcinogenicity and mutagenicity ('the CL Working Group') at a meeting held on 20 and 21 April 2004 (document ECBI/74/04 Rev. 2). Subsequently, the DEPA's proposal was further discussed by the TCCL at its meetings held on 12 to 14 May 2004 (document ECBI/147/04 Rev. 3) and on 21 to 24 September 2004 (document ECBI/139/04 Rev. 2). At the latter meeting, the TCCL agreed to recommend the proposed classification relating to the nickel carbonates, and that it be included in the draft proposal for the 30th ATP Directive which was to be sent to the Commission.

38 It is apparent, in particular, from the minutes of the meeting of 20 and 21 April 2004 that the experts took into consideration the fact that certain data were missing, including as regards nickel carbonate and its bioavailability, that is to say the fraction of that substance that can be absorbed and used by the metabolism of a living organism. However, when deciding on the final recommendation, they decided not to await any more extensive data on the bioavailability of that substance, which would have required, in particular, the carrying out of additional tests on animals.

39 So far as concerns, for example, carcinogenic potential, in an initial stage the experts essentially concluded at that meeting that nickel sulphate and nickel chloride should be classified as substances carcinogenic to man in category 1 on the basis of existing data. Then, applying the read-across method, and taking the view that the degree of water solubility of nickel nitrate was sufficiently similar to that of nickel sulphate and of nickel chloride, the experts decided upon the same classification for this substance.

40 The experts concluded that nickel carbonate should be given the same classification because, even though it is only sparingly soluble in water, it is, however, soluble in biological fluids – like nickel sulphate. This conclusion was also supported by the fact that Annex I to Directive 67/548 already contained insoluble inorganic nickel compounds that were classified as carcinogenic to man.

41 In this context, use of the criterion of the degree of water solubility was founded on the theory that, once dissolved in water, a nickel salt, such as nickel carbonate, will have the same toxic characteristics as other nickel salts with a similar degree of water solubility since, on dissolution in water, the nickel atoms and ions, whose toxic

properties are well-known, separate from the other substances forming the nickel salt whilst retaining the same characteristics.

42 Consequently, the classifications of the nickel carbonate substances as carcinogenic to man in category 1, mutagenic in category 3 and reprotoxic in category 2 were supported by use of the read-across method founded on the criterion of the degree of water solubility and on existing data as to other similar nickel substances.

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

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

45 The nickel hydroxides and one hundred or so other grouped nickel substances at issue in the main proceedings were classified by the 31st ATP Directive.

46 In this regard, the conclusions which had been reached by the specialised experts in the comitology procedure that resulted in the adoption of the 30th ATP Directive

persuaded the DEPA to evaluate another whole series of nickel substances and to put forward in 2005 supplementary proposals for the classification of such substances. The evaluation was again carried out with the aid of the read-across method, relying on the degree of water solubility of those substances and on existing data as to the toxic characteristics of the free nickel ion, even if other data on their bioavailability still did not exist.

47 Following discussions within the TCCL, the latter recommended classification of those chemical substances and on 19 November 2008 the ATP Committee decided in favour of the proposal by unanimity save for six abstentions. The 31st ATP Directive was adopted on 15 January 2009. As in the case of the 30th ATP Directive, the Member States were required to transpose the 31st ATP Directive into national law by 1 June 2009 at the latest.

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

49 The content of the 30th and 31st ATP Directives was added to Annex VI to the CLP Regulation by the 1st ATP Regulation. The 1st ATP Regulation was adopted on 10 August 2009 on the basis of Article 53 of the CLP Regulation following a proposal of approval adopted unanimously by the ATP Committee on 25 March 2009, and it entered into force on 25 September 2009. That proposal of the committee was founded, in particular, on the conclusions of a working group of 27 experts who met from 17 to 24 March 2009 within the framework of the International Agency for Research on Cancer (IARC) and who supported the classification of the nickel substances as substances carcinogenic to man in category 1.

The main proceedings and the questions referred for a preliminary ruling

50 The claimant in the main proceedings, the Nickel Institute, is a non-profit organisation representing the interests of 29 companies which, together, account for 90 % of the world's annual nickel output.

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

52 On 2 December 2008 and 9 April 2009, the Nickel Institute brought two actions against the Secretary of State for Work and Pensions before the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court), for judicial review of 'the intention and/or obligation' of the United Kingdom Government to implement the classifications made by the 30th and 31st ATP Directives and the 1st ATP Regulation.

53 First, the Nickel Institute contests the validity of the classification by the 1st ATP Regulation of four nickel carbonate substances initially classified in entry 028-010-00-0 in Annex 1F to the 30th ATP Directive. Second, it contests the validity of the classification by the 1st ATP Regulation of the nickel hydroxides, initially classified in entry 028-008-00-X in Annex 1A to the 31st ATP Directive, and of the classification by that regulation of more than 100 other grouped nickel substances, initially classified in entries 028-013-00-7 to 028-052-002 of Annex 1B to the 31st ATP Directive (collectively 'the classifications at issue').

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

'(1) Are [the 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 end-points, 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 (together, "the contested 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 [the CLP Regulation] were not made out; and/or

(b) the classifications for Table 3.1 of Annex VI to the CLP Regulation were arrived at without adequate assessment of the intrinsic properties of the nickel carbonates and the contested nickel substances in accordance with the criteria and data requirements set out in Annex I to the CLP Regulation, but rather on the application of Annex VII to the CLP Regulation?'

Consideration of the questions referred

Admissibility of Questions 1 and 2

55 In its written observations, the Commission requested that the first two questions referred for a preliminary ruling be declared inadmissible in so far as they relate to the validity of the 30th and 31st ATP Directives, which according to the Commission were repealed when the CLP Regulation entered into force on 20 January 2009. However, at the hearing it withdrew this objection of inadmissibility, taking the view that, in any event, the classifications inserted into Annex VI to the CLP Regulation, by means of the 1st ATP Regulation, merely reproduce the classifications already made in the 30th and 31st ATP Directives on the basis of the scientific recommendations put forward by a number of committees of experts within the framework of Directive 67/548.

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

Questions 1 and 2

57 By its first two questions, which it is appropriate to examine together, the national court asks the Court, in essence, whether the 30th and 31st ATP Directives are valid to the extent that they incorporate the classifications at issue into Annex I to Directive 67/548 and, consequently, whether the 1st ATP Regulation is also valid in so far as it incorporates into the CLP Regulation the same classifications as those contained in the 30th and 31st ATP Directives.

58 The national court seeks more specifically to ascertain, first, whether the methods selected by the Commission for making those classifications, in particular recourse to the read-across method, the lack of examination of the risks associated with normal handling or use of the nickel substances at issue in the main proceedings, and recourse to the derogation statement, are consistent with the need for an appropriate assessment of the intrinsic properties of those substances in accordance with the criteria laid down in Annex VI to Directive 67/548. Second, the national court is uncertain whether the legal basis chosen for adoption of the two directives in question, namely Article 28 of Directive 67/548, was appropriate for achieving that objective. Third, it asks the Court whether there was a failure to state reasons in breach of Article 253 EC, rendering the 30th ATP Directive invalid.

Introductory observations

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

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

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

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

62 The Nickel Institute's main complaint is that the Commission did not analyse the intrinsic properties of the nickel substances at issue in the main proceedings as required in Article 4 of Directive 67/548 and section 1.1 of Annex VI to that directive. It also complains that the Commission applied the read-across method in order to classify those substances despite the lack of data concerning them.

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

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

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

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

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

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

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

70 Thus, whilst it is true that, as the Advocate General has noted in points 63 and 64 of his Opinion, the method based on structure-activity relationships displays certain differences from the read-across method, the fact remains that those two methods are not to be regarded as independent since they are both founded on the principle of extrapolation from existing data on certain substances in order to assess and classify other substances which have a similar structure and on which there are very limited or no data.

71 Furthermore, as is apparent from the explanatory memorandum for the 31st ATP Directive, the read-across method, as a method for assessing substances that is widely recognised by the scientific community, has been used on many occasions when classifying substances in the context of Annex I to Directive 67/548, if only since the entry into force of Commission Directive 91/632/EEC of 28 October 1991 adapting to technical progress for the 15th time Directive 67/548 (OJ 1991 L 338, p. 23).

72 As regards the scientific arguments underlying the classifications at issue, it is apparent from the minutes of the meetings of the CL Working Group, the TCCL and the ATP Committee that, even though the experts agreed on the fact that there were limited data concerning, in particular, the toxic characteristics of the nickel substances at issue in the main proceedings, their bioavailability was assessed principally on the basis of the degree of water solubility, taking account of the well-known toxic characteristics of the nickel ion of which those substances are composed. The current classification of the substances at issue in the main proceedings was therefore decided upon on the basis of the known data concerning other nickel substances, having a structure and degree of water solubility that are similar.

73 Those conclusions were also supported by the minutes of the meeting on 4 May 2006 of the Commission's Scientific Committee on Health and Environmental Risks (SCHER).

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

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

76 In the alternative, the Nickel Institute contends that, even if recourse to such a method were permissible in principle, the application of it in the present instance would

be manifestly flawed because, inter alia, the criterion of water solubility was unable, in itself, to provide the basis for the classifications at issue, the key scientific assumption that the nickel ion is responsible for the biological effects to be assessed was not proven and, in general, the fact that certain assessments result from 'expert judgment' is nevertheless not an apposite response.

77 However, having regard to the scope of the review which the Court is to carry out in this field in accordance with what has been stated in paragraphs 59 and 60 of the present judgment, these arguments of the claimant in the main proceedings do not in themselves permit the view to be taken that the Commission, in the light of the conclusions formulated after several scientific committees completed their work, manifestly exceeded the limits of its discretion in relying, when adopting the classifications at issue, on the judgment of experts who had recourse in particular to the read-across method in order to assess the intrinsic properties of the nickel substances at issue in the main proceedings.

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

78 The national court seeks to ascertain whether the validity of the 30th and 31st ATP Directives and that of the 1st ATP Regulation are affected by the fact that the Commission is said not to have taken into consideration the fact that three of the four nickel carbonates were neither handled nor used outside the laboratory and that other nickel substances were not used in industrial applications. Risks associated with normal handling or use of the nickel substances at issue in the main proceedings are thus stated not to have been taken into account during the assessment.

79 In this regard, although neither Directive 67/548 nor the CLP Regulation or the REACH Regulation defines 'normal handling or use', it must be accepted, as the Commission has maintained, that this concept includes all handling and uses occurring in normal circumstances, which encompasses, in particular, the need to take account of realistic and foreseeable accidents.

80 It must be stated at the outset, as the Advocate General has observed in point 80 et seq. of his Opinion, that the criticism advanced by the claimant in the main proceedings rests, essentially, on confusion between assessment of the hazards and that of the risks presented by a substance.

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

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

83 In light of those considerations, it must be found that, in the course of a valid classification of the substances at issue in the main proceedings on the basis of an assessment of the hazards linked to their intrinsic properties, the Commission was not obliged to take into account the fact that certain nickel carbonates were handled or used only in laboratory conditions.

Recourse to the derogation statement

84 The national court asks the Court whether the fact that the Commission relied, for the purposes of the classifications at issue, on the derogation statement issued in the context of Regulation No 793/93 is such as to affect the validity of the 30th ATP Directive and of the 1st ATP Regulation.

85 The Nickel Institute submits that the Commission exceeded its powers in basing the contested classifications on the request for derogation submitted in May 2003 by several nickel-producing companies to the DEPA under Article 9(3) of Regulation No 793/93, thereby departing from the classification criteria laid down in Annex VI to Directive 67/548.

86 However, first, contrary to the submissions of the claimant in the main proceedings, the Commission did not base its classification decision on the derogation statement. As found in paragraph 75 of the present judgment, the classifications at issue were made within the framework of the comitology procedure on the basis of the recommendations of a broad range of experts who validated use of the read-across method and who deliberately decided not to wait for animal tests to be carried out, taking the view that the indications concerning the bioavailability of the nickel substances at

issue in the main proceedings, derived from their degree of water solubility, and the existing data on nickel substances having a similar structure were sufficient to make those classifications. Thus, the contested classifications were made on a scientific basis, regardless of the request made by the industry concerned for exemption from additional testing.

87 Second, it admittedly follows from section 4.1.3.1.2.6, on mutagenicity, and section 4.1.2.7.2.1, on carcinogenicity, of the risk assessment report submitted by the DEPA in March 2008 that, at a meeting held in April 2004, the experts agreed, taking into consideration the request for exemption submitted by the sector, that nickel carbonate should be classified as a mutagen in category 3 and a carcinogen in category 1.

88 Nevertheless, that derogation statement is no longer mentioned, in particular, in the summary record of the meeting of technical experts within the framework of the ATP Committee of 29 September 2008 (document SB/31ATP/08/2008) or in the explanatory memorandum for the 31st ATP Directive, which refer to the DEPA's proposal to use the category approach and in particular the read-across method to assess the nickel carbonates, upon which limited data were available.

89 Consequently, the argument of the claimant in the main proceedings that the Commission manifestly exceeded the limits of its discretion in basing the classifications at issue solely on the request for derogation must be rejected.

Choice of legal basis for the 30th and 31st ATP Directives

90 The national court asks the Court whether the choice of Article 28 of Directive 67/548 as the legal basis for adoption of the 30th and 31st ATP Directives was appropriate.

91 The Nickel Institute submits that the conditions for use of the procedure provided for in Article 28 of Directive 67/548 were not satisfied as regards the contested classifications because there was insufficient technical or scientific progress to justify an adaptation.

92 However, as is apparent from the minutes of the meetings of experts, forming part of a long consultation process conducted over the period from 2000 to 2008, numerous experts' reports and studies were completed in order to arrive at the final adaptations of Directive 67/548, on adoption of the 30th and 31st ATP Directives.

93 Having regard to the scope of the review which the Court is to carry out in this field in accordance with what has been stated in paragraphs 59 and 60 of the present judgment, it is not apparent that the Commission, in the light of the conclusions formulated upon completion of those experts' reports and studies, manifestly exceeded the limits of its discretion in taking the view that, given the state of scientific knowledge as it stood, there was sufficient technical progress to justify adapting Directive 67/548.

94 It must accordingly be found that Article 28 of Directive 67/548 could validly constitute the legal basis for adoption of the 30th and 31st ATP Directives.

Failure to state reasons for the 30th ATP Directive

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

96 The Nickel Institute considers that the Commission failed to comply with its obligations under Article 253 EC to state reasons since the facts and legal considerations justifying the adoption of the classifications at issue do not appear in the adopted measure itself, the minutes of the meetings of experts published subsequently not being sufficient in this regard.

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

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

99 It is also clear from settled case-law that the scope of the obligation to state reasons depends on the nature of the measure in question and that, in the case of measures of general application, the statement of reasons may be confined to indicating the general situation which led to the adoption of the measure and the general objectives

which it is intended to achieve. In that context, the Court has repeatedly ruled that if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made (see, to this effect, Case C-221/09 *AJD Tuna* [2011] ECR I-1655, paragraph 59 and the case-law cited).

100 Furthermore, as the Advocate General has observed in point 107 of his Opinion, where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed, since they acquire information through their involvement.

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

102 The 30th ATP Directive is a measure of general application, whose preamble states that the measures provided for in the directive are in accordance with the opinion of the ATP Committee and announces that the pertinent list of substances needs to be updated to include further notified new substances and further existing substances, as well as to adapt certain entries to technical progress. In this connection, it is envisaged, in particular, that special attention should be paid to the outcome of the International Agency for Research on Cancer (IARC) discussion of the classification of nickel substances.

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

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

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

106 Having regard to all the foregoing considerations, it must be held that examination of the first and second questions has disclosed no factor of such a kind as to affect the validity of the 30th and 31st ATP Directives and, consequently, that of the 1st ATP Regulation, in so far as they classified the nickel substances at issue in the main proceedings as carcinogenic to man in category 1, mutagenic in category 3 and reprotoxic in category 2.

Question 3

107 By its third question, the national court raises with the Court the validity of the first ATP Regulation, which incorporates into Tables 3.1 and 3.2 in Part 3 of Annex VI to the CLP Regulation the amendments which were made to Annex I to Directive 67/548 by the 30th and 31st ATP Directives.

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

Choice of legal basis for the 1st ATP Regulation

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

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

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

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

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

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

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

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

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

117 As has been stated in paragraph 113 of the present judgment, a repetition of that assessment process was not necessary in view of the fact that the 1st ATP Regulation merely incorporates into the CLP Regulation the same classifications as those which had undergone the complex assessment procedure applicable within the framework of Directive 67/548.

118 As regards the translation table in Annex VII to the CLP Regulation, it is to be recalled that, as provided in Article 61(3) of that regulation, all substances must be

classified in both the old and the new system until 1 June 2015. It follows that all the classifications established under Directive 67/548 must be translated, with the aid of the translation table set out in Annex VII, into the corresponding classifications under the CLP Regulation.

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

120 In light of all the foregoing considerations, it must be held that examination of the third question has disclosed no factor of such a kind as to affect the validity of the 1st ATP Regulation, in so far as that regulation classified the nickel substances at issue in the main proceedings as carcinogenic to man in category 1, mutagenic in category 3 and reprotoxic in category 2.

Costs

121 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

Examination of the questions referred for a preliminary ruling has disclosed no factor of such a kind as to affect the validity, first, of Commission Directive 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and of 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 and, second, of Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, in so far as those directives and that regulation classified as carcinogenic to man in category 1, mutagenic in category 3 and reprotoxic in category 2 substances such as certain nickel carbonates, the nickel hydroxides and other grouped nickel substances at issue in the main proceedings.

[Signatures]