Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

22 November 2017*

(Appeal — Environment — Regulation (EC) No 1272/2008 — Classification, labelling and packaging of certain substances and mixtures — Regulation (EU) No 944/2013 — Classification of pitch, coal tar, high-temperature — Categories of acute aquatic toxicity (H400) and chronic aquatic toxicity (H410) — Duty to act diligently — Manifest error of assessment)

In Case C-691/15 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 17 December 2015,

European Commission, represented by K. Talabér-Ritz and P.-J. Loewenthal, acting as Agents,

appellant,

supported by:

Kingdom of Denmark, represented by C. Thorning and N. Lyshøj, acting as Agents,

Federal Republic of Germany, represented by T. Henze, J. Möller and R. Kanitz, acting as Agents,

Kingdom of the Netherlands, represented by M. Bulterman, C.S. Schillemans and J. Langer, acting as Agents,

interveners in the appeal,

the other parties to the proceedings being:

Bilbaína de Alquitranes SA, established in Luchana-Baracaldo (Spain),

Deza a.s., established in Valašské Meziříčí (Czech Republic),

Industrial Química del Nalón SA, established in Oviedo (Spain),

Koppers Denmark A/S, established in Nyborg (Denmark),

Koppers UK Ltd, established in Scunthorpe (United Kingdom),

Koppers Netherlands BV, established in Uithoorn (Netherlands),

Rütgers basic aromatics GmbH, established in Castrop-Rauxel (Germany),

* Language of the case: English.

Rütgers Belgium NV, established in Zelzate (Belgium),

Rütgers Poland sp. z o.o., established in Kędzierzyn-Koźle (Poland),

Bawtry Carbon International Ltd, established in Doncaster (United Kingdom),

Grupo Ferroatlántica SA, established in Madrid (Spain),

SGL Carbon GmbH, established in Meitingen (Germany),

SGL Carbon GmbH, established in Bad Goisern am Hallstättersee (Austria),

SGL Carbon, established in Passy (France),

SGL Carbon SA, established in La Coruña (Spain),

SGL Carbon Polska S.A., established in Racibórz (Poland),

ThyssenKrupp Steel Europe AG, established in Duisburg (Germany),

Tokai erftcarbon GmbH, established in Grevenbroich (Germany),

represented by K. Van Maldegem, C. Mereu and M. Grunchard, avocats, and by P. Sellar, Advocate,

applicants at first instance,

European Chemicals Agency (ECHA), represented by N. Herbatschek, W. Broere and M. Heikkilä, acting as Agents,

GrafTech Iberica SL, established in Pamplona (Spain), represented by C. Mereu, K. Van Maldegem and M. Grunchard, avocats, and by P. Sellar, Advocate,

interveners at first instance,

THE COURT (Sixth Chamber),

composed of C.G. Fernlund (Rapporteur), President of the Chamber, A. Arabadjiev and E. Regan, Judges,

Advocate General: M. Bobek,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 15 June 2017,

after hearing the Opinion of the Advocate General at the sitting on 7 September 2017,

gives the following

Judgment

1 By its appeal, the European Commission seeks to have set aside the judgment of the General Court of the European Union of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, 'the judgment under appeal', EU:T:2015:767), by which the General Court annulled Commission Regulation (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ 2013 L 261, p. 5) ('the regulation at issue') in so far as it classifies pitch, coal tar, high-temperature (EC No 266-028-2, 'CTPHT') as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.

Legal context

2 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/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 253, p. 1), as amended by Commission Regulation (EU) No 286/2011 of 10 March 2011 (OJ 2011 L 83, p. 1), ('Regulation No 1272/2008') states, in its recitals 4 to 8:

'(4) Trade in substances and mixtures is an issue relating not only to the internal market, but also to the global market. Enterprises should therefore benefit from the global harmonisation of rules for classification and labelling and from consistency between, on the one hand, the rules for classification and labelling for supply and use and, on the other hand, those for transport.

(5) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling have been carefully developed over a period of 12 years within the United Nations (UN) structure, resulting in the Globally Harmonised System of Classification and Labelling of Chemicals (hereinafter referred to as "the GHS").

(6) This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law.

(7) The benefits for enterprises will increase as more countries in the world adopt the GHS criteria in their legislation. The Community should be at the forefront of this process to encourage other countries to follow and with the aim of providing a competitive advantage to industry in the Community.

(8) Therefore it is essential to harmonise the provisions and criteria for the classification and labelling of substances, mixtures and certain specific articles within the Community, taking into account the classification criteria and labelling rules of the GHS, but also by building on the 40 years of experience obtained through implementation of existing Community chemicals legislation and maintaining the level of protection achieved through the system of harmonisation of classification and labelling, through Community hazard classes not yet part of the GHS as well as through current labelling and packaging rules.'

3 Annex I to Regulation No 1272/2008, which sets out, inter alia, the criteria for classification in hazard classes and in their differentiations, consists of five parts. In Part 4 of that annex, point 4.1.3, entitled 'Classification criteria for mixtures', is worded as follows:

'4.1.3.1. The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate:

The "relevant components" of a mixture are those which are classified "Acute 1" or "Chronic 1" and present in a concentration of 0.1% (w/w) or greater, and those which are classified "Chronic 2", "Chronic 3" or "Chronic 4" and present in a concentration of 1% (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see Section 4.1.3.5.5.5)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as "Acute 1" or "Chronic 1" the concentration to be taken into account is (0.1/M)%. (For [an] explanation [of the] M-factor see Section 4.1.3.5.5.5.)

4.1.3.2. The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Figure 4.1.2 outlines the process to be followed.

Elements of the tiered approach include:

– classification based on tested mixtures,

– classification based on bridging principles,

– the use of "summation of classified components" and/or an "additivity formula".'

4 Point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, entitled 'Summation method', provides:

'4.1.3.5.5.1.1. In case of the substance classification categories Chronic 1 to Chronic 3, the underlying toxicity criteria differ by a factor of 10 in moving from one category to another. Substances with a classification in a high toxicity band therefore contribute to the classification of a mixture in a lower band. The calculation of these classification categories therefore needs to consider the contribution of any substance classified as Chronic 1, 2 or 3.

4.1.3.5.5.1.2. When a mixture contains components classified as Acute 1 or Chronic 1, attention must be paid to the fact that such components, when their acute toxicity is below 1 mg/l and/or chronic toxicity is below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable), contribute to the toxicity of the mixture even at a low concentration. Active ingredients in pesticides often possess such high aquatic toxicity but also some other substances like organometallic compounds. Under these circumstances the application of the normal generic concentration limits leads to an "under-classification" of the mixture. Therefore, multiplying factors shall be applied to account for highly toxic components, as described in Section 4.1.3.5.5.5.'

5 As regards mixtures with highly toxic components, point 4.1.3.5.5.5.1 of Annex I to Regulation No 1272/2008 provides:

‘Acute 1 and Chronic 1 components with toxicities below 1 mg/l and/or chronic toxicities below 0.1 mg/l (if non-rapidly degradable) and 0.01 mg/l (if rapidly degradable) contribute to the toxicity of the mixture even at a low concentration and shall normally be given increased weight in applying the summation of classification approach. When a mixture contains components classified as Acute or Chronic 1, one of the following shall be applied:

– the tiered approach described in Sections 4.1.3.5.5.3 and 4.1.3.5.5.4 using a weighted sum by multiplying the concentrations of Acute 1 and Chronic 1 components by a factor, instead of merely adding up the percentages. This means that the concentration of “Acute 1” in the left column of Table 4.1.1 and the concentration of “Chronic 1” in the left column of Table 4.1.2 are multiplied by the appropriate multiplying factor. …

– …’

Background to the dispute

6 It is apparent from the background to the dispute set out in paragraphs 1 to 8 of the judgment under appeal that CTPHT is the residue from the distillation of high-temperature coal tar. This substance is among the substances of unknown or variable composition, complex reaction products or biological materials (‘UVCB substances’).

7 In September 2010, the Kingdom of the Netherlands submitted a dossier to the European Chemicals Agency (ECHA) proposing that CTPHT should be classified as Carcinogenic 1A (H350), Mutagenic 1B (H340), Toxic for reproduction 1B (H360FD), Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410).

8 On 2 October 2013 the Commission adopted the regulation at issue. In accordance with Article 1(2)(a)(i) and (b)(i) of that regulation, read together with Annexes II and IV thereto, CTPHT was classified, inter alia, as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). Pursuant to Article 3(3) of that regulation, that classification is to apply from 1 April 2016.

The proceedings before the General Court and the judgment under appeal

9 Bilbaína de Alquitranes SA, Deza a.s., Industrial Química del Nalón SA, Koppers Denmark A/S, Koppers UK Ltd, Koppers Netherlands BV, Rütgers basic aromatics GmbH, Rütgers Belgium NV, Rütgers Poland Sp. z o.o., Bawtry Carbon International Ltd, Grupo Ferroatlántica SA, SGL Carbon GmbH (Germany), SGL Carbon GmbH (Austria), SGL Carbon, SGL Carbon SA, SGL Carbon Polska S.A., ThyssenKrupp Steel Europe AG and Tokai erftcarbon GmbH (‘Bilbaína and others’) brought an action for annulment of the regulation at issue, in support of which they put forward three pleas in law, the second of which alleged a manifest error of assessment by the Commission regarding the toxicity level of CTPHT.

10 In the judgment under appeal, the General Court held, in essence, that the Commission had committed such an error in that it had failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 polycyclic aromatic hydrocarbon constituents are present in CTPHT and their chemical effects.

11 Consequently, the General Court upheld the second part of the second plea in law and annulled the regulation at issue in so far as it classifies CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance.

Forms of order sought and the proceedings before the Court

12 The Commission requests the Court to set aside the judgment under appeal, refer the case back to the General Court and reserve the costs of the present proceedings.

13 Bilbaína and others contend that the Court should dismiss the appeal or refer the case back to the General Court and order the Commission to pay the costs of the appeal, even in the event that it is upheld in part.

14 The ECHA contends that the Court should set aside the judgment under appeal, refer the case back to the General Court and reserve the costs of the present proceedings.

15 The Danish Government contends that the Court should set aside the judgment under appeal and refer the case back to the General Court.

16 The German Government contends that the Court should set aside the judgment under appeal, refer the case back to the General Court and reserve the costs of the present proceedings.

17 The Netherlands Government contends that the Court should set aside the judgment under appeal.

18 By order of the Vice-President of the Court of 7 July 2016, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P-R, not published, EU:C:2016:597), the application for suspension of operation of the regulation at issue brought on 24 March 2016 by Bilbaína and others was dismissed.

The appeal

The first ground of appeal, alleging a failure to state reasons

Arguments of the parties

19 The Commission submits that the grounds set out in paragraphs 31 to 34 of the judgment under appeal are vitiated by a lack of reasoning because of their contradictory or ambiguous nature. It claims that it is unclear from those grounds whether the General Court annulled the regulation at issue because the Commission used the summation method or because the Commission erred in applying that method.

20 In paragraph 34 of the judgment under appeal, the General Court appears to criticise the Commission for using the characteristics of the constituents of CTPHT rather than the characteristics of that substance as a whole, thus suggesting that the use of the summation method was incorrect. On the other hand, in paragraph 22 of that judgment, the General Court indicates that the plea formulated by Bilbaína and others concerned the principle of that method's application. Moreover, in paragraphs 32 and 33 of that judgment, the General Court states that the Commission should have taken into account the low solubility of the substance as a whole when it applied the summation method.

21 Bilbaína and others dispute the Commission's arguments.

Findings of the Court

22 It follows from settled case-law of the Court that the obligation of the General Court to state reasons requires it to disclose its reasoning clearly and unequivocally, in such a way as to enable the persons concerned to ascertain the reasons for the decision taken and the Court of Justice to exercise its

power of review (see, inter alia, judgment of 7 January 2004, *Aalborg Portland and Others* v *Commission*, C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, EU:C:2004:6, paragraph 372, and order of 1 June 2017, *Universidad Internacional de la Rioja* v *EUIPO*, C-50/17 P, not published, EU:C:2017:415, paragraph 12).

23 In paragraph 30 of the judgment under appeal, the General Court held 'that the Commission [had] committed a manifest error of assessment in that, by classifying CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the basis of its constituents, it [had] failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 [polycyclic aromatic hydrocarbon] constituents are present in CTPHT and their chemical effects'.

24 It is apparent from paragraphs 31 to 34 of that judgment that the General Court held that neither the Commission nor ECHA had been able to establish that 'the Commission [had taken] into consideration the fact that, according to point 1.3 of the background document [annexed to the opinion of ECHA's Risk Assessment Committee], entitled "Physiochemical properties", the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable'.

25 That assessment is based on two factors. The first, set out in paragraph 33 of the judgment under appeal, relates to the fact that neither the opinion of ECHA's Risk Assessment Committee ('the RAC's opinion') nor the background document annexed to that opinion shows that account was taken of the low water solubility of CTPHT. The second factor, set out in paragraph 34 of the judgment, is the finding that the classification of CTPHT was based on the presumption that 16 constituents representing 9.2% of CTPHT could dissolve in water, even though, according to the background document annexed to the RAC's opinion, the maximum rate of water solubility of the substance is 0.0014%.

26 The reasoning underlying paragraphs 31 to 34 of the judgment under appeal therefore discloses clearly and unequivocally that the General Court did not consider that the Commission had erred in using the summation method when adopting the regulation at issue. By holding, on the grounds set out in paragraphs 31 to 34 of the judgment, that the Commission had committed a manifest error of assessment when applying the summation method, the General Court gave sufficient reasons for its decision.

27 Accordingly, the first ground of appeal must be rejected as unfounded.

The second ground of appeal, alleging infringement of Regulation No 1272/2008

28 The second ground of appeal consists of two parts. The first part of the second ground of appeal is based on the premiss that the General Court held that the Commission had erred in using the summation method. However, as that premiss is incorrect, as held in paragraph 26 of the present judgment, the first part of the second ground of appeal must be rejected at the outset. It is therefore necessary to examine the second part of the second ground of appeal.

Arguments of the parties

29 By the second part of the second ground of appeal, the Commission criticises the grounds on which the General Court, in paragraphs 31 to 34 of the judgment under appeal, held that the Commission had committed a manifest error of assessment.

30 The Commission submits that taking into account the solubility of CTPHT as a whole is not consistent with the summation method, which is based on the analysis of that substance's constituents. It claims that the assumption that the constituents of a substance dissolve in water is inherent in the summation

method. Applying that method, it would therefore be presumed that the constituents are entirely soluble because their solubility would already be integrated at an earlier stage during the assessment of their toxicity. The fact that the 16 constituents taken into account in the present case represent only 9.2% of CTPHT is irrelevant, since it is not necessary, when using that method, to take into account either a large number of constituents or that the constituents taken into account represent a significant proportion of the substance. It is important only to ascertain, using the summation method, whether the thresholds set by Regulation No 1272/2008 are met, without the Commission having any margin of discretion whatsoever in that regard. The General Court therefore erred in law in criticising the Commission for not taking into consideration factors that are not prescribed by the summation method referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008.

31 According to Bilbaína and others, since CTPHT has low water solubility, the General Court was right to question whether the summation method came to the correct conclusion. The argument that the Commission is straight-jacketed by a procedure which prohibits it from taking into account factual evidence that proves the opposite of a theoretical assumption which it insists on pursuing risks, in their view, leading to absurd, unjust and scientifically unfounded results.

32 The Danish and German Governments approve the methodology followed by the Commission. Point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 does not, in their view, require the solubility of the mixture as a whole to be taken into account, contrary to the General Court's findings in the judgment under appeal.

Findings of the Court

33 The second part of the second ground of appeal questions whether the Commission, when it applies the summation method in order to determine whether a UVCB substance comes within the categories of acute or chronic aquatic toxicity, is required to limit its assessment solely to the factors expressly referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, excluding any other factor, or, on the contrary, whether it must, under its duty to act diligently, examine carefully and impartially other factors which, although not expressly referred to by those provisions, are nevertheless relevant.

34 It should be observed in this regard, as the General Court held, in essence, in paragraph 23 of the judgment under appeal, that, if the Commission is to be able to classify a substance pursuant to Regulation No 1272/2008, account being taken of the complex scientific and technical assessments which it must undertake, it must be recognised as enjoying a broad discretion (judgments of 18 July 2007, *Industrias Químicas del Vallés* v *Commission*, C-326/05 P, EU:C:2007:443, paragraph 75, and of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60).

35 The exercise of that discretion is not, however, excluded from review by the Court. In particular, where a party claims that the institution competent in the matter has committed a manifest error of assessment, the EU judicature must verify whether that institution has examined, carefully and impartially, all the relevant facts of the individual case on which that assessment was based (see, inter alia, judgments of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14; of 18 July 2007, *Industrias Químicas del Vallés* v *Commission*, C-326/05 P, EU:C:2007:443, paragraph 77; of 6 November 2008, *Netherlands* v *Commission*, C-405/07 P, EU:C:2008:613, paragraph 56; and of 22 December 2010, *Gowan Comércio Internacional e Serviços*, C-77/09, EU:C:2010:803, paragraph 57). That duty to act diligently is inherent in the principle of sound administration and applies generally to the actions of the EU administration (judgment of 4 April 2017, *European Ombudsman* v *Staelen*, C-337/15 P, EU:C:2017:256, paragraph 34; see also, to that effect, judgment of 29 March 2012, *Commission* v *Estonia*, C-505/09 P, EU:C:2012:179, paragraph 95).

36 In the present case, it is common ground that the classification of a UVCB substance in respect of the aquatic environmental hazards which it involves must be established in accordance with the provisions of Regulation No 1272/2008 governing the classification of mixtures. Point 4.1.3.2 of Annex I to that regulation states the following:

'The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. …

Elements of the tiered approach include:

– classification based on tested mixtures,

– classification based on bridging principles,

– the use of "summation of classified components" and/or an "additivity formula".'

37 That point establishes a decreasing order of precedence between those three methods. When, as in the present case, the information available does not allow use of the first two methods, the classification of a UVCB substance must therefore be determined on the basis of the summation method, in accordance with the rules set out in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008.

38 For the Acute 1 and Chronic 1 categories, that method consists, in essence, of calculating the sum of the concentrations of the constituents classified in those categories, multiplied by factor M. That factor M increases by an order of magnitude in a way that is inversely proportional to the toxicity level of the substance in question, in order to reflect the fact that the substances coming within those hazard categories 'contribute to the toxicity of the mixture even at a low concentration and shall normally be given increased weight in applying the summation of classification approach', within the meaning of point 4.1.3.5.5.5.1 of Annex I to Regulation No 1272/2008. If the sum of the concentrations weighted by factor M is greater than or equal to 25%, the substance in question is classified as Acute 1 or as Chronic 1.

39 It is true that point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 does not provide for the use of criteria other than those expressly referred to in that provision. However, it should be noted that no provision expressly prohibits other factors liable to be relevant to the classification of a UVCB substance from being taken into consideration.

40 Point 4.1.3.5.5 should not, moreover, be read out of context.

41 According to point 4.1.3.1 of Annex I to Regulation No 1272/2008, the approach followed to classify mixtures, previously described in summary form in paragraph 38 of the present judgment, '[is applied where appropriate] in order to make use of all available data for [the] purposes of classifying the aquatic environmental hazards of the mixture'. As the Advocate General has observed in point 73 of his Opinion, the use of the expressions 'where appropriate' and 'all available data' tends to undermine the interpretation that taking into account information other than that expressly used in the course of the summation method should, in all circumstances, be excluded.

42 Furthermore, it is apparent from recitals 4 to 8 of Regulation No 1272/2008 that the EU legislature intended 'to contribute to the global harmonisation of criteria for classification and labelling, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law'. To that effect, Annex I to that regulation reproduces verbatim almost all of the GHS provisions.

43 However, as the Advocate General noted in point 79 of his Opinion, it is apparent from the very wording of the GHS, in particular Annex 9, entitled 'Guidance on hazards to the aquatic environment', that the indicated methodological approach for determining the classification of substances' hazards to the aquatic environment is difficult due, inter alia, to the fact that 'the term substances covers a wide range of chemicals, many of which pose difficult challenges to a classification system based on rigid criteria'. That document therefore highlights 'a complex interpretational problem, even for experts' presented by classification, in particular of so-called 'complex or multi-component' substances for which 'biodegradation, bioaccumulation, partitioning behaviour and water solubility all present problems of interpretation, where each component of the mixture may behave differently'.

44 The authors of that document thus sought to draw attention to the limits inherent in the methodological criteria laid down in the GHS for classification of hazards to the aquatic environment, in respect of certain substances characterised by, inter alia, their complexity, stability or low water solubility.

45 The EU legislature integrated the provisions of the GHS in Annex I to Regulation No 1272/2008, without demonstrating any intention to deviate from that approach. In those circumstances, it cannot be held that, by thus integrating the GHS in Regulation No 1272/2008, the EU legislature disregarded its methodological limitations.

46 The strict and automatic application of the summation method in all circumstances is liable to result in an undervaluing of the aquatic toxicity of a UVCB substance with few known constituents. Such a result cannot be regarded as consistent with the goal of protection of the environment and human health pursued by Regulation No 1272/2008.

47 It must therefore be held that, when it applies the summation method in order to determine whether a UVCB substance comes within the categories of acute or chronic aquatic toxicity, the Commission is not required to limit its assessment solely to the factors expressly referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008, to the exclusion of any other factor. In accordance with its duty to act diligently, the Commission is required to examine carefully and impartially other factors which, although not expressly referred to by those provisions, are nevertheless relevant.

48 In the present case, the Commission, supported by ECHA and the Danish and German Governments, submits that the low solubility of CTPHT is irrelevant for the purposes of applying the summation method. In its view, the summation method indirectly takes into account the solubility of the constituents coming within the 'acute toxicity' and 'chronic toxicity' categories of hazards to the aquatic environment.

49 Whether the low solubility of CTPHT may be regarded as relevant and must, in that regard, be taken into consideration for the purposes of classifying the aquatic environmental hazards posed by that substance is a question of the legal characterisation of facts coming within the jurisdiction of the Court in the course of its review on appeal.

50 The ground in paragraph 28 of the judgment under appeal, according to which 'in order to take the view that a substance falls within the categories of acute aquatic toxicity or chronic aquatic toxicity, that substance — and not merely its constituents — must satisfy the classification criteria', is not contested.

51 The classification method referred to in point 4.1.3.5.5 of Annex I to Regulation No 1272/2008 is based on the assumption that the constituents taken into consideration are 100% soluble. On the basis of that assumption, that summation method implies that there is a concentration level of constituents below

which the threshold of 25% cannot be reached and, thus, consists of calculating the sum of the concentrations of the constituents coming within the categories of acute or chronic toxicity, each weighted by factor M corresponding to their toxicity profile.

52 It is, however, inherent in that method that it loses reliability in situations where the weighted sum of the constituents exceeds the level of concentration corresponding to the threshold of 25% in a proportion less than the ratio between the observed solubility rate at the level of the substance in question as a whole and the hypothetical solubility rate of 100%. In such situations, it thus becomes possible that the summation method may lead, in specific cases, to a result greater than or less than the level corresponding to the regulatory threshold of 25%, according to whether the hypothetical solubility rate of the constituents is taken into consideration or that of the substance as a whole.

53 It is common ground that Table 7.6.2 of Annex I to the report attached to the RAC's opinion shows that, first, the summation method leads to the result of 14 521% and that, secondly, that result is 581 times greater than the minimum level required for the threshold of 25%, after weighting by factor M, to be reached. Nor is it disputed that it is, moreover, apparent from point 1.3 of that document, entitled 'Physiochemical properties', that the maximum rate of water solubility of CTPHT was 0.0014%, a rate approximately 71 000 times lower than the hypothetical solubility rate of 100% used for the constituents taken into consideration.

54 The General Court therefore did not distort or err in the legal classification of the facts in holding, in paragraph 34 of the judgment under appeal, that, 'by assuming that all of those [constituents] dissolve in water, the Commission therefore, in essence, based the classification in question on the assumption that 9.2% of CTPHT could dissolve in water. However, as can be seen from point 1.3 of the background document [annexed to the RAC's opinion], such a value is not realistic, given that the maximum rate is 0.0014%'.

55 Since it found, in paragraph 32 of that judgment, that 'neither the Commission nor ECHA [had been] able to establish … that … the Commission [had taken] into consideration the fact that, according to point 1.3 of the background document [annexed to the RAC's opinion], entitled "Physiochemical properties", the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable', the General Court held, without erring in law, in paragraph 30 of the judgment that 'the Commission [had] committed a manifest error of assessment in that, by classifying CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the basis of its constituents, it [had] failed to comply with its obligation to take into consideration all the relevant factors and circumstances so as to take due account of the proportion in which the 16 … constituents are present in CTPHT and their chemical effects'.

56 Accordingly, the second ground of appeal must be rejected as unfounded.

The third ground of appeal, alleging abuse of the limits of judicial review and distortion of the evidence

57 The Commission claims to have adopted the regulation at issue on the basis of a wide range of scientific evidence. This, it submits, is very complex evidence that justifies the application of the summation method. The General Court, in paragraph 34 of the judgment under appeal, took from that vast set of scientific and technical evidence only the sentence according to which 9.2% of CTPHT could dissolve in water in order to invalidate the Commission's assessment. However, according to the Commission, that factor is inherent in the summation method. By holding, in that paragraph 34, that the maximum solubility rate of CTPHT as a whole is 0.0014%, the General Court substituted its own assessment for that of the Commission. Furthermore, by doing so, the General Court distorted the evidence on the basis of which the regulation at issue had been adopted.

58 However, it should be noted that this third ground of appeal is based on an erroneous reading of the judgment under appeal. The General Court did not, in paragraph 34 of the judgment under appeal, substitute its own assessment of the scientific and technical facts for that of the EU authorities. According to the settled case-law on the scope of judicial review, recalled in paragraph 35 above, the General Court's assessment, based on the data in the background document annexed to the RAC's opinion, focused exclusively on the procedural question of determining whether the Commission, in classifying CTPHT, complied with its obligation to take into consideration all the relevant factors and circumstances.

59 Accordingly, the third ground of appeal must be rejected as unfounded.

60 It follows from all of the foregoing considerations that the appeal must be dismissed in its entirety.

Costs

61 Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to the costs. Under Article 138(1) of those Rules, which applies to the procedure on appeal by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

62 Article 140(1) of the Rules of Procedure, which applies to the procedure on appeal by virtue of Article 184(1) thereof, provides that the Member States and institutions which have intervened in the proceedings are to bear their own costs.

63 Article 184(4) of the Rules of Procedure provides that, where an intervener at first instance takes part in the proceedings, the Court may decide that it is to bear its own costs.

64 Since Bilbaína and others have applied for costs to be awarded against the Commission, and as the latter has been unsuccessful, the Commission must be ordered to pay, in addition to its own costs, those incurred by Bilbaína and others, including the costs relating to the interlocutory proceedings that gave rise to the order of the Vice-President of the Court of 7 July 2016, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P–R, not published, EU:C:2016:597).

65 The Kingdom of Denmark, the Federal Republic of Germany and the Kingdom of the Netherlands, interveners in the appeal, shall bear their own costs.

66 ECHA, intervener at first instance, shall bear its own costs.

67 GrafTech Iberica SL, intervener at first instance, which participated in the oral part of the proceedings without applying for the Commission to pay the costs, shall bear its own costs.

On those grounds, the Court (Sixth Chamber) hereby:

1. **Dismisses the appeal;**

2. **Orders the European Commission to pay, in addition to its own costs, those incurred by Bilbaína de Alquitranes SA, Deza a.s., Industrial Química del Nalón SA, Koppers Denmark A/S, Koppers UK Ltd, Koppers Netherlands BV, Rütgers basic aromatics GmbH, Rütgers Belgium NV, Rütgers Poland Sp. z o.o., Bawtry Carbon International Ltd, Grupo Ferroatlántica SA, SGL Carbon GmbH (Germany), SGL Carbon GmbH (Austria), SGL Carbon, SGL Carbon SA, SGL Carbon Polska S.A., ThyssenKrupp Steel Europe AG and**

Tokai erftcarbon GmbH, including the costs relating to the interlocutory proceedings that gave rise to the order of the Vice-President of the Court of 7 July 2016, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P–R, not published, EU:C:2016:597);

3. **Orders the Kingdom of Denmark, the Federal Republic of Germany and the Kingdom of the Netherlands to bear their own costs;**

4. **Orders GrafTech Iberica SL and the European Chemicals Agency to bear their own costs.**

Fernlund Arabadjiev Regan

Delivered in open court in Luxembourg on 22 November 2017.

A. Calot Escobar
Registrar

C.G. Fernlund
President of the Sixth Chamber