Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 7 September 2017 [1]

Case C-691/15 P

European Commission
v
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
SGL Carbon GmbH
SGL Carbon
SGL Carbon, SA
SGL Carbon Polska S.A.
ThyssenKrupp Steel Europe AG

Tokai erftcarbon GmbH

(Appeal — Environment — Classification, labelling and packaging of certain substances and mixtures — Adaptation to technical progress — Classification of pitch, coal tar, high-temperature as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410))

I. Introduction

1. This case concerns the reconciliation of complex scientific assessments with the requirement of legality of administrative action. In cases in which the legislation has laid down a list of 'relevant factors' to be taken into account in the course of such an assessment, should that list be read as an exhaustive one, requiring administrators to ignore all other factors? That is the fundamental question of law underlying this appeal.

1 Original language: English.

2. Pitch, coal tar, high-temperature ('CTPHT') (EC No 266-028-2) is a black solid, the residue from the distillation of high-temperature coal tar. It is a kind of 'UVCB', that is a substance having a complex and variable composition. CTPHT was classified under Regulation (EU) No 944/2013 ('the contested regulation')[2] as Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410). That classification was based on the 'summation method', which classifies substances according to the classification of their constituents.

3. Bilbaína de Alquitranes, SA and others[3] ('the respondents') are suppliers and downstream users of CTPHT. They challenged the validity of the contested regulation before the General Court. By judgment in Case T-689/13,[4] the General Court annulled parts of the contested regulation concerning the classification of the CTPHT ('the contested judgment'). It did so essentially on the grounds that, in classifying CTPHT as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), the Commission failed to take into account the fact that CTPHT hardly dissolves in water.

4. By its present appeal, the Commission challenges the contested judgment, raising three grounds. First, the Commission argues that the contested judgment is vitiated by a lack of reasoning. Second, the General Court committed a manifest error, in particular by holding that the Commission, when it applied the 'summation method' of classification, should have taken into account the solubility of CTPHT as a whole. Third, the General Court exceeded the limits of its competence to review the matter, and in doing so distorted the evidence presented to it.

II. Legal framework

A. EU law

1. Regulation (EC) No 1272/2008 ('the CLP Regulation')

5. Article 1 of the CLP Regulation on the classification, labelling and packaging of substances and mixtures[5] states that 'the purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles ... by: (a) harmonising the criteria for classification of substances and mixtures …'.

6. Title V lays down rules for harmonisation of classification of substances, foreseeing that Member States may propose harmonised classification in certain cases (Article 37(1)). In such cases, the proposal is submitted to the Risk Assessment Committee set up under Article 76(1)(c) of Regulation (EC) No 1907/2006 ('the REACH Regulation'),[6] which delivers its opinion to the Commission after giving the parties concerned the opportunity to comment (Article 37(4)).

2 Commission Regulation 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).

3 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; SGL Carbon GmbH; SGL Carbon; SGL Carbon, SA; SGL Carbon Polska S.A.; ThyssenKrupp Steel Europe AG; Tokai erftcarbon GmbH.

4 Judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767).

5 Regulation of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1).

6 Regulation 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).

7. Article 37(5) provides that:

'Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, without undue delay, submit a draft decision concerning the inclusion of that substance together with the relevant classification and labelling elements …'

8. That draft is then adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54(3).

9. Part 4 of Annex I to the CLP Regulation is entitled 'Environmental hazards'. Point 4.1 contains the rules on aquatic hazard classification.

10. According to points 4.1.2.3 and 4.1.2.4 and Table 4.1.0:

'The criteria for classification of a substance in category Acute 1 are defined on the basis of acute aquatic toxicity data only (EC_{50} or LC_{50}). The criteria for classification of a substance into the categories Chronic 1 to 3 follow a tiered approach where the first step is to see if available information on chronic toxicity merits long-term hazard classification. In [the] absence of adequate chronic toxicity data, the subsequent step is to combine two types of information, i.e. acute aquatic toxicity data and environmental fate data (degradability and bioaccumulation data)

...

The system also introduces a "safety net" classification (referred to as category Chronic 4) for use when the data available do not allow classification under the formal criteria for acute 1 or chronic 1 to 3 but there are nevertheless some grounds for concern (see example in Table 4.1.0).

…

"Safety net" classification

Category Chronic 4

Cases when data do not allow classification under the above criteria but there are nevertheless some grounds for concern. This includes, for example, poorly soluble substances for which no acute toxicity is recorded at levels up to the water solubility (note 4), and which are not rapidly degradable in accordance with section 4.1.2.9.5 and have an experimentally determined BCF ≥ 500 (or, if absent, a log K_{ow} ≥ 4), indicating a potential to bioaccumulate, which will be classified in this category unless other scientific evidence exists showing classification to be unnecessary. Such evidence includes chronic toxicity NOECs > water solubility or > 1 mg/l, or other evidence of rapid degradation in the environment than the ones provided by any of the methods listed in section 4.1.2.9.5.

…

Note 4:

"No acute toxicity" is taken to mean that the $L(E)C_{50}$(s) is/are above the water solubility. Also for poorly soluble substances, (water solubility < 1 mg/l), where there is evidence that the acute test does not provide a true measure of the intrinsic toxicity.'

11. Point 4.1.3 of Annex I, entitled ‘Classification criteria for mixtures’ provides 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 …

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:

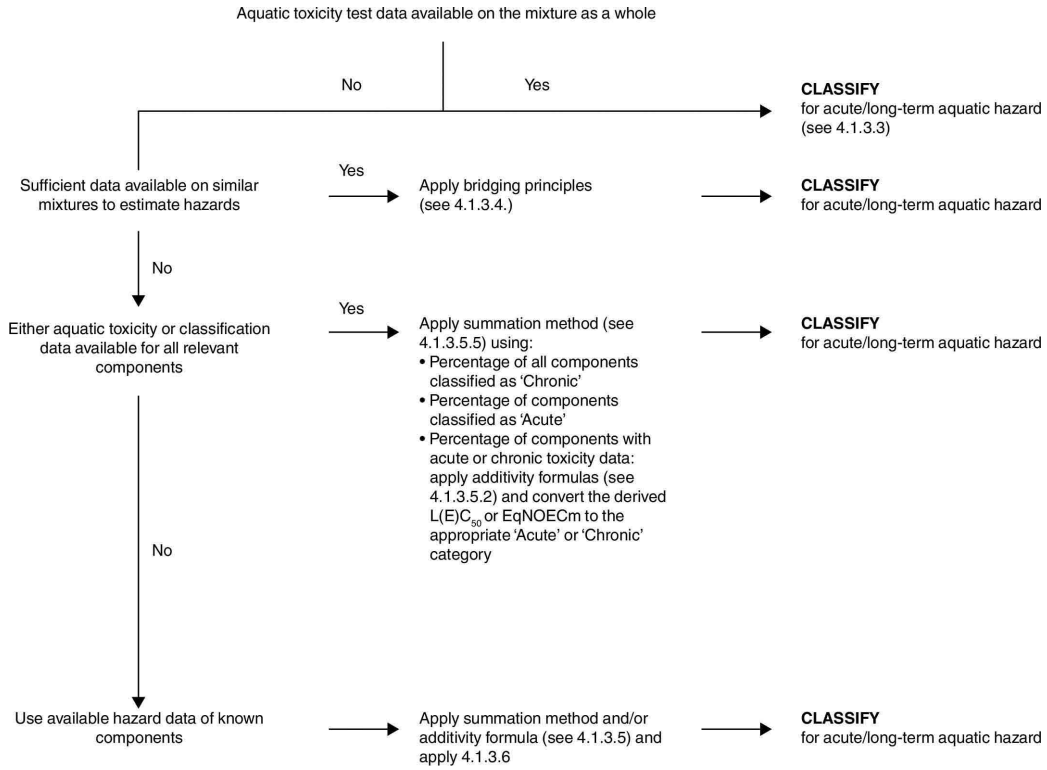
– classification based on tested mixtures,

– classification based on bridging principles,

– the use of ‘summation of classified components’ and/or an ‘additivity formula’.’

Figure 4.1.2

Tiered approach to classification of mixtures for acute and long-term aquatic environmental hazards



12. Point 4.1.3.5.5 of Annex I goes on to describe the summation method in detail. That method essentially consists in: (i) identifying the proportion of the substance under examination represented by each classified constituent (in percentages); (ii) multiplying each of those percentages by an M-factor (a coefficient reflecting the hazardousness of the given constituent); and, (iii) adding up the results for all constituents to get to a final percentage figure. That result is then compared to a series of thresholds representing different classifications (Chronic 1, 2, 3 and Acute 1).

2. Regulation No 944/2013

13. Regulation No 944/2013, among others, classifies CTPHT as regards aquatic toxicity as Aquatic Acute 1 and Aquatic Chronic 1.

III. Facts and procedure

14. The background to the dispute is set out at paragraphs 1 to 8 of the contested judgment.

15. The respondents are suppliers and downstream users of CTPHT, a black solid, the residue from the distillation of high-temperature coal tar. CTPHT is among the substances of unknown or variable composition, complex reaction products or biological material because it cannot be fully identified by its chemical composition.

16. On 21 November 2011, Risk Assessment Committee ('RAC')[7] of the European Chemicals Agency's (ECHA) adopted an opinion on CTPHT. That opinion, which was accompanied by a background document containing the RAC's detailed analysis ('the background document'), proposed inter alia to classify CTPHT as Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410).

17. The RAC considered that classification for aquatic toxicity could not be 'direct', based on data relating to CTPHT itself, citing weaknesses in that data. The data had been obtained in the absence of ultraviolet (UV) irradiation, even though certain polycyclic aromatic hydrocarbon ('PAH') constituents of CTPHT are phototoxic. Also, the studies concerned had been carried out with only a single loading.

18. The RAC therefore took the view that the classification of CTPHT was to be based on an alternative approach to classification, the 'summation method'. According to that approach, the 16 PAH constituents of CTPHT, which have been defined as priority substances by the United States Environmental Protection Agency (EPA), and for which sufficient effect and exposure data were available ('the 16 PAH constituents'), were analysed separately in accordance with their aquatic toxicity effects. By applying a method consisting in finding the sum of the results obtained by the attribution of multiplication factors to the different PAHs in order to attach more weight to the highly toxic constituents of CTPHT, that analysis showed, according to the RAC's opinion, that CTPHT had to be classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

19. On 2 October 2013, on the basis of the RAC's opinion, the Commission adopted the contested regulation classifying CTPHT as Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410).

IV. The proceedings before the General Court and the contested judgment

20. On 20 December 2013, the respondents bought an action for partial annulment of the contested regulation before the General Court, to the extent it classified CTPHT as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

21. By judgment of 7 October 2015, the General Court upheld that action, partially annulling the contested regulation.

7 Referred to in Article 76(1)(c) of Regulation No 1907/2006.

22. At paragraphs 32 to 34 of the contested judgment, which will be discussed in detail below, the General Court held as follows:

‘32 However, neither the Commission nor ECHA was able to establish before the Court that, in basing the classification of CTPHT as an Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) substance on the assumption that all of the PAHs present in that substance dissolved in the water phase and were thus available to aquatic organisms, the Commission took into consideration the fact that, according to point 1.3 of the background document, entitled “Physiochemical properties”, the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable.

33 First, neither the RAC’s opinion on CTPHT nor the background document contains any reasoning which demonstrates that, in assuming that all of the PAHs present in that substance dissolve in the water phase and are available to aquatic organisms, account was taken of the low water solubility of CTPHT. Moreover, in response to a written question from the Court, the Commission and ECHA were able to demonstrate only that the water solubility of 16 PAH constituents, considered in isolation, had been taken into account during the classification procedure of CTPHT. In addition, in response to a question from the Court at the hearing, the Commission and ECHA merely indicated that it had been assumed that all of the PAHs in CTPHT dissolved in water inasmuch as the examination of the aquatic toxicity of that substance had been conducted on the basis of its constituents. Such reasoning does not, however, establish that the low solubility of that substance was taken into consideration.

34 Secondly, it must be noted that, according to point 1.3 of the background document, the highest rate of water solubility of CTPHT in relation to a loading was 0.0014% at maximum. Given the low water solubility of CTPHT, the Commission has in no way demonstrated that it could base the classification in question of that substance on the assumption that all of the PAHs present in CTPHT dissolved in the water phase and were available to aquatic organisms. It is apparent from Table 7.6.2 in the background document that the 16 PAH constituents of CTPHT constitute 9.2% of that substance. By assuming that all of those PAHs 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, such a value is not realistic, given that the maximum rate is 0.0014%.’

V. Proceedings before the Court

23. By its appeal, lodged on 17 December 2015, the Commission asks the Court of Justice to set aside the contested judgment, refer the case back to the General Court and to reserve costs.

24. The respondents ask the Court to reject the appeal and order the Commission to pay the costs. The respondents ask that the Commission be ordered to pay the costs also in the event that the appeal is upheld.

25. ECHA and GrafTech Iberica, SL, as interveners before the General Court, in support of the Commission and respondents respectively, are also parties to the proceedings before this Court.

26. The Danish, German and Netherlands Governments intervened in the appeal proceedings in support of the Commission.

27. By order dated 7 July 2016, the Court rejected the respondents’ request for interim measures, lodged on 24 March 2016, effectively aimed at obtaining a suspension of the contested regulation.

28. The Commission, the respondents, ECHA and the Danish, German, and Netherlands Governments submitted written pleadings. The Commission, the respondents, ECHA, GrafTech Ibercia SL and the Danish and German Governments presented their arguments at the hearing held on 15 June 2017.

VI. Assessment

29. The Commission's appeal is based on three grounds, which I shall examine in turn. First, the General Court failed to state reasons (A). Second, the General Court erred in law in holding that the Commission committed a manifest error of assessment by failing to take into account the solubility of CTPHT as a whole (B). Third, the General Court exceeded the limits of its competence to review the matter, and in doing so distorted the evidence presented to it (C).

A. First ground of appeal: failure to state reasons

30. The Commission argues that the General Court violated its duty to state reasons, thereby infringing Articles 36 and 53 of the Statute of the Court of Justice of the European Union. In that regard, the Commission considers that it is unclear from the contested judgment whether the General Court considers that (i) the Commission was wrong to apply the summation method (as opposed to another method, for example, the direct classification method), or (ii) the Commission applied the summation method in an incorrect manner.

31. I do not agree that the contested judgment is unclear in that regard.

32. The key paragraphs of the contested judgment (paragraphs 32 to 34, reproduced above in point 22 of this Opinion), make it clear that the Commission applied the summation method in an incorrect manner.

33. Paragraph 30 of the contested judgment states that the Commission '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 PAH constituents are present in CTPHT and their chemical effects'.

34. The General Court thus refers to the Commission's failure to take into account all relevant factors that would allow it assess properly the chemical effects of the *constituents* of CTPHT. That reference to the assessment of constituents clearly indicates that the General Court is referring to concerns with the way the Commission has applied the summation method (the method based on a classification of constituents rather than the substance as a whole).

35. Paragraph 31 of the contested judgment states that: 'According to point 7.6 of the background document, for the purpose of the classification of CTPHT *on the basis of its constituents*, it was assumed that all of the PAHs present in CTPHT dissolved in the water phase and were thus available to aquatic organisms.' (Emphasis added.)

36. In other words, in the context of its application of the method based on classification of constituents — the summation method — the Commission made an assumption about the solubility of those constituents.

37. In each of the paragraphs from 32 to 34 of the contested judgment, the General Court goes on to link that assumption to the Commission's failure to take into account the solubility of CTPHT as a whole.[8] For example, at paragraph 34 the General Court states: '*Given the low water solubility of CTPHT*, the Commission has in no way demonstrated that it could base the classification in question of that substance on the assumption that all of the PAHs present in CTPHT dissolved in the water phase and were available to aquatic organisms.' (Emphasis added.)

38. It is specifically that failure to take into account the low solubility of CTPHT as a whole which amounted to a manifest error of assessment justifying partial annulment of the contested regulation.

39. It follows from the above that the concern of the General Court relates to the way in which the Commission applied the summation method rather than the choice of that method itself.

40. The General Court therefore has not breached its duty to state reasons. I propose that the first ground of the appeal should be rejected as unfounded.

41. By way of concluding remark, I note that whether the General Court was wrong to hold that the Commission was legally obliged to take into account the solubility of CTPHT as part of its application of the summation method is a question of substance (considered under the second ground below). It is not a question of the adequacy of the General Court's reasoning and is therefore not relevant to the first ground.

B. Second ground of appeal: the choice of the classification method and/or its incorrect application

1. First branch: wrong method chosen

42. In its first ground, the Commission argues that the contested judgment is unclear as to whether: (i) the Commission was wrong to apply the summation method, or (ii) the Commission applied the summation method in an incorrect manner. In its second ground, the Commission considers these two alternative readings of the contested judgment in turn (under the first and second branches of the second ground respectively) and concludes that each is vitiated by errors in law.

43. In the light of my answer to the first ground, which concludes that the first interpretation suggested by the Commission constitutes an incorrect reading of the General Court's judgment, I propose that the first branch of the second ground should be rejected as unfounded.

8 '… neither the Commission nor ECHA was able to establish before the Court that … the Commission took into consideration the fact that … the constituents of CTPHT were released from CTPHT only to a limited extent and that that substance was very stable. … neither the RAC's opinion on CTPHT nor the background document contains any reasoning which demonstrates that … account was taken of the low water solubility of CTPHT … Such reasoning does not, however, establish that the low solubility of [CTPHT] was taken into consideration.'

2. Second branch: application of the summation method in an incorrect manner

(i) The Commission's argument: summation method is exhaustive

44. The Commission argues that it *has discretion* to decide whether there is sufficient data to warrant using the direct classification method, or failing that, the bridging principles.[9] However, once it has determined that there is insufficient data to apply either method, and has thus chosen to apply the summation method, the Commission *cannot* take into account any data or evidence other than that specifically foreseen in the detailed rules describing the summation method in Annex I to the CLP Regulation.

45. The Commission draws four conclusions from that observation. First, the Commission made no error of assessment by not taking into account the solubility of CTPHT as a whole, when classifying that substance. Indeed, it could not take the solubility of CTPHT into account.

46. Second, the Commission did not make an error of assessment by assuming, when applying the summation method, that the relevant PAHs present in CTPHT dissolved in water. That assumption is inherent to the summation method itself.

47. Third, the Commission *did* take into account the proportion in which the relevant constituents are present in CTPHT and their chemical effects, as required by the summation method and the case-law (cited in paragraph 29 of the contested judgment).

48. Fourth, the General Court was wrong to imply that, in order to apply the summation method, the relevant constituents must account for a large proportion of the substance to be classified.

49. As concerns the fourth point, the General Court does not make such an implication, and the Commission's reading of the contested judgment is clearly incorrect in that regard. Indeed the Commission itself put the argument forward somewhat tentatively. I will therefore not discuss that point further.

50. The Commission's first, second and third points above in substance all raise the same issue. As regards the first and third point, in both cases the Commission is basically disagreeing with the General Court's conclusion that the solubility of CTPHT as a whole was a relevant factor that it had a legal obligation to take into account. As regards the second point, the contested judgment does not actually criticise the Commission for the assumption itself, but rather for the fact that no account was taken of the solubility of CTPHT as a whole.

51. For the reasons set out below, in my opinion, the General Court did not err in law.

(ii) What is a 'relevant factor' that must be considered?

52. The crux of the matter is the 'relevancy' of a given factual element and how that is determined.

9 Basically classification using data relating to similar substances.

53. The contested judgment [10] refers to the established case-law that, before adopting an act, the Commission has an obligation to take into consideration 'all the relevant factors and circumstances of the situation which the act was intended to regulate'. That obligation can be clearly traced back through the Court's case-law to the more general duty of good administration, which entails a 'duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case [and] the right of the person concerned to make his views known and to have an adequately reasoned decision'. [11]

54. I do not consider — and indeed none of the parties are arguing — that that case-law is wrong in holding that the Commission has a legal obligation to take account of all relevant factors. Nor does any party argue that the Commission *did* in this case actually take into account the solubility of CTPHT as a whole in its application of the summation method. Rather the dispute is in essence over whether solubility of CTPHT as a whole is a 'relevant factor' that must be considered in the context of the summation method.

55. It should be pointed out, at the outset, that whether a specific piece of data, a report, a finding and so on is a 'relevant factor', giving rise to a legal obligation to take it into account, and whether that relevant factor was in practice taken into account are, in principle, questions of fact. The General Court has exclusive jurisdiction, first, to find the facts, except where the substantive inaccuracy of its findings is apparent from the documents submitted to it, and, secondly, to assess those facts. [12] As a result, in the absence of any claim that the facts have been distorted, [13] (re)assessment of relevancy is in principle outside the jurisdiction of this Court. [14]

56. However, what the Commission's argument essentially boils down to is that the solubility of CTPHT is 'irrelevant', *because the summation method does not identify it as relevant*. In other words, the Commission has no discretion to determine what constitutes a 'relevant factor' and is legally obliged to take into account *those elements and only those elements* provided for in the CLP Regulation (Annex I, points 4.1.3.5, 4.1.3.5.2 and 4.1.3.5.5).

57. Whether or not the CLP Regulation does indeed exhaustively define what constitutes a relevant factor — and in doing so prevents the Commission from taking other factors into account — is a question of law.

58. In my opinion, the Commission is not deprived of its discretion in that way. It must assess whether there are other relevant factors and, according to the case-law cited in footnote 11, where such factors are identified, it has a legal obligation to consider them. [15]

59. To summarise the above and be crystal clear on the legal point under discussion, it is useful at this point to highlight four different legal issues that can potentially be the subject of judicial review:

– whether the Commission has any discretion to identify 'relevant factors' beyond those listed in the relevant parts of the applicable legislation;

– whether the Commission has correctly exercised that discretion and identified a factor as relevant;

10 Judgment of 7 October 2015, *Bilbaína de Alquitranes and Others* v *Commission* (T-689/13, not published, EU:T:2015:767, paragraph 24).

11 Judgments of 21 November 1991, *Technische Universität München* (C-269/90, EU:C:1991:438, paragraph 14), and of 29 March 2012, *Commission* v *Estonia* (C-505/09 P, EU:C:2012:179, paragraph 95).

12 Article 256 TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice.

13 The Commission does in fact argue that the General Court distorted the evidence before it but separately under the third ground and in a way that does not impact on the analysis here (see below in particular in points 104 and 105).

14 Order of 27 March 2014, *Polyelectrolyte Producers Group and Others* v *Commission* (C-199/13 P, not published, EU:C:2014:205, paragraphs 33 to 36).

15 Whether they change the outcome of the assessment is a different matter and in principle falls within the Commission's discretion to conduct complex scientific assessments, as indeed confirmed by the same case-law.

– once a relevant factor has been identified, whether the Commission has in practice fulfilled its legal obligation to take that factor into account in exercising its power of decision;

– whether the Commission has given sufficient weight to that factor in the assessment.

60. It is only the first of the above issues which is under discussion in the context of the second branch of the second ground of appeal.

(iii) Did the Commission have discretion?

61. As a matter of principle, it is possible for the EU legislature to grant powers to the Commission to adopt acts and, in doing so, to exclude consideration of certain factors. An obvious example would be the prohibition of taking into account in its assessment events that happened before a certain date. It is equally possible for the EU legislature to impose on the Commission a task effectively involving no discretion whatsoever, for example, the calculation of tonnages or monetary payments through the application of mathematical formulae.

62. However, I do not consider that one can compare those kinds of situations with situations such as the present one involving a (potentially decisive) stage in a highly complex scientific assessment, which are of a very different nature.

63. As the Court has previously held 'this discretion on the part of the administration, which is essential to enable it to take account of the manifold unforeseeable facts peculiar to each case, is not incompatible with the general principle, relied on by the applicant, of equal treatment .... This general principle does not mean that, in applying the provision concerned, the administration must merely carry out a mechanical application of predetermined rules and criteria. Such an interpretation would conflict with the need for evaluation of the often complicated factual considerations peculiar to each individual case'. [16]

64. Although the context of that quotation was quite different, the more general point is well taken. Requiring an administration to assess highly complex facts while wearing a straitjacket can lead to iniquitous, even bizarre results.

65. Admittedly, the Commission does not argue absence of discretion throughout the *entire* assessment, but only in *specific parts* of it.

66. However, in my view that analysis contains, if not an inherent contradiction, at least a very uneasy juxtaposition. On the one hand, the Commission confirms that it enjoys a broad margin of discretion as regards *the appropriateness of a given classification method*. On the other, it must consider each method of the tiered approach in strict hierarchical order (direct classification method, the bridging principles, and the summation method). Moreover, in case the Commission opts for the summation method, it denies that it has any discretion whatsoever *within that classification method*. It must 'mechanically' follow the method, remaining blind to any factors not explicitly listed in the CLP Regulation.

67. I do not agree.

16 Judgment of 7 June 1972, *Brandau* v *Council* (46/71, EU:C:1972:50, paragraphs 12 to 14). See, also in that sense, judgment of 7 May 1992, *Council* v *Brems* (C-70/91 P, EU:C:1992:201) and Opinion of Advocate General Darmon in *Council* v *Brems* (C-70/91 P, EU:C:1992:77 at pp. 2993 and 2994).

68. First and foremost, I am not convinced by the Commission's proposed dichotomy of (i) broad discretion for choosing the appropriate method, and (ii) absolutely no discretion at all for its application. By their nature, both steps, that is, the choice and the realisation of the method, are *parts of one and the same* highly complex scientific hazard assessment. In practice, it is to be expected that a diligent administrator first assembles all the available data. On the basis of the (in)sufficiency of individual elements of that data, it then decides on the method it will opt for, naturally taking into account what kind of data is needed for each of the methods.

69. I cannot exclude that in cases where the Commission enjoys discretion when the assessment is looked at *overall* that there are some *discrete part(s)* of it where it is indeed deprived of discretion. However, there must be a clear basis for dissecting the assessment in that way. In this case, I do not see one.

70. I wish to stress that I am in no way suggesting that on the merits, the result arrived at by the Commission is unsustainable. I pass no judgment whatsoever on the (in)correct classification of the CTPHT. I am mentioning this element only in order to demonstrate the inherent discretion that exists in the choice of the method and hence in the overall complex scientific assessment.

71. I would add that it is actually not clear that, in this specific case, the Commission did stick rigidly to the approach it proposes. The Commission argues that it must consider each method in strict hierarchical order and has no discretion in that regard. However, it would appear that in reality, in its assessment of CTPHT, the Commission jumped directly from the first method (direct classification) to the third (summation method) without explicitly considering and discarding the second (bridging principles) as an alternative.

72. There are, moreover, at least four further elements that, in my opinion, confirm that the Commission's argument of absolute absence of discretion must be rejected.

73. First, looking into the text itself, under point 4.1.3 of Annex I to the CLP Regulation, entitled 'Classification criteria for mixtures' there is arguably some discretion implied by the choice of wording: '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.*' (Emphasis added.)

74. The section goes on to describe the tiered approach to classification. There is no statement in the parts of Annex I to the CLP Regulation providing for recourse to and describing the content of the summation method, which prohibits the taking into account of factors other than those explicitly mentioned. [17]

75. I understand the Commission's point about legality of administrative action in this context, suggesting in a nutshell that since it is a public authority, it is allowed to act only within the bounds of the law. In general, such a vision can only be commended. However, in this particular scenario, the textual as well as the systemic bounds of the law are simply not as narrow as portrayed by the Commission.

76. Second, there is the broader context and the international origins of the CLP Regulation. According to recital 6 of the CLP Regulation: '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.'

17 See order of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599, paragraph 34), where a similar absence of explicit limitations was used as a factor to support a finding of discretion (see also below, point 90).

77. The tiered approach to aquatic hazard classification accordingly reflects the approach taken at the international level under the Globally Harmonised System of Classification and Labelling of Chemicals ('the GHS'). Indeed, there are significant parts of that approach in Annex I to the CLP Regulation which are almost textually identical to the equivalent GHS guidance. [18]

78. Annex 9 to the GHS is more complete than point 4 of Annex I to the CLP Regulation. In my view, Annex 9 makes it plain that detailed guidance can be given but it is difficult to provide rules in this area which apply in a completely systematic and mechanical way. For example, Annex 9 to the GHS lists challenges to 'interpretational problems' relating to 'difficult substances', which include 'poorly soluble' substances and 'complex or multi-component substances'. [19]

79. Before going on to describe the harmonised classification scheme, Annex 9 to the GHS starts by stating that it '*cannot hope to cover all situations* that arise in classification. It should therefore be seen as a *living document* that in part describes the *fundamental principles* of the system, [that is,] hazard based rather than risk based, and the fixed criteria. It must also, in part, be a repository for the accumulated experience in using the scheme to include the interpretations which allow the *apparently fixed* criteria to be applied in a wide variety of non-standard situations' (emphasis added). [20]

80. It is therefore clear that the international standards that the EU legislature wished to incorporate by means of the CLP Regulation take a much more nuanced stance. They set out principles and, whilst guidance is highly detailed, it is openly acknowledged that there are difficult cases and the rules cannot be considered as completely exhaustive checklists.

81. Third, in my view, it is also important to look beyond the individual case and ponder on the overall system and operation of the CLP Regulation. In the present case, the Commission argues absence of discretion and, on that basis, comes to the conclusion that the *most severe* hazard classification is warranted. In this particular case, that conclusion is indeed in accordance with the CLP Regulation's objective to ensure a high level of protection of human health and the environment. However, what of other cases where the Commission's inability to take into account other relevant factors would ultimately lead to a *lower* hazard classification than might otherwise be justified?

82. It is true that a 'safety net' classification exists, which allows substances that have not been classified Aquatic Acute 1 or Aquatic Chronic 1, 2 or 3, but where there is nonetheless cause for concern, to be classified as Aquatic Chronic 4. That possibility attenuates the risk of classifications that are 'too low'.

83. However, in my opinion a 'safety net' should be treated as such. Its use is by definition of last resort. If highly important, relevant factors come to light that seriously question a hazard classification that is 'too low', they must be considered as part of the main assessment.

84. If there is indeed discretion, it must be accepted that such discretion *can cut both ways*. If highly important, relevant factors come to light that make it appear that a hazard classification is 'too high', those factors must also be considered as part of the main assessment. That is effectively the position of the respondents.

85. I underline that none of the above says anything about what constitutes a 'relevant factor' or about what weight must be given to it (see point 59 above). Those are, in the first instance, questions for the Commission. In the event of review, it is for the General Court to consider whether a manifest error was committed in that regard.

18 Annex 9 to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), fourth edition. Available at https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf.

19 At A9.1.10, see also A9.3.5.7 and A9.3.5.10.

20 At A9.1.16.

86. Finally, the Court has already heard a case relating to CTPHT. The Case T-93/10 *Bilbaína* v *ECHA* (on appeal, C-287/13 P *Bilbaína* v *ECHA*) (‘*Bilbaína I*’)[21] concerned, to the extent it is of interest here, the identification of CTPHT as being very persistent and very bioaccumulative (‘vPvB’).

87. In order to identify a substance as being vPvB, the Commission must follow the requirements set out among others in Annex XIII to Regulation No 1907/2006. In the version applicable at the time, the criteria for identification of a substance as vPvB were laid down in Sections 1.1, 1.2 and 1.3 of Annex XIII. Those criteria made no mention of the properties of the constituents of the substance. Yet CTPHT was in fact identified as vPvB on the basis of the properties of its *constituents*.

88. The applicants challenged that departure from the criteria laid down in Annex XIII. The General Court upheld the Commission’s approach. On appeal, the Court of Justice upheld that judgment stating in paragraph 34 of *Bilbaína I* that: ‘Admittedly, it is true that, in the version applicable on the date of adoption of the contested decision, Annex XIII to the REACH Regulation did not expressly provide that a substance may be identified by taking into account the PBT or vPvB properties of its relevant constituents. Contrary to the appellants’ submissions, that does not, however, mean that Annex XIII to the REACH Regulation precluded any account from being taken of the PBT or vPvB properties of the relevant constituents of a substance.’

89. The Court confirmed that taking the properties of the constituents into account was, moreover, in line with the objectives of the REACH Regulation.

90. There are obvious differences between these cases. In particular, *Bilbaína I* related to the REACH Regulation as opposed to the CLP Regulation. Both cases nonetheless raise the same question of principle. When does the Commission have discretion to depart from the criteria for assessment of a substance laid down in a regulation to identify other relevant factors? In *Bilbaína I*, the General Court and Court of Justice effectively based their confirmation of discretion to identify other relevant factors on: (i) the absence of any wording precluding such discretion, and (ii) the fact that taking those factors into account was in line with the objective of the REACH Regulation.

91. As noted above, in the present case there is similarly no wording in Annex I to the CLP Regulation which clearly precludes identification of other relevant factors when applying the summation method.

92. As regards objectives, I refer to my comments above in points 81 to 84. If one accepts some degree of discretion as a matter of principle, one must accept that that discretion can cut both ways. It can be exercised in a manner which clearly goes in the direction of the objectives by imposing a higher, more stringent hazard classification. However, it can also be exercised in a way that results in a lower, less stringent classification. That does not mean the objectives of the CLP Regulation have been compromised, it simply means a more extensive consideration of available information to make the classification as accurate as possible.

93. Taking all the above points together, I consider that, as a matter of law, the Commission did have discretion to identify other relevant factors in the course of applying the summation method, without breaching the CLP Regulation.

94. In coming to that conclusion, I stress again that what those relevant factors are is a question of fact which, absent any distortion of the facts, has been settled by the General Court and cannot be reopened by this Court. Moreover, I note that at no point does (or indeed could) the General Court hold that *if, hypothetically*, the Commission *had* taken the low solubility of CTPHT into account, it

21 Judgment of 7 March 2013, *Bilbaína de Alquitranes and Others* v *ECHA* (T-93/10, EU:T:2013:106). Order of 22 May 2014, *Bilbaína de Alquitranes and Others* v *ECHA* (C-287/13 P, not published, EU:C:2014:599).

would have committed a manifest error in going on to classify CTPHT as Aquatic Acute 1 or Aquatic Chronic 1. Rather, it is the Commission's *objective failure* to take that element into account in its reasoning, as confirmed by the General Court, which resulted in the partial annulment of the contested regulation.

95. Finally, the above assessment addresses the narrow question of the *existence* of discretion in the specific context of the present case. Although alluding to the issue, it says nothing conclusive about *breadth* of discretion where significant and detailed guidance is given in the basic legislation. That is, in my view, an important question to flag up, but not one that needs to be addressed in the present appeal.

(iv) Conclusion on the second branch of the second ground

96. In the light of the foregoing, I do not consider that the General Court erred in law in holding that the Commission applied the summation method in an incorrect manner and I propose that the second branch of the second ground should be rejected as unfounded. With reference to point 55 above, to the extent the second branch of the second ground should be interpreted as questioning the General Court's factual assessment of the relevance of the solubility of CTPHT as a whole, it should be rejected as inadmissible.

C. Third ground of appeal: exceeding the limits of review and distorting evidence

97. The Commission argues that the General Court exceeded the limits of its review by going beyond an assessment of manifest error and substituting its own assessment for that of the Commission, and in doing so distorted the evidence presented to it.

98. Essentially, the Commission argues that the General Court was wrong to attach so much importance to the assumption that the PAH constituents of CTPHT dissolve in water. That was only one factor among many on which the scientific assessment was based. Moreover, it was taken out of context by the General Court.

99. I disagree.

100. I consider that the Commission's argument is flawed in that it relies on an incorrect reading of the contested judgment. As explained above in point 50, the General Court faults the Commission not specifically for assuming that the constituents of CTPHT dissolve in water. It did not hold that the Commission was prohibited from making that assumption. Instead, the General Court's concern is that, in making that assumption, the Commission failed to take into account the solubility of CTPHT as a whole.

101. On that basis alone, the Commission's third ground could be rejected as unfounded.

102. However, to the extent the third ground might be interpreted as meaning that the General Court exceeded the limits of its review by: (i) identifying solubility of CTPHT as a whole as being a relevant factor, or (ii) by giving too much weight to that factor, I make the following observations.

103. First, whether the Commission has the discretion at all to identify the solubility of CTPHT as a whole as being a relevant factor was discussed above under the second branch of the second ground. It does.

104. Second, as stated above in point 55 whether the solubility of CTPHT as a whole is a 'relevant factor', giving rise to a legal obligation to take it into account, is a question of fact within the exclusive jurisdiction of the General Court, unless there has been a distortion of the facts. [22]

105. The Commission argues that the General Court distorted the facts by taking the reference to the solubility of the *constituents* of CTPHT out of context and not considering its significance in the context of the summation method. The Commission does not explicitly argue that the General Court distorted the facts when it identified the solubility of CTPHT *as a whole* as a relevant factor.

106. However, to the extent that its arguments might be read in that way, suffice it to say that the solubility of the substance as a whole is clearly not a marginal element or minor detail. Solubility of a substance is referred to several times in point 4 of Annex I to the CLP Regulation in relation to the aquatic toxicity assessment and explicitly identified as a source of difficulties in case of low solubility. [23] It is also discussed at length in Annex 9 to the GHS, which is incorporated into EU law in particular through point 4 of Annex I to the CLP Regulation. [24] There is therefore no distortion of the facts by the General Court as regards the relevance of that factor.

107. Third, as regards the weight given by the General Court to the solubility of CTPHT as a whole, I simply note that the contested judgment is silent on that issue. The contested judgment does not say that, if the Commission had taken the solubility of CTPHT as a whole into account, it would inevitably have 'trumped' all other factors. The General Court concludes only that the Commission committed a manifest error by objectively *failing to consider* the solubility of CTPHT as a whole (see also above in point 93).

108. In the light of the foregoing, I consider that the General Court did not exceed the limits of its review of the legality of the contested regulation or distort the facts. As a result, the third ground of appeal should be rejected as unfounded.

VII. Conclusion

109. I propose that the Court:

– dismiss the appeal as unfounded;

– order the European Commission to pay its own costs and those of the respondents and GrafTech Iberica, SL;

– order the European Chemicals Agency (ECHA) and the interveners to bear their own costs.

22 Order of 27 March 2014, *Polyelectrolyte Producers Group and Others* v *Commission* (C-199/13 P, not published, EU:C:2014:205, paragraph 33).

23 Point 4.1.2.10 of Annex I identifying issues with classification of poorly soluble inorganic compounds and metals; point 4.1.2.6 and the category 4 safety net classification referred to above in points 82 and 83. Solubility forms part of the definition of 'availability' under point 4.1.1.1.

24 See above in point 78.