Reports of Cases

OPINION OF ADVOCATE GENERAL
ĆAPETA
delivered on 6 February 2025 [1]

Joined Cases C-71/23 P and C-82/23 P

French Republic
v
European Commission,
CWS Powder Coatings GmbH,
Billions Europe Ltd,
Cinkarna Metalurško-kemična Industrija Celje d.d. (Cinkarna Celje d.d.),
Evonik Operations GmbH,
Kronos Titan GmbH,
Precheza a.s.,
Tayca Corp.,
Tronox Pigments (Holland) BV,
Venator Germany GmbH,
Brillux GmbH & Co. KG,
Daw SE (C-71/23 P)
and
European Commission
v
CWS Powder Coatings GmbH,
Billions Europe Ltd,
Cinkarna Metalurško-kemična Industrija Celje d.d. (Cinkarna Celje d.d.),
Evonik Operations GmbH,
Kronos Titan GmbH,
Precheza a.s.,
Tayca Corp.,
Tronox Pigments (Holland) BV,
Venator Germany GmbH,
Brillux GmbH & Co. KG,

Daw SE (C-82/23 P)

[1] Original language: English.

(Appeal – Protection of human health – Regulation (EC) No 1272/2008 – Classification, labelling and packaging of substances and mixtures – Delegated Regulation (EU) 2020/217 – Classification of titanium dioxide as carcinogen category 2 by inhalation – Criteria for classifying a substance as carcinogenic – Intensity of judicial review in scientific matters – Concept of 'intrinsic properties')

I. Introduction

1. Law and science have one thing in common – more often than not, they are uncertain. [2]

2. While judges are empowered and trained to deal with legal indeterminacy, they are not scientists and are therefore not equipped to decide on the usability of contradictory or simply inconclusive scientific findings.

3. A number of EU acts, including Regulation (EC) No 1272/2008, [3] which is at issue in the present case, empower EU agencies and the European Commission to enact decisions based on scientific evaluations.

4. What should judges do when an administrative decision based on inconclusive scientific evidence becomes the matter of a legal dispute? How can judges review such a decision – which is their task in a system based on the rule of law – without encroaching, at the same time, on the power of appraisal placed on the administration to decide on scientific indeterminacy? Not for the first time do such questions arise before the EU Courts.

5. At issue in the present case is the judgment in *CWS Powder Coatings and Others* v *Commission*, [4] in which the General Court annulled the Commission's decision to classify titanium dioxide as a suspected human carcinogen.

6. The French Government and the Commission have both appealed that judgment. At their heart, those appeals turn on two matters. First, whether the General Court overstepped the limits of permissible judicial review of a Commission decision. Second, whether the General Court erred in attributing a restrictive interpretation to the concept of 'intrinsic properties', as it appears in the CLP Regulation. [5]

2 In respect of science, see, for example, Pouyat, R.V., 'Science and environmental policy – making them compatible', *BioScience*, Vol. 49(4), 1999, pp. 281 to 286, at p. 282, stating that 'the basic nature of science is that there will always be uncertainty'.

3 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), hereinafter 'the CLP Regulation'.

4 Judgment of 23 November 2022, *CWS Powder Coatings and Others* v *Commission* (T-279/20, T-283/20 and T-288/20, EU:T:2022:725; 'the judgment under appeal').

5 At the time of writing, the question of what reading to attribute to the concept of 'intrinsic properties', within the meaning of the CLP Regulation, appears to be pending also in the actions brought on 24 March 2023, *LAT Nitrogen Piesteritz and Cornerstone* v *ECHA*, T-167/23, and on 27 March 2024, *PMC Vlissingen Netherlands* v *Commission*, T-169/24. Moreover, by judgments of 27 November 2024, *Evonik Operations* v *Commission* (T-449/22, EU:T:2024:866, paragraphs 118 to 120), and of 27 November 2024, *BASF and Others v Commission* (T-453/22, not published, EU:T:2024:867, paragraphs 52 to 54), the General Court repeated the interpretation given in the judgment under appeal. Accordingly, the Court of Justice's ruling will provide guidance beyond the present appeals.

II. Background to the proceedings

A. Preliminary remarks on the classification procedure

7. The CLP Regulation sets out the rules for the classification, labelling and packaging of substances and mixtures placed on the EU market. Its purpose 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. [6]

8. With a view to ensuring those objectives, the CLP Regulation provides that, for certain hazards, including carcinogens, the classification and labelling of substances and mixtures should be harmonised at EU level. [7] It thus lays down a procedure for the adoption of harmonised classification and labelling of such substances and mixtures ('the classification procedure').

9. In brief, that procedure requires that a proposal be put forward by the competent authority of a Member State or by a manufacturer, importer or downstream user of a substance. [8] The Committee for Risk Assessment ('the RAC') of the European Chemicals Agency (ECHA) then adopts an opinion on the proposal within 18 months of receipt, giving the parties concerned an opportunity to comment on that opinion. [9] ECHA then forwards the RAC Opinion and any related comments to the Commission for decision. Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it may amend the CLP Regulation 'to adapt [it] to technical and scientific progress'. [10] That adaptation takes the form of a regulation.

10. The RAC formulates its classification proposal by examining the information identified by manufacturers, importers and downstream users on the physical, health or environmental hazard of a given substance for its adequacy, reliability and scientific validity. [11] That information is then evaluated by applying to it the criteria for classification laid down in the CLP Regulation. [12]

11. The relevant criteria to determine the carcinogenicity of a substance are contained in section 3.6 of Annex I to the CLP Regulation. [13]

12. Therein, a 'carcinogen' is defined as 'a substance or a mixture of substances which induce cancer or increase its incidence. Substances which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumour formation is not relevant for humans.' [14]

13. The classification of a substance as a carcinogen involves two interrelated determinations: the evaluations of strength of evidence and consideration of all other relevant information. [15]

6 See recital 1 and Article 1(1) of the CLP Regulation.

7 See, to that effect, recital 8 of the CLP Regulation.

8 See Article 37(2) and (3) of the CLP Regulation.

9 See Article 37(4) of the CLP Regulation.

10 See Article 53(1) and recital 77 of the CLP Regulation.

11 See Article 5 of the CLP Regulation.

12 See Article 9 of the CLP Regulation.

13 As provided for in Article 36(1)(c) of the CLP Regulation.

14 See point 3.6.1.1. of Annex I to the CLP Regulation.

15 See point 3.6.2.2.2. of Annex I to the CLP Regulation.

14. On that basis, carcinogens may be classified into one of two categories, as presented in Table 3.6.1 of Annex I to the CLP Regulation:

Table 3.6.1

Hazard categories for carcinogens

Categories	Criteria
CATEGORY 1:	Known or presumed human carcinogens A substance is classified in Category 1 for carcinogenicity on the basis of epidemiological and/or animal data. A substance may be further distinguished as:
Category 1A:	Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, or
Category 1B:	Category 1B, presumed to have carcinogenic potential for humans, classification is largely based on animal evidence. The classification in Category 1A and 1B is based on strength of evidence together with additional considerations (see section 3.6.2.2). Such evidence may be derived from: — human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or — animal experiments for which there is sufficient (1) evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case-by-case basis, scientific judgement may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.
CATEGORY 2:	Suspected human carcinogens The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B, based on strength of evidence together with additional considerations (see section 3.6.2.2). Such evidence may be derived either from limited (1) evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.

15. Titanium dioxide, the substance at issue in the present case, was classified as a category 2 carcinogen.

16. Classification in that category occurs if there is only a *suspicion*, arising from human and/or animal studies, that a substance or mixture has the potential to cause cancer in humans, but where the evidence is not sufficiently convincing to place that substance intcategory 1. On the contrary, classification in category 1 requires that it is either *known* that a substance may cause cancer, based on evidence of causality obtained from human studies between the exposure to that substance and the development of cancer (category 1A) or that it is *presumed* that the substance has carcinogenic potential for humans, based on animal studies with *sufficient evidence* of animal carcinogenicity (category 1B).

17. Whether of sufficient or only limited value, the evidence on the basis of which classification is determined must come from 'reliable and acceptable studies'. [16] The first main point of the present appeals relates to the question of whether a study that was used for concluding on the carcinogenicity of the substance at issue – titanium dioxide – was correctly deemed 'reliable' in that classification exercise.

18. Apart for human and animal studies, other factors, set out in points 3.6.2.2.4. to 3.6.2.2.6. of Annex I to the CLP Regulation, need to be considered to establish the likelihood that a substance poses a carcinogenic hazard in humans. Some of the enumerated additional factors include the 'routes of exposure' [17] and the 'mode of action and its relevance for humans'. [18]

19. Where the criteria for classification cannot, due to the uncertainty of the scientific information obtained, be applied directly, Article 9(3) of the CLP Regulation and point 1.1.1.3 of Annex I thereto require an evaluation based on the 'weight of evidence' approach. That evaluation demands an expert judgment, in which '*all available information* bearing on the determination of hazard *is considered together*'. [19]

16 See point 3.6.2.2.1. of Annex I to the CLP Regulation.

17 See point 3.6.2.2.6(h) of Annex I to the CLP Regulation.

18 See point 3.6.2.2.6(k) of Annex I to the CLP Regulation.

19 Emphasis added.

20. In that process, 'the quality and consistency of the data shall be given appropriate weight. … Both positive and negative results shall be assembled together in a single weight of evidence determination.' [20]

21. Finally, in accordance with point 3.6.2.2.1. of Annex I to the CLP Regulation, the classification of a substance as a carcinogen is intended for substances which have the 'intrinsic properties' to cause cancer. The second main point of dispute in the present appeals concerns the interpretation of that concept – that is, the 'intrinsic properties' of a substance –, which lacks any definition or further explanation in the CLP Regulation.

B. The classification procedure in the present case and its effects

22. In May 2016, the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food, Environmental and Occupational Health and Safety (ANSES), France) ('the competent French authority') submitted to ECHA a dossier proposing the harmonised classification and labelling of titanium dioxide as a category 1B carcinogen by inhalation (Carc. 1B, H350i). [21]

23. The substance at issue in the present case, titanium dioxide, is an inorganic chemical with the molecular formula TiO2.

24. It is listed under EC number 236-675-5 [22] and occurs in different sizes, as both micro- and nanometric particles.

25. By reason of its ultraviolet ray absorption properties, titanium dioxide is used in powder form in various products, mostly as a pigment for lending whiteness and opacity.

26. Accordingly, the use of titanium dioxide includes paints, coating materials, varnishes, plastics, laminated paper, cosmetic products (including toothpaste and sunscreens), medicinal products and toys. [23]

27. The competent French authority based its classification proposal principally on four inhalation studies. Of those studies, two showed tumour development following exposure to titanium dioxide (the Lee (1985) and Heinrich (1995) studies), while the two other showed no tumour development (the Muhle (1989) and Thyssen (1978) studies). [24]

[20] See point 1.1.1.3. of Annex I to the CLP Regulation.

[21] This submission was done on the basis of Article 37(1) of the CLP Regulation, pursuant to which 'a competent authority may submit to the Agency a proposal for harmonised classification and labelling of substances'.

[22] The EC number is a unique seven-digit identifier for chemical substances. The brief profile of titanium dioxide, as it appears on ECHA's website, can be accessed here: https://echa.europa.eu/brief-profile/-/briefprofile/100.033.327.

[23] While also previously used as a food colourant, Commission Regulation (EU) 2022/63 of 14 January 2022 amending Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the food additive titanium dioxide (E 171) (OJ 2022 L 11, p. 1) withdrew the authorisation to use titanium dioxide as a food additive after the European Food Safety Agency (EFSA) voiced concerns that the consumption of titanium dioxide particles could damage DNA (that is to say, that it had 'genotoxic' properties). See also EFSA, 'Safety assessment of titanium dioxide (E171) as a food additive', *EFSA Journal*, 2021, Vol. 19(5), 6585.

[24] At the hearing, the French Government explained that it grounded its classification proposal on the Lee study, since it considered the Heinrich study insufficiently reliable. However, for its part, the RAC based its opinion on the Heinrich study, considering it to be reliable, and the Lee study less reliable.

28. Following consultations, ECHA referred the matter to the RAC. On 14 September 2017, the RAC adopted a unanimous opinion on the classification of titanium dioxide as a category 2 carcinogen by inhalation ('the RAC Opinion'). [25]

29. The conclusion thus reached is based on a weight of the evidence approach, marked by two different findings.

30. On the one hand, the RAC concluded that there is insufficient evidence based on human or animal studies supporting the classification of titanium dioxide as a category 1A or 1B carcinogen. In other words, it considered that there was insufficient evidence that titanium dioxide constitutes a 'known' or 'presumed' carcinogen.

31. On the other hand, the RAC found that there was sufficient evidence supporting classification as a category 2 carcinogen by reason, inter alia, of (1) toxicity data, including the Lee and Heinrich studies referred to in point 27 of this Opinion; [26] (2) the 'mode of action' in rats; [27] (3) studies regarding 'interspecies differences'; [28] (4) evidence from studies of other poorly soluble, low toxicity particles; [29] (5) the conclusion by a working group of the International Agency for Research on Cancer that there was 'sufficient evidence' that titanium dioxide is carcinogenic in experimental animals; [30] and (6) human epidemiological data. [31]

32. On the basis of the RAC Opinion, the Commission drew up a draft regulation on the harmonised classification and labelling of, inter alia, titanium dioxide, which was submitted for public consultation between 11 January and 8 February 2019.

33. On 18 February 2020, Commission Delegated Regulation (EU) 2020/217 [32] ('the contested regulation') was published.

34. The contested regulation makes the necessary changes to the CLP Regulation to reflect the resulting classification of titanium dioxide. [33] In the table in Annex VI, under index number 022-006-00-2, it introduces the harmonised classification of titanium dioxide 'in powder form containing 1% or more of particles with aerodynamic diameter ≤ 10 μm' as a category 2 carcinogen, with the Hazard statement Code 'H351 (inhalation)'. [34]

35. In its recital 5, the contested regulation explains that 'in its scientific opinion of 14 September 2017 on the substance titanium dioxide, [the] RAC proposed to classify that substance as carcinogen category 2 by inhalation. As titanium dioxide-induced lung carcinogenicity is associated with inhalation of respirable titanium dioxide particles, retention and poor solubility of the particles in the lung, it is appropriate to define respirable titanium dioxide particles in the titanium dioxide entry. The deposited particles, but not solutes of titanium

25 ECHA, Opinion of the Committee for Risk Assessment on a dossier proposing harmonised classification and labelling at EU level (EC No.: 236-675-5; CAS No.: 13463-67-7), report no. CLH-O-0000001412-86-163/F, adopted on 14 September 2017.

26 See the RAC Opinion, pp. 10 to 16.

27 See the RAC Opinion, pp. 19 to 20.

28 See the RAC Opinion, pp. 20 to 26 and 39.

29 See the RAC Opinion, pp. 15 and 21 to 25.

30 See the RAC Opinion, p. 27.

31 See the RAC Opinion, pp. 27 to 32.

32 Commission Delegated Regulation of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation No 1272/2008 and correcting that Regulation (OJ 2020 L 44, p. 1, corrigendum OJ 2021 L 214, p. 72).

33 See the judgment under appeal, paragraphs 9 to 13.

34 See the contested regulation, p. 11.

dioxide, are assumed to be responsible for the observed toxicity in the lung and subsequent tumour development. In order to avoid unjustified classification of non-hazardous forms of the substance, specific notes should be laid down for the classification and labelling of the substance and mixtures containing it. In addition, as some hazardous dust or droplets could be formed during the use of mixtures containing titanium dioxide, it is necessary to inform the users of the precautionary measures that need to be taken to minimise the hazard for human health.'

36. Among the notes that accompany the classification in the contested regulation is Note W. That note provides that:

'it has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung.

This note aims to describe the particular toxicity of the substance; it does not constitute a criterion for classification according to this Regulation.' [35]

37. By reason of the changes brought about by the contested regulation, and pursuant to Article 4(10) of the CLP Regulation, titanium dioxide and mixtures containing titanium dioxide 'shall not be placed on the market unless they comply with this Regulation'. That means that products containing titanium dioxide must also have affixed to them certain warning phrases and labels as well as, where necessary, an accompanying safety data sheet. [36]

38. The classification of a substance as 'carcinogenic' also has effects outside the framework established by the CLP Regulation.

39. As the applicants at first instance in Case T-279/20 and in Case T-288/20 explain, such a classification brings with it, among other effects, a prohibition to use titanium dioxide in the production of cosmetic products and toys, [37] the classification of that substance as hazardous waste and related handling obligations, [38] and the possible exclusion from the use of certain consumer information labels such as the EU Ecolabel. [39]

40. At the same time, a category 2 classification does not necessarily entail a complete prohibition on the use of a substance. For example, the Cosmetic Products Regulation and the Toy Safety Directive each provide for a procedure to declare safe for use a substance that is listed as carcinogenic, mutagenic or toxic for reproduction under the CLP Regulation. [40] These procedures were respectively used to adopt a regulation to permit the continued use of titanium dioxide in cosmetic products [41] and to confirm, by means of a report, that there is no or negligible risk to

35 See the contested regulation, p. 8.

36 See the judgment under appeal, paragraph 9, on the use of the pictogram 'H 351' (), and paragraph 12, on the affixation of labels 'EUH211: "Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist."' and 'EUH212: "Warning! Hazardous respirable dust may be formed when used. Do not breathe dust."'

37 See, in that regard, Article 15(1) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009 L 342, p. 59) ('the Cosmetic Products Regulation') and Article 4(1) of Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ 2009 L 170, p. 1) ('the Toy Safety Directive').

38 See, in that regard, Article 3(2) and Chapters III and VI of, and the entry H 7 'Carcinogenic' in Annex III to, Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3).

39 See, in that regard, criteria 5 and 5(a) of the annex to Commission Decision 2014/312/EU of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (OJ 2014 L 164, p. 45).

40 See, respectively, Article 15 of the Cosmetic Products Regulation and Article 46 of the Toy Safety Directive.

41 Commission Regulation (EU) 2021/850 of 26 May 2021 amending and correcting Annex II and amending Annexes III, IV and VI to Regulation No 1223/2009 (OJ 2021 L 188, p. 44).

children arising from the use of titanium dioxide in toys.[42] At the time of writing, a proposal for a regulation on the safety of toys that would declare certain uses of titanium dioxide safe is under negotiation by the co-legislators.[43]

C. The judgment under appeal

41. On 12 and 13 May 2020, CWS Powder Coatings GmbH (in Case T-279/20), Billions Europe Ltd, Cinkarna Metalurško-kemična Industrija Celje d.d., Evonik Operations GmbH, Kronos Titan GmbH, Precheza a.s., Tayca Corp., Tronox Pigments (Holland) BV and Venator Germany GmbH (in Case T-283/20), Brillux GmbH & Co. KG and DAW SE (in Case T-288/20), all suppliers or downstream users of titanium dioxide on the EU market (collectively, 'the applicants at first instance') brought actions requesting the annulment of the contested regulation.[44]

42. On 23 November 2022, the General Court handed down the judgment under appeal, by which it annulled the contested regulation on two grounds: (1) the failure by the RACto take account of a possible difference in particle density in one of the studies (Heinrich study) used to show tumour development following exposure to titanium dioxide; and (2) the failure to correctly interpret the concept of 'intrinsic properties', as used in the CLP Regulation, to conclude that titanium dioxide has an 'intrinsic property' to cause cancer.

1. The first reason for annulment: the particle density of titanium dioxide

43. The first reason for annulment essentially related to the failure, in the RAC Opinion, to take account of a possible difference in particle density between micro- and nano-sized particles of titanium dioxide when calculating what constitutes the inhalation of a maximal tolerated dose of titanium dioxide particles by rats.[45]

44. That element of discussion arises from the RAC's attempt to respond to criticism of the Lee study that the experimental exposure level in that study 'clearly exceeded' the maximal tolerated dose.[46]

45. Exposure above the maximal tolerated dose of a chemical is important because such a dose may cause effects 'which can lead to tumour development as a secondary consequence unrelated to the intrinsic potential of the substance itself to cause tumours at lower less toxic doses'.[47] Thus, if it can be found that a study exceeded the maximal tolerated dose, that study may not be reliable to conclude that the tested substance has the intrinsic properties of a carcinogen.

42 See Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), *Opinion on the safety of titanium dioxide in toys*, 12 October 2023.

43 Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48 (COM(2023) 462 final of 28 July 2023). See also General Secretariat of the Council, Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48, ST 9740/1/24-REV-1, p. 18.

44 By order of 11 March 2022, the President of the Ninth Chamber of the General Court joined the actions in Cases T-279/20, T-283/20 and T-288/20 for the purposes of the oral part of the procedure and the decision closing the proceedings.

45 While the CLP Regulation does not refer to the concept of 'maximal tolerated dose', ECHA, in its *Guidance on the Application of the CLP Criteria*, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 5.0, July 2017 ('the CLP Guidance Document'), at p. 385, describes the maximal tolerated dose as 'the highest dose of the test agent during the bioassay that can be predicted not to alter the animal's normal longevity from effects other than carcinogenicity'.

46 See the RAC Opinion, p. 16.

47 See the CLP Guidance Document, p. 385.

46. To assess whether the maximal tolerated dose was exceeded in the Heinrich and Lee studies, the RAC used the overload calculation proposed by 'Morrow' (in two studies dated 1988 and 1992) ('the Morrow overload calculation'). [48]

47. While it is not necessary to discuss the details of that analysis, what is important is that the RAC Opinion found that the exposure doses, and therefore the lung overload of the Lee study, were excessive. [49]

48. For the Heinrich study, however, the RAC Opinion made no such conclusion.

49. The General Court's criticism of the contested regulation, and, by extension, of the RAC Opinion, concerned the RAC's finding that the Heinrich study was relevant.

50. First, in the judgment under appeal, the General Court determined that the Heinrich study constituted the 'decisive study' for the purposes of the RAC Opinion. The hazard classification at issue was therefore 'based' on that study, and 'the other studies, including the Lee study, were taken into account purely on a supplementary basis'. [50]

51. Second, the General Court explained that 'it is common ground that the Heinrich and Lee studies did not indicate the density of the particles tested'. [51] Those studies indicated only 'certain characteristics of those particles, namely, as regards the Lee study, micro-sized particles and, as regards the Heinrich study, "P25" grade nano-sized particles'. [52]

52. The judgment under appeal then found that those 'P25' particles have a tendency to agglomerate, [53] which would result in a lower particle density than that assumed by the RAC: 'the agglomeration creates void spaces which are less dense than the material.' [54]

53. Third, the judgment under appeal found that 'by applying a density value corresponding to the particle density of 4.3 g/cm^3 and, therefore, a density higher than the agglomerate density of nano-sized titanium dioxide particles …, the RAC did not take into account all the relevant factors of the present case, namely the characteristics of the particles tested in the Heinrich study, in particular their nano size and their "P25" grade, the fact that those particles tend to agglomerate and the fact that the agglomerate density of the particles was lower than the particle density and that, consequently, the agglomerates of particles occupied more volume in the alveolar macrophages of the lungs'. [55]

54. The General Court ultimately concluded that 'by failing to take into account the factors set out in paragraph 100 above [agglomeration of particles and consequent lower density], the RAC failed to take into account all the relevant factors in order to calculate the lung overload in the

48 See, to that effect, judgment under appeal, paragraph 52, and the RAC Opinion, p. 17. In the judgment under appeal, paragraph 86, the General Court explained that 'the Morrow overload calculation links the quantity of inhaled particles and the impairment of the functioning of particle clearance mechanisms with the volume occupied by particles in the alveolar macrophages of the lungs'.

49 Judgment under appeal, paragraph 90. See also the RAC Opinion, p. 39, which states that 'RAC takes the view, that these exposure conditions represent excessive exposure which invalidates the results of the Lee et al. (1985) study on their own for classification purposes.'

50 See judgment under appeal, paragraphs 75 to 78 and 121.

51 Judgment under appeal, paragraph 92.

52 Judgment under appeal, paragraph 92.

53 Judgment under appeal, paragraphs 100 and 107.

54 Judgment under appeal, paragraph 99.

55 Judgment under appeal, paragraph 100.

Heinrich study by means of the Morrow overload calculation and therefore committed a manifest error of assessment. That error renders implausible the result of the application of that calculation to that study and, consequently, the RAC's findings that the lung overload in that study was acceptable and that the results of that study were sufficiently reliable, relevant and adequate for the assessment of the carcinogenic potential of titanium dioxide.' [56]

55. The Heinrich study not being sufficiently reliable and acceptable, within the meaning of point 3.6.2.2.1. of Annex I to the CLP Regulation, to support the contested classification and labelling, [57] and given its 'decisive' nature in the assessment, the General Court therefore found that such a manifest error warranted the annulment of the contested regulation. [58]

2. The second reason for annulment: the interpretation of the concept of 'intrinsic properties'

56. The second reason for annulment arose from the RAC's consideration that titanium dioxide has 'an intrinsic property to cause cancer' and should therefore be classified as a carcinogen.

57. In the judgment under appeal, the General Court considered that finding vitiated by a manifest error, since it was based on an incorrect interpretation of the concept of 'intrinsic properties', as it appears in point 3.6.2.2.1. of Annex I to the CLP Regulation. [59]

58. In that regard, the General Court considered that the concept of 'intrinsic properties', which is not defined in the CLP Regulation, 'must be interpreted in its literal sense as referring to the "properties which a substance has in and of itself"'. [60]

59. That interpretation would be consistent with the objective and purpose of the CLP Regulation and the classification criteria agreed under the Globally Harmonised System of Classification and Labelling of Chemicals ('GHS'), and with the fact that harmonised classification and labelling relate to *hazard* assessment, and not *risk* assessment. [61]

60. Against the background of that definition, the General Court then reasoned that the mode of action of carcinogenicity described in the RAC Opinion did not point to an intrinsic property of titanium dioxide particles to cause cancer. [62]

61. In that regard, it recalled that the RAC Opinion noted that 'the reason for the toxicity observed is not the properties of the titanium dioxide particles in themselves, but the deposit and retention of those particles in the alveolar macrophages of the lungs in sufficient quantities to give rise to lung overload leading to a significant impairment of particle clearance mechanisms in the lung'. [63]

56 Judgment under appeal, paragraph 103.

57 Judgment under appeal, paragraph 121.

58 See, to that effect, judgment under appeal, paragraph 121 and 122.

59 Judgment under appeal, paragraph 160.

60 Judgment under appeal, paragraph 138.

61 Judgment under appeal, paragraphs 139 to 141.

62 Judgment under appeal, paragraphs 156 to 160.

63 Judgment under appeal, paragraph 156.

62. However, it explained that the accumulation of titanium dioxide particles in the lung in sufficient quantities to bring about a significant impairment of particle clearance mechanisms 'cannot be regarded as forming part of the intrinsic properties of the particles at issue'. [64]

63. Instead, that mode of action should be viewed as a 'hazard which is not covered by the classification criterion for the carcinogenicity hazard, referred to in point 3.6.2.2.1. of Annex I to [the CLP Regulation], according to which the substance must have the intrinsic property to cause cancer'. [65]

64. In support of that interpretation, the General Court relied, first, on Note W, which it claimed described a hazard which is not covered by the concept of 'intrinsic property' to cause cancer, [66] and, second, on the fact that the RAC Opinion itself considered that the mode of action of titanium dioxide for the lung carcinogenicity in rats could not be considered '"intrinsic toxicity" in a classical sense'. [67]

D. Procedure before the Court of Justice

65. By their appeals lodged on 8 February and 14 February 2023 respectively, the French Government and the Commission request that the Court set aside the judgment under appeal, reject the relevant issues raised therein, refer the case back to the General Court for consideration of the pleas not already assessed, and reserve the costs.

66. That course of action is supported by ECHA and the Netherlands and Swedish Governments.

67. A hearing was held on 7 November 2024 at which the Commission, the French Government, the applicants at first instance in T-279/20 and in T-288/20, the applicants at first instance in T-283/20 and the Conseil Européen de l'Industrie Chimique – European Chemical Industry Council ('the Cefic') presented oral argument.

III. Analysis

68. This Opinion is structured as follows. I will first discuss the two main grounds of appeal – that the General Court exceeded its powers of judicial review (A) and that it incorrectly interpreted the notion of 'intrinsic properties' (B) – and propose that the Court accept both grounds. I will then consider the grounds of appeal relating to the distortion of the evidence (C) and the failure to state reasons (D). In my conclusion, I will propose that the Court overturn the judgment under appeal and refer the case back to the General Court for resolution of the remaining pleas in law (IV).

64 Judgment under appeal, paragraph 158.

65 Judgment under appeal, paragraph 159.

66 Judgment under appeal, paragraph 159.

67 Judgment under appeal, paragraph 154.

A. The General Court exceeded its powers of judicial review

69. By their respective second grounds of appeal, the French Government and the Commission submit that, in the context of the first reason for annulment referred to in points 43 to 55 of this Opinion, the General Court exceeded the limits of permissible judicial review.

70. In essence, those parties argue that the General Court went beyond an assessment of manifest error and substituted its own assessment for that of the RAC when it criticised the latter, in the context of the Morrow overload calculation, for having adopted a lower density value than the General Court considered fit.

71. I agree with the French Government and the Commission in that respect.

72. In two groups of case-law, the Court of Justice has developed an approach according to which its power of judicial review is limited to establishing whether the administration committed a 'manifest' error. The first group of case-law concerns those situations in which the EU legislature left discretion to the Commission to decide between different possible regulatory options.[68] Discretion, in that sense, means *a power to make policy choices*.[69] Discretion is never unlimited; it is framed by constitutional principles, by fundamental rights and, in the case of administrative regulatory discretion, by the applicable legislation. The EU Courts have the role of verifying whether the rules and principles that frame discretion are complied with.

73. The second group, also often referred to as cases involving discretion, concern situations in which the administration's decision is based on complex scientific, economic or technical appraisals.[70] I prefer to refer to such cases as relating to *the appraisal of complex facts*, rather than as involving discretion.[71] While a situation involving the appraisal of complex facts does not imply making policy choices, in certain situations the regulatory framework against which that assessment is made grants the administration discretion to choose how to react to the established facts.

74. The case at hand belongs to that second group of judgments.

68 See, for example, judgments of 12 July 2005, *Alliance for Natural Health and Others* (C-154/04 and C-155/04, EU:C:2005:449, paragraph 52); of 7 July 2009, *S.P.C.M. and Others* (C-558/07, EU:C:2009:430, paragraph 42); of 22 December 2010, *Gowan Comércio Internacional e Serviços* (C-77/09, EU:C:2010:803, paragraph 82); and of 22 November 2018, *Swedish Match* (C-151/17, EU:C:2018:938, paragraph 36).

69 See, in that respect, Mendes, J., 'Bounded Discretion in EU Law: A Limited Judicial Paradigm in a Changing EU', *The Modern Law Review*, Vol. 80(3), 2017, p. 461, who described discretion as 'the absence of legal norms or principles that, once interpreted, would be capable of indicating the solution that should apply in a specific case'.

70 See, for example, judgments of 21 November 1991, *Technische Universität München* (C-269/90, EU:C:1991:438, paragraph 14); of 21 July 2011, *Nickel Institute* (C-14/10, EU:C:2011:503, paragraph 60; 'the judgment in *Nickel Institute*'); of 21 July 2011, *Etimine* (C-15/10, EU:C:2011:504, paragraph 60; 'the judgment in *Etimine*'); of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others* (C-691/15 P, EU:C:2017:882, paragraph 34; 'the judgment in *Bilbaína*'); and of 9 March 2023, *PlasticsEurope* v *ECHA* (C-119/21 P, EU:C:2023:180, paragraph 46).

71 Some scholars formulate that difference by reference to 'cognitive' and 'volitive' appraisals; see, for example, Nehl, H.P., 'Judicial review of complex socio-economic, technical, and scientific assessments', in Mendes, J. (ed.), *EU Executive Discretion and the Limits of Law*, Oxford University Press, Oxford, 2019, pp. 162 and 163.

75. In the present proceedings, the classification of a product under the CLP Regulation concerns the identification and communication of the potential hazard that a substance may hold for human health. A hazard classification is only the first part of a decision-making procedure based on risk assessment. [72]

76. However, hazard assessment is a different exercise from the risk assessment that follows and from the adoption of a decision based on that risk assessment. Hazard classification depends on the scientific assessment of the potential effects of a substance under review. The question, however, of whether it is necessary to take certain measures because of the existence of a hazard and the situations in which such measures should be taken is a political decision based on risk assessment and its balancing in relation to other interests involved. [73]

77. Within the CLP Regulation, the EU legislature has already laid down the consequences that follow once the Commission identifies a hazard. Thus, the legislature has decided that once a hazard is detected, the public must be informed of it by making that information available in the relevant annex of the CLP Regulation, and that the hazardous substance at issue must be labelled and packed appropriately.

78. Accordingly, in my view, in adopting a decision on the harmonised classification of a substance as harmful to human health, the Commission enjoys very little political discretion. [74] In a situation such as the one at issue in the present case, the Commission is under an obligation – and does not have the choice in that respect – to classify a substance either as a category 1A carcinogen or as a category 1B carcinogen, where scientific evidence is conclusive that that substance causes cancer in humans or animals, [75] or to classify that substance as a category 2 carcinogen, where only limited and inconclusive studies exist, but which nevertheless point to potential carcinogenicity. [76] Conversely, where no scientific study leads to a conclusion on a substance's carcinogenicity, the Commission is, in principle, precluded from classifying that substance as a carcinogen.

72 According to the Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2 February 2000), point 5.1.2., risk assessment consists of four steps, that is, hazard identification, hazard characterisation, appraisal of exposure and risk characterisation. In Annex III to that communication, the first two steps are described as follows: 'hazard identification means identifying the biological, chemical or physical agents that may have adverse effects … Hazard characterisation consists of determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity. It is at this stage that a relationship between the amount of the hazardous substance and the effect has to be established.'

73 See, for instance, Vos, E., 'The European Court of Justice in the face of scientific uncertainty and complexity', in Dawson, M., de Witte, B. and Muir, E. (eds.), *Judicial activism at the European Court of Justice*, Edward Elgar, 2013, pp. 142 to 166, who, at pp. 164 and 165, points out that 'risk assessment is not neutral, but is a social construct and as such a political act'. In that sense, a decision taken by virtue of the application of the precautionary principle and a decision taken without applying that principle to the same type of risk might significantly differ in terms of the justifiable restrictions a measure can impose.

74 One of the reasons for the adoption of the CLP Regulation was indeed to regulate hazard classification. According to its Article 1(1)(a), that act harmonises the criteria for the classification of substances and mixtures, and the rules on labelling and packaging for those substances and mixtures which are identified as hazardous. Thus, hazard classification criteria are largely provided for in the legislative act itself.

75 See Table 3.6.1. of Annex I to the CLP Regulation, reproduced in point 14 of this Opinion.

76 In opting for the second choice, the EU legislature was, most likely, guided by the precautionary principle. The Court has already confirmed that that principle is applicable in the field of the classification of chemicals under the CLP Regulation; see judgment of 16 June 2022, *SGL Carbon and Others* v *Commission* (C-65/21 P and C-73/21 P to C-75/21 P, EU:C:2022:470, paragraph 97). See, more generally, on the precautionary principle, Donati, A., *Le principe de précaution en droit de l'Union européenne*, Bruylant, Brussels, 2021, p. 49 et seq., and Goldner Lang, I., '"Laws of Fear" in the EU: The Precautionary Principle and Public Health Restrictions to Free Movement of Persons in the Time of COVID-19', Vol. 14(1), *European Journal of Risk Regulation*, 2023, pp. 141 to 164.

79. The applicants at first instance have challenged the Commission's classification of titanium dioxide as a category 2 carcinogen on the basis that the Heinrich study does not constitute reliable evidence of carcinogenicity of that substance. That is because the CLP Regulation prescribes that the scientific evidence on which the Commission can rely must come from 'reliable' studies.[77]

80. That assessment of reliability constitutes a question of scientific appraisal, which nevertheless has important consequences for the present case, since, as I have explained, if the Heinrich study cannot be deemed reliable and there is no other reliable study on which to base its decision, the Commission cannot, in principle, classify titanium dioxide as a carcinogen.

81. In the present case, the RAC's assessment, as endorsed by the Commission, of the reliability of the Heinrich study might therefore have significant repercussions for the rights and interests of the applicants at first instance, which are manufacturers or downstream users of titanium dioxide. For that reason, it is necessary to allow for judicial review of the Commission's decision.

82. However, the question remains as to what exactly the EU Courts can review.

83. A situation of scientific uncertainty entails that the results of a study may be interpreted in different ways. That is similar to the uncertainty of legal rules, which exists when the same rule may be understood in different ways.

84. In cases of legal uncertainty, the Treaties bestow upon the Court the role of final interpreter. In other words, it falls to the Court to choose the 'correct' interpretation. In cases of scientific uncertainty relevant for the identification and classification of hazardous substances, the CLP Regulation bestows the role of final interpreter on the Commission, which in turn renders its decision on the basis of an assessment by the RAC. In other words, the Commission chooses the 'correct' interpretation of scientific data.

85. The General Court cannot therefore replace its scientific assessment for that of the Commission.[78] In doing so, it would encroach on the jurisdiction of the administration.

86. The reason the legislature (or the Treaties) did not bestow the power of final interpreter of scientific uncertainty on the EU Courts is likely due to the fact that the judicature does not possess the necessary expertise to understand and choose between divergent possible interpretations of scientific results. The courts are not scientists and cannot become scientists.[79]

87. What, then, can the EU Courts examine in order to determine whether the Commission committed a manifest error of appreciation?

77 See point 3.6.2.2.1. of Annex I to the CLP Regulation.

78 See, to that effect and *ex multis*, the judgment in *Nickel Institute*, paragraph 60 and the case-law cited, where the Court explains that 'in such a context, the [EU] 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.'

79 See, along those lines, Vos, E., footnote 73 to this Opinion, p. 164 (taking the position that 'judges should remain judges. They should not become "amateur scientists"'), and Jasanoff, S., 'Judging Science: Issues, Assumptions, Models', in *Report of the 1997 Forum for State Court Judges: Scientific Evidence in the Courts: Concepts & Controversies*, Roscoe Pound Foundation, 1997, p. 19 (explaining that 'judges need to reject mythical versions of both "pure science" and "junk science." … Most of all, they need to retain the conviction that courts are not a forum for resolving scientific disputes definitively, but rather for doing justice on a case-by-case basis with the aid of all available scientific knowledge that meets threshold tests of relevance and reliability').

88. The case-law which the General Court quoted in the judgment under appeal adheres to the procedural standard of review.[80] That standard is often expressed in the following manner: '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.'[81] That assessment is understood as a control of the duty of diligence, inherent in the right to good administration.[82]

89. To be able to perform such a review, the EU Courts might need to dive deeply into the world of science. That might be necessary in order to fully understand the opposing arguments of the parties and to enable those courts to ascertain which scientific facts are relevant, which, in turn, is a precondition for verifying whether the Commission took 'all relevant facts' into consideration. Nevertheless, learning and understanding part of the science that is relevant to the case does not turn the EU Courts into scientific experts. Indeed, those courts cannot replace their own understanding for that of the Commission, regardless of how much of the science behind a particular decision those courts have learned in the judicial procedure. That is legally relevant as it safeguards the institutional balance as envisaged under the Treaties.

90. When performing its appellate role of reviewing whether the General Court has indeed limited itself to procedural review, the Court of Justice cannot satisfy itself with verifying whether, *in words*, the General Court claims to perform procedural review; rather, it must assess what that court has decided *in substance*.[83]

91. In other words, the Court of Justice has to verify whether the General Court annulled a decision because it concluded that the Commission *ignored* the relevant facts or because it considered that the Commission's *interpretation* of those facts was wrong.

92. In the present case, the Court of Justice has to decide between two possibilities. Either the General Court annulled the contested regulation because the Commission did not take into account the phenomenon of agglomeration of nano-particles of titanium dioxide when concluding on the appropriate density value for the Morrow overload calculation. In such a scenario, the General Court did not commit an error of appraisal of the Commission's decision. Alternatively, the General Court annulled the contested regulation because, notwithstanding the fact that the Commission took into consideration all the relevant scientific data, that institution came to the wrong conclusion.

93. As the French Government explained, to remain within the context of procedural review, the General Court would have had to confine itself to verifying whether the RAC (i) was aware of the possibility of agglomeration of nano-sized particles of titanium dioxide and (ii) had examined, with all objectivity, the factors necessary to determine what it considered to be the relevant density of titanium dioxide particles in that particular setting. Where those factors are

80 Judgment under appeal, paragraph 42.

81 See the judgment in *Bilbaína*, paragraph 35.

82 See the judgment in *Bilbaína*, paragraph 35, referring, in particular, to the judgment of 4 April 2017, *Ombudsman* v *Staelen* (C-337/15 P, EU:C:2017:256, paragraph 34 and the case-law cited).

83 In that respect, in an excellent case-law review, Leonelli explains that the line between procedural and substantive review may easily be blurred and shows how the procedural framing of the review in the judgment in *Bilbaína* obscures the substantive implications of the adoption of different scientific methodologies. See Leonelli, G.C., 'The fine line between procedural and substantive review in cases involving complex technical-scientific evaluations: Bilbaína', *Common Market Law Review*, Vol. 55(4), 2018, p. 1230.

established on the basis of the file before it, the General Court cannot annul the Commission's decision for having committed a manifest error. Even if that court were to disagree with the Commission's scientific conclusion, it must nevertheless defer to it.

94. As the General Court itself confirmed in the judgment under appeal, the RAC Opinion took into consideration the phenomenon of agglomeration and its possible influence on the density value to be used in the Morrow overload calculation. Despite that assessment, the RAC nonetheless came to the conclusion that it would be appropriate to use the standard density value. [84]

95. In the judgment under appeal, the General Court did not agree with that conclusion. It explained that taking into consideration the standard particle density value of titanium dioxide for the purposes of the Morrow overload calculation would be wrong; a lower density value should have been used in the circumstances at issue.

96. In doing so, the General Court took issue with how the Commission interpreted the relevant facts, refused to defer to that interpretation and replaced its own assessment for that of the Commission.

97. Therefore, by going further than simply judging whether the administration was aware of and had assessed all of the aspects that current scientific knowledge required it to take into consideration, the General Court exceeded the limit of its power of judicial review.

98. It follows that the General Court annulled the Commission's decision not because that institution did not take into account all of the relevant (scientific) factors, but because it disagreed with how the administration had assessed those factors.

99. In my opinion, an annulment of the contested regulation would still be possible if the option chosen by the Commission were scientifically impossible. However, faced with two different but possible interpretations of scientific data, it was not for the General Court to make that choice; rather, it should have deferred to the choice made by the Commission.

100. That being said, I do have sympathy for the argument, raised by the applicants at first instance at the hearing, that the RAC Opinion does not clearly explain why the RAC opted for the standard particle density value despite being aware of the agglomeration phenomenon. In response, the Commission and ECHA explained that the choice of standard density value was not raised until after the finalisation phase of the RAC Opinion, hence why it did not feature therein. To my mind, if the standard density of titanium dioxide particles constitutes a criterion that the RAC should have assessed of its own motion, given the current level of scientific knowledge, that body should have explained the reasons underlying its choice of appropriate density value in its report. However, an insufficient explanation in a report is not, in itself, a

[84] See, in that regard, paragraphs 98 and 105 of the judgment under appeal and p. 8 of the RAC Opinion (highlighting that the RAC was aware that 'primary particles … notably nano-sized primary particles tend to agglomerate'), and paragraph 105 of the judgment under appeal and p. 17 of the RAC Opinion (highlighting that, on the basis of the evidence before it, the RAC took the view that it should apply the standard particle density for titanium dioxide particles for the purposes of the Morrow overload calculation to compare the Heinrich and Lee studies). See also p. 12 of the RAC Opinion regarding the characteristics of the particles which were tested in the Heinrich study ('Ultrafine TiO_2 (P25, Degussa, classical nano-sized TiO_2 test material; here without further characterisation of purity) with a primary particle size of 15-40 nm and a composition of ~80% anatase and ~20% rutile was used to generate a test atmosphere with an MMAD of 0.8 µm (GSD of 1.80)').

reason to conclude that the RAC did not take into consideration all of the relevant facts; that is, an element that goes to the statement of reasons underlying the RAC Opinion and, by extension, the contested regulation.

101. For the above reasons, I propose that the Court of Justice uphold the respective second grounds of appeal of the French Government and the Commission.

B. The General Court misinterpreted and misapplied the concept of 'intrinsic properties'

102. By its fourth ground of appeal in Case C-71/23 P and the third ground of appeal in Case C-82/23 P, the French Government and the Commission respectively submit that the General Court erred in law when it considered that the Commission had wrongly applied the concept of 'intrinsic property'. Because of its erroneous understanding of the concept of 'intrinsic property' within the meaning of point 3.6.2.2.1. of Annex I to the CLP Regulation, those parties essentially submit that the General Court wrongly applied that concept to find that the Commission had committed a manifest error when deciding to classify titanium dioxide as a category 2 carcinogen.

103. The interpretation of concepts of EU law falls within the scope of the jurisdiction of the EU Courts. [85]

104. In that exercise, the Court of Justice is not restrained by the principle of interinstitutional balance, delimiting its powers from those of the EU administration, as it is in the case of the interpretation of science.

105. On the contrary, the law – in the present case, the CLP Regulation – imposes constraints on the administration. Thus, the same constitutional principle of institutional balance that mandates deference to the administration's assessment of complex economic, scientific and technical factors *requires* that the Court be free to exercise its full powers of review of the administration's interpretation of the law. [86]

106. Therefore, it was in the General Court's power to interpret the notion of 'intrinsic property'.

107. In the present case, the argument raised on appeal is that the General Court erred in that interpretation. I agree.

[85] See, for example, judgments of 13 February 1979, *Hoffmann-La Roche* v *Commission* (85/76, EU:C:1979:36, paragraph 89), on the interpretation of the concept of 'dominant position', as arising from Article 102 TFEU; of 14 November 1984, *Intermills* v *Commission* (323/82, EU:C:1984:345, paragraph 16 et seq.), on the interpretation of the concept of 'parties concerned' within the meaning of Article 108(2) TFEU; and of 13 December 1989, *Brother International* (C-26/88, EU:C:1989:637, paragraph 11), on the interpretation of the concept of 'subsidy', as it appears in what is now Article 3 of Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union (OJ 2016 L 176, p. 55).

[86] Until the year 2024, the US courts took quite a different approach to the one followed by the EU Courts. Ever since the decision of the US Supreme Court in *Chevron v. Natural Resources Defense Council*, 467 U.S. 837 (1984), p. 843 ('the judgment in *Chevron*'), a judge is required to adopt an administrative agency's interpretation of an ambiguous statute, so long as that interpretation constitutes a 'permissible construction of the statute' (the judgment in *Chevron*, p. 843). However, in June 2024, the US Supreme Court overruled the *Chevron* approach, explaining that the US Administrative Procedure Act 'incorporates the traditional understanding of the judicial function, under which courts must exercise independent judgment in determining the meaning of statutory provisions', such that an agency's expertise may inform but not bind a court (*Loper Bright Enterprises et al. v. Raimondo, Secretary of Commerce, et al.*, 603 U.S. 369 (2024), pp. 16 and 35).

108. In point 3.6.2.2.1. of Annex I to the CLP Regulation it is provided that 'classification as a carcinogen … is intended to be used for substances which have an intrinsic property to cause cancer.'

109. The concept of intrinsic property also appears in several other provisions of the CLP Regulation: in recital 27 thereof[87] and in points 3.4.2.2.2.2.,[88] 4.1.1.1. and 4.1.2.4.[89] of Annex I thereto. However, the CLP Regulation does not define that concept, and in none of the provisions in which that concept is mentioned is it further elaborated. Thus, the wording alone is not sufficient to enable an understanding of the intended meaning of that concept.

110. In those circumstances, it is necessary to go beyond the words, and look into the context in which the concept of 'intrinsic properties' occurs and into the purpose of the act of which it is part.[90]

111. In the judgment under appeal, the General Court concluded that the concept of 'intrinsic properties' must be interpreted in its literal sense, which, according to that court, is 'the "properties which a substance has in and of itself"'.[91]

112. Apart from the fact that the General Court does not explain why such a definition represents the literal sense of that expression, there are additional problems with that proposal.[92]

113. For one, as claimed by the Commission, that kind of definition is circular, or tautological. In a way, it is close to saying 'intrinsic property' means intrinsic property.

114. For another, as the French Government also explains, such a definition is not very enlightening: one can easily agree that 'intrinsic property' means 'the properties which the substance has in and of itself'. However, from the General Court's definition alone, one cannot understand why it considered that the Heinrich study cannot be relied on to establish the intrinsic properties of titanium dioxide to cause cancer.

115. Indeed, the General Court's error in the interpretation of the concept 'intrinsic properties' does not necessarily follow from the wording it has used to define it – the 'properties which a substance has in and of itself'. Rather, that court's error is manifested in how it applied that interpretation.

87 That recital calls for the use of alternative methods to performing tests on animals in order to, among other things, generate information on intrinsic properties of substances and mixtures.

88 That point is situated in the section of Annex I to the CLP Regulation that relates to hazards to the skin. In the relevant part it provides that 'evaluation of human data must therefore be carried out with caution, as the frequency of cases reflect, in addition to the intrinsic properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken.'

89 Those points belong to the part relating to hazards to the aquatic environment. Point 4.1.1.1. provides that 'acute aquatic toxicity means the intrinsic property of a substance to be injurious to an organism in a short-term exposure to that substance' and that 'chronic aquatic toxicity means the intrinsic property of a substance to cause adverse effects to aquatic organisms during exposures which are determined in relation to the life-cycle of the organism.' Point 4.1.2.4. provides that 'the intrinsic properties of a lack of rapid degradability and/or a potential to bioconcentrate in combination with acute toxicity are used to assign a substance to a chronic (long term) hazard category.'

90 See, to that effect and *ex multis*, judgments of 17 November 1983, *Merck* (292/82, EU:C:1983:335, paragraph 12), and of 7 June 2005, *VEMW and Others* (C-17/03, EU:C:2005:362, paragraph 41 and the case-law cited).

91 Judgment under appeal, paragraph 138.

92 Even a quick internet search produces evidence that different sciences have different interpretations about the intrinsic property of a substance. Moreover, that concept is anything but simple in philosophical terms, including the philosophy of physics. See, in that respect, 'Intrinsic vs. Extrinsic Properties', Stanford Encyclopaedia of Philosophy, available at: https://plato.stanford.edu/entries/intrinsic-extrinsic/.

116. In the judgment under appeal, the General Court excludes the possibility that the carcinogenicity arising from the inhalation of titanium dioxide in powder form may be connected to its intrinsic properties. It comes to that conclusion on the basis that (1) said carcinogenicity appears only if a certain quantity of that substance is inhaled and (2) because said carcinogenicity results only from inflammation in the lung due to the accumulation of titanium dioxide particles therein. These are, to the understanding of that court, properties that are extrinsic to the substance itself. [93]

117. Such an understanding of the concept of 'intrinsic properties' appears too narrow to me. Even though the General Court explained that its interpretation is consistent with the objectives and purpose of the CLP Regulation as well as with the GHS criteria, [94] I am inclined to accept the arguments of the appellants to the contrary.

118. Indeed, to my mind, in the light of the context and purpose of the CLP Regulation, the concept of 'intrinsic properties' must be interpreted broadly. In what follows, I will offer arguments to support that position, starting with the purpose and internal structure of the CLP Regulation before moving to its external context.

Purpose of the CLP Regulation

119. First, the purpose of the CLP Regulation is aimed at '[ensuring] a high level of protection of human health and the environment'. [95] That aim is to be achieved by 'harmonising the criteria for classification of substances and mixtures', identifying, on the basis of those criteria, hazardous substances and mixtures and informing the public about them through a list of substances and mixtures considered hazardous. [96] The process of identifying and listing substances which have an intrinsic property to cause cancer therefore serves the purpose of ensuring a high level of protection of human health.

120. The CLP Regulation aims to identify and classify *every* chemical substance or mixture that is known, presumed or suspected to be hazardous to human health. The substances and mixtures to which it does not apply, such as radioactive substances for instance, are expressly excluded from its scope of application. [97]

121. It would thus appear clear that, unless otherwise defined, the concept of 'intrinsic properties' must also cover hazards emanating from a specific form, physical state, characteristic or use of a substance and cannot be limited to the chemical composition of that substance alone.

93 The often-used example to explain the difference between 'intrinsic' and 'extrinsic' properties is the difference between mass and weight. Mass is the intrinsic property of a body, whereas its weight depends on the gravity of the planet with regard to where the body is situated, and thus constitutes an extrinsic property. In the present case, the General Court seems to understand the form (powder), quantity (containing 1% or more of particles with aerodynamic diameter ≤ 10 μm), insolubility and mode of action (inhalation) by which titanium dioxide causes the cancer as being properties extrinsic to that substance; thus, to use my analogies, as its 'weight', not its 'mass'.

94 See judgment under appeal, paragraphs 139 and 140.

95 See Article 1(1) of the CLP Regulation.

96 See Article 1(1)(a), (d) and (e) of the CLP Regulation.

97 See, in that respect, Article 1(2) of the CLP Regulation.

122. In that respect, the fact that it is proven that only a certain quantity of a substance may, only in certain circumstances, cause cancer does not mean that *that* substance does not have the 'intrinsic property' to be carcinogenic.[98] To neglect to identify and list a harm that arises only from the inhalation of a certain quantity of a substance would undermine the purpose of ensuring a high level of protection of human health.

123. Likewise, to neglect to list a substance as carcinogenic because the scientific study which demonstrated its harmful effects could be read as meaning that those effects were the result of an inflammation arising from the accumulation of that substance's particles in the lung, and not from the direct influence of that substance on the cells therein, would be contrary to the purpose of ensuring the high level of human health.[99]

124. As explained by ECHA at the hearing, when an experimental study is conducted on a specific substance and a harmful effect is observed, that alone suffices to establish a link between that substance and the consequence and, therefore, subject to the weight of evidence approach, may lead to the conclusion of a potential hazard of that specific substance.

125. Confining the notion of 'intrinsic properties' solely to the chemical composition of a substance – to the exclusion of its other characteristics such as, for instance, its poor solubility – or insisting that that substance 'as such', in any of its forms and notwithstanding the type of interaction with the human body, must have the ability to cause cancer would therefore exclude, from the scope of the framework established by the CLP Regulation, a number of important markers relating to that substance's potential hazards. Again, that would be contrary to the regulation's purpose to ensure a high level of protection of human health.

Internal structure of the CLP Regulation

126. Additional arguments in favour of a broad interpretation of the concept of 'intrinsic property' may be based on the internal consistency of the CLP Regulation as a whole.

127. Thus, as the Swedish Government and the Commission correctly point out, when defining the hazardous properties of a substance, such as its carcinogenicity, Article 5(1), Article 6(1), Article 8(6) and Article 9(5) of the CLP Regulation, which form part of Title II ('*Hazard classification*') and the self-classification system laid down by that regulation, all make reference to the 'forms or physical states' of a substance. Contrary to the position of the General Court in the judgment under appeal,[100] those rules apply *mutatis mutandis* where the Commission adopts a harmonised classification for a substance in accordance with Title V of the CLP Regulation.[101]

98 As the Swedish Government also explains, an 'intrinsic property' to cause harm is inherently linked to the dosage, which is why experimental animal studies are designed in such a way that the test animals are given different dosages of a substance. The fact that negative effects may be shown at higher dosages of the substance but not, for example, at lower dosages does not preclude the negative effects from being regarded as being caused by an 'intrinsic property' of the substance.

99 At the hearing, the Cefic remarked that other substances with similar characteristics (like their low solubility) may also cause cancer in a similar mode of action (inhalation of large quantities, for example). That would demonstrate that cancer is not caused by the intrinsic property of the tested substance, but rather constitutes a secondary effect of an inflammation caused by the accumulation of large quantities of particles, for example in the lung. However, even if, as contended by the French Government, it is true that the RAC Opinion does not indicate whether the carcinogenic effects are caused merely by inflammation due to the accumulation of particles in the lung or by the ability of titanium dioxide to generate oxidative stress capable of leading to genotoxicity, or whether both mechanisms are involved, it remains that neither of those possibilities precludes the conclusion that the intrinsic properties of titanium dioxide may lead to the development of cancer.

100 See judgment under appeal, paragraphs 165 and 166.

101 For example, as Article 4(3) of the CLP Regulation lays down, where no entry for the substance at issue already exists, classification occurs pursuant to the rules of Title II of that regulation.

128. Similarly, that regulation distinguishes between different hazard classes by route of exposure. That is the case, for example, for the hazard class 'acute toxicity' in section 3.1 of Annex I thereto, which is differentiated into acute oral toxicity, acute dermal toxicity and acute inhalation toxicity (see point 3.1.1.2. thereof). In turn, inhalation toxicity is, under point 3.1.2.1. of Annex I, differentiated into gases, vapours, dusts and mists, thereby drawing a clear distinction as to the physical state of a substance.

129. Finally, confirmation of a broad reading of that concept may be found in the wording of the CLP Regulation in the part devoted to the environmental hazards. For example, point 4.1.2.4. of Annex I thereto refers to the 'lack of rapid degradability and/or a potential to bioconcentrate in combination with acute toxicity' as intrinsic properties relevant for the classification as environmental hazards. [102]

130. Accordingly, the only reading of the concept of 'intrinsic properties' that corresponds to the internal structure of the CLP Regulation is one that is not restricted to the chemical composition of the substance alone.

The external context of the CLP Regulation

131. The same conclusion in favour of the need for a broad interpretation of the concept of 'intrinsic properties' also arises from an assessment of the use of that concept in the GHS.

132. In this regard, I observe that the CLP Regulation seeks to maintain consistency between the concepts used at UN level in the GHS, and at EU level in the CLP Regulation. [103]

133. Where the concept of 'intrinsic properties' appears in the GHS, it is not described restrictively: the GHS refers to the notion of intrinsic properties as a substance's 'capacity to interfere with normal biological processes'. [104]

134. Accordingly, the General Court's restrictive interpretation would misalign the CLP Regulation from the GHS and establish an EU-specific meaning to that concept – contrary to the very objective set out by the EU legislature in that regulation.

135. Finally, the broad reading proposed above also aligns with the REACH Regulation. [105]

102 See footnote 89 to the present Opinion.

103 See recital 12 of the CLP Regulation, which explains that 'the terms and definitions used in this Regulation should be consistent with … the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade.'

104 See, paragraph 1.1.2.6.2.1 of the GHS. See also paragraph 4.1.1.1 and the definition of the concept of 'chronic aquatic toxicity' in the GHS: 'the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism'. In addition, paragraph 3.6.2.2 of the GHS explains that 'classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects.' Finally, see footnote 1 to paragraph 1.1.1.6 of the GHS, which explains that 'in some cases it is necessary also to take into account hazards arising from other properties, such as the physical state of the substance or mixture … or properties of substances produced by certain chemical reactions'.

105 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) ('the REACH Regulation').

136. In this regard, I observe that recital 12 of the CLP Regulation specifically explains that its terms and definitions should be consistent with those of the REACH Regulation.

137. The latter act, which provides for the registration, evaluation, authorisation and restriction of chemical substances, may define a 'substance' in relation to its chemical composition,[106] but it also lays down specific characteristics required for the identification of the substance at issue. Those characteristics include the particle size, shape and other morphological elements.[107]

138. It follows that for reasons of context relating to the external consistency of the CLP Regulation, the concept of 'intrinsic properties' may not be limited to its chemical composition alone.

Interim conclusion

139. For all of the above reasons, the General Court erred when attributing a narrow interpretation to the concept of 'intrinsic properties'.

140. Contrary to what the General Court concludes, it is irrelevant, for the purposes of the hazard classification of titanium dioxide, that the RAC Opinion did not find toxicity based on the properties of that substance 'in and of itself'.[108]

141. As I have explained, what matters is that on the basis of the form, size and poor solubility of titanium dioxide, the RAC Opinion found – and the Commission accepted – that, if inhaled in certain quantities, toxicological effects may manifest themselves in the lung, leading to the development of tumours.

142. Given that, as properly interpreted, those elements fall within the scope of the concept of a 'substance that has the intrinsic property to cause cancer', construed broadly, the Commission did not commit a manifest error in following the RAC Opinion when it adopted the contested regulation.

143. No other conclusion may be reached from the judgments of the Court of Justice in *Nickel Institute* and *Etimine*. With regard to the former, the General Court draws inferences without taking account of the context within which the statement at issue was made.[109] However, as the French Government observes, in that judgment the Court of Justice did not lay down that an assessment of the hazards linked to the intrinsic properties of a substance need necessarily be

106 See Article 3(1) of the REACH Regulation, which defines a 'substance' as 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition'.

107 See, for example, section 2.4 of Annex VI to the REACH Regulation. See also recital 8 of Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances (OJ 2018 L 308, p. 1), which explains that 'for nanoforms, specific minimum characterisation information should be provided as part of the composition information under the substance identification. Particle size, shape and surface properties of a nanoform may influence its toxicological or ecotoxicological profile, exposure as well as behaviour in the environment.'

108 See, in that respect, judgment under appeal, paragraph 156.

109 In paragraph 39 of the judgment under appeal, the General Court refers to paragraph 82 of the judgment in *Nickel Institute* to suggest that an assessment of the hazards linked to the intrinsic properties of a substance must not be limited to the specific circumstances of its use. In full, that paragraph 82 of the judgment in *Nickel Institute* reads as follows: '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.'

independent of the levels of exposure to the substance or of its mode of action. Instead, the Court held that the hazard assessment of a substance '*may* be properly carried out regardless of the place where the substance is used',[110] even if the underlying assessment is conducted only under laboratory conditions.

144. Similarly, in the judgment in *Etimine*, which was discussed at the hearing, the Court of Justice did not preclude the possibility that, for the purpose of the hazard assessment, a substance's intrinsic properties may be established through studies based on its oral administration to animals –[111] despite the fact that it was claimed that, ordinarily, exposure conditions to that substance would be by inhalation or dermal penetration.[112]

145. Finally, my proposed conclusion is not affected by the RAC Opinion explaining that titanium dioxide lacked the intrinsic property to cause cancer in the 'classical sense' of the term. Aside from it not being clear what exactly the RAC understands as intrinsic toxicity in that sense, it still concluded that the Heinrich study demonstrated that the intrinsic properties of titanium dioxide cause cancer.

146. In conclusion, I propose that the Court also uphold the French Government's fourth ground of appeal in Case C-71/23 P and the Commission's third ground of appeal in Case C-82/23 P and reject that part of the action at first instance.

C. The General Court did not distort the evidence before it but disregarded the principles laid down in the CLP Regulation

147. The first part of the French Government's first ground of appeal in Case C-71/23 P and the Commission's first ground of appeal in Case C-82/23 P alleges a distortion of the evidence on the part of the General Court. First, the French Government and the Commission both argue that the General Court distorted the evidence before it when it found that the Heinrich study was 'decisive' for the RAC's proposal for the labelling of titanium dioxide as a carcinogen.[113] Second, the Commission adds that the General Court also distorted the evidence when it concluded that the Morrow overload calculation was 'decisive' in supporting the RAC's assessment of the acceptable degree of lung overload.[114] The second part of the French Government's first ground of appeal in Case C-71/23 P claims that, in attributing the Heinrich study said 'decisive' nature, the General Court also disregarded the principles laid down in the CLP Regulation concerning the classification of substances as carcinogenic.

148. I can be brief on those arguments.

110 See paragraph 82 of the judgment in *Nickel Institute*; emphasis added.

111 See, to that effect, the judgment in *Etimine*, paragraph 75, which reads as follows: '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, the route by which contact with the substance might arise (by ingestion, by inhalation or by dermal penetration) and the possible levels of exposure to the substance.'

112 See, to that effect, the judgment in *Etimine*, paragraph 70.

113 That part of the French Government's and the Commission's appeals is directed against paragraph 74 of the judgment under appeal.

114 That part of the Commission's appeal is directed against paragraph 120 of the judgment under appeal.

149. First, where a distortion of the evidence is alleged, it is not sufficient to show that a document could reasonably be interpreted differently from how it was construed by the General Court. [115]

150. What is necessary is that the General Court manifestly exceeded the limits of a reasonable assessment of that document, in particular by reading it in a manner contrary to its wording. [116]

151. I am not convinced that that is the case in the judgment under appeal.

152. As it transpires from the respective arguments put forward by the French Government and the Commission, what those parties take issue with is the General Court's reading of the RAC Opinion in a manner that attributes greater weight to the Heinrich study and the Morrow overload calculation than they consider to have been the case.

153. However, those parties do not show that the General Court's reading of the RAC Opinion exceeds the bounds of what is reasonable.

154. In fact, the RAC Opinion itself dismisses the possibility of relying on the Lee study such that it should not have a 'determining' influence on the classification of titanium dioxide. [117] Given that the Heinrich study constituted one of 'two key carcinogenicity studies' [118] (and the only other study showing tumour development, aside from the Lee study), it is not unreasonable – even if wrong under the applicable legal standard – to draw inference from the RAC's statements that the Heinrich study had 'decisive' character for the resulting classification of titanium dioxide. Similarly, since the RAC Opinion itself thought it necessary to have recourse to the Morrow overload calculation – despite not being a 'generally accepted' concept – to uphold the conclusions drawn on the basis of the Heinrich study, it is not unreasonable to label that calculation as 'decisive in supporting the RAC's findings'. [119]

155. It follows that I consider that the first part of the French Government's first ground of appeal in Case C-71/23 P and the Commission's first ground of appeal in Case C-82/23 P should be held as unfounded.

156. Second, it is, to my mind, obvious that what the French Government and the Commission take issue with in reality is the introduction of a superseding criterion of 'decisiveness' into the legal evaluation laid down in Article 9(3) of the CLP Regulation and in point 1.1.1.3. of Annex I thereto.

157. That is precisely the issue that the French Government raises in the second part of its first ground of appeal in Case C-82/23 P and which I agree with. [120]

115 See, to that effect, judgments of 10 February 2011, *Activision Blizzard Germany* v *Commission* (C-260/09 P, EU:C:2011:62, paragraph 54); of 26 September 2013, *France* v *Commission* (C-115/12 P, EU:C:2013:596, paragraph 60); and of 27 June 2024, *Commission* v *Servier and Others* (C-176/19 P, EU:C:2024:549, paragraph 128 and the case-law cited) (all concerning documents that allowed for different reasonable interpretations).

116 See, in particular, judgment 25 February 2021, *Dalli* v *Commission* (C-615/19 P, EU:C:2021:133, paragraph 139 and the case-law cited).

117 See, for example, the RAC Opinion, p. 39 ('RAC takes the view, that these exposure conditions represent excessive exposure which invalidates the results of the Lee et al. (1985) study on their own for classification purposes') and p. 35 ('Because of the complete cessation of alveolar clearance, RAC takes the view that the results of the Lee et al. (1985) rat study should not have a determining influence on classification of TiO_2'). See also the RAC Opinion, p. 36.

118 See the RAC Opinion, p. 13.

119 See paragraph 120 of the judgment under appeal and p. 17 of the RAC Opinion.

120 The Commission does not appeal that issue in Case C-71/23 P.

158. As that party, supported by the Commission, ECHA and the Swedish and Netherlands Governments, correctly highlights, the 'weight of evidence' determination constitutes an approach that requires that all available information bearing on the determination of hazard be considered together.

159. In the judgment under appeal, however, the General Court introduced the concept of 'decisiveness' to assess the evidence relied on by the RAC when classifying titanium dioxide as a carcinogen. [121]

160. That concept, which implies the determinative nature of one piece of evidence over another, does not appear in the CLP Regulation.

161. In fact, that concept is antagonistic to the very idea of weighing different pieces of evidence against one another to determine – also in view of the objective of the CLP Regulation – a high level of protection of human health. It is thus the precise opposite of the 'weight of evidence' determination.

162. It may accordingly come as little surprise that that concept was not used in the RAC Opinion. [122]

163. In those circumstances, as the French Government asserts, the General Court's reliance on the concept of 'decisiveness' in its review of the RAC Opinion departs from the legal framework laid down by the EU legislature.

164. In the light of the foregoing, I propose that the Court of Justice dismiss as unfounded the first part of the French Government's first ground of appeal in Case C-71/23 P and the Commission's first ground of appeal in Case C-82/23 P and uphold the second part of the French Government's first ground of appeal in Case C-71/23 P and reject the relevant part of the action at first instance.

D. The General Court did not fail to state reasons

165. By its third ground of appeal in Case C-82/23 P, the French Government argues that the General Court failed to fulfil its obligation to state reasons when it held that the mode of action of carcinogenicity described in the RAC Opinion did not point to an 'intrinsic property' of titanium dioxide. [123]

166. The obligation to state reasons is laid down in Article 296 TFEU and is reflected in Article 36 and the first paragraph of Article 53 of the Statute of the Court of Justice of the European Union. It thus constitutes an essential procedural requirement. [124]

[121] See, in particular, paragraphs 76 to 78, 120 and 121 of the judgment under appeal.

[122] See the RAC Opinion, p. 39, which explains that the 'RAC takes the view that the experimental and human evidence does not support titanium dioxide to be classified as Carc. 1A or 1B. RAC also considered whether TiO_2 fulfills the classification criteria for category 2 for carcinogenicity or whether no classification for carcinogenicity is more appropriate. Balancing the reasons for category 2 or no classification, RAC looked closely at the experimental conditions in the rat inhalation studies and at interspecies differences.' See also p. 35 of that opinion, which explains that 'in the context of a preferred weight-of-evidence approach RAC discussed additional considerations for classification … RAC considers it essential to additionally take the following factors into consideration: the overload concept, specifically the related mode of action for genotoxicity and carcinogenicity and species differences, including consideration of human relevance of experimental animal data.'

[123] That ground of appeal appears to be directed against paragraphs 157 and 158 of the judgment under appeal.

[124] See, to that effect, judgments of 20 March 1959, *Nold* v *High Authority* (18/57, EU:C:1959:6, p. 51), and of 2 September 2021, *EPSU* v *Commission* (C-928/19 P, EU:C:2021:656, paragraph 108 and the case-law cited).

167. However, that requirement must be distinguished from the question of whether the reasoning is well founded, which goes to the substantive legality of the question at issue. [125]

168. In the present case, the French Government specifically takes issue with the General Court's conclusion that titanium dioxide would not hold the intrinsic properties to cause cancer unless inhaled in certain quantities, all the while considering that the quantity of inhaled particles would constitute only 'one of the key elements of the toxicity observed'. [126]

169. It is true that contradictory reasoning, in itself, may constitute an infringement of the obligation under Article 296 TFEU, where the parties concerned are unable to understand the grounds on which the judgment under appeal is based. [127]

170. However, even supposing that the statements highlighted by the French Government were contradictory, I do not consider that it was on the basis of those statements alone that the General Court took the view that the 'mode of action' of carcinogenicity described in the RAC Opinion did not point to an 'intrinsic property' of titanium dioxide particles to cause cancer.

171. In fact, the General Court extensively explains how it reached that conclusion. [128]

172. In those circumstances, I take the view that the judgment under appeal enables all the parties concerned, the French Government and the Commission in particular, to understand the grounds of the judgment under appeal. It also provides the Court of Justice with sufficient information to exercise its powers of review in the present appeals.

173. Rather, and as the applicants at first instance essentially explain, it appears that the French Government's criticism of the General Court's reasoning is linked to the correctness of the conclusion reached, which constitutes an element going to the *substance* of the judgment under appeal. As such, the French Government cannot claim that the General Court failed to comply with its duty to state reasons.

174. In those circumstances, I propose that the Court of Justice reject the French Government's third ground of appeal in Case C-82/23 P as unfounded.

IV. Consequences

175. Under Article 61 of the Statute of the Court of Justice of the European Union, the Court may, where the state of the proceedings so permits, give itself final judgment on the matter.

176. In the present case, that condition is not satisfied.

[125] See, to that effect, judgments of 2 April 1998, *Commission* v *Sytraval and Brink's France* (C-367/95 P, EU:C:1998:154, paragraphs 66 to 68), and of 6 October 2020, *Bank Refah Kargaran* v *Council* (C-134/19 P, EU:C:2020:793, paragraph 62 and the case-law cited).

[126] Judgment under appeal, paragraph 158.

[127] See, *ex multis*, judgment of 20 September 2016, *Mallis and Others* v *Commission and ECB* (C-105/15 P to C-109/15 P, EU:C:2016:702, paragraph 45 and the case-law cited).

[128] See judgment under appeal, paragraphs 135 to 177.

177. In the judgment under appeal, the General Court examined only a select number of arguments put forward in relation to the density of titanium dioxide particles and the intrinsic nature of that substance. [129] Nor did it assess all the pleas in law raised by the applicants at first instance. [130]

178. Since those two elements involve assessments of fact which would require, on the part of the Court of Justice, the adoption of additional measures of organisation of the procedure or investigation of the case, it is not in a position to itself give judgment in the present matter. [131]

179. I am therefore of the opinion that the case must be referred back to the General Court. [132]

V. Conclusion

180. I propose that the Court of Justice should:

– set aside the judgment of 23 November 2022, *CWS Powder Coatings and Others* v *Commission* (T-279/20, T-283/20 and T-288/20, EU:T:2022:725);

– refer the case back to the General Court for the resolution of the remaining pleas in law; and

– order that the costs be reserved.

[129] See, in that respect, judgment under appeal, paragraphs 122 and 178.

[130] As explained in paragraph 21 of the judgment under appeal, the General Court limited itself to assessing the second plea, the first and fifth parts of the seventh plea and the eighth plea in Joined Cases T-279/20 and T-288/20, and the first plea in Case T-283/20. That leaves all of the pleas in law summarised in paragraphs 22 to 27 of the judgment under appeal unaddressed.

[131] See, to that effect, judgment of 14 September 2023, *Land Rheinland-Pfalz* v *Deutsche Lufthansa* (C-466/21 P, EU:C:2023:666, paragraph 112).

[132] See the alternative in the second sentence of the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union.