Reports of Cases

JUDGMENT OF THE COURT (Fifth Chamber)

1 August 2025 *

(Appeal – Environment and 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 in powder form containing 1% or more of particles of a diameter equal to or below 10 μm – Criteria for classification of a substance as carcinogenic – Reliability and acceptability of scientific studies – Calculation of lung overload in particles – 'Decisive' nature of a scientific study – Distortion of the evidence – Error of law – Choice of calculation parameters – Particle density – Scientific assessment – Exceeding the limits of judicial review – Concept of 'intrinsic properties' – Grounds included for the sake of completeness)

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

TWO APPEALS under Article 56 of the Statute of the Court of Justice of the European Union, brought on 8 and 14 February 2023,

French Republic, represented initially by G. Bain, J.-L. Carré and B. Fodda, subsequently by G. Bain, B. Fodda and B. Travard, and, lastly, by P. Chansou, B. Fodda and B. Travard, acting as Agents,

appellant in Case C-71/23 P,

European Commission, represented by A. Dawes, S. Delaude, R. Lindenthal and M. Noll-Ehlers, acting as Agents,

appellant in Case C-82/23 P,

the other parties to the proceedings being:

CWS Powder Coatings GmbH, established in Düren (Germany),

Brillux GmbH & Co. KG, established in Münster (Germany),

Daw SE, established in Ober-Ramstadt (Germany),

represented by V. Lemonnier, C. Wagner, Rechtsanwälte, and R. van der Hout, advocaat,

applicants at first instance,

* Languages of the case: German and English.

Billions Europe Ltd, established in Stockton-on-Tees (United Kingdom),

Cinkarna Metalurško-kemična Industrija Celje d.d. (Cinkarna Celje d.d.), established in Celje (Slovenia),

Evonik Operations GmbH, established in Essen (Germany),

Kronos Titan GmbH, established in Leverkusen (Germany),

Precheza a.s., established in Přerov (Czech Republic),

Tayca Corp., established in Osaka (Japan),

Tronox Pigments (Holland) BV, established in Rozenburg (Netherlands),

Venator Germany GmbH, established in Duisburg (Germany),

represented initially by P. Chopova-Leprêtre, T. Delille and J.-P. Montfort, avocats, and subsequently by P. Chopova-Leprêtre and J.-P. Montfort, avocats,

applicants and interveners at first instance,

European Commission, represented by A. Dawes, S. Delaude, R. Lindenthal and M. Noll-Ehlers, acting as Agents (C-71/23 P),

defendant at first instance,

Kingdom of Denmark,

French Republic, represented initially by G. Bain, J.-L. Carré and B. Fodda, subsequently by G. Bain, B. Fodda and B. Travard, and, lastly, by P. Chansou, B. Fodda and B. Travard, acting as Agents (C-82/23 P),

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

Republic of Slovenia,

Kingdom of Sweden, represented by H. Eklinder, F.-L. Göransson, C. Meyer-Seitz, A. Runeskjöld, M. Salborn Hodgson, R. Shahsavan Eriksson, H. Shev and O. Simonsson, acting as Agents,

European Parliament,

Council of the European Union,

European Chemicals Agency (ECHA), represented by W. Broere, A. Hautamäki, M. Heikkilä, C. Jacquet and J.-P. Trnka, acting as Agents,

Sto SE & Co. KGaA, formerly Sto AG, established in Stühlingen (Germany),

Ettengruber GmbH Abbruch und Tiefbau, established in Dachau (Germany),

Ettengruber GmbH Recycling und Verwertung, established in Dachau,

TIGER Coatings GmbH & Co. KG, established in Wels (Austria),

Rembrandtin Coatings GmbH, established in Vienna (Austria),

represented by V. Lemonnier, C. Wagner, Rechtsanwälte, and R. van der Hout, advocaat,

Conseil Européen de l'Industrie Chimique – European Chemical Industry Council (Cefic), established in Brussels (Belgium), represented initially by D. Abrahams, Z. Romata and H. Widemann, avocats, and subsequently by D. Abrahams and Z. Romata, avocats,

Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art (CEPE), established in Brussels,

British Coatings Federation Ltd (BCF), established in Coventry (United Kingdom),

American Coatings Association, Inc. (ACA), established in Washington (United States),

represented by I. Antypas and D. Waelbroeck, avocats,

Mytilineos SA, established in Maroussi (Greece),

Delfi-Distomon Anonymos Metalleytiki Etaireia, established in Maroussi,

interveners at first instance,

THE COURT (Fifth Chamber),

composed of M.L. Arastey Sahún, President of the Chamber, D. Gratsias (Rapporteur), J. Passer, B. Smulders and N. Fenger, Judges,

Advocate General: T. Ćapeta,

Registrar: M. Krausenböck, Administrator,

having regard to the written procedure and further to the hearing on 7 November 2024,

after hearing the Opinion of the Advocate General at the sitting on 6 February 2025,

gives the following

Judgment

1 By their respective appeals, the French Republic and the European Commission ask the Court of Justice to set aside the judgment of the General Court of the European Union of 23 November 2022, *CWS Powder Coatings and Others* v *Commission* (T-279/20, T-283/20 and T-288/20, 'the judgment under appeal', EU:T:2022:725), by which the General Court annulled

Commission Delegated Regulation (EU) 2020/217 of 4 October 2019 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting that regulation (OJ 2020 L 44, p. 1, and corrigendum OJ 2021 L 214, p. 72; 'the regulation at issue'), as regards the harmonised classification and labelling of titanium dioxide in powder form containing 1% or more of particles of a diameter equal to or below 10 μm ('the contested classification and labelling').

Legal context

2 Article 1 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1), as amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 (OJ 2019 L 198, p. 241) ('Regulation No 1272/2008'), entitled 'Purpose and scope', provides, in paragraph 1 thereof:

'The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:

(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

…

(d) establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI;

…'

3 Article 2 of Regulation No 1272/2008, entitled 'Definitions', states:

'For the purpose of this Regulation, the following definitions shall apply:

1. "hazard class" means the nature of the physical, health or environmental hazard;

2. "hazard category" means the division of criteria within each hazard class, specifying hazard severity;

…'

4 Article 3 of that regulation, entitled 'Hazardous substances and mixtures and specification of hazard classes', provides:

'A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.

…'

5 Article 36 of Regulation No 1272/2008, entitled 'Harmonisation of classification and labelling of substances', provides in paragraph 1 thereof:

'A substance that fulfils the criteria set out in Annex I for the following shall normally be subject to harmonised classification and labelling in accordance with Article 37:

…

(c) carcinogenicity, category 1A, 1B or 2 (Annex I, section 3.6);

…'

6 Article 37 of that regulation, entitled 'Procedure for harmonisation of classification and labelling of substances', is worded as follows:

'1. A competent authority may submit to the [European Chemicals Agency (ECHA)] a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits …

…

4. The Committee for Risk Assessment of [ECHA] set up pursuant to Article 76(1)(c) of Regulation (EC) No 1907/2006 [of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 849, and corrigendum OJ 2007 L 136, p. 3)] shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment. [ECHA] shall forward this opinion and any comments to the Commission.

5. The Commission shall without undue delay adopt delegated acts … where it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by inclusion of that substance together with the relevant classification and labelling elements in Table 3.1 of Part 3 of Annex VI and, where appropriate, the specific concentration limits …

…'

7 Annex I to Regulation No 1272/2008, entitled 'Classification and labelling requirements for hazardous substances and mixtures', includes, in Part 1 thereof on the general principles for classification and labelling, Section 1.1.1, entitled 'The role and application of expert judgement and weight of evidence determination', worded as follows:

'1.1.1.1. Where the criteria cannot be applied directly to available identified information … the weight of evidence determination using expert judgment shall be applied …

…

1.1.1.3. A weight of evidence determination means that all available information bearing on the determination of hazard is considered together, such as the results of suitable in vitro tests, relevant animal data, … human experience …, epidemiological and clinical studies and well-documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. Information on substances or mixtures related to the substance or mixture being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be assembled together in a single weight of evidence determination.

…'

8 Annex I also contains Part 3, entitled 'Health hazards', which includes Section 3.6, entitled 'Carcinogenicity', worded as follows:

'3.6.1. Definition

3.6.1.1. Carcinogen means 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.

3.6.2. Classification criteria for substances

3.6.2.1. For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional considerations (weight of evidence). …

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. …
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 … evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
…	

3.6.2.2. Specific considerations for classification of substances as carcinogens

3.6.2.2.1. Classification as a carcinogen is made on the basis of evidence from reliable and acceptable studies and is intended to be used for substances which have an intrinsic property to cause cancer. The evaluations shall be based on all existing data, peer-reviewed published studies and additional acceptable data.

3.6.2.2.2. Classification of a substance as a carcinogen is a process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

…

3.6.2.2.4. Additional considerations (as part of the weight of evidence approach …). Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors need to be considered that influence the overall likelihood that a substance poses a carcinogenic hazard in humans. …

…’

Background to the dispute

9 The facts of the dispute, which are set out in paragraphs 2 to 15 of the judgment under appeal, may be summarised as follows.

10 Titanium dioxide is an inorganic chemical substance composed of oxygen and titanium with the molecular formula 'TiO_2' and which can be found in nature or produced industrially. It is used, in particular in the form of a white pigment, for its colourant and covering properties in various products, such as paints, coating materials, varnishes, plastics, laminated paper, cosmetics, including sunscreen, medicinal products, toys and foodstuffs.

11 The applicants at first instance are manufacturers, importers, downstream users and suppliers of titanium dioxide.

12 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) submitted to ECHA, pursuant to Article 37(1) of Regulation No 1272/2008, a dossier proposing the harmonised classification and labelling of titanium dioxide as a category 1B carcinogen by inhalation (Carc. 1b, H350i).

13 On 31 May 2016, that dossier was published, in accordance with Article 37(4) of that regulation. A number of parties concerned submitted their comments within the prescribed period.

14 On 14 September 2017, the ECHA Committee for Risk Assessment ('RAC') adopted an opinion on titanium dioxide, in which it concluded that it was justified to classify titanium dioxide as a category 2 carcinogen, with the hazard statement 'H351 (inhalation)' ('the RAC Opinion').

15 On the basis of that opinion, the Commission drew up a draft delegated 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.

16 On 4 October 2019, the Commission adopted the regulation at issue, which amends Regulation No 1272/2008, in particular by proceeding with the contested classification and labelling. In accordance with Article 3 of the regulation at issue, the amendments to that classification and labelling are to apply from 1 October 2021.

17 Annex I to the regulation at issue states:

'Part 2 of Annex II to [Regulation No 1272/2008] is amended as follows:

…

(2) Section 2.12 is added:

"2.12 Mixtures containing titanium dioxide

The label on the packaging of liquid mixtures containing 1% or more of titanium dioxide particles with aerodynamic diameter equal to or below 10 μm shall bear the following statement:

EUH211: 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'

The label on the packaging of solid mixtures containing 1% or more of titanium dioxide shall bear the following statement:

EUH212: 'Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.'

In addition, the label on the packaging of liquid and solid mixtures not intended for the general public and not classified as hazardous which are labelled with EUH211 or EUH212, shall bear statement EUH210.'"

18 In accordance with Annex III to the regulation at issue:

'Annex VI to [Regulation No 1272/2008] is amended as follows:

(1) Part 1 is amended as follows:
(a) in point 1.1.3.1, the following notes V and W are added:

…

"Note W:

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.";
(b) in point 1.1.3.2, the following note 10 is added:

"Note 10:

The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm.";

(2) in Part 3, Table 3 is amended as follows:

…

(c) the following rows are inserted:

Index No	Chemical Name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
'022-006-002	titanium dioxide; [in powder form containing 1 % or more of particles with aerodynamic diameter ≤ 10 µm]	236-675-5	13463-67-7	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			V, W, 10'

…'

The actions before the General Court and the judgment under appeal

19 By three applications lodged at the Registry of the General Court, the first, on 12 May 2020, by CWS Powder Coatings GmbH ('CWS') in Case T-279/20, the second, on 13 May 2020, by 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 and Venator Germany GmbH (together, 'Billions Europe and Others') in Case T-283/20 and the third, on 13 May 2020, by Brillux GmbH & Co. KG and Daw SE in Case T-288/20, those applicants at first instance brought actions for annulment of the regulation at issue, in so far as it proceeded with the contested classification and labelling.

20 By an order of the President of the Ninth Chamber of the General Court of 11 March 2022, Cases T-279/20 and T-288/20 were joined for the purposes of the oral part of the procedure and the decision closing the proceedings. Those cases and Case T-283/20 were joined for the purposes of the judgment in paragraph 1 of the operative part of the judgment under appeal.

21 In paragraphs 20 to 27 of the judgment under appeal, the General Court held, in essence, that the various pleas and arguments raised by the applicants at first instance, which overlapped, consisted of seven complaints.

22 In paragraph 21 of that judgment, the General Court thus identified a first complaint raised in the context of the second plea and the first and fifth parts of the seventh plea and the eighth plea of CWS, Brillux and Daw in Joined Cases T-279/20 and T-288/20, of the arguments relied on by Billions Europe and Others in support of their statements in intervention in those cases, and in the context of the first plea of Billions Europe and Others in Case T-283/20. According to the General Court, that complaint alleges that the contested classification and labelling were vitiated by manifest errors of assessment and that they did not comply with the criteria laid down in Regulation No 1272/2008 for the classification of a substance as carcinogenic. In paragraph 49 of the judgment under appeal, the General Court held that the first complaint was divided into two parts. The first part alleged manifest errors and infringement of those criteria in the context of the examination of the acceptability and reliability of the Heinrich et al. study (1995) ('the Heinrich study') on which the RAC Opinion was based. The second part alleged manifest errors of assessment and infringement of the criteria laid down, in Regulation No 1272/2008, for the classification and labelling of a substance as carcinogenic, in that the contested classification and labelling did not relate to a substance that has the intrinsic property to cause cancer.

23 In paragraphs 50 to 122 of the judgment under appeal, the General Court examined that first part. In paragraph 52 of that judgment, it noted, inter alia, in that regard, that Billions Europe and Others claimed, in their application in Case T-283/20 and their statements in intervention in Joined Cases T-279/20 and T-288/20, that the RAC Opinion was vitiated by an error, in that that committee, for the purposes of examining the acceptability and reliability of the Heinrich study and, in particular, the degrees of lung overload of titanium dioxide particles ('lung overload') in that study, had used a titanium dioxide particle density value of 4.3 g/cm^3 in its assessment, based on the method proposed by the Morrow studies (1988 and 1992) ('the Morrow calculation'), which, according to those applicants, had led the RAC to conclude, wrongly, that that study had been conducted under acceptable lung overload conditions.

24 In paragraphs 78 and 79 of that judgment, the General Court, first, rejected the Commission's argument that the RAC Opinion was not based solely on the Heinrich study. The General Court considered that the latter 'was the decisive study on which the RAC Opinion, and therefore the contested classification and labelling, were based'.

25 In paragraphs 81 to 122 of that judgment, the General Court then examined the argument of Billions Europe and Others referred to in paragraph 23 of the present judgment.

26 In the context of that examination, the General Court held, in paragraphs 100 to 103 of the judgment under appeal, that, by failing to take into account the characteristics of the particles tested in the Heinrich study, and in particular the fact that they tend to agglomerate, and the lower agglomerate density of the particles, leading to them occupying more volume in the alveolar macrophages, the RAC had made a manifest error of assessment, rendering implausible the conclusion which it had reached. In paragraphs 104 to 120 of that judgment, the General Court held, in essence, that the arguments of the Commission and ECHA did not call that conclusion into question.

27 Lastly, in paragraph 121 of the judgment under appeal, the General Court inferred from that examination that, in so far as the regulation at issue was based on the RAC Opinion as regards the contested classification and labelling, and since the Heinrich study had been decisive for the classification proposal for titanium dioxide set out in that opinion, the manifest error of assessment made by that committee rendered implausible its conclusion, which the Commission had followed for the purposes of adopting the regulation at issue, that the results of that study were sufficiently reliable and acceptable, within the meaning of point 3.6.2.2.1 of Annex I to Regulation No 1272/2008. Consequently, in paragraph 122 of the judgment under appeal, it upheld the first part of the first complaint.

28 Furthermore, 'in the interests of the sound administration of justice' and 'in order to provide a complete resolution of the dispute', the General Court, in paragraphs 124 to 179 of the judgment under appeal, examined the second part of that first complaint.

29 On the basis of the grounds set out, inter alia, in paragraphs 157, 158, 160 and 161 of the judgment under appeal, the General Court held, in paragraph 178 of that judgment, that the second part of that first complaint had to be upheld.

30 Consequently, and holding that there was no need to examine the other pleas and arguments of the applicants at first instance, the General Court annulled the regulation at issue as regards the contested classification and labelling.

The procedure before the Court of Justice and the forms of order sought

31 By order of the President of the Court of 19 July 2023, Cases C-71/23 P and C-82/23 P were joined for the purposes of the written and oral procedure, and the judgment.

Forms of order sought by the parties in Case C-71/23 P

32 By its appeal, the French Republic, supported by the Kingdom of the Netherlands, the Kingdom of Sweden, the Commission and ECHA, claims that the Court should:

– set aside the judgment under appeal;

– itself give final judgment in the matter and dismiss the actions brought by the applicants at first instance, or, if the Court of Justice considers that the state of the proceedings does not permit final judgment to be given, refer the case back to the General Court; and

– order the applicants at first instance to pay the costs.

33 CWS, Brillux, DAW and Sto SE & Co. KGaA, formerly Sto AG (together, 'CWS and Others'), contend that the Court should:

– dismiss the appeal, and

– order the French Republic to pay the costs.

34 Billions Europe and Others contend that the Court should:

– dismiss the appeal in its entirety as inadmissible or unfounded;

– in the alternative, refer Case T-283/20 back to the General Court in its entirety, including for it to examine the arguments put forward by the applicants at first instance in the context of their first plea and on which the General Court did not rule in the judgment under appeal;

– order the French Republic to pay the costs of the proceedings before the Court of Justice and to bear its own costs at first instance; and

– order the Commission to pay the costs of the proceedings at first instance.

35 ECHA contends that the Court should:

– set aside the judgment under appeal;

– itself give final judgment in the matter and dismiss the actions, or, if the Court of Justice considers that the state of the proceedings does not permit final judgment to be given, refer the case back to the General Court; and

– order the applicants at first instance to pay the costs or, if the case is referred back to the General Court, reserve the costs relating to the present proceedings.

36 The Conseil Européen de l'Industrie Chimique – European Chemical Industry Council (Cefic), the Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art (CEPE), British Coatings Federation Ltd (BCF) and American Coatings Association, Inc. (ACA) (together 'Cefic and Others') contend that the Court should:

– dismiss the appeal in its entirety, and

– order the French Republic to pay the costs incurred by them in the present proceedings and in the proceedings before the General Court.

Forms of order sought by the parties in Case C-82/23 P

37 By its appeal, the Commission, supported by the Kingdom of the Netherlands, the Kingdom of Sweden and ECHA, claims that the Court should:

– set aside the judgment under appeal;

– reject 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;

– refer the case back to the General Court for it to examine the pleas on which it did not rule in its judgment; and

– reserve the costs of the present proceedings.

38 Billions Europe and Others contend that the Court should:

– dismiss the appeal in its entirety as inadmissible or unfounded;

– in the alternative, refer Case T-283/20 back to the General Court in its entirety, including for it to examine the arguments put forward by the applicants at first instance in the context of their first plea and on which the General Court did not rule in the judgment under appeal; and

– order the Commission to pay the costs of the proceedings before the Court of Justice and at first instance.

39 CWS and Others contend that the Court should:

– dismiss the appeal, and

– order the Commission to pay the costs.

40 ECHA contends that the Court should:

– set aside the judgment under appeal;

– reject 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;

– refer the case back to the General Court for it to examine the pleas on which it did not rule in its judgment; and

– reserve the costs of the present proceedings.

41 Cefic and Others contend that the Court should:

– dismiss the appeal in its entirety, and

– order the Commission to pay the costs incurred by them in the present proceedings and in the proceedings before the General Court.

The application to reopen the oral part of the procedure

42 Following the delivery of the Advocate General's Opinion, Billions Europe and Others, by letter lodged at the Court Registry on 14 March 2025, applied for the oral part of the procedure to be reopened, pursuant to Article 83 of the Rules of Procedure of the Court of Justice.

43 In support of their application, they submit, first, that the Court of Justice lacks sufficient information to enable it to rule in the present joined cases, on the ground that that Opinion is based on incorrect factual premisses and misleading assumptions, and, second, that that Opinion contains, in point 100 thereof, a new argument, relating to RAC's infringement of its obligation to state reasons, which the Court should raise of its own motion after that argument has been debated between the parties.

44 Under Article 83 of the Rules of Procedure, the Court may at any time, after hearing the Advocate General, order the reopening of the oral part of the procedure, in particular if it considers that it lacks sufficient information or where a party has, after the close of that part of the procedure, submitted a new fact which is of such a nature as to be a decisive factor for the decision of the Court, or where the case must be decided on the basis of an argument which has not been debated between the interested persons.

45 As regards, first, the first ground relied on by Billions Europe and Others in support of their application, it should be noted that it is intended, ultimately, to enable those parties to put forward their arguments in response to the Advocate General's Opinion, which, in their view, is based on incorrect factual considerations such as to mislead the Court.

46 It suffices to recall that the Statute of the Court of Justice of the European Union and the Rules of Procedure do not provide for such a possibility for the parties. Under the second paragraph of Article 252 TFEU, the Advocate General, acting with complete impartiality and independence, is to make, in open court, reasoned submissions on cases which, in accordance with the Statute of the Court of Justice of the European Union, require his or her involvement. The Court is not bound either by the Advocate General's submissions or by the reasoning which led to those submissions. Consequently, a party's disagreement with the Opinion of the Advocate General, irrespective of the questions that he or she examines in the Opinion, cannot in itself constitute grounds justifying the reopening of the oral procedure (see, to that effect, judgment of 8 February 2024, *Pilatus Bank* v *ECB*, C-750/21 P, EU:C:2024:124, paragraphs 27 and 28 and the case-law cited).

47 Moreover, the points on which Billions Europe and Others wish to have the opportunity to submit additional arguments were extensively debated between the parties both in the written part of the procedure and at the hearing on 7 November 2024.

48 As regards, second, point 100 of the Opinion, it should be noted that, in that point, the Advocate General gave her opinion on an argument raised at the hearing by the applicants at first instance, according to which the RAC Opinion lacked clarity in certain respects. Although she stated that she had sympathy for that argument, she did not, however, invite the Court to raise of its own motion a plea alleging infringement, by the RAC, of its obligation to state reasons, but, on the contrary, considered that that argument should be rejected, since it related to the statement of reasons for the RAC Opinion and did not, in itself, constitute a reason for concluding, as those parties did, that the RAC had not taken into consideration all the relevant facts.

49 In any event, the Court considers, after hearing the Advocate General, that it has all the information necessary to rule on the appeals and that the cases do not need to be decided on the basis of an argument which has not been debated between the parties.

50 In the light of the foregoing considerations, the application that the oral part of the procedure be reopened must be rejected.

The appeals

51 In support of its appeal in Case C-71/23 P, the French Republic puts forward four grounds of appeal. The first ground of appeal, which is divided into two parts, concerns the alleged errors vitiating the General Court's assessment, in paragraph 78 of the judgment under appeal, that the Heinrich study is the 'decisive' study on which the RAC Opinion is based. The first part alleges distortion, by the General Court, of the evidence submitted to it and the second part alleges an error of law, in that it disregarded the principles relating to the classification of carcinogenic substances, set out in Regulation No 1272/2008. By the second ground of appeal, the French Republic claims that the General Court exceeded the limits of its judicial review, in that, in paragraphs 100 to 103 of that judgment, it substituted its own assessment for that of the RAC as regards the determination of density in the context of the Morrow calculation. By its third ground of appeal, the French Republic submits that the General Court's conclusion that titanium dioxide does not have the intrinsic property to cause cancer, set out in paragraphs 157 and 158 of that judgment, is vitiated by a failure to state reasons. By its fourth ground of appeal, the French Republic submits that that conclusion is vitiated by an error of law, in that it is based on a misinterpretation of the concept of 'substance that has the intrinsic property to cause cancer', within the meaning of point 3.6.2.2.1 of Annex I to Regulation No 1272/2008.

52 In support of its appeal in Case C-82/23 P, the Commission puts forward three grounds of appeal. By its first ground of appeal, the Commission claims that the General Court distorted the evidence before it in concluding that the RAC and the Commission made a manifest error of assessment in relation to the reliability and acceptability of the Heinrich study. That ground of appeal consists of two parts. The first part is directed against the same assessment by the General Court as that which is the subject of the French Republic's first ground of appeal. The second part relates to the conclusion, set out in paragraph 120 of the judgment under appeal, that the Morrow calculation was 'decisive' in supporting the RAC's assessment as regards the reliability and acceptability of that study. The second and third grounds of appeal are based, in essence, on the same complaints as, respectively, the French Republic's second and fourth grounds of appeal.

53 In its response in Case C-71/23 P, ECHA relies, in support of the second ground of appeal put forward by the French Republic, on two additional parts, by which that agency submits, in essence, that the General Court exceeded its powers by carrying out the assessment referred to in the first part of the first ground of appeal and the assessment which is the subject of the second part of the Commission's first ground of appeal in Case C-82/23 P. Furthermore, in that response, ECHA relies on a ground of appeal alleging that the General Court exceeded the limits of its judicial review because it ruled on the causes of the tumours observed in the Heinrich study. In its response in Case C-82/23 P, ECHA also relies, in essence, on those two additional parts and that new ground of appeal.

Admissibility of the grounds of appeal and the parts of the grounds of appeal relied on independently by ECHA in the two joined cases

Arguments of the parties

54 ECHA submits that, according to the case-law of the Court of Justice, the other parties to the appeals may raise new points of law in their responses.

55 In their rejoinders, CWS and Others and Billions Europe and Others submit that ECHA's response is inadmissible, in so far as it contains additional grounds of appeal and arguments, relied on independently by that agency, since those arguments do not seek, as required by Article 174 of the Rules of Procedure, to allow or dismiss the appeals and may be submitted only in the context of a cross-appeal, in accordance with Articles 176 and 178 of those rules.

Findings of the Court

56 It should be borne in mind that, under Article 174 of the Rules of Procedure, a response must seek to have the appeal allowed or dismissed, in whole or in part. Furthermore, under Articles 172 and 176 of those rules, parties authorised to lodge a response may submit, by a document separate from the response, a cross-appeal, which, in accordance with Article 178(1) and (3), second sentence, of the rules, must seek to have set aside, in whole or in part, the decision of the General Court on the basis of pleas in law and arguments separate from those relied on in the response.

57 It is apparent from those provisions, read together, that the response may not seek the annulment of the decision of the General Court on the basis of distinct and independent grounds from those raised in the appeal, since such grounds may only be raised as part of a cross-appeal (judgment of 3 September 2020, *Vereniging tot Behoud van Natuurmonumenten in Nederland and Others* v *Commission*, C-817/18 P, EU:C:2020:637, paragraph 48 and the case-law cited).

58 In the present case, it must be noted that, as is explicitly stated in ECHA's responses, the two additional parts of the second ground of appeal and the new ground of appeal put forward by that agency in those pleadings, referred to in paragraph 53 of the present judgment, seek to have the judgment under appeal set aside on separate and independent grounds from those relied on in the two appeals and can therefore be examined by the Court only in the context of a possible cross-appeal.

59 The judgment of 11 February 1999, *Antillean Rice Mills and Others* v *Commission* (C-390/95 P, EU:C:1999:66, paragraphs 20 to 23), relied on by ECHA in its response, cannot call that finding into question, given that, in that judgment, the Court of Justice relied on an earlier version of its Rules of Procedure, which included provisions allowing the parties to the proceedings before the General Court to lodge a response containing grounds of appeal not raised in the appeal but, by contrast, did not provide for the possibility for those parties to lodge a cross-appeal.

60 It follows that those two additional parts and that new ground of appeal must be rejected as inadmissible.

The first grounds of appeal of the two appeals, alleging distortion of the evidence and an error of law, in that the General Court considered the Heinrich study and the Morrow calculation to be 'decisive' for the RAC Opinion

The first parts of the first grounds of appeal, alleging distortion of the evidence, in that the General Court considered the Heinrich study to be 'decisive' for the RAC Opinion

– *Arguments of the parties*

61 The French Republic, supported by ECHA, submits that the General Court was wrong to hold that the Heinrich study was the only study on which the RAC Opinion was based.

62 In that regard, it claims that, by classifying the Heinrich study as a 'decisive study' in paragraph 78 of the judgment under appeal, the General Court held that the RAC Opinion was based on that study alone. The French Republic relies, in that regard, on paragraph 67 of that judgment, in which the General Court stated that it was necessary to examine whether the Heinrich study was, in itself, decisive for the contested classification and labelling, 'failing which the … line of argument [of the applicants at first instance] challenging the reliability and acceptability of that study should be rejected as ineffective'.

63 However, in paragraphs 74, 76 and 77 of that judgment, the General Court itself found, first, that, according to the RAC, the Lee et al. study (1985) ('the Lee study') and the Heinrich study were the 'key studies' relating to carcinogenicity by inhalation, second, that, among those two studies, that committee had based its proposal for classification of titanium dioxide 'for the most part' on the Heinrich study, since the Lee study is not 'in itself, decisive or sufficient' to support that proposal and, third, that 'in addition to those two key studies, the RAC Opinion [referred] to other studies, but [that] it [did] so only as supporting or supplementing the results of the Heinrich study'. It is therefore apparent from those factors that the Heinrich study was not the only 'key study' on which the RAC relied and that the other studies, even if they had only been taken into account by that committee in a supplementary capacity, nonetheless contributed to the scientific assessment of that committee. Consequently, by finding that the Heinrich study was the 'decisive study' for the RAC Opinion, the General Court carried out a manifestly incorrect assessment of the evidence submitted to it and therefore distorted that evidence.

64 For its part, the Commission, supported by the Kingdom of Sweden, also claims that that assessment is vitiated by a distortion of the evidence, claiming, more specifically, that it is clear from the RAC Opinion that that committee carried out a weight of evidence determination and

relied on all the information deemed relevant for the assessment of the hazards associated with titanium dioxide, without attributing any 'decisive' importance to the Heinrich study, in accordance with points 1.1.1.3 and 3.6.2.1 of Annex I to Regulation No 1272/2008.

65 CWS and Others and Billions Europe and Others claim that the arguments of the French Republic and the Commission seek, in reality, to obtain from the Court a re-examination of the evidence and are therefore inadmissible. In addition, those parties dispute the merits of those arguments.

– *Findings of the Court*

66 According to settled case-law, in accordance with the second subparagraph of Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, an appeal is to be limited to points of law. The General Court therefore has exclusive jurisdiction to find and appraise the relevant facts and to assess the evidence placed before it. The appraisal of those facts and the assessment of that evidence thus do not, save where the facts or evidence are distorted, constitute a point of law which is subject, as such, to review by the Court of Justice on appeal (judgment of 15 October 2020, *Deza* v *Commission*, C-813/18 P, EU:C:2020:832, paragraph 37 and the case-law cited).

67 There is such distortion where, without recourse to new evidence, the assessment of the existing evidence is clearly incorrect. However, such distortion must be obvious from the documents on the Court's file, without there being any need to carry out a new assessment of the facts and the evidence. Moreover, where an appellant alleges distortion of the evidence by the General Court, he or she must indicate precisely the evidence alleged to have been distorted by that court and show the errors of appraisal which, in his or her view, led to that distortion (judgment of 15 October 2020, *Deza* v *Commission*, C-813/18 P, EU:C:2020:832, paragraph 38 and the case-law cited).

68 In the present case, as regards the admissibility of the present parts of the grounds of appeal, which is disputed by CWS and Others and by Billions Europe and Others, it should be noted that the appellants submit that, in the light of the factors of the RAC Opinion to which the General Court itself referred, the General Court's conclusion that the Heinrich study is the 'decisive study' on which that committee's proposal for classification of titanium dioxide is based is manifestly incorrect and constitutes a distortion of that evidence. That line of argument therefore does not seek to have the Court of Justice carry out a new assessment of the RAC Opinion, but seeks to ascertain whether the conclusion which the General Court drew from the findings of fact made in respect of that opinion is manifestly incompatible with those findings, which falls within the Court of Justice's jurisdiction. In addition, the appellants refer precisely to the parts of that opinion which, in their view, were distorted and adequately set out the errors of analysis allegedly committed by the General Court. Their line of argument is therefore admissible.

69 However, as regards, in the first place, the French Republic's line of argument, it should be noted at the outset that it is based on a misreading of paragraph 78 of the judgment under appeal, according to which, by classifying the Heinrich study as a 'decisive study' in paragraph 78, the General Court intended to establish that the RAC Opinion was based on that study alone.

70 As is explicitly clear both from paragraph 78 of the judgment under appeal as a whole and from paragraphs 67 to 77 of that judgment, of which paragraph 78 constitutes the conclusion, the classification of the Heinrich study as 'decisive' must be understood as meaning that the General Court thus considered that that study had been decisive, in itself, for the RAC's classification

proposal for titanium dioxide, since the other studies and scientific evidence taken into account by that committee, including the Lee study, had only a complementary role in that regard, given that that committee had considered that they were not sufficient, in themselves, to support that proposal.

71 Accordingly, the French Republic's line of argument must be rejected as unfounded.

72 As regards, in the second place, the Commission's line of argument, it should be noted, first, that, contrary to what the Commission appears to consider, the fact that the RAC carried out a weight of evidence determination and relied on all the information deemed relevant for the assessment of the hazards associated with titanium dioxide is not, in itself, incompatible with the General Court's conclusion that the Heinrich study was 'decisive' for the purposes of classifying that substance.

73 In that regard, according to point 1.1.1.3 of Annex I to Regulation No 1272/2008, 'a weight of evidence determination means that all available information bearing on the determination of hazard is considered together'. In that context, 'both positive and negative results shall be assembled together in a single weight of evidence determination'. In addition, in accordance with the provisions of point 3.6.2.1 of Annex I, Table 3.6.1 in that point states that the classification of a substance in category 2, that is to say, in the category of substances suspected of being carcinogenic to humans, must be 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, namely as a proven or presumed carcinogen, and must be based on strength of evidence together with additional considerations. Lastly, pursuant to point 3.6.2.2.1 of Annex I, the classification of a carcinogenic substance, including category 2 carcinogens, must be made on the basis of evidence from reliable and acceptable studies.

74 It follows that, in the context of such an assessment, and in particular in the context of the assessment of the 'reliability and acceptability' of the studies taken into account and of the 'weight' of evidence from those studies, the RAC is likely to attribute more weight to some of the evidence from those studies than to other evidence in order to conclude whether or not it is necessary to proceed with the harmonised classification and labelling of a substance as being carcinogenic to humans.

75 Second, the Commission does not maintain that the findings made by the General Court in paragraphs 70 to 77 of the judgment under appeal, on the basis of which it concluded that the Heinrich study was 'decisive' for the findings of the RAC Opinion, are vitiated by a distortion of the facts.

76 Thus, first, according to the findings made in paragraph 70 of that judgment, the RAC considered that the Lee and Heinrich studies, which alone revealed tumour development following exposure to titanium dioxide, were, according to the RAC, the 'key carcinogenicity studies by inhalation'.

77 Second, according to the General Court's analysis in paragraphs 74 and 75 of that judgment, it is apparent from the comparison between the Lee study and the Heinrich study, carried out by that committee, that the Lee study did not have to have a 'determining influence' on the classification of titanium dioxide, given that the exposure conditions during that study had been excessive, whereas that was not the case with the Heinrich study, since the results of that study were 'sufficiently reliable, relevant and adequate for the assessment of the carcinogenic potential of [titanium dioxide]'. Consequently, as noted in paragraph 76 of that judgment, of the two studies

which, according to that committee, were the key studies on carcinogenicity by inhalation, the RAC found that the Heinrich study took precedence over the Lee study, since the latter was not, in itself, decisive or sufficient to support the classification proposal for titanium dioxide.

78 Third, although, in accordance with the weight of evidence approach, the RAC took into consideration not only the inhalation toxicity studies in rats, but also, as the Commission states by referring specifically to the relevant sections of the RAC Opinion, the other available studies and information, the General Court does not state that that committee did not take account of all those factors. By contrast, it states, in paragraph 77 of its judgment, that the RAC Opinion refers to other studies, but only 'as supporting or supplementing the results of the Heinrich study'.

79 It must be stated that, by inferring from that entire analysis of the RAC Opinion that the Heinrich study had been 'decisive' for the purposes of that opinion and therefore, ultimately, for the harmonised classification and labelling of titanium dioxide, which complies with that opinion, the General Court did not distort that opinion.

80 It follows that the Commission's line of argument and, consequently, the first parts of the first grounds of appeal in their entirety must be rejected as unfounded.

The second part of the first ground of appeal in Case C-71/23 P, alleging an error of law, in that the General Court disregarded the principles relating to the classification of carcinogenic substances set out in Regulation No 1272/2008

– *Arguments of the parties*

81 The French Republic, supported by the Kingdom of Sweden and by ECHA, submits that, by classifying the Heinrich study as a 'decisive' study, the General Court thereby rejected all the other evidence which had been used by the RAC and, consequently, disregarded the principles set out in points 1.1.1.3 and 3.6.2.1 of Annex I to Regulation No 1272/2008, relating to the weight of evidence determination. Although, in the context of such a determination, some evidence may carry more weight than other evidence, it follows from those provisions that it is their combined reading which provides the basis for the scientific assessment. Moreover, the concept of a 'decisive study', for the purposes of classifying a study used in the context of a scientific assessment based on the weight of evidence determination, does not exist either in the applicable legislation or in the case-law.

82 CWS and Others and Billions Europe and Others dispute the merits of that line of argument.

– *Findings of the Court*

83 It should be noted, first, that, as is apparent from paragraphs 72 to 74 of the present judgment and as, moreover, the French Republic itself acknowledges, the principles relating to the weight of evidence determination set out in Annex I to Regulation No 1272/2008 do not preclude the RAC from being led to attribute more weight to some of the evidence over other evidence in order to conclude whether or not it is necessary to proceed with the harmonised classification and labelling of a substance as being carcinogenic to humans.

84 Second, it is apparent from paragraph 70 of the present judgment that, contrary to what the French Republic maintains, by classifying the Heinrich study as a 'decisive study', the General Court did not, as a result, 'disregard' all the other evidence taken into account by the RAC.

85 Consequently, the second part of the first ground of appeal in Case C-71/23 P must be rejected as unfounded.

The second part of the first ground of appeal in Case C-82/23 P, alleging distortion of the evidence, in that the General Court concluded that the Morrow calculation had been 'decisive' in substantiating the RAC's assessment as regards the reliability and acceptability of the Heinrich study

– *Arguments of the parties*

86 The Commission, supported by the Kingdom of Sweden, submits that it is clear from the RAC Opinion that, contrary to the General Court's conclusion in paragraph 120 of the judgment under appeal, the Morrow calculation was not 'decisive' in substantiating that committee's assessment of the acceptable degree of lung overload used in the Heinrich study, and therefore the reliability and acceptability of that study.

87 In that regard, the Commission claims, first, that the RAC used 'cautious' wording to qualify the use of that calculation, stating that it 'could contribute to a constructive discussion regarding the term "overload"', even though it 'might not be a generally accepted concept'. Second, it is clear from the RAC Opinion that that committee based its assessment of the acceptable degree of lung overload on other factors, such as lung clearance half-time, approaching the period of approximately one year recommended by the relevant Organisation for Economic Cooperation and Development (OECD) guidance document, the 'relatively low' exposure level of 10 mg/m^3, the mean mass aerodynamic diameter (MMAD) of titanium dioxide particles, close to the range of values recommended by point 3.1.2.3.2 of Annex I to Regulation No 1272/2008 and the external validation of the Heinrich study resulting from another scientific study. However, none of the factors relied on by the RAC was, on its own, 'decisive'. Lastly, the General Court was wrong to hold, in paragraph 112 of the judgment under appeal, that the arguments of the Commission and ECHA stating that the RAC had also relied on those factors were 'contradicted' by the RAC Opinion.

88 CWS and Others and Billions Europe and Others contend that the present part of the first ground of appeal in Case C-82/23 P is inadmissible on the ground that it seeks a re-examination of the evidence by the Court of Justice. In addition, they dispute the merits of the line of argument in support of that part of the ground of appeal.

– *Findings of the Court*

89 As regards the admissibility of the present part of the ground of appeal, it should be noted that, by its line of argument in support of that part, the Commission seeks to demonstrate that the General Court's assessment that the Morrow calculation was 'decisive' in order to support the findings set out in the RAC Opinion relating to the fact that the lung overload measured in the Heinrich study was in the acceptable range is manifestly contradicted by the very wording of that opinion, from which it is clear that those findings are also based on other factors and that no factor relied on in that opinion is 'decisive'. It follows that, contrary to what CWS and Others and Billions Europe

and Others maintain, that line of argument does not seek a fresh assessment by the Court of Justice of the RAC Opinion, but rather a finding that the General Court distorted that opinion. That line of argument is therefore admissible.

90 As regards the substance, in paragraph 112 of the judgment under appeal, the General Court held that the arguments of the Commission and ECHA, 'that the evaluation of the Heinrich study by the RAC was not carried out solely on the basis of the [Morrow calculation], or even that it was not dependent on that calculation', are contradicted by the RAC Opinion and, in paragraphs 113 to 119 of that judgment, set out the reasons supporting that finding.

91 In particular, in paragraph 113 of that judgment, the General Court found that the RAC had identified a number of relevant factors concerning the exposure conditions used in the Lee and Heinrich studies, such as the lung clearance half-time and the exposure level, measured in the light of the dose and concentration of the substance, and had concluded, in the part of its opinion entitled 'Overall conclusion', first, that the excessive exposure conditions during the Lee study invalidated the results of that study for classification purposes and, second, that the results of the Heinrich study were sufficiently reliable, relevant and adequate for the assessment of the carcinogenic potential of titanium dioxide. In addition, the General Court stated that, in particular, as regards the Lee study, the RAC had mentioned an excessive lung clearance half-time during the maximum exposure level of 250 mg/m^3 and, as regards the Heinrich study, a relatively low exposure level of 10 mg/m^3.

92 In paragraph 114 of that judgment, the General Court noted, however, that, in the context of that overall conclusion, the RAC had also recalled that the lung overload measured in the Lee study was not in the acceptable range, since it had led to an almost complete cessation of particle clearance mechanisms, whereas that had not been the case with the Heinrich study, in the context of which the lung overload was in the acceptable range. In paragraph 115 of that judgment, the General Court recalled that it was on the basis of the Morrow calculation that that committee drew its findings as to whether the degree of lung overload measured in the Lee and Heinrich studies had been acceptable. In paragraph 116 of that judgment, the General Court inferred that it was not on the basis of the lung clearance half-time and the dose and concentration of titanium dioxide particles that the RAC had drawn its conclusions on the degree of lung overload measured in the Heinrich study and therefore on the acceptability of the results of that study.

93 It is clear from the sections of the RAC Opinion to which the Commission refers that, in the context of the comparison between the Lee and Heinrich studies, which constituted, according to the wording of that opinion, the 'key studies' on carcinogenicity for the classification of titanium dioxide, that committee sought to assess whether the degree of lung overload in rats in those two studies was acceptable on the basis of the Morrow calculation. Accordingly, notwithstanding the fact that, as the Commission submits, that committee used cautious wording, suggesting that the use of that calculation could be open to discussion, the fact remains that, as the General Court found, it was solely on the basis of that calculation that it concluded that the degree of lung overload was in the acceptable range as regards the Heinrich study, but that that was not the case as regards the Lee study.

94 Admittedly, as is apparent from the 'Overall conclusion' section of that opinion cited in paragraphs 113 and 114 of the judgment under appeal, the RAC did not rely solely on the results which it arrived at by means of the Morrow calculation as regards the acceptable degree of lung overload in order to find, first, that the exposure conditions of the Lee study were excessive and

invalidated the results of that study for the purposes of classifying titanium dioxide as a carcinogenic substance and, second, that the results of the Heinrich study were reliable, relevant and consistent with the results of the Gebel et al. study (2012), relating to the carcinogenicity by inhalation in rats of other substances known as 'poorly soluble low-toxicity particles'.

95 However, it is also clear from that section of the RAC Opinion that the assessment of the acceptable degree of lung overload on the basis of the Morrow calculation played a decisive role in concluding that the Heinrich study was reliable and acceptable, with the result that by classifying, in paragraph 120 of the judgment under appeal, that calculation as 'decisive' to substantiate the RAC's findings in that regard, the General Court did not carry out a manifestly erroneous assessment of the evidence.

96 It follows that the second part of the first ground of appeal in Case C-82/23 P must be rejected as unfounded.

97 In the light of the foregoing considerations, the first grounds of appeal of the two appeals must be rejected as unfounded.

The second grounds of appeal, alleging that the General Court exceeded the limits of its judicial review, in that it substituted its own assessment for that of the RAC as regards the determination of particle density in the context of the Morrow calculation

Arguments of the parties

98 By their second grounds of appeal, the French Republic and the Commission submit that, in paragraphs 100, 102 and 103 of the judgment under appeal, the General Court erred in law by substituting its own assessment for that of the RAC and that of the Commission thereby exceeding the limits of its judicial review.

99 According to the appellants, by finding that, for the purposes of applying the Morrow calculation, the RAC should have used a lower density of titanium dioxide particles than the 4.3 g/cm^3 which it used and that, for the purposes of that calculation, it should instead have used the agglomerate density of nano-sized titanium dioxide particles, the General Court encroached upon the discretion of the RAC and the Commission.

100 In support of the second grounds of appeal, the appellants submit, first, that, contrary to what the General Court held in paragraph 100 of the judgment under appeal, the RAC examined the factors necessary to determine the particle density, in particular the fact that, on account of their nano size, titanium dioxide particles tended to agglomerate.

101 Second, they claim that, in the context of its scientific expertise, the RAC could legitimately consider it appropriate to use the 'standard' particle density value of 4.3 g/cm^3.

102 Thus, according to the French Republic, the RAC was able to take into account the existence of the packing of particles in the lungs. Furthermore, it cannot be presumed that the particle agglomerate density was 1.6 g/cm^3. For its part, the Commission states that the Heinrich study did not indicate the density, the extent of the agglomeration and the packing of the titanium dioxide particles tested.

103 Third, the appellants claim that, by concluding that there was a manifest error of assessment on the ground that the RAC had used a density value corresponding to that of titanium dioxide particles and not the agglomerates of those particles, which is apparent, in particular, from paragraphs 100 and 102 of the judgment under appeal, the General Court adopted a position on the scientific findings reached by the RAC on the basis of the information available to it, which is not within its jurisdiction to adopt.

104 In support of the second grounds of appeal, the Kingdom of Sweden and ECHA submit that the issue of the agglomeration of particles, in particular in the environment within the lungs, is a particularly complex scientific issue which does not fall within the jurisdiction of the General Court.

105 CWS and Others and Billions Europe and Others dispute the merits of the appellants' line of argument and that of the Kingdom of Sweden and of ECHA.

– Findings of the Court

106 In that connection, it should be recalled that where the EU authorities have a broad discretion, in particular in so far as concerns the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt in that context, review by the Courts of the European Union is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the Courts of the European Union cannot substitute their assessment of scientific and technical facts for that of the institutions on which alone the FEU Treaty has entrusted that task (see, to that effect, judgments of 21 July 2011, *Nickel Institute*, C-14/10, EU:C:2011:503, paragraph 60 and the case-law cited, and of 9 November 2023, *Chemours Netherlands* v *ECHA*, C-293/22 P, EU:C:2023:847, paragraph 134 and the case-law cited).

107 More specifically, the Court has held, in that context, that the broad discretion of the EU authorities, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that the EU authorities which have adopted the act in question must be able to show before the Courts of the European Union that in adopting the act they actually exercised their discretion, which presupposes that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (judgment of 9 November 2023, *Chemours Netherlands* v *ECHA*, C-293/22 P, EU:C:2023:847, paragraph 135 and the case-law cited).

108 In the present case, it is apparent from the file submitted to the Court of Justice that, before the General Court, Billions Europe and Others relied on a manifest error of assessment by the RAC and by the Commission on the ground that, when applying the Morrow calculation to the Lee and Heinrich studies, carried out for the purposes of assessing the reliability and acceptability of those studies, the RAC used a density value of titanium dioxide particles of 4.3 g/cm^3, whereas it should have taken into account the agglomerate density of 'P25' grade titanium dioxide particles, which, according to the scientific studies indicated by those parties, was 1.6 g/cm^3.

109 In response, the Commission and ECHA maintained that the RAC was fully entitled to take into account the density not of agglomerates of nano-sized particles of titanium dioxide, but of the particles of that substance, given that the Heinrich study did not indicate either the density of the

particles tested or the extent of the agglomeration and packing of those particles and that, in those circumstances, it was appropriate for the RAC to take into account the standard value of the density of titanium dioxide particles, that is to say, the reference value used by the scientific community as regards that density.

110 In paragraph 97 of the judgment under appeal, the General Court noted that, 'irrespective of the precise density value that had to be taken into account by the RAC for the purposes of the [Morrow calculation] – a question, in any event, which it [was] not for the [General] Court to examine – the … line of argument [of the applicants at first instance] [raised] above all the question whether the RAC [had] made a manifest error of assessment concerning the type of density used'.

111 It is in that context that, in paragraph 100 of that judgment, the General Court held that, although 'it [was] indeed true … that the Heinrich study did not provide any indication as to the density or the extent of the agglomeration and the packing of the titanium dioxide particles tested', '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 [had] not [taken] into account all the relevant factors of the present case'. According to the General Court, those factors were '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'.

112 In paragraph 103 of that judgment, the General Court concluded that the 'RAC [had] failed to take into account all the relevant factors in order to calculate the lung overload in the Heinrich study by means of the [Morrow calculation]' by failing to take into account the factors set out in paragraph 100 of that judgment and '[that it] therefore [had] committed a manifest error of assessment'. In addition, in that same paragraph, the Court stated that '[the RAC's] error [rendered] 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 … [were] also vitiated by a manifest error of assessment'.

113 It is therefore apparent from the General Court's findings, recalled in paragraphs 110 to 112 of the present judgment, that, as the Advocate General observed, in essence, in point 95 of her Opinion, it considered that the taking into consideration, by the RAC, of the standard density value of titanium dioxide particles for the purposes of the Morrow calculation constituted an error and that, in the circumstances of the present case, a lower density value, corresponding to the value of the agglomerate density of nano-sized particles, should have been used.

114 In carrying out that assessment, the General Court did not confine itself to verifying that the RAC had duly taken into account all the relevant evidence that the available scientific knowledge required it to take into consideration, in particular, in the present case, as that committee itself noted in its opinion, the tendency of 'P25' grade nano-sized particles, such as those observed during the Heinrich study, to form agglomerates with a lower density than the particles themselves.

115 Although the General Court noted, in paragraph 100 of the judgment under appeal, that, as the Commission and ECHA had argued before it and as Billions Europe and Others did not dispute, the Heinrich study did not provide any indication as to the density or the extent of the agglomeration and packing of the titanium dioxide particles tested, it considered that, in any event, the value used by the RAC, corresponding to the standard density value of titanium dioxide particles, was not appropriate, given that that value was 'higher' than that of the agglomerate density.

116 However, in a context where, as is apparent from the General Court's own findings, there was no available data enabling the appropriate type of density to be used for the purposes of applying the Morrow calculation to the Heinrich study to be reliably established, it was not for the General Court itself to decide the question of the appropriateness of the value of the density of titanium dioxide particles adopted by the RAC in the light of the phenomenon of agglomeration of those particles, which question required a scientific assessment to be carried out and, ultimately, to substitute its own findings in that regard for those of the competent authorities.

117 Nevertheless, it is settled case-law that, if the grounds of a decision of the General Court contain an infringement of EU law but its operative part is shown to be well founded on other legal grounds, such an infringement is not one that should cause that decision to be set aside, and a substitution of grounds must be made (judgment of 23 January 2019, *Deza* v *ECHA*, C-419/17 P, EU:C:2019:52, paragraph 87 and the case-law cited).

118 In that regard, as has been recalled in paragraph 107 of the present judgment, even where the EU authorities have a discretion which also applies, to some extent, to the finding of the facts which must serve as the basis for the adoption of an act falling within their powers, the review carried out by the Courts of the European Union in relation to that act nevertheless requires that those authorities be able to establish that the act in question was adopted on the basis of an actual exercise of that discretion and, in particular, that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate.

119 In the present case, it is sufficient to note that, as the General Court pointed out in paragraph 98 of the judgment under appeal, in its opinion, the RAC found that nano-sized primary particles, such as the titanium dioxide particles used in the evaluation in the Heinrich study, tended to agglomerate. However, as also stated in paragraph 98, it was only 'with regard to aerosols, that is to say, air-suspended particles' and without indicating any possible link with the type of density that it was appropriate to take into account for the purposes of applying the Morrow calculation that the RAC made that finding.

120 The appellants and the other parties supporting their position do not dispute that, as the General Court stated, in essence, in paragraph 101 of the judgment under appeal, that phenomenon of agglomeration of titanium dioxide particles was likely to have an impact on the assessment of the density value of those particles and, therefore, on the application of the Morrow calculation to the studies under consideration, given that that value was one of the parameters of that calculation. The RAC was therefore required to take that parameter into consideration for the purposes of that calculation.

121 Nevertheless, and although the General Court stated in paragraph 99 of the judgment under appeal that it was common ground between the parties that the agglomerate density of titanium dioxide particles is lower than that of primary particles, it is apparent from the grounds of that judgment that the RAC Opinion contained nothing which would have enabled the General Court

to conclude that that committee had effectively exercised its discretion and duly taken into consideration that agglomeration phenomenon in order to decide that it was necessary, notwithstanding that difference in density, to adopt a value corresponding to the standard value of primary particles of titanium dioxide.

122 Furthermore, it is apparent from the case-law of the Court of Justice that, notwithstanding the broad discretion enjoyed by the competent EU authorities, the Courts of the European Union have jurisdiction to check that those authorities have not disregarded relevant elements of a reliable study which, if those elements had been taken into account, would have altered the overall assessment of the evidence available to them and would have rendered implausible the final decision that they reached in the contested act (see, to that effect, the judgment of 9 March 2023, *Plastics Europe* v *ECHA*, C-119/21 P, EU:C:2023:180, paragraph 52).

123 Consequently, the uncertainties relating to the agglomeration phenomenon and the density of titanium dioxide particles in the context of the assessment of the Heinrich study, relied on by the Commission and by ECHA, could not relieve the RAC of the obligation to assess that phenomenon and its possible impact on the particle density value to be used in the application of the Morrow calculation to that study, on the basis of the most reliable and recent scientific studies, in order to ensure that the choice of density value ultimately adopted was appropriate. Nor could those uncertainties prevent the General Court, ruling on a challenge to that choice based on scientific studies, from verifying whether that committee had fulfilled that obligation.

124 As regards the argument of the Commission and ECHA alleging a desire to facilitate the comparison between the Lee study and the Heinrich study and to avoid introducing a factor of uncertainty in that comparison, those parties have not explained, either before the General Court or before the Court of Justice, how the choice of a density value different from the standard density value of titanium dioxide particles could compromise the reliability of the comparison between those two studies, even if the density value used were more consistent with the available information from the Heinrich study.

125 It follows from the foregoing that, notwithstanding the fact that the General Court erred in finding that, in the present case, it was for it to assess the appropriateness of the choice of the standard density value of titanium dioxide particles used by the RAC for the purposes of applying the Morrow calculation, it did not err in law in holding that the RAC had failed to take into account all the relevant factors in order to calculate the lung overload for the purposes of the assessment of the Heinrich study by means of that calculation.

126 In the light of all those considerations, the second grounds of appeal must be rejected.

The third and fourth grounds of appeal in Case C-71/23 P and the third ground of appeal in Case C-82/23 P, alleging a failure to state reasons and an error of law in that the General Court concluded that titanium dioxide was not a 'substance that has the intrinsic property to cause cancer' within the meaning of point 3.6.2.2.1 of Annex I to Regulation No 1272/2008

Arguments of the parties

127 By its third ground of appeal, the French Republic submits that paragraphs 157 and 158 of the judgment under appeal are vitiated by a failure to state reasons. In that regard, the French Republic notes that, while the General Court found, in paragraph 158 of that judgment, that 'one

of the key elements of the toxicity observed' was the quantity of inhaled particles, it relied exclusively on that fact in order to conclude that the mode of action for carcinogenicity of titanium dioxide particles did not point to an intrinsic property to cause cancer. In order to reach that conclusion, the General Court should necessarily have had to examine all the 'key elements of the toxicity observed' and not just one of them.

128 The French Republic, by its fourth ground of appeal, and the Commission, by its third ground of appeal, supported by the Kingdom of Sweden and by ECHA, submit that the General Court erred in law by misinterpreting the concept of 'intrinsic properties' of a substance in the light of the scheme and objectives of Regulation No 1272/2008.

129 The French Republic submits, first, that the General Court's reasoning, in particular paragraph 158 of that judgment, is based on the premiss that a substance the carcinogenicity of which manifests itself in the presence of a certain quantity of inhaled particles cannot be regarded as having the intrinsic property to cause cancer. That premiss is both artificial and erroneous. Second, that reasoning is not consistent with the objective of Regulation No 1272/2008, set out in recital 1 and Article 1(1) thereof, of ensuring a high level of protection of human health and the environment. Lastly, paragraph 141 of the judgment under appeal is based on a misinterpretation of the judgment of 21 July 2011, *Nickel Institute* (C-14/10, EU:C:2011:503).

130 For its part, in the context of the first part of its third ground of appeal, the Commission claims that the General Court's interpretation of the concept of 'intrinsic properties', in paragraphs 135 to 142 of the judgment under appeal, does not take sufficient account of the context and purpose of Regulation No 1272/2008 and infringes the precautionary principle. In the light of that contextual and teleological interpretation, it should be considered that the chemical composition of a substance is not necessarily sufficient to determine its intrinsic properties, which may lead to its classification as a hazardous substance. In particular, the specific form or physical state in which the substance in question is placed on the market could itself have such properties requiring that classification in order to ensure that users are fully protected. That is the case here, having regard to the retention and poor solubility of titanium dioxide. In addition, the Commission submits that the failure to take into consideration the carcinogenic effects of a substance in the context of its harmonised classification and labelling limits the provision of information on that basis and the ability of users to take appropriate precautions and prevents the application of other legislative acts based on risk assessment.

131 Furthermore, the Commission disputes the relevance of the distinction made by the General Court, in paragraph 166 of the judgment under appeal, between the provisions of Regulation No 1272/2008 applicable in the context of self-classification and the provisions applicable to harmonised classification and labelling.

132 By the second part of its third ground of appeal, the Commission submits that, in paragraphs 157 to 160 of the judgment under appeal, the General Court erred in law by confusing the relevance of the quantity of inhaled particles and the associated mode of action for carcinogenicity of titanium dioxide particles, on the one hand, with the concept of 'intrinsic properties', on the other, which refers, in the present case, to the form and retention and poor solubility of the substance in question. The General Court thus failed to take account of point 3.6.1.1 of Annex I to Regulation No 1272/2008.

133 CWS and Others and Billions Europe and Others dispute the merits of that line of argument.

– Findings of the Court

134 According to settled case-law, complaints directed against the grounds included in a decision of the General Court purely for the sake of completeness cannot lead to that decision being annulled and are therefore ineffective (judgment of 10 November 2022, *Laboratoire Pareva* v *Commission*, C-702/21 P, EU:C:2022:870, paragraph 52 and the case-law cited).

135 In the present case, it should be noted that, in paragraph 122 of the judgment under appeal, the General Court upheld the first part of the first complaint, alleging manifest errors of assessment as regards the acceptability and reliability of the Heinrich study. In paragraph 123 of that judgment, however, it stated that, 'in the interests of the sound administration of justice', it was appropriate to continue the examination of the action and to give a ruling on the second part of that first complaint, alleging that the contested classification and labelling did not cover a substance that has the intrinsic property to cause cancer, 'in order to provide a complete resolution of the dispute'.

136 It follows that the third and fourth grounds of appeal in Case C-71/23 P and the third ground of appeal in Case C-82/23 P, which concern the considerations on which the General Court relied in its examination of that second part of the first complaint, are directed against considerations included in the judgment under appeal purely for the sake of completeness and must, consequently, be rejected as ineffective.

137 It follows from all of the foregoing that the two appeals must be dismissed.

Costs

138 Under Article 184(2) of the Rules of Procedure, where the appeal is unfounded, the Court is to make a decision as to the costs.

139 Article 138(1) of those rules, applicable to appeal proceedings pursuant to Article 184(1) thereof, provides that the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

140 In the present case, since CWS and Others and Billions Europe and Others have applied for costs against the French Republic and the Commission and the latter have been unsuccessful, they must be ordered to bear their own costs and to pay those incurred by CWS and Others and by Billions Europe and Others in connection with Cases C-71/23 P and C-82/23 P.

141 Under Article 184(4) of the Rules of Procedure, the Court may decide that an intervener at first instance who takes part in the appeal proceedings is to bear its own costs.

142 In the present case, the Kingdom of the Netherlands, the Kingdom of Sweden, ECHA and Cefic and Others must be ordered to bear their own costs.

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

1. Dismisses the appeals;

2. **Orders the French Republic to bear its own costs and to pay the costs incurred by CWS Powder Coatings GmbH, Brillux GmbH & Co. KG, Daw SE, 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 and by Sto SE & Co. KGaA in Case C-71/23 P;**

3. **Orders the European Commission to bear its own costs and to pay the costs incurred by CWS Powder Coatings GmbH, Brillux GmbH & Co. KG, Daw SE, 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 and by Sto SE & Co. KGaA in Case C-82/23 P;**

4. **Orders the Kingdom of Netherlands, the Kingdom of Sweden, the European Chemicals Agency (ECHA), the Conseil Européen de l'Industrie Chimique – European Chemical Industry Council (Cefic), the Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art (CEPE), British Coatings Federation Ltd (BCF) and American Coatings Association, Inc. (ACA) to bear their own costs.**

Arastey Sahún Gratsias Passer

Smulders Fenger

Delivered in open court in Luxembourg on 1 August 2025.

A. Calot Escobar
Registrar

M.L. Arastey Sahún
President of the Chamber