Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

9 November 2023 *

(Appeal – Regulation (EC) No 1907/2006 (REACH Regulation) – Registration, evaluation, authorisation and restriction of chemicals – Annex XVII – Updating – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles – Restrictions concerning octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) – Persistent, bioaccumulative and toxic substances – Very persistent and very bioaccumulative substances – Unacceptable risks)

In Case C-558/21 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 8 September 2021,

Global Silicones Council, established in Washington, DC (United States),

Wacker Chemie AG, established in Munich (Germany),

Momentive Performance Materials GmbH, established in Leverkusen (Germany),

Shin-Etsu Silicones Europe BV, established in Almere (Netherlands),

Elkem Silicones France SAS, established in Lyon (France),

represented initially by A. Bartl, advokát, R. Cana, avocat, A. Kołtunowska, adwokat, and E. Mullier, avocate, and subsequently by A. Bartl, advokát, R. Cana and E. Mullier, avocats,

appellants,

the other parties to the proceedings being:

European Commission, represented by R. Lindenthal and K. Mifsud-Bonnici, acting as Agents,

defendant at first instance,

Federal Republic of Germany, represented initially by J. Möller and D. Klebs, acting as Agents, and subsequently by J. Möller, acting as Agent,

United Kingdom of Great Britain and Northern Ireland,

* Language of the case: English.

European Parliament,

Council of the European Union,

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

American Chemistry Council Inc. (ACC), established in Washington, represented initially by A. Moroni, avocate, B. Natens, advocaat, and K. Nordlander, advokat, and subsequently by S. De Knop, advocaat, A. Moroni, avocate, and B. Natens, advocaat, and finally by S. De Knop, advocaat, and A. Moroni, avocate,

interveners at first instance,

THE COURT (Fourth Chamber),

composed of C. Lycourgos, President of the Chamber, O. Spineanu-Matei (Rapporteur), J.-C. Bonichot, S. Rodin, and L.S. Rossi, Judges,

Advocate General: J. Kokott,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 20 April 2023,

gives the following

Judgment

1 By their appeal, Global Silicones Council, Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV and Elkem Silicones France SAS (together, 'the appellants') seek to have set aside the judgment of the General Court of the European Union of 30 June 2021, *Global Silicones Council and Others v Commission* (T-226/18, EU:T:2021:403; 'the judgment under appeal'), by which the latter dismissed their action seeking annulment of Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5') (OJ 2018 L 6, p. 45; 'the regulation at issue').

Legal context

The REACH Regulation

2 Article 13(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and corrigendum OJ 2007 L 136, p. 3), as amended by Commission Regulation (EU) No 2017/1510 of 30 August 2017 (OJ 2011 L 224, p. 110) ('the REACH Regulation'), provides:

'Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a [European] Commission Regulation or in accordance with other international test methods recognised by the Commission or the [European Chemicals Agency (ECHA)] as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.'

3 Under Article 57(d) and (e) of that regulation:

'The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

…

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII [to] this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII [to] this Regulation'.

4 Title VIII of the REACH Regulation, headed 'Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles', comprises Articles 67 to 73 of that regulation.

5 Article 68 of the REACH Regulation, headed 'Introducing new and amending current restrictions', provides, in paragraph 1 thereof:

'When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

…'

6 Article 69 of that regulation, headed ‘Preparation of a proposal’, provides:

‘1. If the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask [ECHA] to prepare a dossier which conforms to the requirements of Annex XV.

…

4. If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify [ECHA] that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. …

…’

7 Under Article 70 of the regulation, headed ‘[ECHA] opinion: Committee for Risk Assessment’, ‘… the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier’.

8 Article 71 of the REACH Regulation, headed ‘[ECHA] opinion: Committee for Socio-economic Analysis’, provides, in paragraph 1 thereof:

‘…the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. …’

9 Under the heading ‘Submission of an opinion to the Commission’, Article 72 of that regulation provides, in paragraph 1 thereof:

‘[ECHA] shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on restrictions suggested for substances on their own, in mixtures or in articles. …’

10 Article 73 of that regulation, headed ‘Commission decision’, provides, in paragraph 1 thereof:

‘1. ‘If the conditions laid down in Article 68 are fulfilled, the Commission shall prepare a draft amendment to Annex XVII, …

Where the draft amendment diverges from the original proposal or if it does not take the opinions from [ECHA] into account, the Commission shall annex a detailed explanation of the reasons for the differences.

2. A final decision shall be taken in accordance with the procedure referred to in Article 133(4). The Commission shall send the draft amendment to the Member States at least 45 days before voting.’

11 Annex I to the REACH Regulation, as amended by Commission Regulation (EU) No 252/2011 of 15 March 2011 (OJ 2011 L 69, p. 3) ('Annex I'), headed 'General provisions for assessing substances and preparing chemical safety reports', is worded as follows:

'0. Introduction

…

0.6. Steps of a chemical safety assessment

0.6.1. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps 1 to 4 in accordance with the respective sections of this Annex:
1. Human health hazard assessment.
2. Human health hazard assessment of physicochemical properties.
3. Environmental hazard assessment.
4. PBT and vPvB assessment.

0.6.2. In the cases referred to in point 0.6.3 the chemical safety assessment shall also include the following steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:
5. Exposure assessment.
5.1. The generation of exposure scenario(s) (or the identification of relevant use and exposure categories, if appropriate).
5.2. Exposure estimation.
6. Risk characterisation.

0.6.3. Where as a result of steps 1 to 4 the manufacturer or importer concludes that the substance is assessed to be [persistent, bioaccumulative and toxic (PBT)] or [very persistent and very bioaccumulative (vPvB)], the chemical safety assessment shall also include steps 5 and 6 in accordance with Sections 5 and 6 of this Annex:

…

4. PBT and VPVB assessment

4.0. Introduction

4.0.1. The objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. A hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XIII. Therefore, a separate PBT and vPvB assessment is required.

4.0.2. The PBT and vPvB assessment shall comprise the following two steps, which shall be clearly identified as such in Part B, Section 8 of the Chemical Safety report …:

Step 1: Comparison with the Criteria.

Step 2: Emission Characterisation.

…

4.1. Step 1: Comparison with the criteria

This part of the PBT and vPvB assessment shall entail the comparison of the available information with the criteria given in Section 1 of Annex XIII and a statement of whether the substance fulfils or does not fulfil the criteria. The assessment shall be conducted in accordance with the provisions laid down in the introductory part of Annex XIII as well as Sections 2 and 3 of that Annex.

4.2. Step 2: Emission Characterisation.

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. …

…

6. Risk characterisation

…

6.3. The risk characterisation consists of:

– a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL [(Derived No-Effect Level – levels of exposure to the substance above which humans should not be exposed)];

– a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs [(predicted no-effect concentration – the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur)], and

– an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.4. For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

– the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and,

– the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

6.5. For those human effects and those environmental spheres for which it was not possible to determine … a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

…'

12 Annex XIII to the REACH Regulation ('Annex XIII'), headed 'Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances', lays down the criteria for the identification of persistent, bioaccumulative and toxic substances ('PBT substances'), and very persistent and very bioaccumulative substances ('vPvB substances'), as well as the information that must be considered for the purpose of assessing the P (persistent), B (bioaccumulative) and T (toxic) properties of a substance.

13 Annex XV to the REACH Regulation ('Annex XV') 'lays down the general principles for preparing dossiers to initially propose and justify … the identification of … PBTs, vPvBs … [and] restrictions of the manufacture, placing on the market or use of a substance within the Community'.

Regulation (EU) No 253/2011

14 On 15 March 2011, the Commission adopted Regulation (EU) No 253/2011 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 Annex XIII (OJ 2011 L 69, p. 7).

15 Recitals 5 and 6 of Regulation No 253/2011 state:

'(5) Experience shows that, for the adequate identification of PBT and vPvB substances, all relevant information should be used in an integrated manner and applying a weight-of-evidence approach by comparing the information to the criteria set out in Section 1 of Annex XIII.

(6) A weight-of-evidence determination is particularly relevant in cases where the application of the criteria set out in Section 1 of Annex XIII to the available information is not straightforward.'

16 Annex XIII, as amended by Regulation No 253/2011, states in the preamble thereto:

'This Annex lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

For the identification of PBT substances and vPvB substances a weight-of-evidence determination using expert judgement shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1. This shall be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information.

A weight-of-evidence determination means that all available information bearing on the identification of a PBT or a vPvB substance is considered together, such as the results of monitoring and modelling, suitable in vitro tests, relevant animal data, information from the application of the category approach (grouping, read-across), (Q)SAR [(qualitative or quantitative structure-activity relationship)] results, human experience such as occupational data and data from accident databases, epidemiological and clinical studies and well documented case reports and observations. The quality and consistency of the data shall be given appropriate weight. The available results regardless of their individual conclusions shall be assembled together in a single weight-of-evidence determination.

The information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions.

The identification shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation and/or degradation products.

This Annex shall apply to all organic substances, including organo-metals.'

17 Points 1.1.2. And 1.2.2. of Annex XIII, as amended by Regulation No 253/2011, are worded as follows:

'1.1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor in aquatic species is higher than 2 000.

…

1.2.2. Bioaccumulation

A substance fulfils the "very bioaccumulative" criterion (vB) when the bioconcentration factor in aquatic species is higher than 5 000.'

18 Under points 3.2. and 3.2.2. of Annex XIII, as amended by Regulation No 253/2011:

'3.2. Assessment Information

The following information shall be considered for the assessment of P, vP [(very persistent)], B, vB and T properties, using a weight-of-evidence approach.

…

3.2.2. Assessment of B or vB properties:

(a) Results from a bioconcentration or bioaccumulation study in aquatic species;

(b) Other information on the bioaccumulation potential provided that its suitability and reliability can be reasonably demonstrated, such as:

– Results from a bioaccumulation study in terrestrial species;

…

(c) Information on the ability of the substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors.'

Regulation (EC) No 440/2008

19 On 30 May 2008, the Commission adopted, pursuant to Article 13(3) of the REACH Regulation, Regulation (EC) No 440/2008 (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ 2008 L 142, p. 1).

20 Section C.13 of the Annex to Regulation No 440/2008, as amended by Commission Regulation (EU) 2017/735 of 14 February 2017 (OJ 2017 L 112, p. 1), concerns 'bioaccumulation in fish:

21 The first paragraph of the introduction to that Section C.13 is worded as follows:

'This test method is equivalent to [Organisation for Economic Co-operation and Development (OECD)] test guideline (TG) 305 (2012). The major goal of this revision of test method is two-fold. Firstly, it is intended to incorporate a dietary bioaccumulation test suitable for determining the bioaccumulation potential of substances with very low water solubility. …'

Background to the dispute

22 The background to the dispute is set out in paragraphs 9 to 20 of the judgment under appeal in the following terms:

'9 … Global Silicones Council … is a non-stock corporation, established in the United States, representing companies which manufacture and sell silicone products throughout the world. … … Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV and Elkem Silicones France SAS … are companies established in the European Union which manufacture, sell and supply silicone products, in particular the chemical substances octamethylcyclotetrasiloxane ("D4") and decamethylcyclopentasiloxane ("D5").

10 On 1 October 2014, the competent authority of the United Kingdom of Great Britain and Northern Ireland submitted to [ECHA] parts of a dossier based on Annex XV … relating to the PBT and vPvB properties of D4 and D5.

11 On 14 October 2014, the Executive Director of ECHA requested the ECHA Member State Committee ("the MSC") to prepare an opinion on the persistence and bioaccumulation of D4 and D5 against the criteria in Annex XIII.

12 Between 15 October and 1 December 2014, a public consultation took place regarding the documents provided by the United Kingdom relating to the PBT and vPvB properties of D4 and D5.

13 On 17 April 2015, the United Kingdom submitted to ECHA a dossier prepared in accordance with Annex XV ("Annex XV dossier") proposing a restriction on the use of D4 and D5 in cosmetic products that were washed off in normal conditions of use. According to that dossier, action on a Union-wide basis was necessary to address the risks to the environment posed by the use of D4 and D5 when discharged into waste water.

14 On 22 April 2015, the MSC adopted an opinion ("the opinion of the MSC") according to which both D4 and D5 met the criteria set out in Annex XIII regarding the identification of vP and vB substances.

15 Between 18 June and 18 December 2015, a public consultation took place on the envisaged restriction of the use of D4 and D5. As part of that public consultation, the applicants provided comments and submitted evidence.

16 On 10 March 2016, the ECHA Committee for Risk Assessment ("the RAC") adopted an opinion concluding, on the one hand, that D4 met the criteria set out in Annex XIII for the identification of PBT substances and vPvB substances and, on the other, that D5 met the criteria for the identification of vPvB substances ("the opinion of the RAC"). The RAC confirmed that the hazard properties of D4 and D5 gave rise to specific concerns for the environment when those substances were present in cosmetic products used or disposed of with water. It also concluded that the proposed restriction was a targeted and appropriate EU-wide measure to minimise emissions of the substances at issue caused by wash-off products.

17 On 11 March 2016, the ECHA Committee for Socio-economic Analysis ("the SEAC") in turn adopted a draft opinion. A public consultation took place between 16 March and 16 May 2016. On 9 June 2016, the SEAC adopted its final opinion, indicating that the proposed restriction was the most appropriate Union-wide measure for reducing the discharge of D4 and D5 to waste water in terms of its socio-economic benefits and costs ("the opinion of the SEAC"). …

18 On 10 August 2016, ECHA submitted the opinions of the RAC and the SEAC to the Commission.

19 On 10 May 2017, the Commission submitted its proposal for a regulation for consideration by the Committee established by Article 133 of [the REACH Regulation].

20 On 10 January 2018 the Commission adopted the [regulation at issue]. That regulation provides that neither D4 nor D5 is to be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0.1% by weight of either substance, after 31 January 2020.'

The procedure before the General Court and the judgment under appeal

23 By application lodged at the Registry of the General Court on 2 April 2018, the appellants, applicants at first instance, brought an action for annulment of the regulation at issue.

24 By decision of the President of the Fifth Chamber of the General Court of 5 September 2018, the Federal Republic of Germany, the United Kingdom, the European Parliament and the Council of the European Union were granted leave to intervene in support of the form of order sought by the Commission.

25 By order of 25 October 2018, the President of the Fifth Chamber of the General Court granted ECHA leave to intervene in support of the form of order sought by the Commission.

26 By order of 13 December 2018, the President of the Fifth Chamber of the General Court granted the American Chemistry Council Inc. (ACC) leave to intervene in support of the forms of order sought by the applicants.

27 In support of their action, the appellants relied on eight pleas in law, alleging (i) manifest errors of assessment; (ii) infringement of the principle of proportionality, in that the regulation at issue was neither appropriate nor necessary, did not constitute the least onerous measure and caused disadvantages which were disproportionate to the aims pursued; (iii) breach of essential procedural requirements, in particular in that the Commission 'never adequately or sufficiently considered or reviewed the fundamental basis for the [regulation at issue]' and that the RAC – and not the MSC – should have assessed all the underlying factors and justifications for the restriction established by the regulation at issue; (iv) breach of the principle of legal certainty and of the principle of legitimate expectations; (v) breach of the institutional balance of powers, in that ECHA 'made law' in reaching a conclusion on the B and vB properties of D4 and D5, outside and independently of the applicable law; (vi) breach of the principle of good administration, in particular in that the Commission and ECHA breached the requirement to ensure that administrative procedures in risk assessments ensure scientific objectivity and preclude arbitrary measures; (vii) breach of the rights of the defence and of the right to be heard; and (viii) breach of the obligation to state the reasons for the regulation at issue.

28 By the judgment under appeal, the General Court rejected each of the pleas in law relied upon and, accordingly, dismissed the action in its entirety.

Forms of order sought by the parties before the Court of Justice

29 By their appeal, the appellants, supported by the ACC, claim that the Court should:

– set aside the judgment under appeal;

– annul the regulation at issue;

– alternatively, refer the case back to the General Court to rule on the application for annulment;

– order the Commission to pay the costs of the present proceedings, including the costs of the proceedings before the General Court.

30 The Commission, supported by the Federal Republic of Germany and ECHA, contends that the Court should:

– dismiss the appeal; and

– order the appellants to pay the costs.

The appeal

31 In support of their appeal, the appellants rely on five grounds of appeal:

– first, error on the part of the General Court in that (i) it found that the Commission had not infringed Article 68(1) of the REACH Regulation by failing explicitly to make a finding of unacceptable risk, and (ii) it failed to determine a critical probability threshold for adverse effects that are deemed unacceptable for society;

– second, error on the part of the General Court in that it found that the Commission had not failed to state reasons for its decision that the risks associated with D4 and D5 in wash-off products were unacceptable;

– third, error on the part of the General Court in that it found that the uncertainty in the assessment of PBT or vPvB substances justified an approach whereby emissions from a substance can be a proxy for risk;

– fourth, misinterpretation of Annex XIII and of Regulation No 253/2011, in that the General Court ruled that bioconcentration factor ('BCF') data has 'certain priority' or 'greater weight' than other data for the assessment of B/vB properties;

– fifth, misinterpretation of Annex XIII, in that the General Court ruled that ECHA did not manifestly err by failing to take into account the relevance of the hybrid nature of D4 and D5.

The second ground of appeal

Arguments of the parties

32 By their second ground of appeal, which it is appropriate to examine in the first place, the appellants, supported by the ACC, submit that the General Court wrongly ruled that the Commission had not breached the obligation to state reasons, under the second paragraph of Article 296 TFEU, by failing to mention, in the regulation at issue, that the risks associated with D4 and D5 in certain wash-off products were 'unacceptable', within the meaning of Article 68(1) of the REACH Regulation.

33 According to the appellants, while recitals 8 and 9 of the regulation at issue refer, with regard to the use of D4 and D5, to the existence of a risk, they do not state that those risks are unacceptable. The reference to the Annex XV dossier, and the opinions of the MSC, RAC and SEAC, cannot equate to a statement of reasons, in so far as the EU legislature did not charge those committees with the responsibility to make the ultimate determination of whether the risks were unacceptable. Furthermore, even if the Commission were entitled to make an implicit determination as to risk, the regulation at issue is vitiated by a failure to state reasons and consequently cannot meaningfully be the subject of a judicial review.

34 The appellants challenge paragraph 187 of the judgment under appeal, in that it may be inferred from that paragraph, in their submission, that the Commission fulfilled its obligation to state reasons by the simple fact of having issued the regulation at issue.

35 The appellants submit that the General Court wrongly held, in paragraph 204 of the judgment under appeal, that 'it does not follow from the case-law that the Commission should have used the expression "unacceptable risk"' and claim that the obligation to use that expression follows directly from Article 68(1) of the REACH Regulation.

36 By accepting that the Commission was entitled to carry out an implicit risk assessment, the General Court upheld the view that, where a decision follows the opinion of a scientific body, the content of that opinion, referred to in the recitals of that decision, is an integral part of the statement of reasons for that decision. The appellants submit that it is incorrect to consider that ECHA can carry out an assessment of whether a risk is unacceptable and that the Commission can simply make implicit reference to that assessment.

37 The General Court's assertion, in paragraph 337 of the judgment under appeal, that the absence of the term 'unacceptable' does not affect the ability of the persons concerned to understand the full significance of and the reasons for that regulation are, in the appellants' view, in clear contradiction with the requirements arising from the obligation to state reasons.

38 The Commission, supported by the Federal Republic of Germany, and ECHA, submits that the appellants' arguments are unfounded.

Findings of the Court

39 It should be observed that the appellants criticise, by relying on an infringement of the second paragraph of Article 296 TFEU, the manner in which the General Court addressed, in particular in paragraphs 187, 204 and 337 of the judgment under appeal, the criticisms alleging the absence of the term 'unacceptable', within the meaning of Article 68(1) of the REACH Regulation, in the regulation at issue.

40 In that connection, it should be recalled that the question whether the statement of reasons is sufficient must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (judgment of 29 September 2022, *ABVL Bank* v *SRB*, C-202/21 P, EU:C:2022:734, paragraph 193 and the case-law cited).

41 In the present case, it should be noted that, after setting out, in paragraphs 327 to 331 of the judgment under appeal, the scope of the obligation to state reasons which is incumbent on the institution which adopted the act concerned, the General Court examined, in paragraph 337 of that judgment, the appellants' complaint as to the absence of the term 'unacceptable' in the regulation at issue, in relation to the risk to the environment posed by the presence of D4 and D5 in certain cosmetic products.

42 It found that the absence of that term in that regulation did not affect the ability of the persons concerned to understand the full significance of and the reasons for that regulation, or on the ability of the EU judicature to exercise its power of review. In order to do so, the General Court referred to paragraph 204 of the judgment under appeal, from which it is clear that it follows from recitals 8 and 9 as well as from the legal basis of the regulation at issue that the Commission

implicitly but necessarily regarded the risks associated with the presence of D4 and D5 in certain cosmetic products as constituting an unacceptable risk to the environment. That same finding is also apparent from paragraph 187 of that judgment.

43 Furthermore, in paragraph 338 of that judgment, the General Court held that it was appropriate to take account of the reasons provided in the documents in the Annex XV dossier as well as the opinions of the MSC, the RAC and the SEAC – which are public – the findings of which were followed by the Commission when drafting the regulation at issue, as is apparent from recitals 1, 3 to 5 and 7 of that regulation.

44 Accordingly, the General Court was able, without erring in law, to infer from the elements referred to in paragraphs 42 and 43 of the present judgment that the absence of the terms 'unacceptable risk' in the regulation at issue did not constitute a gap in the statement of reasons for that regulation, since it follows from both the wording and the context of that regulation that the Commission had necessarily to consider the risks associated with the presence of D4 and D5 in certain wash-off products as unacceptable risks.

45 It follows that the second ground of appeal must be rejected as unfounded.

The first ground of appeal

First part of the first ground of appeal

– *Arguments of the parties*

46 By the first part of the first plea in law, the appellants, supported by the ACC, complain that the General Court infringed Article 68(1) of the REACH Regulation by endorsing the approach taken by the Commission, which consists in implicitly determining the existence of unacceptable risks to human health or to the environment, within the meaning of that provision, and endorsing the findings in the opinions of the MSC, the RAC and the SEAC without carrying out its own assessment of whether those risks were unacceptable.

47 In the first place, in the appellants' submission, it is apparent from a combined reading of Article 68(1), Article 69(1) and (4), and Article 70 of the REACH Regulation that neither ECHA, the RAC nor the Member States are empowered to classify such a risk as unacceptable. According to the appellants, in the present case, although the submitter of the Annex XV dossier states that 'mere emissions and subsequent exposure, in the case of a PBT or vPvB substance, can be considered as a proxy for unacceptable risk', the word 'unacceptable' was not mentioned either in the opinion of the RAC or in that of the SEAC, which demonstrates that those committees are not deemed competent to classify the risk.

48 Such a classification is the result of a political decision made by the Commission, in accordance with the procedure laid down in Article 133(4) of the REACH Regulation. The Commission cannot, in the appellants' view, rely on Annex I for the 'unacceptable risk' assessment, since that annex does not relate to the assessment of such a risk. The General Court therefore erred in law by finding, in paragraph 192 of the judgment under appeal, that '[the] principles established in Annex I apply not only to the Annex XV dossier, but also in the context of the subsequent steps of the process of adopting a restriction'.

49 The appellants submit that there is no legal basis for the General Court to state that the Commission is bound by the principles established in Annex I in its risk assessment under Article 68(1) of the REACH Regulation. The General Court disregarded the fact that the step laid down in that provision, and that laid down in Article 69 of that regulation, are two separate steps, each having a different legal basis, and in the context of which different principles are applied.

50 In the second place, the appellants submit that the General Court contradicted itself in paragraphs 192, 199 and 217 of the judgment under appeal, by stating, on the one hand, that the principles laid down in Annex I apply during all the steps of the process of adopting a restriction and, on the other hand, that the concept of 'unacceptable risk', referred to in Article 68(1) of the REACH Regulation, is different to that of 'risk that is not adequately controlled and needs to be addressed' referred to in Article 69 of that regulation, and that the Commission was not required to carry out a fresh scientific assessment comparable to that carried out by the stakeholders to which that regulation expressly entrusted that task.

51 Thus, contrary to what is apparent from the judgment under appeal, the Commission failed to fulfil its obligation, under Title VIII of the REACH Regulation, to determine whether the use of D4 and D5 in wash-off products presents an unacceptable risk, within the meaning of Article 68(1) of that regulation, since a mere reference to the risk assessment conducted by the RAC pursuant to Article 69 of that regulation is not sufficient. As a consequence, the General Court wrongly found that an implicit determination of the risk is allowed.

52 The Commission, supported by the Federal Republic of Germany and ECHA, contends that the appellants' arguments are unfounded.

– *Findings of the Court*

53 In the first place, it should be recalled that, under Article 68(1) of the REACH Regulation, the adoption of a new restriction in so far as concerns the manufacture, use or placing on the market of substances is to be based on the finding by the Commission of an unacceptable risk to human health or the environment arising from such substances, which needs to be addressed on an EU-wide basis, and is to take into account the socio-economic impact of the restriction, including the availability of alternatives.

54 Under Article 69 of that regulation, the process for adopting a new restriction starts with the preparation of an Annex XV dossier if the Commission or a Member State considers there to be a risk that is not adequately controlled and needs to be addressed. In accordance with Article 70 of that regulation, the RAC is to take a view on whether the restriction is appropriate in reducing the risk to human health or the environment and, according to Article 71(1) of that regulation, the SEAC is to give an opinion on the suggested restrictions, relying in particular on the socio-economic impact of those restrictions. ECHA is to submit the opinions of the RAC and the SEAC to the Commission, pursuant to Article 72(1) of the REACH Regulation, and the latter is to prepare a draft amendment to Annex XVII of that regulation, in accordance with the first subparagraph of Article 73(1) of that regulation.

55 It is clear from those provisions that, while the determination of the unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of a substance falls within the scope of the Commission's discretion, that determination is based, inter alia, on the opinions issued by the RAC and the SEAC. As the Commission argues in its rejoinder,

that determination is the result of a single administrative procedure in which different stakeholders prepare scientific opinions once a public consultation has been held, in order to prepare the final decision.

56 Consequently, the General Court rightly ruled, in paragraph 192 of the judgment under appeal, that the principles established in Annex I apply not only to the Annex XV dossier, but also in the context of the subsequent steps of the process for adopting a restriction, within the meaning of Article 68(1) of the REACH Regulation. As the Advocate General also argues in point 55 of her Opinion, the appellants therefore cannot maintain that the Commission could not rely on Annex I for the purposes of assessing whether the risk is unacceptable, within the meaning of that provision.

57 In the second place, contrary to the appellants' submission, a reading of paragraphs 192, 199 and 217 of the judgment under appeal shows no contradiction. Thus, the finding, in paragraph 192 of that judgment, that the principles established in Annex I apply during all the steps in the process for adopting a restriction, is not contradicted by the distinction, made in paragraph 199 of that judgment, between a risk that is not adequately controlled, within the meaning of Article 69 of the REACH Regulation, and an unacceptable risk, within the meaning of Article 68 of that regulation. The preparation of an Annex XV dossier, along with the opinions of the MSC, the RAC and the SEAC, are all intended to furnish the Commission with essential scientific information so as to allow it to classify the risk. While the Commission is required to carry out such a classification, it does not follow from Article 68(1) of that regulation – as the General Court rightly held in paragraph 217 of the judgment under appeal – that the Commission ought to carry out a new scientific assessment comparable to that carried out by the stakeholders to which the REACH Regulation entrusted that task.

58 Lastly, in so far as the appellants rely on the absence of an express finding, in the regulation at issue, as to the existence of an 'unacceptable risk', and infer therefrom that the Commission failed to determine whether the use of D4 and D5 in wash-off cosmetic products presents such a risk, it is sufficient to recall, as has been set out in paragraph 44 of the present judgment, that it is clear from both the wording and the context of that regulation that the Commission had necessarily to regard the risk associated with the presence of D4 and D5 in certain wash-off cosmetic products as an unacceptable risk.

59 It follows that the first part of the first ground of appeal must be rejected as unfounded.

The second part of the first ground of appeal

– *Arguments of the parties*

60 According to the appellants, supported by the ACC, as is apparent from the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209, 'the judgment in *Pfizer*', paragraph 151), the Commission should have established a critical probability threshold for adverse effects which are not acceptable for human health or the environment, irrespective of whether the assessment of that threshold should be quantitative or qualitative. In paragraphs 185 and 202 of the judgment under appeal, the General Court rejected the application of the judgment in *Pfizer*.

61 The appellants submit that the procedure intended to establish a restriction under the REACH Regulation comprises – as does the risk assessment carried out in the light of the precautionary principle at issue in the case which gave rise to the judgment in *Pfizer* – two steps, the first relating to the scientific identification of the risk, the second intended to determine whether the risk thus identified is acceptable to society. The determination of the 'level of risk deemed unacceptable' that was made by the Court of First Instance in the judgment in *Pfizer* is therefore fully applicable to the determination as to whether the risk is unacceptable for the purposes of Article 68(1) of the REACH regulation. By declining to proceed as per the judgment in *Pfizer*, the General Court misapplied EU case-law.

62 Consequently, in the appellants' submission, when it determines the 'unacceptable risk' within the meaning of Article 68(1) of the REACH Regulation, the Commission should assess whether the risk identified by the dossier submitter reaches the critical probability threshold for adverse effects, regarded as unacceptable to society.

63 The Commission, supported by the Federal Republic of Germany and ECHA, contends that the appellants' arguments are unfounded.

– *Findings of the Court*

64 As a preliminary point, it should be observed that, in paragraph 151 of the judgment in *Pfizer*, the Court of First Instance held that 'it is for the [EU] institutions to determine the level of protection which they deem appropriate for society [and] determine the level of risk – i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects – which in their judgment is no longer acceptable … and above which it is necessary, in the interests of protecting human health, to take preventive measures …'.

65 While it is true that that paragraph relates to risk assessments in the context of the application of the general precautionary principle, that does not mean that it may be inferred from the judgment in *Pfizer* – which was handed down before the REACH Regulation was adopted – that the determination of the level of risk, which may be regarded as being 'unacceptable' within the meaning of that regulation, must necessarily comprise a quantifiable critical probability threshold for adverse effects.

66 As the Advocate General argues in point 81 of her Opinion, it follows from the Court's settled case-law on the precautionary principle that precautionary measures presuppose, first, identification of the potentially negative consequences and, second, a comprehensive assessment of that risk based on the most reliable scientific data available and the most recent results of international research (see, to that effect, judgments of 28 January 2010, *Commission* v *France*, C-333/08, EU:C:2010:44, paragraph 92, and of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800, paragraph 46). On the other hand, a precise determination of the threshold for still acceptable risk is not required by the Court.

67 In the particular context of PBT and vPvB substances, as the General Court also finds in paragraphs 190, 191 and 202 of the judgment under appeal, specific provisions were laid down by the EU legislature in Annex I for the purposes of complying with the precautionary principle.

68 In that connection, it is apparent from Section 4.0.1. of that annex that, in respect of PBT and vPvB substances, the hazard assessment addressing all the long-term effects, in accordance with Sections 1 and 3 of that annex, and the estimation of the long-term exposure of humans and the

environment as carried out in accordance with Section 5.2 of Annex I, cannot be carried out with sufficient reliability. Section 6.5. of that annex provides that, in respect of substances, such as PBT and vPvB substances, for which it was not possible to determine a concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur (PNEC), 'a qualitative assessment of the likelihood that effects are avoided' is to be carried out.

69 Consequently, the General Court did not err in law by upholding the determination as to whether the risk was unacceptable, within the meaning of Article 68(1) of the REACH Regulation, based on the risk assessment carried out in accordance with Annexes I and XV, the assessment as to whether the restriction is appropriate and of the socio-economic impact of such a restriction in the absence of a critical probability threshold for adverse effects.

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

The third ground of appeal

Arguments of the parties

71 By their third ground of appeal, the appellants, supported by the ACC, submit that paragraph 196 of the judgment under appeal is vitiated by an error of law, in that the General Court found that the uncertainty in the assessment of PBT or vPvB substances justifies an approach whereby their emissions can be considered a proxy for risk. The General Court thus misapplied its own case-law on the concept of 'zero-risk', as it follows from the judgment of 17 May 2018, *Bayer CropScience and Others* v *Commission* (T-429/13 and T-451/13, EU:T:2018:280, paragraphs 116 and 123) and from the judgment in Pfizer (paragraph 152) ('the case-law on the concept of "zero-risk"'), and erred in its interpretation of Annex I.

72 As regards, first, the misapplication of the case-law on the concept of 'zero-risk', the appellants submit that the Commission had no criterion for assessing whether the risk is unacceptable within the meaning of Article 68(1) of the REACH Regulation, other than the finding, put forward by the dossier submitter and corroborated by ECHA, that any emission of a substance is a proxy for risk. Such a finding is tantamount to requiring the existence of a 'zero risk', since only the absence of emissions could be considered acceptable. That finding is, therefore, contrary to that case-law, from which it is apparent, in the appellants' submission, that, when determining the level of risk deemed unacceptable, the adoption of a preventive measure, or, conversely, its withdrawal or relaxation, cannot be made subject to proof of the lack of any risk, in so far as such proof is generally impossible to give in scientific terms since zero risk does not exist in practice.

73 As regards, second, the interpretation of Annex I, the appellants argue that the dossier submitter, the RAC, and the General Court when it upheld the RAC's findings, all misinterpreted that annex since (i) it cannot be inferred from the qualitative risk assessment provided for in Section 6.5. of that annex that all emissions are a proxy for risk, and (ii) the assertion that that qualitative assessment precludes the quantification of risk is unfounded.

74 In so far as concerns, in the first place, the qualitative risk assessment laid down in Annex I, Sections 0.1, 0.3, and 0.5 thereof are intended to assess the risks and establish whether these are adequately controlled, by analysing the potential adverse effects of substances and comparing them with the estimated exposure of humans and the environment to those substances. Such a comparison can only be made on the basis of quantified data. Section 0, headed 'Introduction', of

that annex is of general application, including in respect of PBT or vPvB substances. The appellants submit that that section alone rebuts the conclusions set out by the General Court in paragraphs 190, 191 and 196 of the judgment under appeal, according to which the risk related to PBT and vPvB substances cannot be adequately quantified and controlled, which allowed it to assert that any emission of such substances is a proxy for risk.

75 That assertion on the part of the General Court is also invalidated by a systematic interpretation of Annex I. In respect of PBT or vPvB substances, unlike other substances, Section 4 of that annex requires an assessment specific to those substances – and not a hazard assessment as provided under Sections 1 and 3 of that annex – and emission characterisation (Section 4.2) in addition to the exposure assessment provided for in Section 5 (step 2) of that annex. That exposure assessment must be carried out for PBT or vPvB substances, in so far as Section 7 of Annex I, headed 'Chemical Safety Report Format', includes an 'exposure assessment' amongst the mandatory parts of the chemical safety report, within the meaning of Article 14 of the REACH Regulation, for all substances. In the appellants' submission, since the main purpose of such an exposure assessment is to demonstrate that the risks to human health and the environment are adequately controlled, that assessment requires a quantification of risk in order for it to be demonstrated that the risk is adequately controlled. If it were to be accepted that any emission of a substance is a proxy for risk, it would not be necessary to assess the exposure of humans and the environment to PBT or vPvB substances, and the chemical safety assessment in respect of those substances would be confined to determining whether a substance is a PBT or vPvB substance.

76 According to the appellants, the qualitative risk assessment referred to in Section 6.5 of Annex I includes an assessment on a case-by-case basis of the likelihood that adverse effects are avoided and therefore that the risk is adequately controlled. If it were accepted that any emission of a substance is a proxy for risk, Section 6 of that annex would be meaningless, since it could be inferred from the mere fact that a substance has been identified as a PBT or vPvB substance that the risk cannot be quantified or adequately controlled, without there being any need to carry out an assessment.

77 It is apparent from those sections, in the appellants' view, that if emissions and the likelihood of adverse effects of such substances are minimised, the risk may be regarded as being adequately controlled even if those emissions are not at zero. On account of the specific characteristics of D4 and D5 – such as their solubility, partitioning between compartments, biodilution and lack of potential for biomagnification – the risk assessment suggests that there is no likelihood of adverse effects and that the risk is adequately controlled, which was disregarded by the RAC and the General Court, since both confined themselves to asserting that the emissions of the substances at issue are a proxy for risk.

78 The appellants claim that the reference, made in paragraph 191 of the judgment under appeal, to Article 60(3) and (4) of the REACH Regulation, under which authorisation cannot be granted for PBT and vPvB substances on the ground that the risk to the environment is adequately controlled, does not contradict the arguments set out in paragraphs 74 to 77 of the present judgment. That provision merely reflects the intention of the EU legislature to limit the possibility of applying for an authorisation under Article 60(2) of that regulation for substances with a critical probability threshold for adverse effects.

79 The appellants add that, if it were accepted that any emission of a substance is a proxy for risk, the obligation to implement risk management measures to minimise emissions would be meaningless as, irrespective of those measures, the substance would still be subject to restrictions, given that

zero emission cannot be achieved in practice. By minimising emission and exposure in accordance with Section 6 of Annex I, registrants would have fulfilled the conditions for a PBT or vPvB substance to be legally placed on the market. They should consequently be protected by the principle of legal certainty and be assured that their substance will not be banned simply because that substance still produces emissions.

80 In so far as concerns, in the second place, the General Court's assertion that a qualitative assessment precludes the quantification of the risk, it is argued that this contradicts the content of Annex I. In that connection, the appellants submit that, in order to establish the quantification of the risk presented by PBT or vPvB substances, assessors use the Technical Report by the European Centre for Ecotoxicology and Toxicology of Chemicals (Ecetoc) on the 'Risk Assessment of PBT Chemicals', published in 2005, as supplemented and refined by the Ecetoc Report published in 2011. That report states that the 'risk characterisation' step, which corresponds to that laid down in Section 6 of Annex I, includes a 'qualitative and/or quantitative estimation of the probability, frequency and severity of the known or potential adverse effects occurring'.

81 Thus, the appellants maintain that a qualitative assessment of the risks must, in principle, be based on quantitative data in order to quantify the risk, with the result that the General Court incorrectly stated that the risks associated with the substances concerned in the present case and with PBT or vPvB substances in general could not be quantified adequately.

82 The Commission, supported by the Federal Republic of Germany, and ECHA, takes the view that the appellants' arguments are unfounded. In particular, in so far as concerns the argument referred to in paragraph 80 of the present judgment, which relies on the reference to the Ecetoc report mentioned in that paragraph, the Commission claims that this is a fresh argument that was not raised before the General Court and that the submission thereof at the appeal stage is inadmissible. In any event, that argument is unfounded, since the Ecetoc report is the result of a private initiative, financed by undertakings with an interest in the manufacture and use of chemicals.

83 In their reply, the appellants add that the General Court's interpretation of Annex I, which is challenged as part of the third ground of appeal, also results in an infringement of the fundamental freedom to conduct a business inasmuch as that interpretation does not allow any viable business involving PBT or vPvB substances.

84 The appellants also submit that the arguments based on the Ecetoc documents are not new, and that those documents are intended to illustrate that a qualitative risk assessment in accordance with Section 6.5. of Annex I allows the risk to be quantified.

85 In its rejoinder, the Commission states that the fundamental freedom to conduct a business is not absolute, inasmuch as public authorities are capable of limiting the exercise of economic activity in the public interest.

Findings of the Court

86 By the third ground of appeal, the appellants submit, in essence, that paragraph 196 of the judgment under appeal is vitiated by an error of law, in that the General Court upheld the opinion of the RAC according to which the risks associated with D4 and D5 could not be adequately quantified, since emissions of those substances could be regarded as a proxy for risk.

The appellants take the view that the General Court misapplied the case-law on the concept of 'zero-risk' and that it incorrectly interpreted Annex I in so far as concerns the qualitative risk assessment which, according to the appellants, does not preclude the quantification of that risk.

87 As regards, in the first place, the alleged application of a concept of 'zero-risk', it should be observed, as the Advocate General notes in point 91 of her Opinion, that the appellants' arguments are based on a misunderstanding of the judgment under appeal. In paragraph 196 of that judgment, the General Court stated only that it could not be argued that the regulation at issue is vitiated by a manifest error of assessment on the ground that, like the United Kingdom, the RAC concluded that 'the risks associated with D4 and D5 could not be quantified adequately and that their emissions could be considered as a proxy for risk'.

88 Consequently, first, it should be noted that, in that paragraph 196, it is not stated that 'any' emission is a proxy for risk, but rather it is stated that the respective emissions of the substances concerned examined by the RAC – namely, emissions to the aquatic environment on account of the use of those substances in wash-off cosmetic products – could therefore be regarded as a risk. Second, it should be observed that paragraph 196 of the judgment under appeal forms part of the General Court's examination of the risk assessment, which begins at paragraph 193 of that judgment and ends, in paragraph 200, with the finding that the Commission took account of all of the requisite factors when adopting the regulation at issue. In particular, in paragraph 195 of that judgment, the General Court relied on the explanations provided in the opinion of the RAC in order to justify its finding, in paragraph 196 of the judgment under appeal, that the risks associated with D4 and D5 could not be adequately quantified and their emissions in the environment could be considered as a proxy for risk.

89 Consequently, it is not apparent from paragraph 196 of the judgment under appeal that the General Court upheld a 'zero-risk' approach.

90 As regards, in the second place, the alleged misinterpretation of Annex I, it should be observed that PBT and vPvB substances are subject to specific rules in that annex.

91 Section 0, headed 'Introduction', of that annex provides in Subsection 0.6.3 thereof that where, as a result of the first four steps of the chemical safety assessment, it is concluded that the substances concerned are assessed to be PBT or vPvB substances, that safety assessment is also to include steps 5 (exposure assessment) and 6 (risk characterisation) in accordance with Sections 5 and 6 of that annex.

92 Section 4 of Annex I is headed 'BPT and vPvB Assessment'. Under Subsection 4.0.1 thereof, the objective of the 'PBT and vPvB assessment' is to characterise the potential emissions of substances classified as PBT or vPvB substances. It is apparent from that subsection that, on account of the fact that the hazard assessments relating to long-term effects, laid down in Sections 1 and 3 of Annex I, and the estimation of the long-term exposure of humans and the environment to those substances, laid down in Section 5.2 of that annex, are not sufficiently reliable in respect of those substances, separate assessments are required, namely a comparison with the criteria (Section 4.1.) and an emission characterisation (Section 4.2.). Those assessments are listed in part B, Section 8 of the chemical safety report, for the purposes of Article 14 of the REACH Regulation.

93 Consequently, while, in respect of PBT and vPvB substances, Subsection 0.6.3 requires that an exposure assessment be carried out, for the purposes of Section 5 of Annex I, that subsection must be read in conjunction with Subsection 4.0.1, under which the results obtained after the second step in the exposure assessment (Section 5.2 – Exposure Estimation) are not sufficiently reliable, which is why Section 4.2 provides that an emission characterisation, which comprises the relevant elements of the exposure assessment described in Section 5, is to be carried out.

94 Section 6, headed 'Risk characterisation', contains a subsection 6.5 which is specific to PBT substances, under which a qualitative assessment is to be carried out as to the likelihood that effects are avoided when implementing exposure scenarios for those human effects and those environmental spheres for which it was not possible to determine a PNEC. As was rightly held in paragraph 190 of the judgment under appeal, the PNEC cannot be reliably determined in respect of the long-term effects of PBT or vPvB substances.

95 It is therefore clear from the scheme of Annex I that, in respect of PBT and vPvB substances, the application of specific rules takes precedence. Furthermore, contrary to the appellants' submissions, it is clear from that annex not that the emission characterisation, laid down in Section 4.2 thereof, is additional to the exposure assessment, set out in Section 5 of that annex, but rather that the emission characterisation specific to PTB and vPvB substances includes the relevant elements of the exposure assessment set out in that Section 5, as far as the particularity of those substances allows. As the Commission also contends, in its response, under Section 4.2 of Annex I, only the relevant parts of the exposure assessment set out in that Section 5 apply to PBT or vPvB substances.

96 Consequently, while it follows from the foregoing that Section 5 of Annex I – the purpose of which consists in establishing a quantitative and qualitative estimation of the dose/concentration of a substance to which humans and the environment are or may be exposed – applies to the 'PBT or vPvB assessment' of substances, that does not mean that a quantitative estimation of the risk posed by the substances must of necessity be carried out.

97 As the General Court rightly stated in paragraph 191 of the judgment under appeal, it is not possible to address with sufficient reliability and in a quantitative manner the risks associated with PBT and vPvB substances. That assertion is corroborated by Article 60(3) and (4) of the REACH Regulation, which precludes the grant of an authorisation for the use of PBT and vPvB substances on the ground that the risk to the environment is adequately controlled, since such an authorisation may be granted only where it is demonstrated that the socio-economic advantages outweigh the risk and there are no suitable alternative substances or technologies.

98 As to the argument that the finding of the General Court, in paragraph 191 of the judgment under appeal, could be invalidated by the conclusions of the Ecetoc report, it should be noted, as the Commission submits, that that argument has been raised for the first time on appeal and that, by way thereof, the appellants ask the Court of Justice to carry out a factual examination, which exceeds the scope of its power of review (see, to that effect, judgment of 9 March 2023, *PlasticsEurope* v *ECHA*, C-119/21 P, EU:C:2023:180, paragraph 84 and the case-law cited). That argument is therefore inadmissible.

99 In support of their third ground of appeal, the appellants also rely on an infringement of the principle of legal certainty and submit that they complied with the requirements laid down by the REACH Regulation in order to minimise emission and exposure in accordance with Section 6 of Annex I, and that they thereby satisfied the requisite conditions for the use of the substances

concerned. In that connection, it should be recalled that the principle of legal certainty requires that EU rules enable those concerned to know precisely the extent of the obligations which are imposed on them, and that those persons must be able to ascertain unequivocally what their rights and obligations are and take steps accordingly (judgment of 29 March 2011, *ArcelorMittal Luxembourg* v *Commission* and *Commission* v *ArcelorMittal Luxembourg and Others*, C-201/09 P and C-216/09 P, EU:C:2011:190, paragraph 68 and the case-law cited). However, reliance on an infringement of the REACH Regulation before the General Court and the claim that the substances concerned meet the requisite conditions for their placement on the market were not sufficient for the appellants to succeed. Acceptance of the position defended by the appellants would suppose that, in all the situations in which registrants take the necessary steps to minimise emissions of a substance, the use thereof be authorised irrespective of the fact that a risk deemed unacceptable exists, which would not be in line with the intentions of the EU legislature.

100 In so far as concerns the complaint alleging infringement of the freedom to conduct a business, it should be observed that that complaint was not raised in the appeal, but only at the reply stage, with the result that it must be rejected as inadmissible.

101 The third ground of appeal must therefore be rejected in its entirety as unfounded in part and inadmissible in part.

The fourth ground of appeal

Arguments of the parties

102 The appellants submit that it is apparent from the second paragraph of the preamble to Annex XIII and from recitals 5 and 6 of Regulation No 253/2011 that the assessment of the B and vB properties of a substance should not be based solely on the data relating to bioconcentration or bioaccumulation, laid down in point (a) of Section 3.2.2 of Annex XIII, but that it should also consider different categories of information, such as the biomagnification factor ('BMF') or the trophic magnification factor ('TMF'), which are expressly referred to in point (c) of that section.

103 According to the appellants, the General Court, in the first place, erred in law by holding, in paragraph 88 of the judgment under appeal, that 'the legislature chose to give a certain priority to the results of reliable studies on the BCF of a substance in aquatic species or, at the very least, that the MSC, without committing a manifest error of assessment, considered that the BCF values had, in the case at hand, greater weight than the other data cited by the applicants'. That error is explained, in the appellants' submission, by the fact that the General Court, first, wrongly considered, in paragraph 86 of that judgment, that the EU legislature chose to lay down, in Sections 1.1.2 and 1.2.2 of Annex XIII, the criteria for identifying B or vB substances by reference to their BCF in aquatic species, thus giving priority to BCF data and, second, justified that priority in paragraph 87 of that judgment by the fact that, where reliable information on the BCF is available, the criteria established by reference to the BCF may be applied to that information directly.

104 The interpretation given in the judgment under appeal is incompatible, it is argued, with Section 3.2 of Annex XIII and with ECHA's 'Guidance on Information Requirements and Chemical Safety Assessment' which states, in Section R.11.4.1.2 thereof, that 'in addition to BCF values, other relevant information should be considered' and that the '… Annex XIII Introduction requires all other available bioaccumulation data to be taken into account in an

integrated manner and applying a Weight-of-Evidence approach using expert judgement to derive the conclusion' and which do not 'define the order of importance or weight of individual data types'.

105 The appellants submit that, in paragraph 87 of the judgment under appeal, the General Court also misinterpreted the second paragraph of the preamble to Annex XIII and recital 6 of Regulation No 253/2011, which state that a weight-of-evidence determination is of particular relevance where the criteria set out in Section 1 of that annex cannot be applied directly to the available information. In the appellants' view, by considering that the data referred to in Section 3.2.2 of that annex gain in importance when the BCF data cannot be applied directly to the available information, the General Court actually held that it is appropriate to attach no particular relevance or effect to the data referred to in points (b) and (c) of that section where results, within the meaning of point (a) of that section, are available.

106 However, that finding is supported neither by the second paragraph of the preamble to Annex XIII nor by recitals 5 and 6 of Regulation No 253/2011, which do not state that a weight-of-evidence determination is particularly relevant where the direct application of B/vB criteria to BCF data is not possible, but instead state that that determination is particularly relevant where the direct application of B/vB criteria to all the available information is not possible. Such an interpretation is also in accord with the third paragraph of the preamble to Annex XIII, which stresses the need to consider all the available information, regardless of the individual conclusions. The judgment under appeal wrongly gives priority to BCF data precisely on account of the possibility of applying those conclusions numerically to the criteria laid down in Section 1 of that annex. However, a weight-of-evidence approach should have been used in the present case in the assessment of the B and vB properties of D4 and D5 irrespective of whether the General Court considered that BCF data could be applied directly/numerically to the criteria in Section 1 of Annex XIII.

107 According to the appellants, Annex XIII requires that both BCF and BMF and/or TMF data be considered, without there being any order of priority. Where results from those data are available but contradictory, as in the present case, and where the properties of the examined substance indicate that one category of data is not relevant, as is also the case for the BCF, it is consistent with the inherent consistency of that annex that a weight-of-evidence determination, examining data other than the BCF which are of equal importance, should in principle have particular relevance.

108 In the second place, the appellants submit that, in paragraph 96 of the judgment under appeal, the General Court reversed the burden of proof by finding that the absence of biomagnification of a substance in one food chain does not prove the absence of biomagnification of that substance in other food chains. In doing so, the General Court disregarded the fact that the REACH Regulation does not require that evidence be adduced as to the absence of biomagnification in all possible food chains, but nevertheless requires ECHA to demonstrate that a substance meets the criteria set in order to be identified as a B or vB substance, which has not been demonstrated in the present case.

109 The Commission submits that the fourth ground of appeal is in part inadmissible and in part ineffective. Thus, in so far as the appellants challenge the General Court's assessments relating to the weight of evidence of the BCF, their line of argument is inadmissible, since it actually seeks that a fresh assessment of the facts be carried out. By contrast, in so far as the appellants' line of argument relates to the error of assessment which the General Court allegedly committed by

relying on the priority given to the results of reliable studies on the BCF, that is ineffective. Even if the General Court had erred in law by giving fundamental priority to those results, *quod non*, its assessment cannot be called into question since, in the present case, the MSC considered, without committing a manifest error of assessment, that the BCF values had greater weight than the other data to which the appellants refer.

110 In any event, according to the Commission, supported by ECHA, the fourth ground of appeal is unfounded, inasmuch as the priority given to the results of reliable studies on the BCF of a substance in aquatic species reflects, scientifically, the greater weight of evidence of the BCF data.

111 In its response, the Federal Republic of Germany, adds that since the BCF for D4 and D5 is clearly above the thresholds set by Annex XIII, it would have been sufficient in itself, in order to justify a ban, to use the bioconcentration of those substances as a basis for the decision, even though the Commission and ECHA examined other information referred to in Section 3.2.2 of that annex.

Findings of the Court

112 In the context of the fourth ground of appeal, the appellants, supported by the ACC, essentially submit that paragraphs 86 to 88 and 96 of the judgment under appeal are vitiated by errors of law consisting in (i) a misinterpretation of Annex XIII in so far as concerns the priority given by the General Court to BCF data, and (ii) a reversal of the burden of proof.

113 As regards, in the first place, the priority given to the results of reliable studies on the BCF of a substance in aquatic species, on which the General Court relied in paragraphs 86 to 88 of the judgment under appeal, it follows from the scheme of Annex XIII, as amended by Regulation No 253/2011, that the weight-of-evidence determination assumes that all the available information which may have an impact on the identification of a PBT or vPvB substance is taken into consideration together, irrespective of the respective conclusions thereof, with appropriate importance being given to the quality and consistency of the data.

114 Under the second paragraph of the preamble to that annex, for the identification of PBT substances and vPvB substances, in a weight-of evidence determination, a comparison is to be made of all relevant and available information listed in Section 3.2 of that annex – namely, in particular, the relevant and available BCF, BMF and TMF data – with the criteria set out in Section 1 thereof.

115 According to Section 1 of Annex XIII on the criteria for the identification of PBT and vPvB substances, bioaccumulation is defined by reference to the BCF in aquatic species. Thus, a substance is 'bioaccumulative' where the BCF is higher than 2 000 and 'very bioaccumulative' where the BCF is higher than 5 000.

116 It is clear from the second paragraph of the preamble to Annex XIII that the weight-of-evidence determination is to be applied in particular where the criteria set out in Section 1 thereof – in this instance, the BCF – cannot be applied directly to the available information. That is also clear from recital 6 of Regulation No 253/2011, under which a weight-of-evidence determination is particularly relevant in cases where the application of the criteria set out in Section 1 of Annex XIII to the available information is not straightforward.

117 As is also observed in points 44 to 50 of the Opinion of Advocate General Kokott in *Global Silicones Council and Others* v *ECHA* (C-559/21 P, EU:C:2023:321), it is apparent from a combined reading of that preamble and that recital 6 that the weight-of-evidence determination must first of all clarify, by taking into account all the available information set out in Section 3.2 of Annex XIII, whether the available studies have determined the BCF relevantly and reliably. If that is the case, the relevant and reliable BCF data take priority in the scheme of Annex XIII inasmuch as bioaccumulation is directly related to that data. That interpretation cannot be called into question by the inclusion by Regulation 2017/735, amending Regulation No 440/2008, of the dietary exposure test method – that is, the biomagnification or trophic amplification test method – which is adapted to substances with very low water solubility, as a method used for determining bioaccumulation in fish, as in exposure via the aquatic environment.

118 Consequently, the General Court was able to find, without erring in law, in paragraphs 86 to 88 of the judgment under appeal, that the EU legislature chose to give priority to the results of reliable studies on the BCF of a substance in aquatic species. As the General Court rightly stated in paragraph 87 of that judgment, that priority does not affect the application of the weight-of-evidence determination. It is in that context that the General Court held that the MSC had not committed a manifest error of assessment by finding that the BCF data had greater weight than that of other data to which the appellants referred, namely the BMF and TMF data. Consequently, the appellants' line of argument that it is apparent from the judgment under appeal that no particular relevance or effect should be attached to the data referred to in Section 3.2.2 (b) and (c) of Annex XIII where results on bioconcentration are available, is evidence of a misreading of that judgment and must, accordingly, be rejected as unfounded.

119 Moreover, in so far as the fourth ground of appeal concerns the General Court's assessment of the specific way in which the weight-of-evidence determination was applied in the present case and the weight given to BCF data in the weighing up of the various items of evidence, that ground of appeal must be rejected, in the absence of any claim of distortion, as inadmissible, on the same grounds as those referred to in paragraph 98 of the present judgment.

120 In so far as concerns, in the second place, the alleged reversal of the burden of proof by the General Court in paragraph 96 of the judgment under appeal, in that it implicitly considered that the appellants had to adduce evidence of the absence of biomagnification in all food chains, it is sufficient to observe that, in paragraph 95 of that judgment, the General Court rightly noted that the absence of biomagnification does not mean that there is no bioaccumulation and does not necessarily dispel the concerns arising from bioconcentration. It is in that context that, in paragraph 96 of the judgment under appeal, the General Court stated, without reversing the burden of proof, that the appellants had failed to prove that the existence of biodilution in certain food chains ruled out biomagnification in other food chains.

121 The fourth ground of appeal must therefore be rejected in its entirety as unfounded in part and inadmissible in part.

The fifth ground of appeal

Arguments of the parties

122 The appellants, supported by the ACC, submit that Annex XIII applies to organic substances, including organo-metals, but not to inorganic substances. D4 and D5 have unique properties on account of their hybrid nature, which translates into different properties in terms of solubility and partitioning between environmental media, which influence their distribution and fate in the environment; this, according to the appellants, explains why priority should not be given to BCT data for the assessment of the B and vB properties of those substances. The studies on bioconcentration were conducted under artificial conditions, in which the substances are prevented from partitioning to air or sediment and/or the concentration of those substances in water is kept constant. The BCF consequently fails to reflect the behaviour of D4 and D5 in the environment under realistic conditions. By contrast, the BMF and TMF are relevant parameters under those conditions.

123 According to the appellants, in addition to the solubility and partitioning properties described above, D4 and D5 biodilute, as their concentration decreases with increases in trophic level, for instance from sediment-dwelling organisms to fish, and metabolise once taken up by organisms via the dietary route, which means that they will not build up in the food chain. ECHA should have taken the hybrid nature of D4 and D5 into account and, as a consequence, adjusted the application of the criteria set out in Sections 1.1.2 and 1.2.2 of Annex XIII.

124 The appellants take the view that the General Court failed to address the arguments set out in paragraphs 121 and 122 of the present judgment and confined itself to stating, in paragraph 105 of the judgment under appeal, that a substance having a hybrid nature would not necessarily be excluded from the scope of Annex XIII or, in paragraph 108 of that judgment, that none of the arguments raised by the appellants was capable of demonstrating that D4 and D5 are inorganic substances, or that Annex XIII or the criteria defined therein do not apply to those substances.

125 However, the appellants submit that the General Court was called upon to determine not whether Annex XIII applies to those substances, but rather whether the Commission and ECHA had erred in failing to examine the impact of the specific nature of those substances on the way in which the criteria under Annex XIII could be applied to them. Inasmuch as the appellants claim to have demonstrated that ECHA did not take account of the intrinsic properties of D4 and D5 arising from their hybrid nature, it was incumbent on ECHA to prove otherwise and on the General Court to exercise its power of review in that regard. However, the finding made by the General Court in paragraph 108 of the judgment under appeal is tantamount to a reversal of the burden of proof, since that court also erred in law by ruling that that failure on the part of ECHA did not constitute a manifest error of assessment vitiating the lawfulness of the regulation at issue.

126 The Commission, supported by ECHA, contends that the fifth ground of appeal is inadmissible, inasmuch as the appellants seek, in reality, to obtain a fresh assessment of the facts and evidence examined by the General Court, in particular in so far as concerns the question whether ECHA considered the unique properties or hybrid nature of D4 and D5.

127 The Commission takes the view, as does the Federal Republic of Germany, that, in any event, the fifth ground of appeal is unfounded since, as is apparent from paragraph 118 et seq. of the judgment under appeal, the General Court correctly understood and addressed the appellants' arguments.

128 In their reply, the appellants clarify that they do not seek to obtain a fresh assessment of a scientific evaluation but rather a ruling from the Court on whether the General Court erred in law in its interpretation of Annex XIII, distorted their pleas and the evidence that they produced before it, and whether it infringed their right to be heard.

129 In its rejoinder, the Commission contends that the argument relating to the distortion of the pleas raised by the appellants and the infringement of the right to be heard was only raised at the reply stage and must, accordingly, be rejected as inadmissible, on the same grounds as those set out in paragraph 100 of the present judgment.

Findings of the Court

130 By their fifth ground of appeal, the appellants submit, in essence, that the General Court was called upon to determine not whether Annex XIII applies to D4 and D5 – as it held in paragraphs 107 and 108 of the judgment under appeal – but rather to assess the consequences which ensue from the hybrid nature of those substances as to the application of the criteria set out in that annex.

131 As regards, in the first place, the findings of the judgment under appeal relating to the classification of D4 and D5 as organic substances which fall within the scope of Annex XIII, while it is apparent from the procedural documents lodged with the General Court, in particular from the application, that the appellants maintained, furthermore, that 'the criteria under Annex XIII, including the Section 1.1.2 and 1.2.2 criteria … needed to be adjusted in order to determine … bioaccumulation for D4 and/or D5', the General Court's finding in relation to the application of that annex to the substances concerned does not prejudice the appellants' interests. In the scheme of that judgment, that finding is a preliminary step in the analysis of the intrinsic properties arising from the hybrid nature of those substances and from their influence on the assessment of the PBT or vPvB properties, which analysis the General Court also carried out. Moreover, as is apparent from paragraphs 106, 107, 109 and 111 of the judgment under appeal, which are not disputed by the appellants, their line of argument before the General Court also concerned the organic/inorganic nature of those substances, the General Court having responded thereto in paragraphs 107 and 108 of that judgment.

132 As regards, in the second place, the alleged failure, on the part of the General Court, to examine the appellants' argument as to the consequences arising from the hybrid nature of D4 and D5, it follows from paragraphs 118 to 126 of the judgment under appeal, which are not disputed by the appellants, that the physicochemical properties of D4 and D5 were examined by the General Court, which found, in paragraph 122 of that judgment, that all those properties had been observed by the MSC when evaluating the P and vP properties as well as the B and vB properties of those substances.

133 It should also be observed that the General Court did not reverse the burden of proof in its examination of the consequences which ensue from the hybrid nature of D4 and D5. In that connection, it should be recalled that, without it constituting a reversal of the burden of proof, the party that relies on an inadequate investigation of the relevant factors by the EU authority concerned, or on manifest errors of assessment committed by that authority, must produce evidence capable of justifying significant doubts as to the assessment carried out by that authority, with it being for the latter, if necessary, to rebut those doubts.

134 As regards, in the third place, the alleged distortion of the pleas and evidence, as well as the infringement of the right to be heard, it must be stated that those complaints, which are uncorroborated, were relied on for the first time at the reply stage and are, consequently, inadmissible, on the same grounds as those referred to in paragraph 100 of the present judgment.

135 It follows that the fifth ground of appeal must be rejected as unfounded in part, and inadmissible in part.

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

Costs

137 In accordance with Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to the costs. Under Article 138(1) of those rules, applicable to appeal proceedings by virtue of Article 184(1) thereof, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

138 Under Article 184(4) of the Rules of Procedure of the Court of Justice, where the appeal has not been brought by an intervener at first instance, he or she may not be ordered to pay costs in the appeal proceedings unless he or she participated in the written or oral part of the proceedings before the Court. Where an intervener at first instance takes part in the proceedings, the Court may decide that he or she is to bear his or her own costs.

139 Under Article 140(1) of those Rules of Procedure, the Member States and institutions which have intervened in the proceedings are to bear their own costs.

140 Since the Commission has applied for costs against the appellants and they have been unsuccessful, they must be ordered to pay the costs.

141 Since the Federal Republic of Germany, ECHA and the ACC, interveners at first instance, participated in the written part of the proceedings, they shall bear their own costs.

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

1. **Dismisses the appeal;**

2. **Orders Global Silicones Council, Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV and Elkem Silicones France SAS to bear their own costs and to pay those incurred by the European Commission;**

3. **Orders the Federal Republic of Germany, the European Chemicals Agency (ECHA) and American Chemistry Council, Inc. (ACC) to bear their own costs.**

Lycourgos Spineanu-Matei Bonichot

Rodin Rossi

Delivered in open court in Luxembourg on 9 November 2023.

A. Calot Escobar
Registrar

C. Lycourgos
President of the Chamber