Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

9 March 2023 *

(Appeal – Establishment of a list of substances subject to authorisation – Regulation (EC) No 1907/2006 – Annex XIV – List of substances identified for eventual inclusion in Annex XIV – Updating of the entry of the substance bisphenol A as 'a substance of very high concern')

In Case C-119/21 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 25 February 2021,

PlasticsEurope AISBL, established in Brussels (Belgium), represented by R. Cana and E. Mullier, avocates,

appellant,

the other parties to the proceedings being:

European Chemicals Agency (ECHA), represented by W. Broere and A. Hautamäki, acting as Agents, and by S. Raes, advocaat,

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,

French Republic, represented by G. Bain and T. Stéhelin, acting as Agents,

ClientEarth, established in London (United Kingdom), represented by P. Kirch, lawyer,

interveners at first instance,

THE COURT (Fourth Chamber),

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

Advocate General: M. Szpunar,

* Language of the case: English.

Registrar: A. Calot Escobar,

having regard to the written procedure,

after hearing the Opinion of the Advocate General at the sitting on 8 September 2022,

gives the following

Judgment

1 By its appeal, PlasticsEurope AISBL, an association representing the interests of European producers of plastics, asks the Court of Justice to set aside the judgment of the General Court of the European Union of 16 December 2020, *PlasticsEurope* v *ECHA* (T-207/18, EU:T:2020:623; 'the judgment under appeal'), by which the latter dismissed its action for annulment of Decision ED/01/2018 of the Executive Director of the European Chemicals Agency (ECHA) of 3 January 2018 ('the decision at issue'), by which the existing entry relating to bisphenol A on the list of identified substances with a view to their eventual inclusion in Annex XIV to 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 253/2011 of 15 March 2011 (OJ 2011 L 69, p. 7) ('the REACH Regulation'), was supplemented to the effect that bisphenol A is also identified as belonging to the group of substances under Article 57(f) of the REACH Regulation, namely those with endocrine disrupting properties that may have serious effects on the environment which give rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of that regulation.

Legal context

2 Article 2 of the REACH Regulation, entitled 'Application', provides in paragraph 8(b) thereof that on-site isolated intermediates and transported isolated intermediates are to be exempted from Title VII of that regulation, which renders substances of very high concern for the purposes thereof subject to the authorisation procedure.

3 Article 3 of that regulation, entitled 'Definitions', provides in paragraph 15 thereof:

'intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

(a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the

pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

(b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

(c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites'.

4 Article 7 of that regulation, entitled 'Registration and notification of substances in articles', provides, in paragraph 2 thereof:

'Any producer or importer of articles shall notify [ECHA], in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1% weight by weight (w/w).'

5 Article 17 of the REACH Regulation, entitled 'Registration of on-site isolated intermediates', provides in paragraph 3 thereof:

'Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.'

6 Article 18 of that regulation, entitled 'Registration of transported isolated intermediates', provides in paragraph 4 thereof:

'Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

…'

7 Under Article 33 of that regulation, entitled 'Duty to communicate information on substances in articles':

'(1) Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1% weight by weight (w/w)

shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

(2) On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1% weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.'

8 Article 57 of that regulation, entitled 'Substances to be included in Annex XIV', is worded as follows:

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

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;

(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;

(f) substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) – for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.'

9 Article 59 of the REACH Regulation, entitled 'Identification of substances referred to in Article 57', states in paragraphs 3, 4, 7 and 8 thereof:

'(3) Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to [ECHA]. The dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008. [ECHA] shall make this dossier available within 30 days of receipt to the other Member States.

(4) [ECHA] shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. [ECHA] shall invite all interested parties to submit comments within a specified deadline to [ECHA].

…

(7) When comments are made or received, [ECHA] shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.

(8) If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, [ECHA] shall include the substance in the list referred to in paragraph 1. [ECHA] may include that substance in its recommendations under Article 58(3).'

10 The REACH Regulation contains Annex XI, entitled 'General rules for adaptation of the standard testing regime set out in Annexes VII to X', point 1.2 of which, entitled 'Weight of evidence', states:

'There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the [European] Commission or [ECHA] as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

– further testing on vertebrate animals for that property shall be omitted,

– further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.'

Background to the proceedings

11 Bisphenol A (2,2-bis(4-hydroxyphenyl)propane or 4,4'-isopropylidenediphenol, EC No 201-245-8, CAS 0000080-05-7) is a substance which is mainly used as an intermediate, as a monomer for the manufacture of polymers such as polycarbonate and epoxy resins. Moreover, bisphenol A can be used for non-intermediate purposes, for example in the manufacture of thermal paper.

12 On 4 January 2017, ECHA adopted Decision ED/01/2017 by way of which it found that bisphenol A must be included on the list of substances to be included in Annex XIV to the REACH Regulation ('the Candidate List'), on the ground that that substance had been identified as a 'hazard class reproductive toxicity' substance within the meaning of Article 57(c) thereof.

13 On 6 July 2017, ECHA adopted Decision ED/30/2017, whereby the existing entry relating to the substance bisphenol A on the Candidate List was supplemented to the effect that that substance was also identified as belonging to the group of substances under Article 57(f) of the REACH Regulation, namely those with endocrine disrupting properties that may have serious effects on human health which give rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of that regulation.

14 On 29 August 2017, the Umweltbundesamt (Federal Environment Agency, Germany) submitted, pursuant to Article 59(3) of the REACH Regulation, a dossier in accordance with Annex XV thereto ('the dossier prepared in accordance with Annex XV') in which it proposed that bisphenol A also be identified as an endocrine disruptor for which there is scientific evidence of probable serious effects to the environment, within the meaning of Article 57(f) of that regulation.

15 On 5 September 2017, ECHA published the dossier prepared in accordance with Annex XV.

16 On the same day, in accordance with Article 59(4) of the REACH Regulation, ECHA invited all interested parties to submit their comments on that dossier.

17 On 20 October 2017, the appellant submitted comments, on behalf of its members, on that dossier.

18 The Umweltbundesamt (Federal Environment Agency) subsequently produced a document dated 14 December 2017 and containing its responses to all the comments concerning the identification of bisphenol A received by ECHA in the course of the public consultation.

19 ECHA forwarded the dossier containing the comments concerning the identification of bisphenol A to the Member State Committee ('the MSC'), in accordance with Article 59(7) of the REACH Regulation. The MSC received the dossier prepared in accordance with Annex XV, a draft agreement of the MSC and a working document containing the assessment of the intrinsic properties of bisphenol A for the purposes of its identification under Article 57(f) of that regulation ('the Support Document').

20 At its 57th meeting, which took place from 11 to 15 December 2017, the MSC unanimously decided to identify bisphenol A as a substance that meets those criteria. Four Member States abstained from the vote. The grounds for the identification of bisphenol A were set out in an amended version of the Support Document, as adopted on 14 December 2017.

21 First, the final version of the Support Document concluded, on the basis of an analysis of multiple studies, that bisphenol A meets the definition of endocrine disruptor as established by the World Health Organization (WHO) and interpreted by the Commission's Endocrine Disrupters Expert Advisory Group. More specifically, that document found that the *in vitro* and *in vivo* data analysed indicate that bisphenol A acts as an oestrogen agonist in certain species of fish, and as a thyroid antagonist in certain species of amphibian.

22 Next, that document finds that the analyses of various taxa of invertebrates show that it is possible that the serious effects of bisphenol A are the result of the endocrine mode of action.

23 Lastly, it is stated in the Support Document that the effects of bisphenol A on fish and amphibians are regarded as giving rise to a level of concern equivalent to that of substances listed in Article 57(a) to (e) of the REACH Regulation, namely substances that are carcinogenic,

mutagenic or toxic to reproduction, or persistent, bioaccumulative and toxic substances ('PBT substances') and very persistent and very bioaccumulative substances ('vPvB substances'). To those ends, the final version of the Support Document notes, inter alia, the severe and irreversible nature of the effects on organisms and populations, as well as the difficulties encountered in determining a safe level of exposure to bisphenol A.

24 On 3 January 2018, following the unanimous agreement of the MSC and in accordance with Article 59(8) of the REACH Regulation, ECHA adopted the decision at issue, whereby the existing entry relating to the substance bisphenol A on the Candidate List was supplemented to the effect that that substance also belongs, for the reasons set out in the final version of the Support Document, to the group of substances under Article 57(f), namely those with endocrine disrupting properties that may have serious effects on the environment which give rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of that regulation.

The procedure before the General Court and the judgment under appeal

25 By application lodged at the Court Registry on 23 March 2018, the appellant, who was the applicant in those proceedings, brought an action for annulment of the contested decision.

26 In support of its action, the appellant relied on four pleas in law. The first plea alleged several manifest errors of assessment in the identification of bisphenol A as a substance of very high concern, within the meaning of Article 57(f) of the REACH Regulation. By the second plea, the appellant alleged infringement of Article 59 of that regulation, read in conjunction with Article 57(f) thereof. The third plea alleged infringement of Article 2(8)(b) of that regulation. By its fourth plea, the appellant alleged infringement of the principle of proportionality.

27 By the judgment under appeal, the General Court dismissed that action.

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

28 The appellant submits that the Court should:

– set aside the judgment under appeal;

– annul the decision at issue;

– in the alternative, refer the case back to the General Court for a ruling on its action for annulment; and

– order ECHA to pay the costs, including the costs of the proceedings before the General Court, and including those incurred by the interveners.

29 ECHA contends that the Court should:

– dismiss the appeal; and

– order the appellant to pay the costs.

30 The Federal Republic of Germany submits that the Court should:

– dismiss the appeal; and

– order the appellant to pay the costs.

31 The French Republic submits that the Court should dismiss the appeal.

32 ClientEarth submits that the Court should:

– dismiss the appeal; and

– order the appellant to bear its own costs and to pay the costs incurred by ECHA, the French Republic and ClientEarth, including the costs incurred at first instance.

The appeal

33 In support of its appeal, the appellant raises five grounds of appeal.

34 The first ground alleges several errors of law committed by the General Court in the context of the review that it is required to carry out of ECHA's evaluation of scientific evidence for the purposes of applying Article 57(f) of the REACH Regulation. That ground of appeal comprises four parts relating to the General Court's review in so far as concerns (i) ECHA's failure to take into account reliable and relevant studies contradicting its final decision; (ii) the taking into account, by ECHA, of studies with poor reliability supporting its final decision; (iii) the greater weight given by ECHA to studies supporting its final decision; and (iv) ECHA's failure to take into account studies of bisphenol A conducted by other agencies and institutions of the European Union.

35 The second ground of appeal alleges misinterpretation of Article 57(f) of the REACH Regulation, distortion of the appellant's written pleadings and infringement of the right to be heard.

36 The third ground of appeal alleges that the General Court erred in law in its assessment of the evidence relating to the reliability of scientific studies and an alleged distortion of the evidence.

37 The fourth plea alleges misinterpretation of the precautionary principle.

38 The fifth ground of appeal alleges misinterpretation of Article 2(8)(b) of the REACH Regulation and infringement of the obligation to state reasons.

The first ground of appeal, alleging several errors of law on the part of the General Court in the review that it is required to carry out of ECHA's evaluation of scientific evidence for the purposes of applying Article 57(f) of the REACH Regulation

The first part of the first ground of appeal, relating to the review carried out by the General Court in so far as concerns ECHA's failure to take into account reliable and relevant studies contradicting its final decision

– *Arguments of the parties*

39 By the first part of the first ground of appeal, the appellant submits that, in paragraph 64 of the judgment under appeal, the General Court misinterpreted and misapplied the principle of scientific excellence, the concept of 'weight of evidence' and ECHA's obligation to take account of all relevant information.

40 The appellant argues that by considering, in paragraph 64, that 'there could be a finding of a manifest error of assessment only if ECHA had completely and wrongly disregarded a reliable study, the inclusion of which would have altered the overall assessment of the evidence in such a way that the … decision [at issue] would have been implausible', the General Court allowed ECHA not to take into account reliable scientific studies provided that it did not do so 'completely and wrongly'. In so doing, the General Court failed to have regard to the scope of its judicial review of ECHA decisions even though such review is confined to that of manifest errors of assessment. The appellant submits that if a study is reliable and relevant, the results of that study should be included in the application of the weight of evidence approach, in accordance with the obligation incumbent on ECHA to take account of all relevant information.

41 It is argued, furthermore, that the judgment under appeal sets an unacceptable and unachievable standard of proof in order to challenge the weight of evidence on which ECHA relies in the context of its evaluation under Article 57(f) of the REACH Regulation, thus imposing on the appellant the burden of proving, first, that ECHA completely and wrongly disregarded a study and, second, that the taking into account of that study would have altered the overall assessment of the evidence in such a way that the final ECHA decision would have been implausible.

42 The appellant submits that such a requirement would also be contrary to the *ratio legis* and the concept of 'weight of evidence', as defined in point 1.2 of Annex XI to that regulation. A weight of evidence assessment applies, by definition, where there is more than one study justifying a conclusion, since a single study is never sufficient to invalidate a finding made by ECHA. In the appellant's submission, any failure to take into account the results of a reliable scientific study on bisphenol A, which are relevant to the property being examined in a weight of evidence assessment, constitutes a manifest error of assessment, a failure of ECHA's obligation to take all relevant information into account and a breach of the principle of scientific excellence.

43 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the appellant's arguments and contend that the first part of the first plea is unfounded.

– *Findings of the Court*

44 It should be noted that the arguments put forward by the appellant in the first part of its first ground of appeal are based on a misreading of the relevant grounds of the judgment under appeal.

45 In paragraph 62 of the judgment under appeal, the General Court rightly held that ECHA should be recognised as enjoying a broad discretion in the identification of substances of very high concern under Article 57(f) of the REACH Regulation, in the light of the complex scientific and technical assessments which that agency must undertake (see, by analogy, judgments of 22 November 2017, *Commission* v *Bilbaína de Alquitranes and Others*, C-691/15 P, EU:C:2017:882, paragraph 34, and of 15 October 2020, *Deza* v *Commission*, C-813/18 P, not published, EU:C:2020:832, paragraph 40).

46 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 placed that task (judgments of 21 July 2011, *Nickel Institute*, C-14/10, EU:C:2011:503, paragraph 60, and of 15 October 2020, *Deza* v *Commission*, C-813/18 P, not published, EU:C:2020:832, paragraph 41).

47 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 (order of 4 September 2014, *Cindu Chemicals and Others* v *ECHA*, C-283/13 P, not published, EU:C:2014:2175, paragraph 26 and the case-law cited).

48 In paragraph 63 of the judgment under appeal, the General Court observed that 'in the present case, the identification of the substance at issue as being of very high concern was made using the weight of evidence approach. Under point 1.2 of Annex XI to [the REACH Regulation], this approach is characterised by the fact that the hypothesis that a substance has or has not a particular dangerous property can be validly confirmed by evidence from multiple independent sources of information, while the information from each single source alone is regarded [as] insufficient to support that hypothesis or finding'.

49 The General Court again pointed out, in that paragraph, that 'the identification of a substance using the weight of evidence approach must be made on the basis of complete data which allows the competent authority to exercise the discretion which it enjoys under Articles 57 and 59 of [that regulation] whilst taking into account all relevant evidence available at the time when the authority adopts its decision'.

50 It is in the light of those principles set out by the General Court in paragraphs 62 and 63 of the judgment under appeal, and which the appellant does not call into question in its appeal, that the scope of paragraph 64 of that judgment must be examined. The General Court correctly held in paragraph 64 that it is open to ECHA, in the context of the evaluation of the weight of evidence, to 'exclude studies that it does not deem relevant for plausible reasons connected to the internal consistency of the assessment carried out'. The General Court also did not err in holding that the obligation incumbent on ECHA to take all relevant and available evidence into consideration does

not mean that all the studies conducted, irrespective of the reliability or relevance thereof, must necessarily be included in ECHA's assessment, in the light, in particular, of the fact that bisphenol A is one of the most studied substances in the world.

51 In the last sentence of paragraph 64 of the judgment under appeal, the General Court found that 'there can be a finding of a manifest error of assessment only if ECHA completely and wrongly disregarded a reliable study, the inclusion of which would have altered the overall assessment of the evidence in such a way that the final decision would have been implausible'.

52 Contrary to the appellant's assertions, that sentence cannot be interpreted as meaning that the General Court found that ECHA could, in the light of its broad discretion, disregard the relevant elements of a reliable study the taking into account of which would have altered the overall assessment of the evidence in such a way that the final decision would have been implausible. In particular, the words 'completely and wrongly', interpreted in the light of the context of which they are part, refer specifically to the case where ECHA has failed to fulfil its obligation to take account of such relevant, reliable and decisive elements in its assessment. By contrast, the fact that ECHA disregarded the irrelevant elements of a reliable study, or elements that would not, in any event, have been capable of altering the overall assessment in such a way that the final decision was implausible, cannot constitute a manifest error of assessment.

53 On the basis of those considerations, the General Court examined, in paragraphs 66 to 70 of the judgment under appeal, whether, in the light of the various studies submitted by the appellant, ECHA had disregarded relevant elements of a reliable study the taking into account of which would have altered the overall assessment of the evidence.

54 As the Advocate General states in point 90 of his Opinion, the General Court noted, in paragraphs 67 and 69 of the judgment under appeal, that ECHA took into consideration, even indirectly, the relevant elements of two of the four studies relied upon by the appellant. As regards those elements of the studies relied upon by the appellant which were not taken into account by ECHA, the General Court did in fact review, in paragraphs 66 to 68 of the judgment under appeal, ECHA's assessment as to the irrelevance of those elements. In so doing, the General Court did not disregard the scope of the judicial review that it is required to conduct under the case-law referred to in paragraphs 45 to 47 of the present judgment.

55 As to the alleged error of law committed by the General Court as regards the burden of proof that rests on the appellant, it is sufficient to note that that argument is based on the same misreading of the relevant grounds of the judgment under appeal, identified in paragraph 52 of the present judgment.

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

The second part of the first ground of appeal, relating to the review carried out by the General Court in so far as concerns the taking into account, by ECHA, of studies with poor reliability which support its final decision

– *Arguments of the parties*

57 By the second part of the first ground of appeal, the appellant criticises the General Court for finding, in paragraph 82 of the judgment under appeal, that ECHA could rely on studies of low reliability in order to identify bisphenol A as a substance of very high concern. However, the poor reliability of a study absolutely and generally precludes its being taken into account.

58 Although the appellant does not dispute the fact that non-standard studies may be taken into account as evidence, it submits, however, that the General Court erred in law by finding that ECHA could rely, as items of substantiated evidence, studies that were only slightly reliable, or even not reliable, to form the basis of the decision at issue.

59 The appellant submits that, in granting such leeway to ECHA, the judgment under appeal allows the latter agency to make an arbitrary selection of scientific data and to select, from amongst such data, those that corroborate ECHA's hypothesis. ECHA cannot under any circumstances rely, in the appellant's submission, on the results of studies that are not reliable or are of low reliability to validate its finding, since only key studies may be used to that end. The General Court therefore wrongly held, in paragraphs 168, 169, 174 and 184 of the judgment under appeal, that ECHA could take into account such studies that were not reliable or were of low reliability, not only as studies 'supporting' its conclusions but also as key studies.

60 According to the appellant, studies that are of low reliability or are not reliable are studies which do not comply with the general requirements of scientific quality set by the scientific bodies in order for the results thereof to be reliable as scientific evidence. Non-standard studies should not be automatically excluded, but they may be unreliable and irrelevant where, for example, their methodology is not properly documented or justified, or where they have been conducted on the basis of an incorrect study. By contrast, poor-quality scientific data cannot be relied on as scientific evidence in order to justify ECHA decisions.

61 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the appellant's arguments and contend that the second part of the first plea is unfounded.

– *Findings of the Court*

62 In paragraphs 71 to 90 of the judgment under appeal, the General Court examined the complaint by way of which the appellant criticised the taking into account, by ECHA, of 'non-standard' or 'exploratory' studies, namely studies which were not conducted in compliance with nationally or internationally validated methods.

63 In paragraph 76 of that judgment, the General Court recalled that 'ECHA [had arrived] at the identification of bisphenol A as a substance of very high concern under Article 57(f) of [the REACH] Regulation] by following the weight of evidence approach', which requires that the competent authority take account 'of all relevant evidence'.

64 Following an examination of the relevant provisions of that regulation, the General Court ruled, in paragraph 82 of that judgment, 'that non-standard or non-validated data can be used to support findings as to the intrinsic properties of a certain substance where ECHA takes the weight of evidence approach in the identification of a substance as being of very high concern'. The General Court also stated, in that paragraph, that it is 'inherent to that approach that the non-standard nature and, where applicable, the poor reliability of [those] data must be taken into consideration when weighting evidence with a view to making a finding as to the intrinsic properties of a substance, without the poor reliability of a certain study absolutely and generally precluding its being taken into account in the identification of a substance under Article 57(f) of [the REACH Regulation]'.

65 That paragraph must be read in conjunction with paragraph 106 of the judgment under appeal, from which it is clear that the Support Document, in its final version, identified the key studies according to their reliability and their relevance. Reliable studies which offer the most information on endocrine mode of action and its effects are classed as 'key studies', whereas studies which are less reliable and contain less information on endocrine mode of action are used solely to support findings made principally on key studies and therefore contribute to the weight of evidence.

66 It follows from the foregoing that the General Court considered that ECHA could take into account, in evaluating the weight of evidence available to it, studies with varying degrees of reliability, provided that their degree of reliability was taken into consideration when weighing the evidence, so as to confer greater importance on the most reliable studies. In so doing, the General Court did not err in law, contrary to the appellant's assertion.

67 On the basis of those considerations, the General Court also did not err in law in holding, in paragraphs 168, 169, 174, 175 and 184 of the judgment under appeal, that ECHA could take into account certain studies of low reliability, in particular where those studies supported conclusions drawn from studies with greater evidential weight and constituting key studies.

68 Accordingly, the second branch of the first ground of appeal must be rejected as unfounded.

The third part of the first ground of appeal, relating to the error of law and distortion of the evidence, on the part of the General Court, when it ruled that ECHA could favour the scientific studies supporting its final decision

– *Arguments of the parties*

69 By the third part of the first ground of appeal, the appellant submits that, in paragraphs 106, 116 to 118, 152 and 208 of the judgment under appeal, the General Court erred in law by endorsing ECHA's approach of attributing greater weight to scientific studies which supported that agency's hypothesis. In so doing, the General Court also distorted the evidence produced before it, infringed the principle of scientific excellence, the principles relating to the applicability of the concept of 'weight of evidence', as defined in point 1.2 of Annex XI to the REACH Regulation, and the obligation to take into account all relevant information.

70 As regards paragraphs 106 and 208 of the judgment under appeal, the appellant submits that the General Court found that the selection of key studies is not strictly based on the reliability of those studies, but also rests the question whether they supported ECHA's hypothesis.

71 It is argued that in paragraphs 116 to 118 of the judgment under appeal, the General Court stated that ECHA should rely, when evaluating the weight of evidence available to it, on the data resulting from *in vitro* studies despite their possibly less reliable and inconclusive nature, in so far as, first, those data support the effects observed in the *in vivo* studies on fish and amphibians and, second, fit with conclusions drawn from the *in vivo* effects observed. The General Court thus limited the possibility for affected parties to challenge ECHA's conduct effectively before the Courts of the European Union.

72 In paragraph 152 of the judgment under appeal, the General Court held, furthermore, that the shortcomings of the Chen et al. (2015) study should be assessed having regard to the ability of that study nevertheless to substantiate the conclusion that it was called upon to support.

73 In the appellant's submission, the General Court also ruled, incorrectly, that ECHA could decide whether or not to rely on studies of low reliability depending on whether their results validated or refuted that agency's hypothesis.

74 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the appellant's arguments and contend that the third part of the first plea is unfounded.

– *Findings of the Court*

75 By the third part of the first ground of appeal, the appellant takes the view that the General Court endorsed the approach taken by ECHA, according to which the evidential weight of the studies must depend on their ability to confirm or refute ECHA's hypothesis. However, that part is based on a misreading of paragraphs 106, 116 to 118, 152 and 208 of the judgment under appeal.

76 As has been noted in paragraphs 65 and 66 of the present judgment, paragraph 106 of the judgment under appeal describes the distinction drawn in the Support Document, in its final version, between, on the one hand, reliable studies which offer the most information on endocrine mode of action and its effects, which are classed as 'key studies', and, on the other hand, studies which are less reliable and contain less information on endocrine mode of action and are used solely to support findings made principally on key studies. In other words, the approach described in paragraph 106 draws a distinction not between studies confirming or casting doubt on ECHA's hypothesis, but rather between reliable and less reliable studies.

77 That finding is also applicable to paragraphs 116 to 118, 152 and 208 of the judgment under appeal.

78 Consequently, the General Court did not 'endorse', in paragraphs 106, 116 to 118, 152 and 208 of the judgment under appeal, an alleged approach on the part of ECHA consisting in favouring scientific studies which support that agency's hypothesis.

79 Accordingly, the third branch of the first ground of appeal must be rejected as unfounded.

The fourth part of the first ground of appeal, relating to the review carried out by the General Court with regard to the failure, on the part of ECHA, to take into account studies on bisphenol A conducted by other agencies and institutions of the European Union

– *Arguments of the parties*

80 By the fourth part of the first ground of appeal, the appellant submits that the General Court erred in law by holding, in paragraphs 109 and 176 of the judgment under appeal, that ECHA had been entitled to disregard, in the assessment leading to the adoption of the decision at issue, the findings on the data concerning bisphenol A made by other agencies and EU institutions, namely the European Union Risk Assessment Report on Bisphenol A, drawn up by the United Kingdom in February 2010 in accordance with Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ 1993 L 84, p. 1), and the Bisphenol A Hazard Assessment Protocol, prepared by the European Food Safety Authority (EFSA).

81 The appellant submits that relevant scientific findings and/or data assessment approaches made at EU level on the same substance cannot be ignored on the mere basis that they are adopted with a different objective in mind. Doing so is liable to favour regulatory divergence and contradictions and is not compatible with the principle of scientific excellence. That would lead to the absurd result that no data or best practices from other regulatory frameworks would ever be relevant to an identification of a substance as a substance of very high concern under the REACH Regulation.

82 It is submitted, furthermore, that the General Court ruled that the different objectives pursued by various sources of information could lead to different conclusions on the reliability of the scientific data. The reliability of a scientific study is intrinsic and dependent on compliance with minimum scientific requirements, and cannot vary in relation to the context in which that study was conducted.

83 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the arguments put forward by the appellant and contend that the fourth part of the first plea is unfounded.

– *Findings of the Court*

84 It should be noted that under 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 has exclusive jurisdiction to find and appraise the relevant facts and assess the evidence. It follows that, in the context of an appeal, the Court of Justice has no jurisdiction to establish the facts or, in principle, to examine the evidence which the General Court accepted in support of those facts (see, to that effect, judgment of 28 October 2021, *Vialto Consulting* v *Commission*, C-650/19 P, EU:C:2021:879, paragraph 58 and the case-law cited).

85 The jurisdiction of the Court of Justice to review the findings of fact by the General Court therefore extends, inter alia, to that of the substantive inaccuracy of those findings as apparent from the documents in the file, the legal characterisation thereof, distortion of the facts and evidence, and whether the rules relating to the burden of proof and the taking of evidence have been observed (judgments of 25 January 2007, *Sumitomo Metal Industries and Nippon Steel* v *Commission*, C-403/04 P and C-405/04 P, EU:C:2007:52, paragraph 39, and of 11 May 2017, *Dyson* v *Commission*, C-44/16 P, EU:C:2017:357, paragraph 31).

86 Suffice it to note, in that regard, that, by this line of argument submitted as part of the fourth part of the first ground of appeal, the appellant is in fact seeking a re-examination of the findings of fact made by the General Court, in respect of which the Court of Justice does not have jurisdiction in an appeal, as follows from the case-law referred to in paragraphs 84 and 85 of the present judgment (see, to that effect, judgment of 21 December 2021, *PlasticsEurope* v *ECHA*, C-876/19 P, not published, EU:C:2021:1047, paragraph 80).

87 Accordingly, the fourth part of the first ground of appeal must be rejected as inadmissible.

88 It follows that the first ground of appeal must be rejected as in part unfounded and in part inadmissible.

The second ground of appeal, alleging distortion of the appellant's written pleadings, misinterpretation of Article 57(f) of the REACH Regulation, and infringement of the right to be heard

Arguments of the parties

89 By its second ground of appeal, the appellant submits that, in paragraphs 220 to 226 of the judgment under appeal, relating to the criterion of the equivalent level of concern to those of other substances listed in Article 57(a) to (e) of the REACH Regulation, laid down in paragraph (f) of that article, the General Court distorted the appellant's written pleadings, misinterpreted the latter provision and infringed the appellant's right to be heard.

90 In the appellant's submission, in paragraph 224 of the judgment under appeal, the General Court confused the equivalence of the level of concern with the equivalence of properties. Thus, the General Court distorted the arguments on which the appellant relied in so far as it found that the appellant claimed that a substance must have PBT and/or vPvB properties in order to fall within the scope of Article 57(f) of the REACH Regulation.

91 The appellant submits that it maintained before the General Court that a substance could fall within that provision only if the level of concern for the environment to which that substance gives rise was equivalent to the level of concern to which the PBT and/or vPvB substances, referred to in Article 57(d) and (e) of that regulation, give rise, without the properties of that substance necessarily having to be equivalent to those of PBT and/or vPvB substances.

92 Furthermore, the appellant claims to have demonstrated the shortcomings vitiating the assessment of the equivalent level of concern carried out by ECHA. In that regard, the appellant claims that that demonstration is set out in its reply to the questions put by the General Court. In the first place, in paragraph 63 of that response, the appellant stated that it is apparent from Annex XIII to the REACH Regulation and from the *travaux préparatoires* for that regulation that the level of very high concern beyond which a substance must be classified as a PBT and/or vPvB substance is intrinsically linked to the irreversible nature of the effects of such substances after accumulation in the environment.

93 In the second place, in paragraph 65 of that response, the appellant's argument concerned whether ECHA had established an equivalent level of concern for the environment to those of substances with PBT and/or vPvB properties for bisphenol A, which is rapidly degradable and has a low potential for bioaccumulation.

94 In the third place, in paragraphs 66 to 75 of that response, the appellant maintained, it is argued, that ECHA had failed to demonstrate the existence of such a level of concern by properties other than persistence or bioaccumulation, which are specific to PBT and vPvB substances, and that ECHA's reference to the severity of effect, irreversibility and difficulty in establishing a safe level did not meet that test.

95 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the appellant's arguments and contend that the second ground of appeal is unfounded.

Findings of the Court

96 In so far as concerns, in the first place, the argument alleging distortion by the General Court of the appellant's pleadings in paragraph 224 of the judgment under appeal, it must be observed that the latter claimed in the application for annulment, its reply and its answers to the questions put by the General Court that, on account of the easy and immediate biodegradability of bisphenol A, ECHA had wrongly concluded that that substance presented an 'equivalent level of concern' to those of other substances, within the meaning of Article 57(f) of the REACH Regulation.

97 In support of that claim, the appellant referred on several occasions to the fact that bisphenol A did not have the properties of persistence and bioaccumulation that characterise the PBT and vPvB substances and which justified the level of concern to which those substances give rise. By way of illustration, in paragraph 83 of its reply, the appellant expressly argued that, for the purposes of establishing that a substance presents an 'equivalent level of concern' to those of other substances within the meaning of Article 57(f) of the REACH Regulation, 'reference must be [made] to the properties which are relevant for the identification of PBT and vPvB substances, i.e. persistence and bioaccumulation', given that, 'in this case, [bisphenol A] does not meet the properties of either persistence in the environment (as it rapidly degrades) or bioaccumulation (as it has a low bioaccumulation potential)'.

98 In paragraph 224 of the judgment under appeal, far from distorting the appellant's written pleadings, the General Court recalled them, in accordance with its obligation to state reasons, by noting the contradictory nature thereof.

99 In so far as concerns, in the second place, the appellant's arguments relating to ECHA's assessment that bisphenol A presented 'an equivalent level of concern' within the meaning of Article 57(f) of the REACH Regulation, it should be noted that the appellant merely summarises the observations which it submitted to the General Court in that regard, criticising the latter for having rejected the interpretation which it had put forward.

100 It must be borne in mind that, as is clear from the case-law cited in paragraph 46 of the present judgment, the General Court is to confine itself to reviewing whether ECHA's evaluation is vitiated by a manifest error or constitutes a misuse of powers, or whether ECHA has manifestly exceeded the limits of its discretion.

101 In paragraph 229 of the judgment under appeal, the General Court held, following a detailed examination of the arguments put forward by the appellant, that the latter had failed to demonstrate how ECHA could have committed a manifest error of assessment in establishing an 'equivalent level of concern'. None of the arguments put forward by the appellant in support of its appeal can invalidate that assessment or allow it to be considered that the General Court erred in law in concluding that there was no manifest error of assessment on ECHA's part.

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

The third ground of appeal, alleging errors of law in the assessment of the evidence relating to the reliability of scientific studies and distortion of evidence

Arguments of the parties

103 By its third ground of appeal, the appellant submits that the General Court committed several errors of law in its assessment of the evidence relating to the reliability of certain scientific studies and, moreover, distorted some of that evidence.

104 In the first place, the appellant claims that the General Court distorted the evidence by holding, in paragraph 66 of the judgment under appeal, that ECHA had not committed a manifest error of assessment by not finding that the Bjerregaard et al. (2008) study constituted relevant evidence, inasmuch as the authors of that study had not, in ECHA's view, observed major changes in the gonad development for the fish after exposure of egg and fry to bisphenol A. The General Court arrived at that conclusion, according to the appellant, on the basis of speculative comments made by the authors of that study suggesting that a longer exposure period might have resulted in effects on gonad differentiation.

105 In the second place, the appellant submits that the General Court erred in holding, in paragraph 69 of the judgment under appeal, that ECHA had not failed to take into account the Rhodes et al. (2008) study, as published in Mihaich et al. (2012). According to the appellant, if ECHA had taken that study into account, it would have had to conclude that that study showed no population-relevant adverse effects of bisphenol A for the fathead minnow (*Pimephales promelas*).

106 In the third place, the appellant submits that the General Court distorted the evidence available to it, by considering that the Sumpter et al. (2001) study corroborates ECHA's conclusions since that study also finds that vitellogenin is induced following exposure to bisphenol A, whereas the increase in vitellogenin does not, in itself, constitute an adverse effect.

107 In the fourth place, the appellant criticises the General Court for misinterpreting, in paragraphs 140 to 144 of the judgment under appeal, the exercise, by ECHA, of its discretion, and for distorting the evidence, by finding that both the Heimeier et al. (2009) study and the Iwamuro et al. (2003) study, two *in vivo* studies on amphibians of the species *Xenopus laevis*, could be given a reliability score of 2, namely 'reliable with restrictions', in the Klimisch scoring system and thus be part of ECHA's scientific evidence as key studies.

108 In the fifth place, the appellant criticises the General Court for holding, in paragraphs 152 to 163 of the judgment under appeal, that ECHA had not committed a manifest error of assessment by regarding the Chen et al. (2015) study as reliable and constituting a key study, thus distorting the evidence and breaching the principle of scientific excellence.

109 In the sixth place, the appellant submits that the General Court erred by finding that the Chen et al. (2015) study is reliable by reference to the Segner et al. (2003a) study, the Keiter et al. (2012) study and the Yokota et al. (2000) study, and failed to address the appellant's argument that the Segner et al. (2003a) and Keiter et al. (2012) studies had failed to evaluate sex ratio. In the appellant's submission, the General Court found, in paragraph 158 of the judgment under appeal,

that the latter two studies report other indicators confirming the existence – or, at the very least, the probability – of an endocrine mode of action of bisphenol A, namely, in particular, vitellogenin induction, whereas vitellogenin induction is not an indicator of adverse effects.

110 In the seventh and last place, the appellant submits that the General Court wrongly affirmed, in paragraph 159 of the judgment under appeal, and without addressing the arguments put forward by the appellant, that, taken together, the Chen et al. (2015) study and the Yokota et al. (2002) study contribute to the weight of evidence in so far as concerns the effects of bisphenol A on sex ratios in fish populations. The Yokota et al. (2002) study was, in the appellant's submission, conducted at a concentration four orders of magnitude higher than that of the Chen et al. (2015) study, as the General Court acknowledged in the judgment under appeal, and the only concentration in the Yokota et al. (2000) study where a shift in sex ratio was observed was in the range of lethal toxicity.

Findings of the Court

111 It is settled case-law of the Court that where an appellant alleges distortion of the evidence by the General Court, he or she must, under Article 256 TFEU, the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union and Article 168(1)(d) of the Rules of Procedure of the Court of Justice, indicate precisely the evidence alleged to have been distorted and show the errors of appraisal which, in his or her view, led to such distortion. Furthermore, that distortion must be obvious from the documents in the Court's file, without there being any need to carry out a new assessment of the facts and the evidence (judgment of 12 May 2022, *Klein* v *Commission*, C-430/20 P, EU:C:2022:377, paragraph 23 and the case-law cited).

112 In the present case, it is clear that none of the distortions claimed by the appellant is obvious from the documents in the file within the meaning of the case-law referred to in paragraph 111 of the present judgment.

113 In so doing, by its line of argument, the appellant seeks, in reality, to obtain a re-examination by the Court of Justice of the evidence produced before the General Court, the assessment of which falls within the exclusive jurisdiction of the General Court, in accordance with the case-law referred to in paragraph 84 of the present judgment.

114 It follows from the foregoing that the third ground of appeal must be rejected in its entirety as inadmissible.

The fourth ground of appeal, alleging misinterpretation of the precautionary principle

Arguments of the parties

115 By its fourth ground of appeal, the appellant claims that, in paragraphs 88 and 223 of the judgment under appeal, the General Court misinterpreted the precautionary principle in order to allow ECHA to rely, in its assessment of the evidence, on non-validated and unreliable scientific studies and on alleged uncertainties concerning the determination of a safe level of exposure. The appellant submits that that principle, which underlies all the provisions of the REACH

Regulation, cannot be relied on by ECHA in order to avoid fulfilling its obligation under Article 57(f) of the REACH Regulation and not to comply with the principle of scientific excellence.

116 According to the appellant, it is apparent from the judgment of 1 October 2019, *Blaise and Others* (C-616/17, EU:C:2019:800, paragraphs 43 and 46), that the precautionary principle only allows protective measures to be adopted when there is uncertainty as to the existence or extent of the risks. However, that principle does not mean that EU agencies may adopt measures on the basis of unreliable scientific data.

117 The appellant also relies on heading 5.1 of the Communication from the Commission on the precautionary principle, entitled 'Factors triggering recourse to the precautionary principle', from which it follows, in the appellant's submission, that the scope of the precautionary principle is circumscribed to uncertainty surrounding whether or to what extent a substance poses a risk. By contrast, that principle cannot be invoked as a trump card in case of insufficient, in this case unreliable, evidence that a substance even has an intrinsic property, that is to say, a hazard, which is a step before assessing whether the substance actually poses a risk to human health or the environment.

118 ECHA, the Federal Republic of Germany, the French Republic and ClientEarth dispute the appellant's arguments and contend that the fourth ground of appeal is unfounded.

Findings of the Court

119 As regards paragraph 88 of the judgment under appeal, it should be observed that this forms part of a series of grounds set out by the General Court in paragraphs 71 to 90 of the judgment under appeal, in order to respond to a complaint by way of which the appellant criticised the taking into account, by ECHA, of 'non-standard' or 'exploratory' studies, namely studies which were not conducted in compliance with nationally or internationally validated methods.

120 Even if the General Court had erred in law in paragraph 88 of the judgment under appeal, by misinterpreting the precautionary principle, that error has no influence on the finding that there is no prohibition in principle on ECHA taking 'non-standard' or 'exploratory' studies into account. In that regard, it should be noted that the General Court rejected the appellant's complaint on the basis of the arguments set out in paragraphs 87 and 89 of the judgment under appeal, which were not called into question by the appellant in its appeal.

121 Accordingly, in so far as it relates to paragraph 88 of the judgment under appeal, the fourth ground of appeal must be rejected as ineffective.

122 As to paragraph 223 of the judgment under appeal, it is part of a series of grounds set out by the General Court in paragraphs 211 to 230 of the judgment under appeal, with a view to responding to a complaint by way of which the appellant alleged a manifest error of assessment, on the part of ECHA, in identifying an 'equivalent level of concern' within the meaning of Article 57(f) of the REACH Regulation.

123 More specifically, paragraphs 221 to 223 of the judgment under appeal concern the assessment carried out by ECHA, and the appellant's challenge thereto, concerning the impossibility of establishing a safe level of exposure to bisphenol A.

124 In paragraph 222 of the judgment under appeal, the General Court found that ECHA had taken into account the uncertainties in the determination of a safe level of exposure, resulting, on the one hand, from the fact that certain effects can be observed only during certain life stages, time windows or seasons and, on the other hand, from the fact that bisphenol A affects a wide variety of organisms by means of different endocrine modes of action.

125 It is in that context that, in paragraph 223 of the judgment under appeal, the General Court observed that in the light of those uncertainties – which are, at the very least, plausible – ECHA had taken a cautious approach to the question of the possibility of determining a safe level of exposure to bisphenol A; that caution was 'particularly' justified in the light of the precautionary principle on which the provisions of the REACH Regulation are based pursuant to Article 1(1) thereof. The General Court inferred therefrom that ECHA could not be criticised for having justified the level of concern arising from the effects of bisphenol A on account of its endocrine mode of action, in particular, by relying on the uncertainties that it had identified for the determination of a safe level of exposure to bisphenol A.

126 On reading the relevant grounds of the judgment under appeal, it does not appear, contrary to the appellant's claims, that the General Court interpreted the precautionary principle in such a way that ECHA could base the decision at issue on unreliable scientific data. In paragraph 223 of the judgment under appeal, the General Court states that ECHA, on account of the existence of uncertainties, took a cautious approach to the question of the possibility of determining a safe level of exposure to bisphenol A, such caution being justified in the light of that principle.

127 It should, moreover, be borne in mind that the precautionary principle entails that, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because the results of studies conducted are inconclusive, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures (judgment of 16 June 2022, *SGL Carbon and Others* v *Commission*, C-65/21 P and C-73/21 P to C-75/21 P, EU:C:2022:470, paragraph 96 and the case-law cited).

128 In the light of the uncertainties surrounding the determination of a safe level of exposure to bisphenol A, the General Court rightly found that ECHA's caution in that regard was particularly justified in the light of the precautionary principle, as interpreted by the case-law recalled in paragraph 127 above.

129 It follows that the fourth ground of appeal must be rejected as in part inoperative and in part unfounded.

The fifth ground of appeal, alleging misinterpretation of Article 2(8)(b) of the REACH Regulation and disregard for the obligation to state reasons

Arguments of the parties

130 By the first part of its fifth ground of appeal, the appellant complains that the General Court erred in law in paragraphs 243 to 271 of the judgment under appeal by holding that intermediates such as bisphenol A were not exempt from identification under Articles 57 and 59 of the REACH

Regulation, on the ground that those provisions relate only to the intrinsic properties of a substance and not to its use, and that it was not disproportionate for ECHA to include bisphenol A in the Candidate List of substances.

131 In that regard, the appellant submits, first of all, citing the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802, paragraph 59), that the General Court's interpretation is contrary to the literal interpretation of Article 2(8)(b) of the REACH Regulation, which exempts all intermediates from Title VII of that regulation, in so far as their existence is temporary and they are intended, under Article 3(15) of the REACH Regulation, to be transformed into other substances.

132 Next, the appellant submits that, in paragraph 255 of the judgment under appeal, the General Court justified its interpretation, in particular, by the need to ensure that intermediates do not escape the procedure for identifying substances as being of very high concern. The requirements set out in Article 7(2) and Article 33 of the REACH Regulation were not designed to cover intermediates. The application of those provisions is triggered by the presence, in objects made from chemical substances, of substances meeting the criteria set out in Article 57 of that regulation. Consequently, those provisions are not intended to cover intermediates, since these are intended, by definition, to be transformed into other substances in such a way that they are no longer deemed to be 'present'.

133 Lastly, the appellant submits, first, that the General Court erred in law in considering, in paragraph 252 of the judgment under appeal, that the concept of 'intermediate' refers to the uses of a substance and, secondly, that the uses of a substance are not relevant for identification as a substance of very high concern. It is necessary to differentiate between the 'use of an intermediate substance', a concept properly used in the application, and 'intermediate as a use', a concept referred to by ECHA and also interpreted by the General Court, in the judgment under appeal and in its earlier judgments, as consisting in a certain type of use of a substance.

134 By the second part of its fifth ground of appeal, the appellant claims that the General Court infringed its obligation to state reasons by failing to address a number of arguments set out in its application, which differed from the arguments put forward in the case that gave rise to the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), to which the General Court referred in the judgment under appeal.

135 It is submitted, first, that the finding made by the General Court in paragraph 252 of the judgment under appeal, that 'a certain type of use of substances is therefore covered, inter alia, by Article 17(3) and Article 18(4) of [the REACH Regulation]' did not address the appellant's observations, set out in paragraph 144 of its application for annulment, concerning the specific provisions of that regulation which relate to information to be submitted for the registration of intermediate substances.

136 Second, the General Court also failed to address the arguments raised in paragraph 149 of the application for annulment, according to which the legal interpretation of an 'intermediate' should not be affected by the specific circumstance that the limited information requirements under Articles 17 and 18 of the REACH Regulation are not applicable to a monomer, as is the case for the registration of bisphenol A as an intermediate.

137 The appellant submits that, despite all the aforementioned arguments, which support the conclusion that intermediate substances have a particular legal status within the REACH Regulation and should not be regarded simply as a 'certain type of use of substances', the General Court merely applied the interpretation given by the Court of Justice in its judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802).

138 By the third part of its fifth ground of appeal, the appellant claims that the General Court erred in law, in paragraph 258 of the judgment under appeal, by misinterpreting its written submissions in so far as they concerned Article 49 of the REACH Regulation.

139 The appellant had stressed in paragraph 148 of the application for annulment that not only are intermediates manufactured and/or used under strictly controlled conditions allowed to be registered with limited information, but on-site isolated intermediates that are used under strictly controlled conditions are also specifically exempt from substance evaluation under Article 49 of the REACH Regulation.

140 In the judgment under appeal, the General Court misconstrued that argument by stating that Article 49 of the REACH Regulation served 'a completely different purpose' than identification under Article 57 of that regulation. That reasoning on the part of the General Court fails to consider the fact that Article 49 of the REACH Regulation specifically applies where a Member State competent authority considers that a risk is equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57 of that regulation. Thus, the mirroring of the term 'equivalent level of concern' and express reference to Article 57 of the REACH Regulation shows the EU legislature's clear intention for Article 49 of that regulation to serve as an alternative risk management process, for on-site isolated intermediates, to that provided under the title 'Authorisation' of that regulation.

141 ECHA, the Federal Republic of Germany and ClientEarth dispute the appellant's arguments and, together with the French Republic, contend that the fifth ground of appeal is unfounded.

Findings of the Court

142 In so far as concerns the first part of the fifth ground of appeal, suffice it to note that the General Court correctly applied, in paragraphs 251 to 257 of the judgment under appeal, the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), in so far as concerns the scope of the exemption provided for in Article 2(8)(b) of the REACH Regulation. In paragraph 63 of that judgment, the Court of Justice held that that exemption is inapplicable to the provisions of Title VII of the REACH Regulation, which govern substances in accordance with their intrinsic properties, and that Article 2(8)(b) of that regulation does not preclude a substance from being capable of being identified as being of very high concern on the basis of the criteria laid down in Article 57 of that regulation, even though it is used merely as an on-site or transported isolated intermediate.

143 The first part of the fifth ground of appeal must therefore be rejected as unfounded.

144 In so far as the second part of that ground of appeal is concerned, it must be recalled that, according to settled case-law of the Court of Justice, the duty incumbent upon the General Court under Article 36 and the first paragraph of Article 53 of the Statute of the Court of Justice of the European Union to state reasons for its judgments does not require the General Court to provide an account that follows exhaustively and one by one all the arguments articulated by the parties to

the case. The reasoning may therefore be implicit, on condition that it enables the persons concerned to understand the grounds of the General Court's judgment and provides the Court of Justice with sufficient information to exercise its powers of review on appeal (judgment of 9 December 2020, *Groupe Canal* + v *Commission*, C-132/19 P, EU:C:2020:1007, paragraph 45 and the case-law cited).

145 In the present case, it must be held that the reasoning set out by the General Court in paragraphs 251 to 257 of the judgment under appeal satisfies the requirements set out in paragraph 144 of this judgment, in that it enables the persons concerned to know the grounds on which the General Court relied and provides the Court of Justice with sufficient material for it to exercise its powers of review on appeal.

146 Consequently, that second part must be rejected as unfounded.

147 In so far as concerns the third part of the fifth ground of appeal, which relates to an alleged error of law committed by the General Court in paragraph 258 of the judgment under appeal, it should be noted that that part is based on the premiss that the provisions of Article 49 of the REACH Regulation, applicable to on-site isolated intermediates, preclude the applicability of Article 57 of that regulation to such substances.

148 As is clear from paragraph 258 of the judgment under appeal, that premiss is incorrect. The rules laid down in Article 49 of the REACH Regulation address the possibility of a risk arising from the use of substances as on-site isolated intermediates that are used in strictly controlled conditions, without it being necessary, in order for that article to apply, that those substances fulfil the criteria of Article 57 of that regulation. Thus, as the General Court stated, Article 49 does indeed serve a completely different purpose than Article 57 and does not in any way preclude the applicability of Article 57 where the intrinsic properties of a substance justify its eventual inclusion in Annex XIV to that regulation.

149 The reference to Article 57 of the REACH Regulation in Article 49 of that regulation does not lead to a different conclusion. The aim of that reference is not to introduce an exception to Article 57, but solely to determine the level of risk required in order for Article 49 to apply, since such risk to human health or the environment must be 'to the level of concern arising from the use of substances meeting the criteria in Article 57'.

150 Consequently, the third part of the fifth ground of appeal must be rejected as unfounded.

151 In those circumstances, the fifth ground of appeal must be rejected as being in part unfounded and, accordingly, the appeal dismissed in its entirety.

Costs

152 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. 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.

153 Under Article 184(4) of the Rules of Procedure, 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.

154 Since ECHA and ClientEarth have applied for costs, and PlasticsEurope has been unsuccessful, the latter must be ordered to pay the costs.

155 The Federal Republic of Germany, intervener at first instance, must bear its own costs.

156 Since the French Republic, intervener at first instance, participated in the written part of the procedure before the Court but did not apply for PlasticsEurope to be ordered to pay its costs, it must bear its own costs.

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

1. **Dismisses the appeal;**

2. **Orders PlasticsEurope AISBL to bear its own costs and to pay the costs incurred by the European Chemicals Agency (ECHA) and ClientEarth;**

3. **Orders the Federal Republic of Germany and the French Republic to bear their own costs.**

Lycourgos Rossi Bonichot

Rodin Spineanu-Matei

Delivered in open court in Luxembourg on 9 March 2023.

A. Calot Escobar
Registrar

C. Lycourgos
President of the Chamber