MRF 2023.7

EU-Domstolens dom af 9. marts 2023, 4. afd., sag C-119/21 P, PlasticsEurope mod ECHA

Ikke grundlag for at underkende Det Europæiske Kemikalieagenturs (ECHA) klassificering af bispenol A, der anvendes i plastindustrien, som hormonforstyrrende, bl.a. fordi det ikke var i modstrid med forsigtighedsprincippet, at klassificeringen ikke var baseret på standardstudier.

Bispenol A er et stof, der anvendes i plastindustrien ved fremstilling af bl.a. plastruder (polycarbonat). Efter forslag fra de tyske kemikaliemyndigheder og forudgående høring besluttede Det Europæiske Kemikalieagentur (ECHA) efter enstemmighed i medlemsstatsudvalget i januar 2018 at klassificere bispenol A som hormonforstyrrende. Pla sticsEurope, der er en forening for den europæiske plastindustri, anlagde herefter annullationssøgsmål ved Retten, idet PlasticsEurope gjorde gældende, at klassificeringen var baseret på et åbenbart urigtigt skøn baseret på undersøgelser, der ikke opfyldte de almindelige krav til standardstudier, og at klassificeringen ikke opfyldte forsigtighedsprincippets betingelser. Den tyske og franske regering indtrådte sammen med ClientEarth som biintervenienter til støtte for ECHA. Ved Rettens dom i sag T-207/18 blev ECHA frifundet, idet Retten fandt, at de undersøgelser, der lå til grund for klassificeringen, opfyldte forsigtighedsprincippets krav til videnskabeligt underbyggede risici for, at de iboende egenskaber ved bispenol A kan have hormonforstyrrende virkninger, og at klassificeringen ikke var i modstrid med proportionalitetsprincippet. PlasticsEurope ankede dommen til EU-Domstolen, hvor PlasticsEurope gjorde gældende, at Retten havde foretaget fejlagtig retsanvendelse, og gjorde til støtte herfor bl.a. gældende, at dommen havde lagt en fejlagtig bevisbyrde til grund og ikke havde taget hensyn til, at klassificeringen var baseret på usikre undersøgelser. EU-Domstolen lagde til grund, at ECHA ved klassificeringen korrekt havde taget hensyn til flere undersøgelsers variable grad af pålidelighed, og at der var taget hensyn hertil i Rettens dom, men at det ikke i en ankesag tilkommer EU-Domstolen at fastlægge eller bedømme de relevante faktiske omstændigheder eller bedømme de beviser, som Retten lagde til grund i dommen (præmis 84). EU-Domstolen afviste ligeledes indsigelsen om urigtig anvendelse af forsigtighedsprincippet, idet Domstolen bl.a. anførte, at det ved klassificeringen var lagt til grund, at det ikke var muligt at fastlægge et sikkert niveau for eksponering med bispenol A, og at det derfor ikke var muligt at begrunde, i hvilken grad bispenol A er hormonforstyrrende, hvorefter EU-Domstolen mere generelt anførte, at forsigtighedsprincippet indebærer, at der, når der er usikkerhed mht. omfanget af risiko for menneskers sundhed, begrunder forsigtighedsprincippet, at der træffes beskyttelsesforanstaltninger uden at afvente, at det fuldt ud påvises, at der er en risiko, og hvilket omfang denne har, når sandsynligheden for en reel skade på den offentlige sundhed varer ved, dersom risikoen indtræder (præmis 127). Efter tillige at have afvist indsigelser om fejlagtig retsanvendelse og manglende begrundelsespligt, blev Kommissionen frifundet.

Kommentar: *Dommen er et godt eksempel på, hvordan EU-Domstolen fortolker forsigtighedsprincippet, der således alene finder anvendelse, når der på grundlag af videnskabelige undersøgelser er usikkerhed, om et stofs (eller aktivitets) alvorlige skadelige virkning på offentlig sundhed. Dette forudsætter, at de iværksatte foranstaltninger er i overensstemmelse med proportionalitetsprincippet, hvilket Retten fandt var tilfældet og ikke efterfølgende blev indbragt for EU-Domstolen.*

JUDGMENT OF THE GENERAL COURT (Eighth Chamber)

16 December 2020 (*) (1)

(REACH – Establishment of a list of substances identified with a view to their eventual inclusion in Annex XIV to Regulation (EC) No 1907/2006 – Supplement to the entry relating to the substance bisphenol A on that list – Articles 57 and 59 of Regulation No 1907/2006 – Manifest error of assessment – Weight of evidence approach – Exploratory studies – Intermediate uses – Proportionality)

In Case T-207/18,

PlasticsEurope, established in Brussels (Belgium), represented by R. Cana, É. Mullier and F. Mattioli, lawyers,

applicant,

v

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

defendant,

supported by

Federal Republic of Germany, represented by J. Möller, D. Klebs and S. Heimerl, acting as Agents,

by

French Republic, represented by A.-L. Desjonquères, J. Traband, E. Leclerc and W. Zemamta, acting as Agents,

and by

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

interveners,

APPLICATION pursuant to Article 263 TFEU seeking the annulment of ECHA Decision ED/01/2018 of 3 January 2018, 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, corrigendum OJ 2007 L 136, p. 3), in accordance with Article 59 of that regulation, was supplemented to the effect that bisphenol A is also identified as a substance 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, within the meaning of Article 57(f) thereof,

THE GENERAL COURT (Eighth Chamber),

composed of J. Svenningsen, President, T. Pynnä and J. Laitenberger (Rapporteur), Judges,

Registrar: E. Coulon,

gives the following

Judgment

I. Background to the dispute

1 Bisphenol A (2,2-bis(4-hydroxyphenyl)propane or 4,4’-isopropylidenediphenol, EC 201-245-8, CAS 0000080-05-7) is a substance which is mainly used as a monomer for the manufacture of polymers such as polycarbonate and epoxy resins. It is thus used as an intermediate. In addition, bisphenol A can be used for non-intermediate purposes. This is the case, for example, where it is used in the manufacture of thermal paper.

2 On 12 January 2017, the European Chemicals Agency (ECHA) published on its website its decision ED/01/2017 of 4 January 2017 on the inclusion of bisphenol A in the list of substances identified 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, corrigendum OJ 2007 L 136, p. 3), as amended, as referred to in Article 59(1) of that regulation (‘the Candidate List’), on the ground that that substance had been identified as toxic for reproduction within the meaning of Article 57(c) thereof.

3 On 21 March 2017, the applicant, PlasticsEurope, brought an action for annulment against ECHA Decision ED/01/2017 of 4 January 2017 concerning the inclusion of bisphenol A in the Candidate List. The applicant is an international professional association, established in Belgium and governed by Belgian law, which represents and defends the interests of over 100 member undertakings, made up of manufacturers and importers of plastic products. It has legal personality and capacity. Five of the applicant’s member undertakings are active in placing bisphenol A on the market in the European Union and form part of the applicant’s ‘Polycarbonate/Bisphenol A’ group. The members of that group market bisphenol A for both intermediate and non-intermediate uses. The Court dismissed that action by judgment of 11 July 2019, *PlasticsEurope* v *ECHA* (T-185/17, not published, EU:T:2019:492).

4 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 a substance 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, within the meaning of Article 57(f) thereof. That decision was published on 7 July 2017. The Court dismissed the action brought by the applicant against that decision by judgment of 20 September 2019, *PlasticsEurope* v *ECHA* (T-636/17, under appeal, EU:T:2019:639).

5 On 29 August 2017, the Umweltbundesamt (Federal Environment Agency, Germany; ‘the competent German authority’) submitted, pursuant to pursuant to Article 59(3) of Regulation No 1907/2006, 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 Regulation No 1907/2006.

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

7 On the same day, in accordance with Article 59(4) of Regulation No 1907/2006, ECHA invited all interested parties to submit their comments on that dossier.

8 On 20 October 2017, the applicant submitted comments, on behalf of its members, on the dossier prepared in accordance with Annex XV.

9 The competent German authority subsequently produced a document dated 14 December 2017 and containing its responses to all the comments received by ECHA in the course of the public consultation.

10 Since comments had been received concerning the identification of bisphenol A, ECHA forwarded the dossier to the Member State Committee ('the MSC'), in accordance with Article 59(7) of Regulation No 1907/2006. In line with its working procedures on the identification of substances of very high concern, the MSC received the dossier prepared in accordance with Annex XV, a draft agreement of the MSC, and a working document ('the Support Document') containing the assessment of the intrinsic properties of bisphenol A in support of its identification under Article 57(f) of Regulation No 1907/2006.

11 At its 57th meeting, which took place from 11 to 15 December 2017, the MSC unanimously decided to identify bisphenol A as a substance of very high concern that meets the criteria set out in Article 57(f) of Regulation No 1907/2006. Four Member States abstained from the vote. Amongst those States, the United Kingdom of Great Britain and Northern Ireland set out the reasons for its abstention in a statement annexed to the minutes of the meeting. 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. 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 Word Health Organisation (WHO) and interpreted by the European Commission's Endocrine Disrupters Expert Advisory Group. More specifically, the Support 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. Moreover, that document takes the view, in further support of its conclusions, 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. 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 that regulation, namely substances that are carcinogenic, mutagenic or toxic to reproduction ('CMR substances'), or persistent, bioaccumulative and toxic substances ('PBT substances') and very persistent and very bioaccumulative substances ('vPvB substances'). To those ends, the Support Document relies, inter alia, on the severity 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.

12 On 3 January 2018, following the unanimous agreement of the MSC and in accordance with Article 59(8) of Regulation No 1907/2006, ECHA adopted Decision ED/01/2018 ('the contested decision'), 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, for reasons set out in the Support Document, as a substance 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 other substances listed in Article 57(a) to (e) of that regulation, within the meaning of Article 57(f) thereof.

13 On 15 January 2018, the Candidate List published on ECHA's website was updated in accordance with the contested decision.

II. Procedure and forms of order sought

14 By application lodged at the Registry of the General Court on 23 March 2018, the applicant brought the present action.

15 On 18 June 2018, the applicant requested that the Court join Cases T-185/17, T-636/17 and T-207/18 for the purposes of the oral phase of the procedure and, where appropriate, the decision which closes the proceedings, pursuant to Article 68 of the Rules of Procedure of the General Court.

16 The defence was lodged at the Court Registry on 19 June 2018.

17 By separate documents, lodged at the Court Registry on 9 July 2018, the applicant made a request, having regard to the fact that the French Republic and ClientEarth were interveners in Cases T-185/16 and T-636/16 and in the event that the present case were joined with those two cases, for confidential treatment of certain information communicated in the application and the defence lodged in the present proceedings vis-à-vis the French Republic and ClientEarth.

18 By documents lodged at the Court Registry on 18 July, 19 July and 24 July 2018, respectively, the Federal Republic of Germany, ClientEarth and the French Republic applied for leave to intervene in support of the form of order sought by ECHA.

19 On 26 July 2018, the President of the Fifth Chamber of the General Court decided not to join the present case to Cases T-185/17 and T-636/17.

20 By separate documents, lodged at the Court Registry on 27 August 2018, the applicant submitted three requests for confidential treatment of certain information communicated in the application vis-à-vis the Federal Republic of Germany, the French Republic and ClientEarth, respectively.

21 A reply was lodged on 10 September 2018.

22 By order of 2 October 2018, the President of the Fifth Chamber of the Court granted ClientEarth leave to intervene. By two orders of 9 October 2018, the President of the Fifth Chamber of the Court granted the Federal Republic of Germany and the French Republic leave to intervene.

23 Since the Federal Republic of Germany and the French Republic did not oppose, within the prescribed time limit, the confidential treatment of certain information communicated in the application, as requested by the applicant on 27 August 2018, the applicant's requests were granted vis-à-vis those intervening parties.

24 By written submission lodged at the Court Registry on 25 October 2018, ClientEarth opposed the applicant's request for confidential treatment of 27 August 2018.

25 On 30 October 2018, the rejoinder was lodged at the Court Registry.

26 On 23 November and 26 November 2018, the French Republic and the Federal Republic of Germany lodged their respective statements in intervention, drafted on the basis of a non-confidential version of the application, at the Court Registry.

27 After hearing the applicant in relation to the objections raised by ClientEarth concerning the request for confidential treatment, by order of 13 December 2018 the President of the Fifth Chamber of the Court rejected that request vis-à-vis ClientEarth.

28 On 28 January 2019, ClientEarth lodged its statement in intervention.

29 By documents lodged at the Court Registry on 14 March and 15 March 2019, ECHA and the applicant submitted their respective observations on the statements in intervention.

30 By document lodged at the Court Registry on 2 May 2019, the applicant requested a hearing, on the basis of Article 106(1) of the Rules of Procedure.

31 As the composition of the Chambers had been altered, the present case was assigned to a new Judge-Rapporteur sitting in the Eighth Chamber.

32 On 10 March 2020, the Court, by way of a measure of organisation of procedure, put questions to the main parties for written answer, to which they duly replied within the time limit prescribed.

33 On 7 April 2020, the Court, by way of a measure of organisation of procedure, asked the main parties whether, in the light of the health crisis associated with COVID-19, they nevertheless intended to be heard at a court hearing.

34 By way of a measure of organisation of procedure of 12 May 2020, the Court invited each party to submit its observations on the replies of the main parties to the Court's written questions of 10 March 2020. The parties complied with that request within the time limit prescribed.

35 By documents lodged at the Court Registry on 28 May and 1 June 2020 respectively, the applicant and ECHA requested that, for reasons associated with the health crisis due to COVID-19, the hearing – then listed for 22 June 2020 – be postponed to a later date. On 5 June 2020, the President of the Eighth Chamber decided not to grant those requests. On the same day, the Court asked ECHA to indicate whether it was able to take part in the hearing via video-conference. By documents lodged at the Court Registry on 10 June 2020, ECHA confirmed its participation in the hearing via video-conference.

36 By document lodged at the Court Registry on 9 June 2020, the applicant stated that, like ECHA, it wished to participate in the hearing via video-conference. However, the applicant stated that it would withdraw its request for a hearing in the event that its participation in a hearing held via video-conference were not technically possible at the same time as ECHA.

37 On 12 June 2020, in the light of the fact that it was technically impossible for the Court to hear both of the main parties at the same time in a hearing via video-conference and of the withdrawal, in that case, of the applicant's request for a hearing, the President of the Eighth Chamber ultimately decided to cancel the hearing. Having due regard to the answers provided by the parties to its questions and to their respective observations on those answers, the Court, considering that it had sufficient information available to it from the documents in the file, therefore decided to close the oral phase of the procedure.

38 The applicant claims that the Court should:

– declare the application admissible and well founded;

– annul the contested decision;

– order ECHA to pay the costs;

– take such other or further measure as justice may require.

39 ECHA contends that the Court should:

– dismiss the action in its entirety;

– order the applicant to pay the costs of both parties.

40 The Federal Republic of Germany and the French Republic contend that the Court should dismiss the action.

41 ClientEarth contends that the Court should:

– dismiss the action in its entirety;

– order the applicant to pay the costs of the proceeding.

III. Law

42 In support of its action, the applicant relies on four pleas in law. The first plea alleges the existence of several manifest errors of assessment in the identification of bisphenol A as a substance of very high concern under Article 57(f) of Regulation No 1907/2006, namely as a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in of other substances listed in Article 57(a) to (e) of that regulation. By the second plea, the applicant alleges infringement of Article 59 of Regulation No 1907/2006, read in conjunction with Article 57(f) thereof. The third plea alleges infringement of Article 2(8)(b) of the regulation. By its fourth plea, the applicant alleges infringement of the principle of proportionality.

A. The first plea: manifest errors of assessment in the application of Article 57(f) of Regulation No 1907/2006

43 By its first plea, the applicant claims that, by adopting the contested decision, ECHA committed several errors of assessment in the light of the requirement set out in Article 57(f) of Regulation No 1907/2006, under which the identification of a substance as an endocrine disruptor of very high concern must be based on 'scientific evidence of probable serious effects to … the environment' which give rise to 'an equivalent level of concern' to the effects covered by Article 57(a) to (e) of that regulation.

44 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contends that that plea should be rejected.

45 The arguments relied on in support of the first plea may be grouped into two separate parts. First, the applicant argues that ECHA committed a manifest error in the assessment of the evidence that it regarded as relevant for the purposes of the identification of bisphenol A, as it failed to take certain data into account and relied on exploratory studies. Second, the applicant relies on a manifest error of assessment in the identification of bisphenol A under Article 57(f) of Regulation No 1907/2006, by claiming in essence that the data evaluated by ECHA cannot substantiate the conclusions that it reached on the basis thereof.

1. The first part of the first plea: manifest error in the assessment of the relevant evidence in the examination referred to in Article 57(f) of Regulation No 1907/2006

46 By the first part of the first plea, which consists in two complaints, the applicant claims in essence that ECHA committed a manifest error in the assessment of the relevant evidence for the identification of bisphenol A as an endocrine disruptor that may have serious effects on the environment under Article 57(f) of Regulation No 1907/2006.

(a) The first complaint in the first part of the first plea: manifest error of assessment owing ECHA's alleged failure to take certain studies into account

47 In the first complaint in the first part of the first plea, the applicant claims that ECHA committed a manifest error of assessment by failing to examine, carefully and impartially, all the relevant facts of the individual case. In that connection, the applicant relies, inter alia, on the duty of care which requires that ECHA take all the relevant facts into account. It is argued that ECHA failed to take into account (i) the research programme known as 'Clarity-BPA' (Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity; 'the Clarity-BPA programme'), which was still ongoing during the period in which bisphenol A was evaluated with a view to adopting the contested decision, and (ii) the results of a certain number of studies which the applicant regards as relevant. That, in the applicant's submission, had an impact on the validity of applying the weight of evidence approach to the evidence in the individual case and, therefore, calls the identification of bisphenol A as a substance of very high concern into question.

(1) The alleged failure to take the Clarity-BPA programme into account

48 The applicant claims, first of all, that ECHA failed to take the results of the Clarity-BPA programme into account. The draft report of the Clarity-BPA programme was published on 23 February 2018, that is only a few weeks after the identification of bisphenol A by ECHA.

49 The Clarity-BPA programme was launched in 2012 under the auspices of the National Toxicology Programme (United States; 'the NTP'), the National Center for Toxicological Research (United States; 'the NCTR'), the United States Food and Drug Administration ('the FDA') and the National Institute of Environmental Health Sciences (United States; 'the NIEHS'). That programme was launched in order to examine the divergent findings reached, up until that point, by a series of toxicological studies concerning bisphenol A. It was designed to examine, inter alia, the potential effects on human health of exposure to low levels of endocrine active agents, and take into account a wide range of doses and new relevant 'parameters' ('endpoints') which had never been used before.

50 The applicant takes the view that any of the findings of the Clarity-BPA programme affected the evidence available to ECHA and, consequently, should have been included in the application of the weight of evidence approach on which the identification of bisphenol A as an endocrine disrupting substance affecting the environment was based. The applicant claims that ECHA ought therefore to have awaited the publication of those results. Furthermore, the applicant takes the view that the fact that the Clarity-BPA programmed focused on the effects on human health rather than on the environment is not of crucial importance. The Clarity-BPA programme is also relevant for environmental purposes. Since any alleged effects on human health are assessed on the basis of animal data, data on human health and data on the environment cannot be completely and drastically separated from one another.

51 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

52 It should be observed that, as the Court has already ruled (judgment of 20 September, *PlasticsEurope* v *ECHA*, T-636/17, under appeal, EU:T:2019:639, paragraph 170), bearing in mind the dynamic and exploratory nature of scientific research generally, there will probably always be an ongoing study or a study about to begin on a substance examined pursuant to one of the points of Article 57 of Regulation No 1907/2006 according to the procedure referred to in Article 59 of that regulation. If ECHA had to await the completion of all the studies conducted on a certain substance, no substance could ever be identified as being of very high concern, which would be contrary to the main objective of that regulation, which is to ensure a high level of protection of human health and the environment, as laid down in Article 1(1) of Regulation No 1907/2006.

53 Moreover, although Regulation No 1907/2006 does not contain express provisions concerning the possibility of re-examining the inclusion of a substance on the Candidate List under Article 59 of Regulation No 1907/2006, it should be recalled that any decision adopted on the basis of that provision can, as a general rule, be re-examined in the light of new information available without any express provision being required (see, to that effect, judgment of 20 September, *PlasticsEurope* v *ECHA*, T-636/17, under appeal, EU:T:2019:639, paragraph 165).

54 In that connection, it should be observed that Article 58(8) of Regulation No 1907/2006 provides that substances included in Annex XIV to that regulation may be removed therefrom where, as a result of new information, they no longer meet the criteria of Article 57 of that regulation. That provision presupposes that ECHA can and, where necessary, must carry out a re-examination on the basis of new, relevant information. Given that the identification of a substance under Articles 57 and 59 of Regulation No 1907/2006 is carried out with a view to the eventual inclusion thereof in Annex XIV to that regulation, the right and, where appropriate, the obligation to carry out a re-examination on the basis of new information applies a fortiori, inter alia also during the period between (i) the identification of a substance under Article 57 of Regulation No 1907/2006 and its inclusion on the Candidate List and (ii) the subsequent inclusion in Annex XIV to that regulation. Consequently, any new information arising from a study that was still ongoing at the time of the identification of a substance as being of very high concern is therefore likely to be taken into account, where appropriate, even after the identification laid down in Articles 57 and 58 of Regulation No 1907/2006, and before the subsequent inclusion of that substance in Annex XIV to that regulation.

55 In the light of the foregoing, it must be found that ECHA committed no error of assessment by omitting to take the Clarity-BPA programme into consideration. ECHA was thus not required to take that programme into account, since it had not yet been completed at the time when the contested decision was adopted.

(2) The studies allegedly disregarded by ECHA

56 The applicant also claims that ECHA wrongly excluded high-quality studies obtained, in part, in accordance with internationally recognised protocols and scored as reliable on the Klimisch scoring scale (as described in an article by Klimisch, H.J., Andreae, M., and Tillmann, U., ‘A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data’, *Regulatory Toxicology and Pharmacology*, 1997, Elsevier, vol. 25, pp. 1-5) (‘the Klimisch scoring

system’). It is argued that by excluding those studies in the present case, ECHA committed a manifest error in its assessment of the relevant information. The applicant takes the view that that assessment was therefore arbitrary and inconsistent, thereby justifying the annulment of the contested decision.

57 First, according to the applicant, ECHA disregarded the Bjerregaard et al. (2008) study relating to brown trout, even though that study was sufficiently sound and substantiated and ought to have been given a reliability score of 2 in the Klimisch scoring system. The applicant argues that that study did not demonstrate any serious effects of bisphenol A on sex ratio or gonad development.

58 Second, the applicant claims that the Support Document does not refer to the Picard (2010c) study on the *Lumbriculus variegatus*, which used the test method approved by Test Guideline No 225 of the Organisation for Economic Co-operation and Development (OECD). The applicant takes the view that this study, which indicates a no-effect concentration level that is four orders of magnitude higher than in a study relied upon by ECHA, namely the Ladewig et al. (2006) study, which ought to have been given a score of 1 in the Klimisch scoring system. Furthermore, the applicant claims that ECHA wrongly excluded the Picard (2010a) study on *Leptocheirus plumulosus* and the Picard (2010b) study on *Chironomus riparius*. ECHA failed to state the extent to which these two studies were not relevant to the identification of bisphenol A.

59 Third, the applicant criticises ECHA for disregarding the Lee (2010) study on *Americamysis bahia*. This study – which, it is argued, complies with good laboratory practice – does not refer to the existence of any endocrine mediated effects of bisphenol A.

60 Fourth and last, according to the applicant, ECHA failed to take into account the Rhodes et al. (2008) study on *Pimephales promelas*, as published in Mihaich et al. (2012). This study was specifically designed and conducted with the aim of addressing certain deficiencies in scientific knowledge, highlighted in the European Union Risk Assessment Report on Bisphenol A, drawn up 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) (‘the EU RAR’), as they may appear in the assessment of spermatogenesis included in the Sumpter et al. (2001) study conducted on the same species. ECHA should therefore have taken into account the results of the Rhodes et al. (2008) study, as published in Mihaich et al. (2008), according to which the observed effects of bisphenol A are the consequence of systemic toxicity rather than an endocrine mode of action.

61 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

62 As a preliminary point, it should be observed that ECHA enjoys a broad discretion in the identification of substances of very high concern under Article 57(f) of Regulation No 1907/2006. In that connection, it should be noted that this broad discretion of the authorities of the European Union, 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 European Union authorities which have adopted the act in question must be able to show before the European Union judicature 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 (see judgment of 30 April 2015, *Polynt and Sitre* v *ECHA*, T-134/13, not published, EU:T:2015:254, paragraph 53 and the case-law cited).

63 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 Regulation No 1907/2006, 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 insufficient to support that hypothesis or finding. That approach presupposes that the competent authority examines all relevant information before identifying a substance as being of very high concern. Annex XV to Regulation No 1907/2006 thus provides that the dossier which initiates the authorisation procedure is to contain an examination of the relevant information from registration dossiers and, where

appropriate, can rely on all other information available. It is therefore clear from Regulation No 1907/2006 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 Regulation No 1907/2006 whilst taking into account all relevant evidence available at the time when the authority adopts its decision.

64 The approach taken by ECHA – that is, the weight of evidence approach – together with the discretion which it enjoys, including with a view to the finding of the basic facts (see, to that effect, judgment of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 164), mean, however, that it may exclude studies that it does not deem relevant for plausible reasons connected to the internal consistency of the assessment carried out. In that regard, it should be observed – as is noted, moreover, by ClientEarth – that bisphenol A is one of the most studied substances in the world. Consequently, the obligation incumbent on the institutions of the European Union to take all relevant evidence into consideration cannot mean that all the studies conducted, irrespective of the reliability or relevance thereof, must necessarily and without exception be included in ECHA's assessment. 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.

65 It is in the light of those preliminary observations that it is necessary to examine whether ECHA committed a manifest error of assessment on the ground that it failed to take into account the studies on which the applicant relies.

66 As regards, first, the Bjerregaard et al. (2008) study, it should be noted that ECHA did not regard it as particularly relevant, on the ground that the authors of that study had not, in ECHA's view, observed 'major changes in the gonad development for the fish' after exposure of brown trout egg and fry to E2 or bisphenol A, and that the authors stated that 'it is possible that the exposure period in the present study should have covered a larger part of the sex differentiation period of the brown trout if gonad differentiation should have been affected'. It is therefore clear from the study itself that the fact that no major change in gonad development was observed can be explained by the possibility that the study's exposure period covered too short a part of the sex differentiation period for brown trout. That possibility found by the authors of the study themselves was capable of leading ECHA to call into question the relevance of the results thereof. Accordingly, ECHA did not commit a manifest error by not finding that the Bjerregaard et al. (2008) study constituted relevant evidence.

67 As regards the Picard (2010a, 2010b, 2010c) studies, on *Leptocheirus plumosus, Chironomus riparius* and *Lumbriculus variegatus*, respectively, it should be noted that, as is apparent, moreover, from the applicant's contribution to the public consultation, the results of those studies were published in the Staples et al. (2016) publication which is itself amongst the evidence examined in the Support Document in support of the identification of bisphenol A. The Support Document cites the Staples et al. (2016) study on chironomids, in so far as that group of insects is a taxon relevant to the evaluation of invertebrates. In that study, the impact on emergence is, it is argued, regarded as relevant for the population and possibly endocrine mediated. However, as ECHA explains, the effects observed on the species *Leptocheirus* and *Lumbriculus* were not at the heart of the evaluation of the endocrine disruptor in that study. Consequently, ECHA cannot be criticised for having failed to include the Picard studies in its assessment, especially given that, in any event, it took them into account through the Staples et al. (2016) study, on which it formally relied with a view to adopting the contested decision.

68 In so far as concerns the Lee (2010) study on *Americamysis bahia*, a species of invertebrate, it should be observed that it is apparent from the Support Document and from ECHA's observations on the applicant's answer in that regard to a question put by the Court that ECHA deliberately did not carry out an exhaustive analysis of the effects of bisphenol A on invertebrates and did not decisively base the identification of bisphenol A on evidence relating to invertebrates. ECHA took into account the fact that endocrine disruption in invertebrates was not sufficiently understood at scientific level. Furthermore, the applicant has failed either to explain or demonstrate the extent to which the results of that study – which does not set out any endocrine mediated effects – contradict the identification of bisphenol A as a substance of very high concern on the basis of evidence other than that relating to invertebrates, with the result that those results invalidate the weight of evidence in the assessment

carried out. Accordingly, the decision not to rely on that study appears, ultimately, to be justified and within the scope of ECHA's discretion in the identification of relevant evidence. Consequently, that decision is not vitiated by a manifest error in that respect.

69 As regards, lastly, the Rhodes et al. (2008) study, as published in Mihaich et al. (2012), it should be observed that, contrary to the applicant's claim, this study was indeed taken into account by ECHA, as is clear from page 44 of the Support Document. In that document, no reference is made to any contradiction between that study and the Sumpter et al. (2001) study. On the contrary, the Support Document concludes that the Rhodes et al. (2008) study, as published in Mihaich et al. (2012) does indeed chime with the results of the Sumpter et al. (2001) study, which not only discusses effects on spermatogenesis, but also finds that vitellogenin is induced following exposure to bisphenol A. In so far as concerns the weaknesses on which the applicant relies as to the data on spermatogenesis in the Sumpter et al. (2001) study, it should be noted, as ECHA also observes, that, whilst it is true that certain weaknesses were included in the EU RAR, the authors of that report nevertheless regarded those data as unsuitable solely in the specific context of determining a predicted no-effect concentration. Thus, that aspect does not, per se, call into question the relevance of those data to the identification of bisphenol A on account of its intrinsic properties, namely its endocrine mode of action. The applicant's claim that ECHA failed to take into account the Rhodes et al. (2008) study, as published in Mihaich et al. (2012), is therefore unfounded.

70 In the light of the foregoing considerations, the applicant's argument that ECHA committed a manifest error of assessment on the ground that it failed to take into consideration the studies relied upon by the applicant and, accordingly, the first complaint in the first part of the first plea, must be rejected.

(b) The second complaint in the first part of the first plea: the taking into account of allegedly unreliable exploratory studies

71 By the second complaint in the first part of the first plea, the applicant claims that ECHA relied on numerous non-standard or exploratory studies, namely studies that were not conducted in compliance with nationally or internationally validated methods, whereas Regulation No 1907/2006 generally does not permit reliance on studies that follow non-validated methods, inasmuch as those studies cannot be regarded as reliable.

72 The applicant acknowledges that such non-standard or exploratory studies, which often relate to new species or new endpoints, are of a certain scientific interest in that they serve to extend knowledge. It argues that such studies are, however, vitiated by shortcomings, namely poor reproducibility, inter alia. That therefore calls their scientific reliability into question, precluding their being used for regulatory purposes.

73 In support of its argument, the applicant relies on Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ 2017 L 301, p. 1), which, it is claimed, provides that the identification of a substance as an endocrine disruptor must be based on either 'scientific data generated in accordance with internationally agreed study protocols' or 'other scientific data selected applying a systematic review methodology'.

74 Furthermore, the applicant relies on version 3.1 of the ECHA Guidance on Data-sharing of January 2017 which, it is argued, recommends that market participants providing information relating to a substance with a view to assessing the risks thereof preferably to use scientific studies with a score of 1 or 2 in the Klimisch scoring system. It is argued that by applying a higher standard of scientific reliability to information provided by market participants than to information on which it may rely for the identification of a substance as being of very high concern, ECHA is applying a 'double standard' which is unacceptable, according to the applicant.

75 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

76 It should be borne in mind that, in the present case, ECHA arrived at the identification of bisphenol A as a substance of very high concern under Article 57(f) of Regulation No 1907/2006 by following the

weight of evidence approach, as described in paragraph 63 above. That approach requires that the competent authority take account of all relevant evidence for the identification of a substance as being of very high concern.

77 It is therefore clear, inter alia, from point 1.2 of Annex XI to Regulation No 1907/2006 that, in a weight of evidence approach, newly developed test methods which are not yet included in the test methods and therefore do not correspond to those defined in a Commission regulation, or an international test method recognised by the Commission or ECHA, may serve as evidence for those purposes.

78 Moreover, it follows from the third paragraph of point I of Annex XV to Regulation No 1907/2006 – which is applicable in the present case pursuant to Article 59(3) of that regulation, read in conjunction with the second indent of the first paragraph of point I of Annex XV – that, for all dossiers referred to in Article 59 of the regulation, the relevant information from registration dossiers is to be considered and that it is possible to use 'any other available information'.

79 Admittedly, it follows from the first subparagraph of Article 13(3) of Regulation No 1907/2006 that, for the purposes of the registration of substances, generally, where tests on substances are required to generate information on intrinsic properties of substances, those tests are to be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or ECHA as being appropriate.

80 However, it follows from the second subparagraph of Article 13(3) of Regulation No 1907/2006, read in conjunction with point 1.1.2 of Annex XI to that regulation, that the provisions referred to in paragraph 79 above do not constitute an absolute rule that from the outset prohibits ECHA from taking into consideration, for the purposes of the identification of substances of very high concern, studies which have not been conducted in compliance with validated methods.

81 Although the first subparagraph of Article 13(3) of Regulation No 1907/2006 requires that tests on substances be carried out in compliance with internationally validated methods, the second subparagraph of Article 13(3) of that regulation allows information to be submitted on the intrinsic properties of substances 'in accordance with other test methods provided that the conditions set out in Annex XI are met'. In that connection, point 1.1.2 of Annex XI to Regulation No 1907/2006 provides, inter alia, that data on environmental properties from experiments not carried out according to good laboratory practice or the test methods referred to in Article 13(3) of that regulation, are considered to be equivalent to such data generated, if certain conditions laid down in the same point, relating for example to exposure duration or key parameters, are met.

82 Furthermore, point 1.2 of Annex XI to Regulation No 1907/2006 states that 'there may be sufficient weight of evidence' from the use of newly developed test methods, not yet included in the international test methods referred to in Article 13(3) of that regulation 'leading to the conclusion that a substance has or has not a particular dangerous property'. Thus Regulation No 1907/2006 recognises 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. It is inherent to that approach that the non-standard nature and, where applicable, the poor reliability of that 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 Regulation No 1907/2006.

83 In the light of the foregoing considerations, it must be concluded that there is no prohibition in principle on ECHA taking into consideration 'non-standard' or 'exploratory' studies in order to substantiate, in the weight of evidence approach, findings based on standard studies that follow a validated test method for the purposes of the identification of a substance as being of very high concern under Article 57(f) of Regulation No 1907/2006.

84 That finding is in no way called into question by the applicant's argument that ECHA applies a double standard in so far as version 3.1 of its Guidance on Data-sharing of January 2017 recommends that

registrants submit studies with a score of 1 or 2 in the Klimisch scoring system, if they believe that they are entitled to financial compensation from another registrant.

85 It should be noted in that connection that version 3.1 of the ECHA Guidance on Data-sharing of January 2017 contains only a mere recommendation, which is not legally binding, the sole aim of which is to identify those studies which are supposed to be the subject of financial compensation on account of their high quality in the context of the rules on data-sharing laid down in Articles 27 and 30 of Regulation No 1907/2006. That recommendation cannot, in itself, constitute a standard which guides ECHA in the selection of studies substantiating the identification of a substance as being of very high concern under Article 57(f) of that regulation. On the contrary, ECHA must satisfy the weight of evidence approach that it has elected to take, which means that it must take into consideration all the relevant evidence whilst weighting it in accordance with its scientific reliability, amongst other criteria.

86 Moreover, the applicant's argument that 'non-standard' or 'exploratory' studies are regularly vitiated by shortcomings that preclude the use thereof for regulatory purposes, must be rejected.

87 First, it is clear that, in the Klimisch scoring system on which ECHA relied in the present case, studies which are not fully compliant with validated methods can nevertheless be regarded as reliable with restrictions.

88 Furthermore, as the Federal Republic of Germany and ClientEarth both rightly point out, there are no validated methods for all questions relating to the endocrine properties of chemical substances. Studies which are compliant with validated methods are not necessarily the most relevant, inasmuch as they do not all explore the most sensitive parameters for the identification of endocrine properties. However, as the French Republic also observes in that connection, exploratory studies are regularly conducted with the specific aim of verifying a particular scientific hypothesis, with the result that they serve, in complementarity with standard studies, to identify such properties. Consequently, an approach which, as a general rule, excludes the use of non-standard or exploratory studies would make it impossible to identify substances which pose a risk to the environment. The precautionary principle, on which the provisions of Regulation No 1907/2006 are based pursuant to Article 1(3) thereof, means 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 (see, to that effect, judgment of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800, paragraph 43).

89 Given that there is therefore no prohibition in principle on ECHA taking non-standard or exploratory studies into consideration in order to substantiate, in the weight of evidence approach, findings already made on the basis of standard studies and that, in any event, ECHA did not base its decision in the present case exclusively on non-standard or exploratory studies in order to justify the contested decision, as is clear from the Support Document, it must be concluded that the applicant's complaint, whereby ECHA committed a manifest error by not generally excluding non-standard or exploratory studies from the evidence supporting the identification of bisphenol A as being of very high concern under Article 57(f) of Regulation No 1907/2006, is unfounded and, in any event, ineffective.

90 In the light of the foregoing and without prejudice to the individual examination of the arguments put forward by the applicant concerning the reliability of certain studies submitted in the second part of the first plea, the second complaint in the first part of the first plea, and that part as a whole, must be rejected.

2. The second part of the first plea: manifest error of assessment in the identification of bisphenol A as a substance with endocrine disrupting properties for which there is scientific evidence that it may have serious effects on the environment which give rise to an equivalent level of concern to those of substances listed in Article 57(a) to (e) of Regulation No 1907/2006

91 By the second part of the first plea, the applicant claims that ECHA committed several manifest errors of assessment in the identification of bisphenol A as an endocrine disruptor that may have serious effects on the environment giving rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006.

92 The second part consists essentially of three complaints. First, the applicant relies on a manifest error of assessment committed by ECHA in the assessment of the evidence for the identification of bisphenol A. Second, it disputes the fact that ECHA established that there was scientific evidence that bisphenol A may have serious effects on account of its endocrine mode of action. Third, it is claimed that ECHA committed a manifest error of assessment in the determination of the level of concern as referred to in Article 57(f) of Regulation No 1907/2006.

(a) The first complaint in the second part of the first plea: manifest error of assessment in the assessment of the evidence for the identification of bisphenol A as an endocrine disruptor with serious effects on the environment

93 By the first complaint in the second part of the first plea, the applicant claims that ECHA committed a manifest error of assessment in the assessment of the evidence on which it relied for the identification of bisphenol A under Article 57(f) of Regulation No 1907/2006, in so far as it took an arbitrary and inconsistent approach in the assessment of the evidence and relied on studies containing multiple serious flaws which it failed to take into account in assessing the reliability thereof. Pursuant to Article 57(f) of Regulation No 1907/2006, only substances 'such as those having endocrine disrupting properties … for which there is scientific evidence of probable serious effects to … the environment' may be included on the Candidate List.

94 As a preliminary point, it should be observed that ECHA enjoyed discretion in the identification of the intrinsic properties of bisphenol A. In those circumstances, according to settled case-law, in order to establish that that agency has committed a manifest error in assessing complex facts such as to justify the annulment of an act, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible. Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the act (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 86 and the case-law cited). Furthermore, the limits to the review by the Courts of the European Union do not, however, affect their duty to establish whether the evidence relied on is factually accurate, reliable and consistent, whether that evidence contains all the information which must be taken into account in order to assess a complex situation, and whether it is capable of substantiating the conclusions drawn from it (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 87 and the case-law cited).

95 It is in the light of those considerations that it is necessary to consider, in the present case, whether ECHA's assessment of the intrinsic properties of bisphenol A as an endocrine disruptor under Article 57(f) of Regulation No 1907/2006 is vitiated by a manifest error of assessment.

(1) The assessment of the evidence

96 The applicant claims that ECHA neither applied an existing systematic review method nor drafted a document to set out the principles for the selection of studies which it took into consideration for the purposes of assessing bisphenol A with a view to adopting the contested decision. It therefore took an arbitrary and inconsistent approach not only in selecting, but also in appraising the evidence. It is argued that ECHA relied, inter alia, on studies presenting numerous serious flaws that it failed to take into account when assessing their reliability.

97 Article 13 of and Annex XI to Regulation No 1907/2006 lay down the criteria relating to the identification of information, and ECHA's Guidance on Data-sharing requires, inter alia, that the reliability of a study be established using the Klimisch scoring system. It is argued that ECHA applied that scoring system incorrectly. Inter alia, it scored as very reliable or reliable with restrictions (1 or 2 in the Klimisch scoring system) studies which should, in the applicant's view, have been scored as not sufficiently documented or not valid (3 or 4 in the Klimisch scoring system). Nevertheless, those studies were subsequently relied upon by ECHA to substantiate its final determination.

98 Moreover, the applicant argues that the reliability assessment of several *in vivo* studies, as set out in the Support Document, is in clear contradiction with the reliability assessments carried out in the EU RAR. Those errors in the reliability assessment of the studies led to ECHA committing a manifest error in applying the weight of evidence approach correctly to all of the information gathered. In particular,

ECHA failed to provide any justification for the different ways in which it weighed the items of evidence relied upon.

99 The applicant submits that it is also apparent from the bisphenol A hazard assessment protocol, as developed by the European Food Safety Authority (EFSA), that, for the purposes of selecting relevant studies for the assessment of its endocrine disrupting effects in the environment, precise and transparent scientific criteria must be laid down. Moreover, the applicant refers to Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, p. 1), which, it is argued, requires that the quality and consistency of data be ensured appropriately in the context of the weight of evidence approach.

100 In support of its arguments, the applicant relies, by reference made to the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209), on ‘the principles of excellence, transparency and independence’.

101 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

102 It must be observed that, contrary to the applicant’s claims, ECHA did apply a systematic review method, which is clear from Section 5.2 of the Support Document. It is stated in that section that the starting point for evaluating bisphenol A is the definition of an endocrine disruptor for the environment laid down by the WHO, as interpreted by the Commission’s Endocrine Disrupters Expert Advisory Group. Furthermore, the Support Document indicates that the evaluation is to follow the guidelines for assessing chemical substances on account of their endocrine disrupting properties, drawn up by the OECD in its Guidance Document No 150.

103 Next, the Support Document explains that both *in vitro* and *in vivo* data were taken into consideration in order to establish the endocrine mode of action, the serious effects, the plausible biological link between those effects and the endocrine mode of action, and the environmental relevance. To those ends, the Support Document explains that two different types of effect were assessed separately, namely (i) the indicators of an endocrine mode of action and (ii) the consequences for apical endpoints. Given that, as stated in the Support Document, the indicators of an endocrine mode of action and the apical effects differed depending on the taxon, the assessment was based on studies of fish, amphibians and invertebrates, whilst stating that the data on invertebrates cannot be used to support the findings drawn principally from data on certain species of fish and amphibian. In other words, the data on invertebrates were not of autonomous, decisive significance in the findings made by ECHA for the purposes of adopting the contested decision.

104 It is also clear from the Support Document that the *in vitro* and *in vivo* data were taken into account in accordance with the weight of evidence approach, as laid down in Annex XI to Regulation No 1907/2006 and as described in paragraph 63 above. For those purposes, the studies used by ECHA were all evaluated as to their scientific reliability. The Support Document also gives a reliability score to each study, using the Klimisch scoring system. The Support Document thus sets out the criteria which it applies in order to determine whether a study can be regarded as reliable without restriction (1 in the Klimisch scoring system), reliable with restrictions (2 in the Klimisch scoring system), not reliable (3 in the Klimisch scoring system), or such that a score is not assignable (4 in the Klimisch scoring system).

105 In that connection, it should be noted that the Support Document contains, on page 22 thereof, a brief description of the scoring system applied which is not wholly identical to the Klimisch scoring system as described in the article cited in paragraph 56 above. Thus, as an example, according to that publication, a score of ‘1 = reliable without restriction’ is given to studies conducted or data obtained in accordance with validated or internationally recognised guidelines, preferably in accordance with good laboratory practice, but equally to studies in which all the parameters are closely comparable to a guideline. According to the Support Document, the score of 1 is given to studies the design, conduct and documentation of which are of high quality, but are not necessarily in full compliance with

guidelines adopted at international level such as, for instance, those adopted by the OECD. When questioned in the context of a measure of organisation of procedure on those differences in the definition of scoring criteria, ECHA nonetheless confirmed that it had used the Klimisch scoring system exclusively for the identification of bisphenol A. Consequently, the differences in the brief description set out in the Support Document are purely terminological and do not alter the scoring system applied in the present case, which is the Klimisch scoring system.

106 Bearing in mind the reliability score given to a study, the Support Document distinguishes between key studies identified according to their reliability, and the relevance of that study. It is therefore clear from ECHA's replies to a question put by the Court that reliable studies (scores of 1 or 2 in the Klimisch scoring system) 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.

107 Accordingly, it should be found that ECHA applied a review method which systematically guaranteed that the identification of *in vivo* and *in vitro* data on different taxa as relevant evidence was made in full compliance with the principle of scientific excellence. Giving a score using the Klimisch scoring system to each study allowed ECHA in particular to weight the data depending on their scientific reliability. Such a weighting exercise is in fact inherent to the approach taken by ECHA for the identification of bisphenol A as a substance of very high concern under Article 57(f) of Regulation No 1907/2006, which is the weight of evidence approach.

108 As regards the Bisphenol A Hazard Assessment Protocol prepared by EFSA, it should be observed that this protocol, on which the applicant relies, cannot define criteria for assessing the intrinsic properties of bisphenol A, which ECHA is required to observe. That protocol is relevant only to the tasks allocated to EFSA, which are different to those incumbent on ECHA. The EFSA Protocol therefore focuses on assessing the risk associated with a specific use of bisphenol A, namely the risk arising from consumer exposure to a substance, particularly dietary exposure to bisphenol A from materials in contact with foodstuffs, in order to determine the tolerable daily intake of bisphenol A.

109 Furthermore, it must be observed that the fact that the reliability of certain studies was evaluated differently in the EU RAR and the Support Document cannot call into question, generally, the assessment of the intrinsic properties of bisphenol A carried out by ECHA. First, that report does not systematically evaluate the reliability of the studies used. In particular, it does not apply the Klimisch scoring system. Moreover, as the Support Document clearly indicates, the aim of the assessment in question is to assess the endocrine properties of bisphenol A, which distinction sets that assessment apart from others relating to bisphenol A, namely, in particular, the assessment apparent from the EU RAR, the aim of which is to define a predicted no-effect concentration for bisphenol A, and not an assessment of its intrinsic properties as an endocrine disruptor.

110 In that connection, it should also be noted that the Klimisch scoring system is admittedly a methodological tool used as a reference in the present case. However, it is only if ECHA had applied that reliability scoring system in a generally inconsistent manner, therefore affecting the weighting of the evidence, that that approach could be classed as being vitiated by a manifest error of assessment in the identification of bisphenol A as a substance of very high concern. The consistency of the application of the Klimisch scoring system must be assessed in the specific context of the identification of bisphenol A, as carried out by ECHA. The fact that other institutions gave a different reliability score to the same study can be explained, inter alia, by the specific context and the aim of that evaluation and does not necessarily call into question, in itself, the fairness of the overall score given by ECHA to a study.

111 In the light of the foregoing, the applicant's argument concerning an alleged absence of a systematic review method must be rejected.

(2) The in vitro studies

112 In the first place, as regards certain *in vitro* data relied upon in support of the finding relating to the *in vivo* data, the applicant takes the view that ECHA acknowledged certain shortcomings such as, inter

alia, a missing control with E2-antagonist in the MCF-7 assays, and limited knowledge on how to interpret results from invertebrate *in vitro* data. The applicant claims that ECHA nonetheless failed to discuss the fact that those data are not conclusive in particular to support the findings made on the basis of the *in vivo* data.

113 The applicant argues that ECHA also failed to take into account, as ECHA itself has also accepted, the fact that the steroid-binding protein assay could not provide data on the receptor protein affinity of the compounds tested.

114 Moreover, the applicant claims that the *in vitro* studies which served as a basis for the finding as to the oestrogen receptor and androgen receptor pathway made in the Support Document are based neither on a test guideline validated by the OECD nor on a protocol validated by the Environmental Protection Agency (United States; 'EPA'). The Support Document further sets out only a small number of studies on androgenic activity and on thyroid hormone-like activity. Furthermore, the studies cited in the Support Document concerning transcriptional activation or reporter genes under control of oestrogen receptors, androgen receptors and thyroid receptors draw conclusions concerning bisphenol A, according to the applicant, whereas they contain no data relating to bisphenol A. The applicant claims that, in the document prepared by the competent German authority (see paragraph 9 above), ECHA acknowledged that those studies had been cited in error. However, it did not alter the findings substantiated by those studies.

115 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects those arguments.

116 It should be observed that the Support Document is cautious in the assessment of the data drawn from the *in vitro* studies, the limited individual weight of which is acknowledged by ECHA. As an example, there is a finding on page 29 of the Support Document that it is not excluded that the effects observed in the MCF-7 assays were caused by an endocrine mode of action of bisphenol A. The Support Document concludes, on page 32, that all the *in vitro* data suggest that bisphenol A 'may' have an endocrine mode of action. The *in vitro* data, if considered alone, do not in fact serve to draw final conclusions on the mode of action of bisphenol A. Nonetheless, it is consistent that ECHA should use that data in the weight of evidence approach, inasmuch as those data support effects observed in the *in vivo* studies of fish and amphibians.

117 In that connection, it is clear that the applicant is not suggesting that the *in vitro* data contradict the effects observed *in vivo*. It confines itself to calling into question the relevance of certain *in vitro* data, without drawing any consequences for the weight of all of the evidence weighted. That approach does not preclude the *in vitro* data – despite their potentially less reliable and inconclusive nature per se – from supporting the conclusions drawn from the data that are deemed more reliable and conclusive.

118 As ECHA also notes, the general picture drawn by the available *in vitro* data fits very well with the conclusions drawn from the *in vivo* effects observed. Thus the weak anti-androgenic effects can, to a certain extent, support the occurrence of apical oestrogenic effects like a sex ratio skewed to females. As regards, more specifically, the plasma sex steroid-binding protein test, it is apparent from the Support Document that this test shows the ability of bisphenol A to displace E2 from the plasma sex steroid binding protein.

119 Consequently, the applicant's arguments do not demonstrate a manifest error of assessment in the evaluation of the *in vitro* studies which allegedly vitiated the identification of bisphenol A as an endocrine disruptor that may have serious effects on the environment under Article 57(f) of Regulation No 1907/2006.

(3) The in vivo studies conducted on invertebrates

120 In the second place, as regards the *in vivo* studies conducted to observe endocrine effects on invertebrates, the applicant claims that snail studies for freshwater compartment and worm studies with oligochaetes for sediment compartment contain erroneous assessments. It argues that those studies nevertheless played a causal role in the adoption of the contested decision.

(i) The Oehlmann et al. (2006) study on the snail Marisa cornuarietis

121 First, according to the applicant, the studies on the snail *Marisa cornuarietis* conducted by Oehlmann – namely, inter alia, Oehlmann et al. (2006) – are vitiated by significant shortcomings in their design and in the details provided, which weaknesses are also mentioned in the EU RAR and published in the Dietrich et al. (2006) study. The serious effects reported by Oehlmann have never been confirmed by any independent laboratory. In particular, the 'superfeminisation' effects observed by Oehlmann could not be reproduced in the Forbes et al. (2008) study which itself used a test design that was more sound and valid from a statistical perspective and relied on a strain of *Marisa cornuarietis* which is better suited to ecotoxicity assays. The lowest no-effect concentration observed by Forbes et al. (2008) was three to four times higher than in the Oehlmann studies. It is argued furthermore that, during the OECD validation process of what became Test Guideline No 242 concerning *Potamopyrgus antipodarum* reproduction tests, it was apparent that the test system could not be validated in respect of 'superfeminisation' effects. In that connection, the applicant observes that *Marisa cornuarietis* and *Potamopyrgus antipodarum* are key species which belong to the same taxonomic group, namely prosobranch molluscs. Consequently, in the applicant's view, it is 'very likely' that they have identical reproductive characteristics and endocrine systems.

122 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects those arguments.

123 As regards the *in vivo* studies conducted on invertebrates, it should be observed, as a preliminary point, that it is clear from the Support Document itself that, in the absence of scientific consensus on the definition of a plausible biological link between the effects and the endocrine mode of action in those species of invertebrate, and on account of the fragmentary nature thereof, the data drawn from those studies served solely as supplementary evidence in support of conclusions drawn, in the first place, from studies on fish and amphibians.

124 As regards the Oehlmann studies, it is not disputed by ECHA that these contain certain flaws in their experimental design, which are explicitly described in the Support Document and were taken into account for the purposes of giving a reliability score to those studies. That document itself draws the conclusion therefrom that those studies should be treated with caution without disregarding the effects reported in those studies, which the Support Document regards as a possible indicator of the fact that *Marisa cornuarietis* responds extremely sensitively to bisphenol A.

125 However, as observed in paragraph 64 above, the weight of evidence approach does not preclude the identification of a substance also being based on data of low scientific reliability per se, where the latter fact is taken into consideration in weighting the data. In the present case, the Oehlmann studies, like all data drawn from studies on invertebrates, are not key data in the assessment of the endocrine mode of action of bisphenol A, but were used only in support of that assessment. It also follows that the fact that the effects reported by Oehlmann could not be reproduced in the Forbes et al. (2008) study cannot call into question, in particular, the conclusions drawn from the key studies on endocrine mode of action conducted on fish and amphibians.

126 Moreover, the Support Document examines the reasons which may explain the fact that the effects reported in the Oehlmann studies could not be reproduced. These include the different species used and the masking effect of a high reproduction rate, together with the fact that seasonality was not taken into consideration in the Forbes et al. (2008) study. According to the Support Document, the effects observed in the Oehlmann studies could, moreover, be attributed to metabolites that can be seen in the relevant concentrations in semi-static conditions but not in flow-through conditions such as those used by Forbes. Furthermore, as the Federal Republic of Germany and ClientEarth observe, the Forbes studies were not intended to reproduce the Oehlmann studies.

127 Consequently, the manner in which ECHA dealt with the Oehlmann studies is not vitiated by errors in the light of the requirements of the weight of evidence approach.

(ii) The Duft et al. (2003) and Jobling et al. (2004) studies on the snail Potamopyrgus antipodarum

128 Second, the applicant submits similar observations in so far as concerns the studies on the snail *Potamopyrgus antipodarum* conducted by Duft et al. (2003) and by Jobling et al. (2004). In that connection, the applicant claims that the results relating to the effects of bisphenol A set out in those studies could not be confirmed by other definitive studies, in particular Forbes et al. (2007), Forbes et al. (2008), Warbritton et al. (2007a) and Warbritton et al. (2007b).

129 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects those arguments.

130 It should be noted that, according to the Support Document, ECHA took into account the effects observed by Duft et al. (2003) and by Jobling et al. (2004) on the snail *Potamopyrgus antipodarum* in the weight of evidence approach as being data used solely to support conclusions on the endocrine mode of action in fish and amphibians. Those studies found a stimulation of embryo production at reduced concentrations which ECHA treated as indicative of a mode of action comparable to that of an oestrogenic mode of action. ECHA therefore gave a lower relative value to that study, as it did to all studies on invertebrates, in the overall weighting of the available data. That being so, the purely indicative nature of the effects reported by Jobling et al. (2004) and Duft et al. (2003) cannot be called into question by the fact that they were not confirmed by the studies on which the applicant relies.

131 Lastly, the applicant has failed, in any event, to submit evidence that would invalidate the effects reported by Jobling et al. (2004) and Duft et al. (2003) and be such as to show that the results presented by those authors could not be used as evidence supporting the conclusions on the endocrine mode of action of bisphenol A.

(iii) The Ladewig et al. (2006) study on Lumbriculus variegatus

132 Third, the applicant argues that ECHA wrongly relied on a study on the annelid worm *Lumbriculus variegatus* conducted by Ladewig et al. (2006). The applicant claims that the aim of that study was not to produce reliable data for risk assessment but rather to present a new technical approach. Furthermore, it should also be noted that the high quality Picard (2010c) study indicates a no-effect concentration level that is four orders of magnitude higher than that of the exploratory Ladewig et al. (2006) study.

133 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects those arguments.

134 In that connection, it is clear that the Support Document explicitly finds that the potential underlying mode of action of bisphenol A is not clear from the Ladewig et al. (2006) study. ECHA therefore did indeed take into consideration the limited evidential weight of that study in the identification of the endocrine disrupting properties of bisphenol A in the weight of evidence approach. Given, moreover, that the studies on invertebrates were used solely to support that identification in the weight of evidence approach, the alleged flaws in the assessment of the Ladewig et al. (2006) study – assuming that these are established – cannot in any event constitute a manifest error of assessment vitiating the identification of bisphenol A under Article 57(f) of Regulation No 1907/2006.

135 In the light of the foregoing considerations, the arguments raised in relation to the studies conducted on invertebrates must be rejected.

(4) The in vivo studies on amphibians

136 In the third place, the applicant claims that ECHA based its decision on certain studies of species of amphibian constituting sound evidence, whereas the MSC acknowledged the reduced availability of the data and the poor quality thereof. More specifically, the existing *in vitro* data do not correspond to the *in vivo* findings in that regard. The *in vitro* data – which, it is argued, are weak and limited – prove there to be interactions with the thyroid hormone receptor and suggest that bisphenol A is an antagonist of that receptor, whereas the *in vivo* data which find there to be accelerated development in amphibians argues in favour of bisphenol A being a thyroid hormone receptor agonist. Consequently, it is argued, the mechanism resulting in accelerated amphibian development remains unclear.

137 Moreover, according to the applicant, the *in vivo* data on amphibians contains serious shortcomings. Thus, in the Heimeier et al. (2009) study on *Xenopus laevis*, which the Support Document regards as a key study and which has been scored as being reliable with restrictions (2 in the Klimisch scoring system), the control animals were at development stage 54 on the relevant Nieuwkoop and Faber scale at the beginning of the study and reached stage 56 only 21 days later, whereas the relevant test method – namely OECD Test Guideline No 231 on amphibian metamorphosis assays – requires that control animals be at development stage 51 at the beginning of the study and that they reach at least development stage 57 after 21 days. Consequently, the applicant disputes the reliability of the study as a whole which should, in the applicant's view, have been given a reliability score of 3 in the Klimisch scoring system and, for that reason, could not constitute sound evidence in the present case. Furthermore, it argues that ECHA failed to take those comments into account during the public consultation on the dossier prepared in accordance with Annex XV.

138 In its observations on the answer to a written question put by the Court sent in that connection to ECHA, the applicant further notes that the observations set out in the Heimeier et al. (2009) study can also be explained by a flawed study design, namely the disregard of the daily feeding regime. Moreover, the applicant claims that the same observations were made in the negative controls which were not exposed to bisphenol A. Lastly, according to the applicant, the Iwamuro et al. (2003) study on the same species could not support the findings as to the existence of a thyroid mode of action, given that the effects were observed only at a concentration equivalent to acute toxicity, which does not comply with the amphibian metamorphosis assay set out in OECD Test Guideline No 231.

139 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects those arguments.

140 It should be observed, first of all, that the Support Document finds that bisphenol A acts as a thyroid antagonist in amphibians. In that connection, it relies, inter alia, on thyroid mode of action indicators, as laid down by OECD Test Guideline No 231, in the light of which the *in vivo* studies conducted on *Xenopus laevis* were evaluated. Those indicators include delayed development as an indicator of an antagonist thyroid mode of action, provided that no systematic toxicity can be observed.

141 Contrary to the applicant's claim, the *in vivo* studies on which the Support Document relies as key studies, namely Heimeier et al. (2009) and Iwamuro et al. (2003), both set out – as ECHA confirmed in reply to a written question put by the Court – such a delay in development which, according to OECD Test Guideline No 231, suggests that bisphenol A neutralises the effects of the T3 thyroid hormone.

142 In so far as concerns, in particular, the Heimeier et al. (2009) study, the Support Document clarifies the differences between the latter study and OECD Test Guideline No 231. In the light of those differences, the reliability score of 2 in the Klimisch scoring system appears to be consistent. Admittedly, this study diverges from that guideline. Nevertheless, ECHA convincingly – or, at the very least, plausibly – sets out the reasons for which it regarded that study as being very well documented. Furthermore, the classification thereof as a key study does not appear to be vitiated by an error, given that, according to the methodology followed by ECHA in the present case, studies given a reliability score of 2 in the Klimisch scoring system can serve as key studies in so far as the effects reported are of particular relevance.

143 In that connection, it must also be held that the differences with OECD Test Guideline No 231 cannot, per se, call into question the significance of the observation of antagonistic activity on thyroid hormones. That observation, made in the Heimeier et al. (2009) study is confirmed by other *in vivo* studies contained in the Support Document, including the Iwamuro et al. (2003) key study on the same species. Admittedly, it follows from that study itself that it was conducted at relatively high concentrations, which is not necessarily in compliance with the recommendations contained in OECD Test Guideline No 231. However, it is only in its observations on ECHA's answers to questions put by the Court that the applicant claims that the Iwamuro et al. (2003) study was conducted at a toxic concentration. In that regard, according to OECD Test Guideline No 231, it is solely in the absence of toxicity that the delay in development is a strong indicator of anti-thyroid activity. However, it is clear that the applicant has not substantiated that claim with detailed factual evidence. In those circumstances, bearing in mind the fact that ECHA gave that study a reliability score of 2 in the

Klimisch scoring system, which takes account of the fact that that study is not fully compliant with a validated method, the taking into account of the Iwamuro et al. (2003) study by ECHA does not constitute a manifest error of assessment. Moreover, the conclusions drawn from the Heimeier et al. (2009) and Iwamuro et al. (2003) studies are substantiated by various other studies on species of amphibian which the Support Document regards as being supporting studies. It is therefore apparent from the Support Document, as well as from ECHA's answer to a written question put by the Court, that the Goto et al. (2006) study reports a spontaneous inhibition of the metamorphosis of *Xenopus (silruna) tropicalis* and *Rana rugosa* caused by exposure to bisphenol A which blocks thyroid hormone – particularly the T3 hormone – receptors. The fact that this study was conducted at a single concentration only, as the applicant observes, was taken into account by the Support Document, inasmuch as it gives that study a reliability score of 2 in the Klimisch scoring system and does not class it as a key study.

144 Furthermore, the thyroid mode of action hypothesis is supported by the *in vitro* assays, taken into account by the Support Document, which showed that bisphenol A disrupted the hypothalamic-pituitary-thyroid axis and reported antagonist activity on the thyroid hormone receptors responsible for the delay in development observed in the *in vivo* studies.

145 In the light of the foregoing, it must be held that the applicant's arguments disputing ECHA's use, in the present case, of studies on amphibians, and particularly the Heimeier et al. (2009) study on *Xenopus laevis*, cannot demonstrate a manifest error vitiating the conclusions that ECHA drew therefrom in relation to the thyroid mode of action of bisphenol A. Consequently, those arguments cannot invalidate the weight of evidence which led ECHA to the identification of bisphenol A under Article 57(f) of Regulation No 1907/2006.

(5) The in vivo studies on fish

146 In the fourth place, the applicant claims that certain studies on the oestrogenic effects of bisphenol A in species of fish do not substantiate ECHA's finding on the intrinsic properties of bisphenol A as an endocrine disruptor that may have serious effects on the environment.

(i) The Chen et al. (2015) study on zebrafish (Danio rerio)

147 First, the applicant claims that the Chen et al. (2015) multi-generational study on zebrafish (*Danio rerio*), referred to on pages 41, 42 and 53 of the Support Document as being a 'key study', is not reliable for the purposes of assessing the endocrine properties of bisphenol A, on the ground that it is vitiated by considerable disadvantages and, in particular, poor replication, a lack of control, analytical inconsistencies and insufficient documentation, with the result that ECHA could not rely on that study in the present case. In that connection, the applicant refers to the statement made by the United Kingdom at the 57th meeting of the MSC, according to which there was not enough information to validate the results of that study. It is argued that the latter was not conducted in accordance with validated test methods which require that assays be carried out at multiple levels of exposure.

148 Furthermore, the applicant claims that the Chen et al. (2015) study is the only study relied upon by ECHA which reports effects at low concentrations, whereas the majority of studies on the endocrine mode of action of bisphenol A report effects at acutely toxic concentrations, which prevents the effects of a specific mode of action being determined reliably, as any effect observed could also be the consequence of an acutely toxic concentration rather than an actual mode of action of bisphenol A.

149 Moreover, according to the applicant, there is uncertainty as to the effects reported by the Chen et al. (2015) study concerning the sex ratio in fish, which ECHA recognised as being a key criterion in determining the endocrine disrupting properties of a substance. That effect was established, it is claimed, by means of a visual inspection which (i) was not reliable in respect of zebrafish on account of the fact that they present few distinct secondary sexual characteristics and (ii) was not confirmed by a histological inspection, namely by a precise determination of sex through the study of cells and tissues. In that respect, in order to constitute a statistically robust assessment, as OECD Test Method No 240 suggests, a large and representative sample should have been the subject of such a histological inspection. The Chen et al. (2015) study does not, the applicant argues, contain details as to the exact number of fish inspected.

150 Lastly, the applicant observes that the data relating to bisphenol A in respect of *Oryzias latipes*, namely the species of fish which was the subject of the greatest number of research studies on the potential change in sex ratios, indicate that no change in sex ratios was generally observed. Only two studies, namely the Yokota et al. (2000) and Na et al. (2002) studies, report changes in sex ratios, although the results of those studies are contradictory. By contrast, six other studies, namely the Metcalfe et al. (2001), Kashiwada et al. (2002), Sun et al. (2014), Bhandari et al. (2015), Kang et al. (2002) and Tabata et al. (2001) studies, did not find any change in sex ratios.

151 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

152 In response to the arguments relating to the Chen et al. (2015) study, it should be noted that the flaws relied upon by the applicant and by the United Kingdom in its statement annexed to the minutes of the 57th meeting of the MSC in relation to that study on zebrafish (*Danio rerio*), arising, inter alia, from the fact that it was conducted using a single concentration, are expressly acknowledged on pages 42 and 43 of the Support Document. That document clearly states that the Chen et al. (2015) study does not comply with good laboratory practice. Furthermore, according to page 53 of the Support Document, the reliability score of 2 in the Klimisch scoring system given to that study takes into account the fact that the study was conducted at a single concentration only. That score is therefore in line with ECHA's methodology which applies the Klimisch criteria described in paragraph 104 above. In that connection, it should be borne in mind that certain, even considerable, shortcomings in studies are not in themselves sufficient to exclude them from the outset. Lastly, those shortcomings must be assessed having regard to the ability of those studies nevertheless to substantiate the conclusion that they are called upon to support. In the context of the broad discretion conferred on ECHA, as described in paragraph 62 above, and more specifically in the weight of evidence approach, differences of opinion concerning such questions are not sufficient to exclude a study or findings based thereon. Such a consequence follows only if ECHA has completely and erroneously disregarded evidence which, if included, would have altered the overall assessment of the evidence in such a way that the final decision would have been implausible.

153 In the light of the foregoing, it cannot be established that ECHA's treatment of the Chen et al. (2015) study is vitiated by a manifest error of assessment. The shortcomings of that study were admittedly highlighted but, with supporting explanations, were not regarded as being so serious as to justify the study being considered unreliable and irrelevant having regard to its findings. Since it may therefore be regarded as a reliable study, and taking into account the fact that this study reports multiple effects of bisphenol A, ECHA also did not commit a manifest error of assessment by classing it as a key study in accordance with its own methodology.

154 In that connection, it should be observed more specifically, as ClientEarth does in its statement in intervention, that the fact that the study was conducted at a single concentration does not per se preclude it being taken into account in the identification of bisphenol A, as the identification of a substance as being of very high concern is based on its intrinsic properties.

155 As regards the effects on sex ratios observed in the Chen et al. (2015) study, it should be observed, first, that the applicant does not dispute that the Support Document regards sex ratios as an endpoint that can serve as an indicator of an endocrine mode of action. As stated in the Support Document, such an approach complies with OECD Test Guideline No 150, according to which there are no cases in which sex ratios are altered that are not caused by an endocrine disruptor.

156 It is apparent from the Support Document and the parties' written submissions that the visual observations of sex ratios were in fact subject to verification by double-blind histological examinations. Nevertheless, ECHA was not able to indicate the exact number of fish that were subject to such a histological inspection. Consequently, it cannot be established whether a sufficiently large and representative sample was subject to such a histological verification, as recommended by OECD Test Method No 240. Nonetheless, it should be noted that the Support Document does not suggest that ECHA treated that study as a study in full compliance with validated methods. However, ECHA gave that study a reliability score of 2 in the Klimisch scoring system so as to reflect the methodological deficiencies vitiating it, without calling into question its overall reliability. Similarly, it is apparent from

page 42 of the Support Document, in so far as concerns that study, that there were no significant differences between the results of the visual inspection, on the one hand, and those of the histological inspection, on the other. Consequently, it is apparent that, in so far as a histological inspection was carried out, the results thereof did not contradict those of the visual inspection It follows that the fact that the extent of the histological inspection in the Chen et al. (2015) study is not more amply documented is not sufficient to call into question the results reported by that study.

157 As regards the question of the reproducibility of the effects on sex ratios, as reported by Chen et al. (2015), the following observations should be made.

158 In the first place, it is apparent from the Support Document that, admittedly, neither the Segner et al. (2003a) key study nor the Keiter et al. (2012) study, which were also conducted on the *Danio rerio* at concentrations higher than those applied in the Chen et al. (2015) study, observed any effects on sex ratios. It should also be noted that ECHA was not able to provide, in response to a written question put by the Court, the underlying reasons that may explain that absence of effects on sex ratios. Nevertheless, those 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. As a consequence, the absence of observations of effects on sex ratios does not, in itself, show there to be a sufficient contradiction to allow the findings of the Chen et al. (2015) study to be called into question at scientific level.

159 In the second place, effects on sex ratios were also observed in another species of fish: *Oryzias latipes*, in the Yokota et al. (2000) key study. It is true that not only does that study concern a different species of fish, but it was also conducted at a higher concentration than in the Chen et al. (2015) study. Consequently, it cannot directly corroborate the findings drawn from the Chen et al. (2015) study on that point. Nonetheless, those two studies, taken together, contribute to the weight of evidence in so far as concerns the effects of bisphenol A on sex ratios in fish populations. In the present case, the various elements put forward by ECHA constitute a body of evidence which supports its hypothesis. However, the evidence put forward by the applicant is not such as to render the weight of that body of evidence completely implausible.

160 Lastly, as regards the six studies on *Oryzias latipes* cited by the applicant (see paragraph 150 above), which did not find there to be any effects on sex ratios, it must be observed that that can be explained, as ECHA argues with regard to the Kang et al. (2002) and Tabata et al. (2001) studies, by the fact that the fish observed in those studies had not been exposed during the sensitive stage in their development. Consequently, the absence of effects on sex ratios in those studies does not necessarily contradict the effects reported in the Yokota et al. (2000) or the Chen et al. (2015) studies. In so far as concerns, second, the Metcalfe et al. (2001), Kashiwada et al. (2002), Sun et al. (2014) and Bhandari et al. (2015) studies, it should be observed that, whilst they do not report any effects on sex ratios, they may nevertheless support the findings drawn from the Chen et al. (2015) study on the endocrine mode of action of bisphenol A. Thus the Metcalfe et al. (2001) study reports testis-ova, morphological changes in the testicles in male fish and accelerated ovogenesis in females. The Kashiwada et al. (2012) study reports vitellogenin induction, while the Sun et al. (2014) study reports reduced hatching and a high level of vitellogenin. As regards the Bhandari et al. (2015) study, it is apparent from the Support Document that that study reports cross-generational reproductive abnormalities, having regard to fertilisation and embryo survival rates, caused by exposure to bisphenol A.

161 In the light of the foregoing, it is clear that, in the weight of evidence approach, the doubts expressed with regard to the Chen et al. (2015) study and, in particular, the verification and reproducibility of the effects on sex ratios, even assuming these to be justified, are not such as to demonstrate that ECHA's finding that bisphenol A has an oestrogenic mode of action in fish is vitiated by a manifest error of assessment.

162 In any event, the Chen et al. (2015) study is not confined to reporting effects on sex ratios, which is the crux of the applicant's criticisms. That study also reports other indicators of an oestrogenic mode of action, namely effects on the number and quality of sperm and larval malformation and mortality. The fact that that study was conducted at a low concentration cannot per se call into question the findings made regarding the oestrogenic mode of action. As noted in paragraph 63 above, information taken

into account in the weight of evidence approach can, moreover, be deficient in respect of a specific endpoint, without that precluding that the conclusion be drawn from an overview of the available data showing similar effects. In the present case, it is particularly the Segner et al. (2003a) study – the classification of which as a key study is not, moreover, disputed by the applicant – which, according to the Support Document, reports other indicators of an oestrogenic mode of action in *Danio rerio*, namely vitellogenin induction, testis-ova and reduced fertility. Furthermore, the Chen et al. (2015) study is not alone in demonstrating effects on sex ratios. Such effects are also reported, inter alia, in the Yokota et al. (2002) key study, the evaluation of which by ECHA is not disputed by the applicant. Lastly, other studies on *Danio rerio* and *Oryzias latipes* report other indicators of an endocrine mode of action and support the conclusions drawn from the key studies, such as, inter alia, the Yokota et al. (2000) study on *Oryzias latipes*, but also the Segner et al. (2003a) study.

163 Accordingly, it must be stated, for the sake of completeness, that, even if the Chen et al. (2015) study could not have been taken into account, ECHA would not have committed a manifest error of assessment by basing its decision on the weight of many other studies, which have not been challenged by the applicant, relating to the endocrine mode of action of bisphenol A.

(ii) The Shioda and Wakabayashi (2000) study on Oryzias latipes

164 Second, the Shioda and Wakabayashi (2000) study on *Oryzias latipes* – which, according to the Support Document, reports long-term effects following short-term exposure to bisphenol A, particularly on egg hatching – cannot, in the applicant's view, support the hypothesis of an oestrogenic mode of action, bearing in mind the low reliability thereof which, furthermore, was acknowledged in the Support Document.

165 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

166 As a preliminary point, it is clear that the Support Document gives the Shioda and Wakabayashi (2000) study a reliability score of 2 in the Klimisch scoring system, which suggests that ECHA regarded the study as being reliable with restrictions. At the same time, the Support Document states, on page 40, that the study is 'of low reliability'.

167 When questioned about this apparent contradiction concerning the Shioda and Wakabayashi (2000) study which is, on the one hand, given a score of 2 in the Klimisch scoring system and, on the other hand, classed as a 'low reliability' study, ECHA explains this as a typographical error and claims that the Support Document should be read and understood as meaning relatively 'lower' reliability, which reflects the fact that only a limited number of organisms were tested. The study remains relevant and valid, nonetheless.

168 Whilst it is true that the same wording can also be found in the dossier prepared in accordance with Annex XV initially proposing the identification of bisphenol A, even assuming that the Shioda and Wakabayashi (2000) study on *Oryzias latipes* ought indeed to have been regarded as being of low reliability, the fact that ECHA also relied on that study cannot constitute a manifest error of assessment to the point of vitiating the identification of bisphenol A as a substance of very high concern, as found in the contested decision.

169 It must be observed that ECHA treated the effects reported by the Shioda and Wakabayashi (2000) study as being merely supplementary indications of a mode of action that support conclusions drawn from studies which were given greater weight and which constituted key studies. That is also illustrated by the fact that the brief examination of the Shioda and Wakabayashi (2000) study in the Support Document is introduced by the words 'in addition' and can be found at the end of the section devoted to the analysis of the effects on *Oryzias latipes* (see page 40 of the Support Document). In particular, ECHA did not regard it as being a key study in the data weighting. The weight of evidence approach does not preclude ECHA from also relying on information that is of low reliability, provided that the weighting of the information takes that low reliability into consideration.

170 It should next be observed that, above all, the applicant has failed to explain the extent to which the effects reported in the Shioda and Wakabayashi (2000) study contradict the conclusions that ECHA

drew regarding the identification of bisphenol A from other studies showing long-term effects following exposure to bisphenol A such as, in particular, the Bhandari et al. (2015) study conducted on the same species.

171 Consequently, the argument put forward with regard to the Shioda and Wakabayashi (2000) study cannot lead to the conclusion that the identification of bisphenol A is vitiated by a manifest error of assessment.

(iii) The Lahnsteiner et al. (2005) study on brown trout (Salmo trutta fario)

172 Third, according to the applicant, the Lahnsteiner et al. (2005) study on brown trout, referred to, inter alia, on page 57 of the Support Document, also has serious flaws, such as poor quality of test fish, poor replication, a lack of analytical confirmation or novel endpoints without validation. It is argued that, as a consequence of the foregoing, the EU RAR concluded that this study was inadequate for regulatory purposes. In spite of that finding, that study was relied upon in the Support Document, and given a reliability score of 2 in the Klimisch scoring system. The applicant takes the view that that study should have been given a score of 3 in the Klimisch scoring system, that is to say ‘not reliable’.

173 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, rejects that argument.

174 In that connection, ECHA admittedly does not dispute the fact that the Lahnsteiner et al. (2005) study contains data characterised by low reliability. Nevertheless, as already noted in paragraph 64 above, it is inherent to the weight of evidence approach that the database used may contain deficient data relating to a certain endpoint. Thus the low reliability of certain data contained in a study used by ECHA does not, per se, preclude ECHA using such a study in the assessment of a substance. In such cases, however, it is for ECHA to take into consideration the low reliability of that data in the weighting of the various data available.

175 In the present case, it is apparent from the Support Document that ECHA confined itself to relying on the reliable endpoints contained in the Lahnsteiner et al. (2005) study, such as the effects observed on egg production and sperm fertility. However, in particular, the endpoint associated with delayed ovulation, for which only six fish were examined, was not taken into account. Consequently, the score of 2 in the Klimisch scoring system (reliable with restrictions) does not appear to be vitiated by a manifest error of assessment, in so far as ECHA relied solely on certain data that it considered to be reliable.

176 As regards the applicant’s argument that ECHA could not rely on the Lahnsteiner et al. (2005) study on the ground that it was not used in the EU RAR, it should be pointed out that the aim of the latter report was to determine a predicted no-effect concentration. However, the evaluation of the Lahnsteiner et al. (2005) study, as carried out by ECHA, is part of a different regulatory context pursuing a different aim, namely that of identifying substances of very high concern under Article 57(f) of Regulation No 1906/2007.

177 In any event, it is clear that, according to the Support Document, the data on brown trout were used solely in support of the findings on endocrine mode of action drawn from *in vivo* studies conducted on other species of fish, namely *Oryzias latipes*, *Danio rerio* and *Pimephales promelas*. It follows that, even assuming that the criticisms put forward by the applicant against the Lahnsteiner et al. (2005) study are well founded, they cannot in any case invalidate the identification of bisphenol A as an endocrine disruptor on the basis of those data primarily taken into account.

178 In the light of the foregoing, the arguments put forward by the applicant in relation to the Lahnsteiner et al. (2005) study on brown trout cannot substantiate the conclusion as to a manifest error of assessment vitiating the identification of bisphenol A as an endocrine disruptor under Article 57(f) of Regulation No 1906/2007.

(iv) The Bowmer and Gimeno (2001) and Mandich et al. (2007) studies on Cyprinus carpio

179 Fourth, the applicant relies on the low reliability of two studies on *Cyprinus carpio*.

180 First, according to the applicant, the Mandich et al. (2007) study on *Cyprinus carpio*, referred to on pages 36 and 48 of the Support Document, was given a score of 1 in the Klimisch scoring system, whereas, in the applicant's view, it is a study that must be regarded as exploratory, given that it does not fully comply with OECD Test Guideline No 240 in so far as concerns certain endpoints on which ECHA nonetheless relied. Furthermore, the applicant argues that that study contains certain shortcomings such as, in particular, insufficient documentation, a lack of detail on histopathology, an absence of data on control fish, poor reproducibility and poor supporting statistics. Bearing in mind those factors, an appropriate assessment of that study would, in the applicant's view, have led to a reliability score of 3 in the Klimisch scoring system (that is to say, 'not reliable').

181 Second, the study conducted by Bowmer and Gimeno (2001), as referred to on pages 36 and 48 of the Support Document, is supported only by a detailed summary. The applicant claims that in spite of the fact that this study has not been published in full, that evidence was been given a score of 2 in the Klimisch scoring system, that is, 'reliable with restrictions', whereas an appropriate scientific assessment would suggest a reliability score of 4, that is to say, 'insufficient documentation'.

182 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

183 In that connection, it should be recalled, as a preliminary point, that the weight of evidence approach does not preclude ECHA from relying on studies containing certain shortcomings affecting the reliability thereof, where ECHA takes these into consideration in the weighting of the data on which it relies. Furthermore, it is clear that the data on *Cyprinus carpio* were used only to support the conclusions drawn from the studies conducted on other species of fish, namely *Danio rerio* and *Oryzias latipes*, in particular. Consequently, none of the studies conducted on *Cyprinus carpio* were used as a key study in the weighting of data for the identification of bisphenol A as an endocrine disruptor.

184 As regards, first of all, the Mandich et al. (2007) study, it should be observed that the Support Document finds that that study complies only in part with OECD Test Guideline No 240. In particular, it contains no indication that the endpoints relating to vitellogenin induction or gonad histopathology were analysed in accordance with that validated test guideline. The Support Document finds that study to be reliable without restriction by giving it a reliability score of 1 in the Klimisch scoring system, without differentiating between the various endpoints. Given that that score is, in principle, reserved for studies conducted in full compliance with internationally validated methods, the score given to that study appears to be incorrect. Nevertheless, as noted in paragraph 182 above, ECHA did not find that that study was a key study for the identification of bisphenol A. It served solely as a supporting study in the context of the weight of evidence approach. That study was therefore not decisive for the identification of bisphenol A as a substance of very high concern, but rather simply supported that identification. It follows that, even supposing that ECHA wrongly assessed the reliability of that study, such an error would not call into question the conclusions drawn in particular from key studies as evaluated by ECHA in the Support Document.

185 Next, as regards the Bowmer and Gimeno (2001) study, it should be observed that it is apparent from the Support Document that (i) only one of the two assays used in that study was carried out in compliance with good laboratory practice, as defined by the OECD and (ii) only an extended summary is available. In the light of those considerations, the score of 2 in the Klimisch scoring system (reliable with restrictions) given to that study does not appear to be vitiated by a manifest error of assessment. That said, it is clear that, as is the case for the Mandich et al. (2007) study, the Bowmer and Gimeno (2001) study was used solely to support the identification of bisphenol A. Consequently, even if the score given to that study were to prove to be mistaken, such an error would not call into question the conclusions drawn, in particular, from the key studies.

186 In the light of the foregoing, the arguments put forward with regard to the studies conducted on *Cyprinus carpio* must be rejected as unfounded and, bearing in mind all of those factors, it must be held that the arguments raised in respect of certain *in vivo* studies conducted on certain species of fish have failed to demonstrate the existence of a manifest error of assessment vitiating the assessment of

those studies which would mean that they could not serve to support the finding of an oestrogenic mode of action of bisphenol A in fish, reached by means of the weight of evidence approach.

(6) Conclusion on the first complaint in the second part of the first plea

187 In the light of the foregoing, it is clear that, in exercising its discretion for the identification, in the present case, of bisphenol A as an endocrine disruptor that can have serious effects on the environment, ECHA followed a clear and systematic methodology whilst respecting the principle of excellence for the purposes of appraising the diverse evidence on which it relied. In the context of the weight of evidence approach, ECHA carried out a weighting of *in vivo* and *in vitro* data drawn from a multitude of scientific studies whilst taking the reliability of each study into account. That weighting led ECHA to identify an endocrine mode of action in the first place on the basis of certain *in vivo* studies on certain species of fish and amphibian, whereas other *in vivo* data – namely, in particular, those on certain species of invertebrate – and *in vitro* data were used in support of those findings.

188 It is the weight of the evidence drawn from the aforementioned data that permitted ECHA to reach its conclusions with regard to the intrinsic properties of bisphenol A as an endocrine disruptor. In particular, those findings were not drawn from a single individual study, and even less so from a single study used as a supporting study. It must be found that the applicant's criticisms of certain studies used by ECHA are confined to calling into question the individual relevance or inconclusive nature of those studies, without however demonstrating a material contradiction in the effects reported or a clear inconsistency in the weighting which would invalidate the weight of the evidence.

189 The first complaint in the second part of the first plea must therefore be rejected.

(b) The second complaint in the second part of the first plea: manifest error of assessment, in that ECHA failed to establish that there was scientific evidence of bisphenol A having serious effects on the environment on account of its endocrine disrupting properties

190 By the second complaint in the second part of the first plea, the applicant claims that ECHA committed a manifest error of assessment, as it failed to establish that there was scientific evidence of bisphenol A having serious effects on the environment on account of its endocrine disrupting properties. The applicant states that, pursuant to Article 57(f) of Regulation No 1907/2006, only substances which have endocrine disrupting properties 'for which there is scientific evidence of probable serious effects to … the environment' can be identified as being of very high concern.

191 The applicant takes the view that the evidence relied upon in the Support Document does not provide a clear hypothesis to demonstrate an endocrine disrupting mode of action in the environment for bisphenol A, but relies solely on the description of individual observations in the context of endocrine disruption, while the scientific arguments are vague and unsubstantiated. The data which supports the existence of low oestrogenic activity for fish and amphibians are not, in the applicant's opinion, sufficient to identify a substance of very high concern under Article 57(f) of Regulation No 1907/2006. The applicant argues that the evidence is, on the contrary, either extremely poor or highly speculative. The latter criticism applies in particular to the suggested mode of action in fish and amphibians. Nor, it is claimed, is there sufficient evidence obtained, for example by means of *in vitro* studies, to identify bisphenol A as having an endocrine disrupting mode of action.

192 In support of its argument, the applicant refers to the observations submitted by the Kingdom of Denmark and the United Kingdom at the public consultation. It claims, more specifically, that the United Kingdom expressed its hesitation as to the conclusion that bisphenol A definitely causes its effects via endocrine disruption.

193 Furthermore, the applicant observes that ECHA's claim that an effect is associated to an endocrine disrupting mode of action does not provide, by itself, sufficient evidence to fulfil the criteria set out in Article 57(f) of Regulation No 1907/2006. The applicant states, generally, that an association between two aspects alone does not, in its view, prove the scientific evidence required.

194 Moreover, the fact that certain serious effects were acknowledged as 'EATS [estrogen, androgen, thyroid and steroidogenic]-mediated' is not sufficient scientific proof for an endocrine mode of action

of bisphenol A *in vivo* resulting in serious effects. According to the applicant, the existence of other potential mechanisms should have been examined and excluded. Given that the majority of the *in vitro* assays on endocrine mechanisms assess molecular initiating events only, other data relating to suspected undesirable effects would have been necessary before it was possible to presuppose that certain effects were 'EATS-mediated'. Furthermore, the mere assertion that certain effects are known to be 'EATS-mediated' is too general, and does not explain which effects are concerned, or how or by whom those effects are known to be 'EATS-mediated', or in what way it allowed ECHA to find that there was a biologically plausible link. Consequently, ECHA should have conducted a detailed analysis of the mode of action.

195 The applicant claims that the Support Document does not establish the key biochemical, cellular, and molecular events in the proposed mode of action, or the temporal and dose-response concordance between them, but rather confines itself to postulating their existence in a hypothetical scenario. In doing so, ECHA failed to satisfy the criteria that it identified itself in the Support Document.

196 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

197 In that connection, it is necessary to examine whether ECHA failed to apply the required standard of proof to establish that bisphenol A causes serious effects on the environment on account of its endocrine mode of action.

198 As a preliminary point, it is clear that in paragraph 173 of the judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329), the Court held that the probability that a substance may have serious effects on the environment was sufficient to establish a causal link within the meaning of Article 57(f) of Regulation No 1907/2006. In particular, such an approach is in accordance with the precautionary principle, on which the provisions of Regulation No 1907/2006 are based, pursuant to Article 1(3) thereof.

199 Furthermore, the Court stated in paragraph 94 of the judgment of 20 September 2019, *PlasticsEurope* v *ECHA* (T-636/17, under appeal, EU:T:2019:639), that 'the facts and evidence relied upon in the examination of a substance [had to] serve to establish that it [was] "plausible" that the mode of action of that substance [could] lead to certain serious effects [and that, by] contrast, Article 57(f) of Regulation No 1907/2006 does not require absolute proof of a causal relationship'.

200 In the light of those considerations, the following observations must be made. In the Support Document, ECHA clearly sets out the methodology followed in order to determine whether there is indeed a plausible biological link between the endocrine mode of action of bisphenol A and the serious effects. Following that methodology, ECHA assessed (i) indicators of an endocrine mode of action and (ii) effects of apical endpoints as evidence substantiating the finding that bisphenol A causes serious effects on account of its endocrine mode of action. In that connection, the Support Document regards the *in vivo* studies in particular as being relevant to determining whether the serious effects are caused by the endocrine mode of action or whether they are solely the consequence of general systemic toxicity.

201 As an example, pages 33 to 35 of the Support Document explain, more specifically, in relation to studies on fish, first, the relevant indicators of an endocrine mode of action, namely, in particular, vitellogenin induction or histological changes and, second, the apical endpoints which, according to the OECD Guidance No 150 for evaluating endocrine disruptors, may be regarded as indicators of an antagonist of oestrogenic hormone receptors, namely, in particular, a reduction in secondary sexual characteristics and the skewing of sex ratios towards females during sexual development. In that regard, the Support Document explains that, in conjunction with the indicators of endocrine activity, the endpoints allow it to be found that there exists an oestrogenic mode of action.

202 It is in the light of those considerations that the Support Document concludes, in respect of *Oryzias latipes* and *Danio rerio*, that there is a direct link between the oestrogenic mode of action and the serious effects observed. Those conclusions were drawn from scientific studies analysed in the Support Document, all of which observed vitellogenin induction in *Oryzias latipes* and *Danio rerio*. Changes in

sex ratios were also observed in *Oryzias latipes*, inter alia, in the Yokota et al. (2000) key study, and in *Danio rerio* in the Chen et al. (2015) study.

203 Similarly, in respect of amphibians, the studies analysed in the Support Document, in particular the Iwamuro et al. (2003) and Heimeier et al. (2009) studies, prove there to be a thyroid mode of action which manifested itself by a disruption of the hypothalamic-pituitary-thyroid axis and a delay in development, which led ECHA to conclude that there exists a plausible biological link between the mode of action and serious effects.

204 In the light of the foregoing, it must be held that, contrary to the applicant's claims, the evidence on which ECHA relied was neither too vague nor too speculative. It was in fact based on the observation of cellular and molecular biochemical events. Those data led ECHA to find that it was biologically plausible that bisphenol A caused its effects on account of an endocrine mode of action. Contrary to what the applicant appears to claim, ECHA did not confine itself to 'associating a certain effect with a certain mode of action'.

205 Moreover, in the present case, ECHA based its decision primarily on certain key studies concerning certain species of fish as well as certain species of amphibian in order to demonstrate the existence of a plausible biological link. A variety of *in vivo* and *in vitro* studies support that conclusion. The plausibility of the existence of a causal link, found by ECHA in the Support Document, therefore cannot be called into question by the mere fact that there remain uncertainties regarding a limited set of data considered in isolation, for example certain elements drawn from the Chen et al. (2015) study, as described above. Even if the studies containing the alleged shortcomings which are relied upon by the applicant had been disregarded by ECHA, the weight of the remaining evidence as a whole would nonetheless have been sufficient to substantiate the conclusion put forward by ECHA as to the plausibility of a causal link between the endocrine mode of action and the serious effects observed.

206 None of the applicant's arguments call that conclusion into question.

207 First of all, as regards the argument that ECHA confined itself, in its assessment, to assuming, without a detailed analysis, that certain effects of bisphenol A were caused by endocrine mediation, it is admittedly true that the Support Document does presume, in the part describing the methodology used, that some of the effects are endocrine-mediated. Nevertheless, the Support Document substantiates that presumption by referring to scientific publications. Thus, on page 34, the Support Document explains that the skewed sex ratios towards females is the known result of oestrogenic or anti-androgenic exposure during sexual development, whilst citing three reference sources which include publications by the OECD and the WHO International Programme on Chemical Safety. In doing so, ECHA began with a hypothesis that appears to be at least plausible from a scientific perspective and, consequently, meets the standard of proof as to the existence of a biologically plausible causal link between the mode of action and serious effects.

208 Second, as regards the applicant's argument that the data supporting the existence of weak oestrogenic activity did not suffice to identify an endocrine disruptor, it should be observed, first, that the applicant has failed to define what it means by weak endocrine activity and, consequently, what data it regards as insufficient. Second, the weight of evidence approach allows and requires that all relevant data which supports a hypothesis be taken into account. ECHA was therefore entitled to base its findings also on data demonstrating weak effects only. Third, the degree of the effects observed is not a criterion necessary to establishing a causal link between an endocrine mode of action and its effects. Such a causal link may also be established plausibly on the basis of weak effects.

209 Lastly, as to the applicant's argument that the United Kingdom expressed its hesitation in relation to the conclusion that bisphenol A undeniably causes its effects through endocrine disruption, it should be noted that that observation on the part of the United Kingdom was in fact made in the light of the data contained in the studies on invertebrates. It follows from page 135 of the Support Document that ECHA did not rely conclusively on the data concerning invertebrates, but confined itself to finding that it was possible that the effects of bisphenol A were caused by endocrine disruption. More specifically, ECHA acknowledges that, in the absence of scientific consensus on the definition of a plausible biological link between the effects and the endocrine mode of action in those species of invertebrate,

that evidence can serve only as supplementary evidence, supporting the conclusions drawn in the first place from the studies on fish and amphibians. Accordingly, ECHA cannot be criticised for excluding hesitations such as those expressed by the Kingdom of Denmark and the United Kingdom during the consultation on the draft identification.

210 In the light of all the foregoing, the second complaint in the second part of the first plea in law must be rejected

(c) The third complaint in the second part of the first plea: manifest error of assessment in the identification of an equivalent level of concern

211 By the third complaint in the second part of the first plea, the applicant claims that ECHA committed a manifest error of assessment in the identification of the criteria laid down in Article 57(f) of Regulation No 1907/2006 by finding that bisphenol A gave rise to 'an equivalent level of concern' to those of other substances set out in Article 57(d) and (e) of Regulation No 1907/2006, namely (i) PBT substances and (ii) vPvB substances.

212 First, the applicant submits that the ready biodegradability of bisphenol A, together with the fact that the potential concentration in the environment does not exceed the safe threshold preclude that substance giving rise to a level of concern equivalent to that of PBT or vPvB substances, on account of the fact that it does not accumulate in the environment. In that connection, the applicant relies on Section 1.1 of Annex XIII to Regulation No 1907/2006, under which a substance does not fulfil the persistence criterion if it is biodegradable. It is argued that the high level of concern associated with PBT and vPvB substances is primarily driven by their accumulation in the environment, due to their persistent and bioaccumulative properties. Although meeting the PBT and vPvB properties is not a precondition to being an endocrine disruptor in the meaning of Article 57(f) of Regulation No 1907/2006, the applicant takes the view that reference should be made to properties that are relevant to the identification of PBT and vPvB substances, namely persistence and bioaccumulation. In support of its argument, the applicant relies on observations made by various Member States, and in particular the Kingdom of the Netherlands and the United Kingdom, on the dossier prepared in accordance with Annex XV, emphasising the ready and immediate biodegradability of bisphenol A. The applicant claims that ECHA responded to those observations by asserting that bisphenol A was readily biodegradable. Nevertheless, ECHA failed to call into question its own conclusions with regard to the equivalent level of concern. The applicant claims furthermore that ECHA failed to demonstrate the existence of an equivalent level of concern by reference to criteria other than persistence or bioaccumulation.

213 In addition, the applicant refers to the determination of a predicted no-effect concentration of bisphenol A in the context of the EU RAR which, it argues, illustrates the possibility of determining a safe level of exposure to bisphenol A. ECHA, however, reached the speculative conclusion that it appeared difficult to find a safe level, but failed to provide any justification for that conclusion, which – according to the applicant – constitutes a manifest error of assessment vitiating the contested decision.

214 Next, inasmuch as ECHA also based its decision on the serious nature of effects as well as the irreversible nature thereof, the applicant maintains that such findings are based on unreliable studies. Moreover, ECHA cannot, in the applicant's view, rely on the serious nature of effects to justify the level of concern, given that, under Article 57(f) of Regulation No 1907/2006, the serious nature of effects is already taken into account in order to determine whether bisphenol A is a substance for which there is scientific evidence of probable serious effects to the environment.

215 Lastly, in the applicant's view, the mere fact that the MSC unanimously accepted that there existed such a level of concern was insufficient and could not compensate for a lack of scientific evidence for that assertion.

216 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

217 In that connection, it should be borne in mind from the outset that Article 57(f) of Regulation No 1907/2006 requires, as regards the identification of substances other than those meeting the classification criteria referred to in Article 57(a) to (e) of that regulation, that it be established, on a case-by-case basis, on the basis of scientific evidence, that (i) the substances concerned can have serious effects on human health or the environment, and (ii) those effects give rise to an equivalent level of concern to those of other substances referred to in Article 57(a) to (e) of Regulation No 1907/2006, namely CMR, PBT and vPvB substances. Those conditions are cumulative, so that the identification of a substance as being of very high concern must be rejected if either of those conditions is not met (judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA*, C-324/15 P, EU:C:2017:208, paragraph 26).

218 As regards the second condition laid down in Article 57(f) of the REACH Regulation, there must be scientific evidence that those effects 'give rise to an equivalent level of concern' to those of CMR, PBT or vPvB substances. As the Court of Justice notes in paragraph 32 of the judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA* (C-324/15 P, EU:C:2017:208), Article 57(f) of Regulation No 1907/2006 does not lay down any criterion and does not provide any clarification as regards the nature of the concerns that may be taken into consideration for the purposes of identifying a substance other than CMR, PBT or vPvB. Under those circumstances, it is necessary to ascertain whether ECHA committed a manifest error of assessment in its determination of the level of concern.

219 First of all, it should be observed that the Support Document contains, through a weight of evidence approach, a series of considerations which led ECHA to find there to be probable serious effects giving rise to an equivalent level of concern. The Support Document relies, inter alia, on the serious nature of the effects on reproduction and sexual development in fish and amphibians, together with the irreversibility of those effects, which potentially have long-term consequences for the population, even after brief exposure to bisphenol A. Moreover, the Support Document explains that (i) bisphenol A acts on a wide variety of ecologically important species and (ii) exposure to that substance is not confined to certain environments but is instead ubiquitous. Lastly, ECHA relies on the difficulty in determining and quantifying a safe exposure threshold.

220 It is clear that the applicant does not call those findings into question in their entirety. In fact, it confines itself to (i) discussing the possibility of establishing a safe level of exposure to bisphenol A, and (ii) claiming that the ready and immediate biodegradability of bisphenol A – which, moreover, is not disputed by ECHA – precludes the finding of a level of concern equivalent to that of PBT and vPvB substances, inter alia.

221 As regards, first, the possibility of determining a safe level of exposure, it should be noted that, admittedly, a predicted no-effect concentration was determined in the EU RAR.

222 As ECHA explains in its observations on the applicant's reply to a written question put by the Court, contrary to the work carried out for the purposes of establishing a predicted no-effect concentration, the identification of a substance under Article 57(f) of Regulation No 1907/2006 is not a question of risk analysis, but rather an assessment of the dangers inherent to the intrinsic properties of a substance. Thus the possibility of inferring a safe level in context must be assessed in relation to the dangers that bisphenol A poses to the environment on account of its endocrine mode of action. It is in that context that ECHA took account of the uncertainties highlighted in deriving a safe level. In that connection, the Support Document refers, inter alia, to the difficulties arising from the fact that certain effects can be observed only during certain life stages, time windows or seasons. Furthermore, difficulties were identified on account of the fact that bisphenol A affects a wide variety of organisms though different endocrine modes of action.

223 In the light of those uncertainties – which are, at the very least, plausible – ECHA took a cautious approach to the question of the possibility of determining a safe level of exposure to bisphenol A. That caution is particularly justified in the light of the precautionary principle on which the provisions of Regulation No 1907/2006 are based pursuant to Article 1(1) thereof. That principle, which is a general principle of EU law, means that, where there is uncertainty, appropriate measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (see, to that effect, judgments of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800, paragraph 43, and of

19 September 2019, *GE Healthcare* v *Commission*, T-783/17, EU:T:2019:624, paragraph 45). Consequently, ECHA cannot 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.

224 Next, as regards the argument that the ready and immediate biodegradability of bisphenol A precludes the determination of an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006, first, it should be found that that argument is contradictory. On the one hand, the applicant rightly acknowledges that it is not necessary that a substance have PBT or vPvB properties in order to be regarded as an endocrine disruptor for the purposes of Article 57(f) of Regulation No 1907/2006. On the other hand, it takes the view that reference should be made to properties relevant to the identification of PBT and vPvB substances in order to establish an equivalent level of concern. In that context, the applicant has failed, however, to explain which criteria would, in its view, allow the identification of a substance as an endocrine disruptor without that substance being both a PBT and vPvB substance.

225 That interpretation of Article 57(f) of Regulation No 1907//2006, put forward by the applicant, would essentially make that provision a mere duplication of the provisions of Article 57(a) to (e) of that regulation, which would render the provisions of Article 57(f) of that regulation ineffective. In particular, such an interpretation would run counter to the main purpose of Regulation No 1907/2006, set out in Article 1(1) thereof, namely that of ensuring a high level of protection of human health and the environment, in so far as that interpretation would give rise to a situation in which substances of a very high level of concern which do not possess the properties referred to in Article 57(a) and (e) of Regulation No 1907/2006 could not be identified as such. According to the very wording of Article 57(f) of that regulation, that provision covers, in particular, substances ‘which do not fulfil the criteria of [Article 57(d) and (e) of the regulation]’.

226 Second, the applicant has failed to explain the extent to which the ready biodegradability of bisphenol A, in itself, would invalidate ECHA’s conclusions on the level of concern to which bisphenol A gives rise. It is apparent from the Support Document that ECHA found that even brief exposure to bisphenol A may suffice to cause serious, irreversible long-term effects on organisms and populations. Accordingly, the ready and immediate biodegradability of bisphenol A cannot affect the level of concern, as identified by ECHA.

227 Third, it should be borne in mind that ECHA arrived at the determination of a level of concern on the basis of the weight of evidence. Thus the argument that ECHA relied on unreliable studies, which corresponds to the first complaint of the first plea, must also be rejected. The weight of the studies assessed allowed ECHA to conclude, without committing a manifest error of assessment, that the effects caused by bisphenol A on account of its endocrine mode of action are irreversible inasmuch as they are transmitted from one generation to the next, as observed by the various multi-generational studies conducted on species of fish analysed in the Support Document.

228 Lastly, as regards the serious nature of the effects caused by bisphenol A on account of its endocrine mode of action, it should be noted that Article 57(f) of Regulation No 1907/2006 admittedly requires that it be proved that bisphenol A causes serious effects to the environment. Nevertheless, that does not prevent ECHA from considering the serious nature of those effects by comparison to the seriousness of the effects caused by the substances set out in Article 57(a) to (e) of that regulation. In particular, such an approach does not constitute a double counting of evidence, but simply an analysis of that evidence from a different angle.

229 Having regard to that evidence, it is clear that the applicant has failed to demonstrate how ECHA could have committed a manifest error of assessment in establishing an equivalent level of concern.

230 In the light of all the foregoing, the third complaint in the second branch of the first plea in law must be rejected, as must that branch and plea in their entirety.

B. The second plea in law: infringement of Article 59(8) of Regulation No 1907/2006, read in conjunction with Article 57(f) of that regulation

231 By the second plea, the applicant claims that ECHA infringed Article 59(8) of Regulation No 1907/2006, read in conjunction with Article 57(f) of that regulation, because it identified bisphenol A as a endocrine disruptor of very high concern on the basis of the criteria laid down in Article 57(f), even though bisphenol A had already been previously identified as a substance of very high concern on account of intrinsic properties, such as those referred to in Article 57(c) of that regulation. In the applicant's view, each of the risks identified in accordance with the criteria set out in Article 57(a) to (e) of Regulation No 1907/2006 can be addressed correctly by their identification according to the various criteria listed in that article. By contrast, Article 57(f) of Regulation No 1907/2006 is intended to cover only those substances which do not fulfil the criteria laid down in Article 57(a) to (e) of that regulation but for which there is scientific evidence of probable serious effects on human health which give rise to an equivalent level of concern to those of other substances set out in Article 57(a) to (e) of Regulation No 1907/2006. According to the applicant, the legislature included Article 57(f) in Regulation No 1907/2006 for the specific purpose of addressing any substance of concern which has not already been identified as such under Article 57(a) to (e) of that regulation. That being the case, according to the applicant, where a substance has already been identified as a substance of very high concern pursuant to Article 57(a) to (e) of Regulation No 1907/2006, it may not be identified as a substance of very high concern a second time pursuant to Article 57(f) thereof.

232 That is, it is claimed, clear from the wording of Article 57 and from the description of the scope of Article 57(f) of Regulation No 1907/2006 contained in paragraphs 24 and 26 of the judgment of 15 March 2017, *Polynt* v *ECHA* (C-323/15 P, EU:C:2017:207). In addition, according to the applicant, if it were necessary to conclude that a substance may be identified both as being a substance which fulfils the criteria set out in Article 57(f) of Regulation No 1907/2006 and as a substance which fulfils the criteria laid down in Article 57(a) to (e) thereof, this would mean that the 'scientific evidence' already used to support the probable serious effects on human health of that substance under one of the criteria laid down in Article 57(a) to (e) of Regulation No 1907/2006 would also be used to support the criterion set out in Article 57(f) of that regulation. This is a case of 'double counting' of the scientific evidence. This means that the effects of the substance do not give rise to an 'equivalent' level of concern, as required by the provisions of Article 57(f), but an 'identical' level of concern. Such a requirement was clearly not foreseen by the legislature, according to the applicant. The requirement of an 'equivalent' level of concern, as referred to in Article 57(f) of Regulation No 1907/2006, in fact highlights that the 'basis' for identification under that provision should be different from the 'basis' for identification under one of the criteria referred to in Article 57(a) to (e) of that regulation.

233 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

234 In that connection, it should be observed that, in paragraph 39 of the judgment of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52), which also concerns the amendment of an existing entry in the Candidate List of substances by the addition of a reference to Article 57(f) of Regulation No 1907/2006, the Court of Justice stated that ECHA was empowered to supplement existing entries in the Candidate List of substances with new grounds within the meaning of Article 57 of Regulation No 1907/2006.

235 The applicant's arguments – which were, moreover, raised identically in support of its action in the case registered under number T-636/17 – do not call that conclusion into question. As in the judgment of 20 September 2019, *PlasticsEurope* v *ECHA* (T-636/17, under appeal, EU:T:2019:639), those arguments must be rejected as unfounded in their entirety in the present case also.

236 First, it is clear that the applicant's reasoning cannot, in any event, succeed with regard to endocrine disruptors of very high concern. To the extent that it refers to those substances, Article 57(f) of Regulation No 1907/2006 is the appropriate provision in that regulation for the regulatory classification of those substances.

237 Second, there is no basis for the claim that the legislature included Article 57(f) in Regulation No 1907/2006 for the 'specific purpose' of addressing any substance of concern which has not already been identified as such under Article 57(a) to (e) of that regulation. Contrary to the applicant's claim, it

is not clear from Article 57(f) of Regulation No 1907/2006 that that provision is meant to cover only substances which do not meet any of the criteria set out in Article 57(a) to (e) of that regulation.

238 Third, the identification of a substance as fulfilling both the criteria laid down in Article 57(f) of Regulation No 1907/2006 and the criteria set out in Article 57(a) to (e) of the same regulation can, admittedly, result in the different identification procedures being based, in part, on the same scientific evidence so far as concerns the effects on human health.

239 However, contrary to the applicant's submission, that does not mean that ECHA's assessment seeks an 'identical' level of concern, as opposed to an 'equivalent' level of concern. In any event, the fact that an endocrine disruptor gives rise to an 'identical' level of concern to that of one of the substances of very high concern referred to in Article 57(a) to (e) of Regulation No 1907/2006 does not preclude the application of Article 57(f) of that regulation. On the contrary, identification as a substance of very high concern is all the more justified if a substance gives rise to an 'identical' level of concern to that raised by one of the substances of very high concern referred to in Article 57(a) to (e) of Regulation No 1907/2006. The interpretation of that provision put forward by the applicant is based on a formalism that runs counter to the purpose pursued by Regulation No 1907/2006 which consists, according to Article 1(1) thereof, in ensuring a high level of protection for human health and the environment.

240 Moreover, the applicant misinterprets paragraphs 24 and 26 of the judgment of 15 March 2017, *Polynt* v *ECHA* (C-323/15 P, EU:C:2017:207). As ECHA rightly contends, there is a major difference between stating, on the one hand, as the Court of Justice did in paragraph 24 of the judgment of 15 March 2017, *Polynt* v *ECHA* (C-323/15 P, EU:C:2017:207), that Article 57(f) of Regulation No 1907/2006 'covers all other substances which do not fulfil any of the foregoing criteria but "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 Article 57(a) to (e)] and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59"' of that regulation and, on the other hand, submitting that only substances which do not fulfil any of the criteria listed in Article 57(a) to (e) of Regulation No 1907/2006 may be covered by Article 57(f).

241 The observation made in paragraph 24 of the judgment of 15 March 2017, *Polynt* v *ECHA* (C-323/15 P, EU:C:2017:207), must be understood as a succinct description of the overall scheme of Article 57 of Regulation No 1907/2006, but which was not made in the light of the question whether it was generally possible, for ECHA, to supplement an existing entry on the Candidate List of substances with dangerous properties under other grounds referred to in Article 57(a) to (f) of the regulation. In other words, the Court of Justice merely noted that substances which did not fulfil any of the criteria listed in Article 57(a) to (e) of Regulation No 1907/2006 can still be covered by Article 57(f) of that regulation, without making the applicability of the latter provision conditional on the non-fulfilment of the criteria listed in Article 57(a) to (e) thereof. On the contrary, in essence, that judgment confirms that the substances referred to in Article 57(f) of Regulation No 1907/2006 do indeed come within the scope of an open category intended to cover the dangerous properties of substances not covered by Article 57(a) to (e) of that regulation.

242 Accordingly, the second plea must be rejected as unfounded.

C. The third plea in law: infringement of Article 2(8)(b) of Regulation No 1907/2006

243 In the context of the third plea, the applicant claims that the contested decision infringes Article 2(8)(b) of Regulation No 1907/2006 because bisphenol A is manufactured and used within the territory of the European Union mostly as an 'intermediate', whereas, under the clear terms of that provision, isolated intermediates are exempt from Title VII of that regulation in its entirety, and are thus outside the scope both of Articles 57 and 59 of Regulation No 1907/2006 and of the authorisation procedure. The identification of bisphenol A as a substance of very high concern, irrespective of its qualities as an intermediate or non-intermediate substance is therefore, according to the applicant, an infringement of Article 2(8)(b) of Regulation No 1907/2006.

244 The applicant takes the view, first, that the clear wording of Article 2(8)(b) of Regulation No 1907/2006 precludes that provision being interpreted in such a way that deviates from the usual

meaning of the words that it contains. Such an interpretation would breach the principle of legal certainty and the principle of inter-institutional balance enshrined in Article 13(2) TEU. It is argued that the legislature made no provision whatsoever for restrictions as to the scope of the similar exception in Article 2(8)(a) of Regulation No 1907/2006, which exempts intermediates from Chapter 1 of Title II 'with the exception of Articles 8 and 9' of that regulation. In that regard, the applicant also relies on page 14 of ECHA's Guidance on Intermediates according to which, first, 'any use of a substance as an on-site isolated intermediate is not subject to authorisation (i.e. Title VII – Authorisation – does not apply) (Article 2(8)[(b) of Regulation No 1907/2006])' and, second, that exemption 'is also valid for intermediates used as monomers for the synthesis of polymers'.

245 Second, the title of Article 57 of Regulation No 1907/2006, 'Substances to be included in Annex XIV', shows, in the applicant's opinion, that the inclusion of a substance in the Candidate List is not an autonomous process, but is only a first step towards the inclusion of that substance in Annex XIV to that regulation. It is claimed that that assessment is supported by the wording of Article 59 of Regulation No 1907/2006, which provides that that article is to apply 'for the purpose of identifying substances meeting the criteria referred to in Article 57 [of that regulation] and establishing a Candidate List for eventual inclusion in Annex XIV' to the regulation. In the applicant's view, the use of the word 'eventual' indicates that the inclusion of a substance in the Candidate List will lead to its inclusion in Annex XIV to Regulation No 1907/2006. It argues further that, in paragraph 35 of its judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA* (C-324/15 P, EU:C:2017:208), the Court of Justice expressly recognised the existence of a link between inclusion on the Candidate List and the scope of the authorisation procedure. Accordingly, given that intermediates are exempt from the authorisation procedure, they should also be excluded from inclusion in the Candidate List.

246 Thirdly, the applicant maintains that a series of provisions shows that, within the context of the system for evaluating substances and authorising uses of those substances, as established by Regulation No 1907/2006, intermediates have a 'special nature'. In that regard, they are a special category of 'substances', which means, moreover, that the provisions of Regulation No 1907/2006 referring to 'intermediates' must not be applied or understood as relating to 'uses'. The 'special nature' of intermediates is recognised in recital 41 of Regulation No 1907/2006 and follows implicitly but necessarily from the requirements relating to the registration of those substances, as laid down in Articles 17 to 19 of that regulation. According to the applicant, if the legislature had considered that the exemption of intermediates from Title VII of Regulation No 1907/2006 in its entirety fell short of a high level of protection because intermediates could not be identified in accordance with Article 59 of that regulation, it would have applied a correction to the exemption referred to in Article 2(8)(b) of Regulation No 1907/2006 similar to that constituted by the reference to 'strictly controlled conditions' in Article 17(3) and Article 18(4) of that regulation. By not applying such a correction, the legislature clearly intended, in the applicant's submission, all intermediates to be exempt from Title VII of Regulation in its entirety, with no exceptions or special conditions.

247 Moreover, on-site isolated intermediates that are used in strictly controlled conditions are exempt from the substance evaluation procedure pursuant to Article 49 of Regulation No 1907/2006. Nevertheless, in the applicant's view, that article provides that a Member State which considers that the use of an intermediate gives rise to a risk equivalent to the level of concern arising from the use of substances which fulfil the criteria under Article 57 of that regulation may request that the registrant provide additional information. The applicant takes the view that such a provision would be meaningless and ineffective if the general risk management provisions laid down under Title VII of Regulation No 1907/2006, and under Article 57 in particular, were to apply to intermediates.

248 Lastly, the applicant submits that the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), is contradictory. On the one hand, the interpretation given by the Court of Justice contradicts its own finding in the judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA* (C-324/15 P, EU:C:2017:208), that Title VII of Regulation No 1907/2006 is a single procedure in which each stage works with the others. On the other hand, the Court of Justice's interpretation, in paragraph 61 of the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), whereby the exemption set out in Article 2(8)(b) of Regulation No 1907/2006 does not apply to the provisions of Title VII which govern substances in relation to

factors other than the uses or categories of use thereof, fails to explain why Article 56 of that regulation deals specifically with the uses of a substance. The applicant claims that the Court of Justice thus failed to explain why the exemption provided for in Article 2(8)(b) is applicable, against its wording, not only to a selected part of Title VII (Chapters 2 and 3 but also to a selected part of Chapter 1 thereof (Articles 57 and 59).

249 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

250 In that connection, it should be pointed out that bisphenol A is used for both intermediate and non-intermediate purposes and that the contested decision makes no distinction between those different types of use. In the context of its third plea, the applicant seeks annulment of the contested decision in the light of those two types of use, whereas its arguments are based in essence solely on the hypothesis that intermediate uses are exempt from Title VII of Regulation No 1907/2006. By contrast, no argument has been put forward in the light of non-intermediate uses of bisphenol A. It follows that, to the extent that it refers to non-intermediate uses of that substance and in the absence of any specific arguments pertaining to that type of use, the fifth plea must be rejected from the outset as ineffective.

251 As regards the intermediate uses of bisphenol A, it should be borne in mind that, under Article 2(8)(b) of Regulation No 1907/2006, ‘on-site isolated intermediates and transported isolated intermediates shall be exempted from Title VII’ of that regulation.

252 In the first place, as regards, in particular, the word ‘intermediate’, it should be observed that, in Regulation No 1907/2006, that word is used as a noun to identify certain substances which, on account of their use, enjoy a derogation, consisting of a reduction in certain obligations laid down by that regulation. In accordance with the definition in Article 3(15) of Regulation No 1907/2006, the word ‘intermediate’ applies to a substance manufactured for and consumed in or used for chemical processing in order to be transformed into another substance, known as ‘synthesis’ (judgment of 25 October 2017, *PPG and SNF* v *ECHA*, C-650/15 P, EU:C:2017:802, paragraphs 30 and 31). It is apparent from the definition of an intermediate, laid down in Article 3(15) of Regulation No 1907/2006, that the classification of a substance as an intermediate depends on the intended purpose of its manufacture and use (judgment of 25 October 2017, *PPG and SNF* v *ECHA*, C-650/15 P, EU:C:2017:802, paragraph 34). Notwithstanding the manner in which reference is made to an ‘intermediate’ as though it were a certain type of substance, contrary to the applicant’s submissions, when Regulation No 1907/2006 refers to an ‘intermediate’, it is not referring to a substance of a ‘special nature’ but to a certain type of use of a substance. A certain type of use of substances is therefore covered, inter alia, by Article 17(3) and Article 18(4) of that regulation.

253 Moreover, Article 3(15) of the regulation divides the uses of a substance for ‘intermediate’ purposes into three categories. The first, that of a ‘non-isolated intermediate’, concerns an intermediate that is not intentionally removed from the equipment in which it is synthesised. Regulation No 1907/2006 does not apply to that first category of use of a substance, by virtue of Article 2(1)(c) of that regulation. The second category, ‘on-site isolated intermediate’, applies to any intermediate in respect of which the manufacturing and synthesis take place on the same site. The third category, known as ‘transported isolated intermediate’, concerns any substance used as intermediate which is transported from one site to another. The latter two categories of intermediates are exempted from Title VII of that regulation, by virtue of Article 2(8)(b) of that regulation (judgment of 25 October 2017, *PPG and SNF* v *ECHA*, C-650/15 P, EU:C:2017:802, paragraph 32).

254 In the present case, it is common ground that since bisphenol A is used primarily as an on-site isolated intermediate or as a transported isolated intermediate, it falls into the second and third categories referred to in paragraph 253 above.

255 In the second place, as regards the question of the exact scope of the exemption provided for in Article 2(8)(b) of Regulation No 1907/2006, it should admittedly be observed that, in paragraph 59 of its judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), the Court of Justice stated in essence that the latter provision, interpreted literally, should lead to the finding that any substance used as an on-site isolated intermediate or as a transported isolated intermediate was, on

that ground, automatically exempt from all of the provisions under Title VII of Regulation No 1907/2006. According to the Court of Justice, such a substance would accordingly escape the identification procedure laid down in Article 59 of that regulation, even if, on account of its intrinsic properties, that substance fell under Article 57 of that regulation and should, consequently, be considered to be of very high concern; the authorisation procedure governed by Chapters 2 and 3 of Title VII of that regulation would therefore also not apply to such a substance.

256 However, having regard to the interpretation based on the objective of Regulation No 1907/2006, as referred to in Article 1 and recitals 69 and 70 thereof, the Court of Justice stated, in paragraph 62 of the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), that the exemption laid down in Article 2(8)(b) of Regulation No 1907/2006 concerned only the authorisation procedure laid down in Chapters 2 and 3 of Title VII of that regulation. By contrast, that exemption is inapplicable to the provisions of Title VII of Regulation No 1907/2006, which govern substances in accordance with their intrinsic properties. 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 (judgment of 25 October 2017, *PPG and SNF* v *ECHA*, C-650/15 P, EU:C:2017:802, paragraph 63).

257 In the present case, in the light of the Court of Justice's interpretation of Article 2(8)(b) of Regulation No 1907/2006 in the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), ECHA correctly applied Article 59 of that regulation as the basis of the contested decision.

258 Contrary to the applicant's claims, Article 49 of Regulation No 1907/2006 is neither meaningless nor ineffective in the light of such an interpretation. That article allows Member States, as an exception to the evaluation of substances laid down in Chapter 2 of Title VII of the regulation, to request additional information relating to the risk arising from the use of an on-site intermediate and, where appropriate, to recommend any suitable measure to reduce those risks. Although the risk which triggers those prerogatives of the Member States must be equivalent to the level of concern arising from those of substances which fulfil the criteria laid down in Article 57 of Regulation No 1907/2006, the evaluation of intermediates laid down in Article 49 of that regulation serves a completely different purpose, specifically that of controlling the risks arising from a certain use of a substance as an on-site isolated intermediate. However, the identification of a substance as being of very high concern under Articles 57 and 59 of the regulation does not, on its own, allow a specific risk arising from practical on-site use to be addressed, but instead is carried out with a view eventually to include that substance in Annex XIV to that regulation. Consequently, the objectives of those two provisions are different, with the result that Article 49 of Regulation No 1907/2006 does not preclude a substance which is also used for intermediate purposes from being identified as a substance of very high concern under Articles 57 and 59 of that regulation.

259 In those circumstances, the third plea must be rejected as, in part, ineffective (see paragraph 250 above) and, in part, unfounded (see paragraphs 251 to 258 above).

D. The fourth plea in law: infringement of the principle of proportionality

260 In the context of the fourth plea, the applicant claims that the contested decision goes beyond what is appropriate and necessary to attain the objectives pursued by Title VII of Regulation No 1907/2006 and was not the least onerous measure available to ECHA.

261 In the first place, the applicant submits that it follows from the objectives mentioned in recital 69 of Regulation No 1907/2006 that the identification procedure laid down in Articles 57 and 59 of that regulation was designed to play a role in ensuring that careful attention is paid to the substances which pose the greatest risks, namely substances of very high concern. However, due to the fact that intermediate substances are consumed during synthesis (Article 3(15) of Regulation No 1907/2006), those substances pose a much lower risk than other substances. In light of their special nature, the legislator decided that isolated intermediates were not of the highest concern and should thus be exempted from the authorisation procedure altogether. In a case such as the present case, where

intermediates represent the majority of the applications of bisphenol A, it is a fortiori disproportionate to include the substance in the Candidate List. In addition, in the applicant's view, the identification procedure laid down in Articles 57 and 59 of Regulation No 1907/2006 pursues a clear objective, namely that of inclusion in Annex XIV to that regulation. The inclusion of intermediate uses of bisphenol A in the Candidate List will not contribute to the inclusion of bisphenol A in that annex. In those circumstances, the inclusion of bisphenol A in the Candidate List is inappropriate. Lastly, in the applicant's view, that inclusion was even less appropriate for the purposes of achieving the objectives of Title VII of Regulation No 1907/2006, given that one of the non-intermediate uses of bisphenol A – namely its use in the manufacturing of thermal paper – is already restricted under that regulation.

262 In the second place, ECHA had, in the applicant's view, a choice of measures and could have acted in a way to avoid confusion and mitigate the effects of lawful use of bisphenol A as an intermediate post inclusion in the Candidate List. In particular, in the applicant's view, ECHA could have included bisphenol A in the Candidate List as a substance of very high concern, explicitly stating that such identification and inclusion did not apply in so far as bisphenol A meets the definition of an 'intermediate'. The applicant claims that that measure is legally sound and less onerous than the contested decision as it reconciles the exemption of intermediates in Article 2(8)(b) of Regulation No 1907/2006 with the identification of non-intermediate uses under Article 59 of that regulation. This solution would allow substances used as both intermediate and non-intermediate to be included in the Candidate List, whilst respecting the provisions of Article 2(8)(b) of Regulation No 1907/2006, by explaining that the inclusion in the Candidate List concerns bisphenol A only when it does not meet the definition of an 'intermediate', and whilst ensuring better legal certainty with regard to the need to apply for authorisation for intermediate uses under Article 60 of Regulation No 1907/2006. That solution would, according to the applicant, be less restrictive, as undertakings which put bisphenol A on the market solely as an intermediate would not be affected by its inclusion in that list, and it would not prevent the objective of including non-intermediate substances in Annex XIV to Regulation No 1907/2006 being achieved.

263 ECHA, supported by the Federal Republic of Germany, the French Republic and ClientEarth, contests those arguments.

264 As a preliminary point, it should be recalled that the principle of proportionality, which is enshrined in Article 5(4) TEU and which forms part of the general principles of EU law, requires, according to settled case-law, that measures adopted by the institutions do not exceed the limits of what is appropriate and necessary in order to attain the aim pursued; when there is a choice between several appropriate measures recourse must be had to the least onerous (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited).

265 In the first place, as regards the argument that 'intermediate substances' are consumed during synthesis and therefore pose a much lower risk than other substances, it should be observed that the applicant proceeds on a false premiss. As has already been noted in paragraph 260 above, despite the fact that the regulation refers, in some of its provisions, to 'intermediates' as though they were a certain type of substance, it refers rather to a certain type of use of certain substances, namely the use of certain substances for intermediate purposes.

266 That being the case, it must be held that, contrary to the applicant's claim, the mere fact that bisphenol A is used only on rare occasions for non-intermediate purposes does not render the inclusion of that substance on the Candidate List inappropriate. The identification of a substance as a substance meeting the criteria in Article 57 of Regulation No 1907/2006 is based solely on the intrinsic properties of that substance and therefore irrespective of the question of which uses are to be taken into account at the stage of the inclusion in Annex XIV to that regulation, or at the stage of the granting of an authorisation pursuant to Article 60(2) or (4) of that regulation.

267 Moreover, it must be held that the inclusion of bisphenol A on the Candidate List of substances was appropriate to achieve the objective pursued by the provisions of Regulation No 1907/2006 on obtaining information, such as Article 31 of that regulation.

268 Lastly, even supposing that restrictive measures are also appropriate for achieving the objective of Regulation No 1907/2006, that does not mean that restrictions and identification of substances as substances of very high concern are mutually exclusive. As the case-law has already confirmed, the mere fact that a substance appears on the Candidate List of substances does not prevent that substance from being subject to restrictions (see, to that effect, judgment of 25 September 2015, *PPG and SNF* v *ECHA*, T-268/10 RENV, EU:T:2015:698, paragraphs 90 and 91).

269 In the second place, as regards the argument that the principle of proportionality has been breached because there is no reference, in the Candidate List of substances, to the intermediate uses of a substance which is capable of being used both for intermediate and non-intermediate purposes, suffice it to observe that, in its judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802), the Court of Justice has already held, in paragraph 79 of that judgment, that the inclusion of a substance in the list of substances for future inclusion in Annex XIV to that regulation with a statement that that listing does not affect the uses exempted under Article 2(8)(b) of that regulation, would be irrelevant for the purposes of applying the principle of proportionality.

270 Furthermore, it should be pointed out that a reference according to which the inclusion of a substance in the Candidate List does not concern intermediate uses – such as that sought by the applicant – could cause confusion as to the question whether information obligations arising from the inclusion in the Candidate List are applicable even in the case of intermediate use.

271 In the light of all of the foregoing, the fourth plea must be rejected as unfounded and, accordingly, the action dismissed in its entirety.

IV. Costs

272 Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered, in accordance with the form of order sought by ECHA and ClientEarth, to bear its own costs and to pay those incurred by both of the latter.

273 In accordance with Article 138(1) of the Rules of Procedure, the Member States which have intervened in the proceedings are to bear their own costs. Consequently, the Federal Republic of Germany and the French Republic must be ordered to bear their own costs.

On those grounds,

THE GENERAL COURT (Eighth Chamber)

hereby:

1. Dismisses the action;

2. Orders PlasticsEurope to bear its own costs and pay those 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.

Svenningsen Pynnä Laitenberger

Delivered in open court in Luxembourg on 16 December 2020.

E. Coulon M. van der Woude

Registrar President

Table of contents

* Language of the case: English.

1 This judgment is published in extract form.

DOMSTOLENS DOM (Fjerde Afdeling)

9. marts 2023 (*)

»Appel – udarbejdelse af en liste over stoffer, der skal godkendes – forordning (EF) nr. 1907/2006 – bilag XIV – liste over stoffer, der er identificeret med henblik på senere at blive optaget i bilag XIV – ajourføring af opførelsen af stoffet bisphenol A som et »særligt problematisk stof««

I sag C-119/21 P,

angående appel i henhold til artikel 56 i statutten for Den Europæiske Unions Domstol, iværksat den 25. februar 2021,

PlasticsEurope AISBL, Bruxelles (Belgien), ved avocates R. Cana og E. Mullier,

appellant,

de øvrige parter i appelsagen:

Det Europæiske Kemikalieagentur (ECHA) ved W. Broere og A. Hautamäki, som befuldmægtigede, bistået af advocaat S. Raes,

sagsøgt i første instans,

Forbundsrepublikken Tyskland, først ved J. Möller og D. Klebs, som befuldmægtigede, derefter ved J. Möller, som befuldmægtiget,

Den Franske Republik ved G. Bain og T. Stéhelin, som befuldmægtigede,

ClientEarth, London (Det Forenede Kongerige), ved avocat P. Kirch,

intervenienter i første instans,

har

DOMSTOLEN (Fjerde Afdeling),

sammensat af afdelingsformanden, C. Lycourgos, og dommerne L.S. Rossi, J.-C. Bonichot, S. Rodin (refererende dommer) og O. Spineanu-Matei,

generaladvokat: M. Szpunar,

justitssekretær: A. Calot Escobar,

på grundlag af den skriftlige forhandling,

og efter at generaladvokaten har fremsat forslag til afgørelse i retsmødet den 8. september 2022,

afsagt følgende

Dom

1 I appelskriftet har PlasticsEurope AISBL, der er en sammenslutning, som repræsenterer europæiske plastproducenters interesser, nedlagt påstand om ophævelse af dom afsagt af Den Europæiske Unions Ret den 16. december 2020, PlasticsEurope mod ECHA (T-207/18, herefter »den appellerede dom«,

EU:T:2020:623), hvorved Retten frifandt ECHA i det søgsmål, som sammenslutningen havde nedlagt med påstand om annullation af afgørelse ED/01/2018 truffet af den administrerende direktør for Det Europæiske Kemikalieagentur (ECHA) den 3. januar 2018 (herefter »den omtvistede afgørelse«), hvorved den eksisterende indgang vedrørende bisphenol A på listen over stoffer, der var identificeret med henblik på senere at blive optaget i bilag XIV til Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 af 18. december 2006 om registrering, vurdering og godkendelse af samt begrænsninger for kemikalier (REACH), om oprettelse af et europæisk kemikalieagentur og om ændring af direktiv 1999/45/EF og ophævelse af Rådets forordning (EØF) nr. 793/93 og Kommissionens forordning (EF) nr. 1488/94 samt Rådets direktiv 76/769/EØF og Kommissionens direktiv 91/155/EØF, 93/67/EØF, 93/105/EF og 2000/21/EF (EUT 2006, L 396, s. 1, og berigtiget i EUT 2007, L 136, s. 3), som ændret ved Kommissionens forordning (EU) nr. 253/2011 af 15. marts 2011 (EUT 2011, L 69, s. 7) (herefter »REACH-forordningen«), blev suppleret, således at bisphenol A ligeledes blev identificeret som et stof, der henhører under REACH-forordningens artikel 57, litra f), dvs. et sådant stof, der på grund af hormonforstyrrende egenskaber kan have alvorlige virkninger på miljøet, og som er problematisk i samme grad som virkningerne af de andre stoffer, der er opregnet i denne forordnings artikel 57, litra a)-e).

Retsforskrifter

2 REACH-forordningens artikel 2 med overskriften »Anvendelse« bestemmer i stk. 8, litra b), at isolerede mellemprodukter anvendt på produktionsstedet og isolerede mellemprodukter, der transporteres, undtages fra bestemmelserne i afsnit VII i denne forordning, som underlægger de særligt problematiske stoffer som omhandlet i dette afsnit godkendelsesordningen.

3 Den nævnte forordnings artikel 3, der har overskriften »Definitioner«, bestemmer følgende i nr. 15):

»15) »mellemprodukt«: et stof, der fremstilles til og forbruges i eller anvendes til kemisk forarbejdning for at blive omdannet til et andet stof (herefter benævnt »syntese«):

a) »ikke-isoleret mellemprodukt«: et mellemprodukt, der under syntesen ikke bevidst fjernes (bortset fra prøveudtagning) fra det udstyr, hvori syntesen finder sted. I sådant udstyr indgår reaktionsbeholderen, hjælpeudstyr hertil samt udstyr, som stoffet/stofferne passerer igennem i en ubrudt strøm eller batchproces, og rørsystemer til overførsel fra en beholder til en anden med henblik på næste reaktionstrin, men det omfatter ikke tanke eller andre beholdere, som stoffet/stofferne opbevares i efter fremstillingen

b) »isoleret mellemprodukt anvendt på produktionsstedet«: et mellemprodukt, der ikke opfylder kriterierne for et ikke-isoleret mellemprodukt, og hvor fremstillingen af mellemproduktet og syntesen af et eller flere andre stoffer fra dette mellemprodukt finder sted på samme produktionssted, der drives af en eller flere juridiske enheder

c) »isoleret mellemprodukt, der transporteres«: et mellemprodukt, der ikke opfylder kriterierne for et ikke-isoleret mellemprodukt, og som transporteres mellem eller leveres til andre produktionssteder«.

4 Samme forordnings artikel 7 med overskriften »Registrering og anmeldelse af stoffer i artikler« bestemmer i stk. 2:

»Enhver producent eller importør af artikler skal underrette [ECHA] i overensstemmelse med stk. 4, hvis et stof opfylder kriterierne i artikel 57 og er identificeret i henhold til artikel 59, stk. 1, og hvis begge følgende betingelser er opfyldt:

a) stoffet er til stede i disse artikler i mængder på over 1 ton pr. producent eller importør pr. år

b) stoffet er til stede i disse artikler i en koncentration på over 0,1 vægtprocent.«

5 REACH-forordningens artikel 17 med overskriften »Registrering af isolerede mellemprodukter anvendt på produktionsstedet« bestemmer følgende i stk. 3:

»Stk. 2 finder kun anvendelse på isolerede mellemprodukter anvendt på produktionsstedet, hvis producenten bekræfter, at stoffet kun fremstilles og anvendes under strengt kontrollerede forhold, således at det er strengt indesluttet ved hjælp af tekniske foranstaltninger i hele sin livscyklus. Der skal anvendes kontrolteknologier og -fremgangsmåder for at reducere emission og deraf følgende eksponering mest muligt.

Hvis disse betingelser ikke er opfyldt, skal registreringen omfatte de oplysninger, der er angivet i artikel 10.«

6 Denne forordnings artikel 18, der har overskriften »Registrering af isolerede mellemprodukter, der transporteres«, bestemmer i stk. 4:

»Stk. 2 og 3 finder kun anvendelse på isolerede mellemprodukter, der transporteres, hvis producenten eller importøren selv bekræfter eller erklærer, at brugeren over for ham har bekræftet, at syntesen af et eller flere andre stoffer fra dette mellemprodukt foregår på andre produktionssteder under følgende nøje kontrollerede betingelser: […]«

7 Den nævnte forordnings artikel 33, der har overskriften »Forpligtelse til at videregive oplysninger om stoffer i artikler«, har følgende ordlyd:

»1. Enhver leverandør af en artikel indeholdende et stof, der opfylder kriterierne i artikel 57 og er identificeret i henhold til artikel 59, stk. 1, i en koncentration på over 0,1 vægtprocent, skal forsyne modtageren af artiklen med oplysninger, som leverandøren råder over, og som er tilstrækkelige til, at artiklen kan anvendes sikkert, herunder som et minimum stoffets navn.

2. På anmodning fra en forbruger skal enhver leverandør af en artikel indeholdende et stof, der opfylder kriterierne i artikel 57 og er identificeret i henhold til artikel 59, stk. 1, i en koncentration på over 0,1 vægtprocent, forsyne forbrugeren med oplysninger, som leverandøren råder over, og som er tilstrækkelige til, at artiklen kan anvendes sikkert, herunder som et minimum stoffets navn.

De relevante oplysninger skal leveres gratis senest 45 dage efter modtagelsen af anmodning.«

8 Samme forordnings artikel 57 med overskriften »Stoffer til optagelse i bilag XIV« er affattet som følger:

»Følgende stoffer kan optages i bilag XIV i henhold til proceduren i artikel 58:

a) stoffer, der opfylder kriterierne for klassificering i fareklassen carcinogenicitet kategori 1A eller 1B i henhold til punkt 3.6 i bilag I til forordning (EF) nr. 1272/2008

b) stoffer, der opfylder kriterierne for klassificering i fareklassen kimcellemutagenicitet kategori 1A eller 1B i henhold til punkt 3.5 i bilag I til forordning (EF) nr. 1272/2008

c) stoffer, der opfylder kriterierne for klassificering i fareklassen reproduktionstoksicitet kategori 1A eller 1B, skadelige virkninger for seksuel funktion og forplantningsevnen eller for udviklingen, i henhold til punkt 3.7 i bilag I til forordning (EF) nr. 1272/2008

d) stoffer, der er persistente, bioakkumulerende og toksiske i henhold til kriterierne i denne forordnings bilag XIII

e) stoffer, der er meget persistente og meget bioakkumulerende i henhold til kriterierne i denne forordnings bilag XIII

f) stoffer – som f.eks. stoffer med hormonforstyrrende egenskaber eller stoffer med persistente, bioakkumulerende og toksiske eller meget persistente og meget bioakkumulerende egenskaber, der ikke opfylder kriterierne i litra d) eller e) – for hvilke der foreligger videnskabelig dokumentation for sandsynlige alvorlige virkninger på menneskers sundhed eller miljøet, der er problematiske i samme grad som virkningerne af de andre stoffer, der er anført i litra a)-e); disse stoffer identificeres enkeltvis i overensstemmelse med den i artikel 59 fastlagte procedure.«

9 REACH-forordningens artikel 59 med overskriften »Identifikation af de stoffer, der er nævnt i artikel [57]« bestemmer følgende i stk. 3, 4, 7 og 8:

»3. Enhver medlemsstat kan udarbejde et dossier i overensstemmelse med bilag XV for stoffer, der efter dens opfattelse opfylder kriterierne i artikel 57, og fremsende dette til [ECHA]. Dossieret kan om fornødent begrænses til en henvisning til en indgang i bilag VI, del 3, i forordning (EF) 1272/2008. [ECHA] gør dette dossier tilgængeligt for de andre medlemsstater inden for 30 dage efter modtagelsen.

4. [ECHA] skal på sin hjemmeside offentliggøre en meddelelse om, at der er blevet udarbejdet et bilag XV-dossier for et stof. [ECHA] skal opfordre alle berørte parter til at fremsætte kommentarer over for [ECHA] inden en bestemt frist.

[…]

7. [ECHA] skal, når det har modtaget eller fremsat kommentarer, forelægge dossieret for Medlemsstatsudvalget senest 15 dage efter udløbet af den periode på 60 dage, der er nævnt i stk. 5.

8. Hvis der i Medlemsstatsudvalget inden for en periode på 30 dage efter forelæggelsen opnås enstemmighed om identifikationen, skal [ECHA] optage stoffet på den i stk. 1 nævnte liste. [ECHA] kan optage det pågældende stof i sine anbefalinger i henhold til artikel 58, stk. 3.«

10 REACH-forordningen indeholder et bilag XI med overskriften »Generelle regler for tilpasning af standardtestprogrammet i bilag VII-X«, hvis punkt 1.2 med overskriften »Oplysningernes vægt (»weight of evidence«) fastsætter:

»Flere uafhængige oplysningskilder kan tilsammen have tilstrækkelig vægt (»weight of evidence«) til, at man kan formode/konkludere, at et stof har eller ikke har en bestemt farlig egenskab, mens oplysningerne fra hver enkelt kilde alene betragtes som utilstrækkelige til at understøtte denne opfattelse.

Nyudviklede forsøgsmetoder, der endnu ikke indgår i forsøgsmetoderne i artikel 13, stk. 3, eller en international forsøgsmetode, der er godkendt af [Europa-]Kommissionen eller [ECHA] som tilsvarende, kan have tilstrækkelig »weight of evidence« og føre til den konklusion, at et stof har eller ikke har en bestemt farlig egenskab.

Når der foreligger tilstrækkelig »weight of evidence« for, om en bestemt farlig egenskab er til stede eller ikke er til stede:

– skal yderligere testning på hvirveldyr vedrørende den pågældende egenskab undlades

– kan yderligere testning, der ikke omfatter hvirveldyr, undlades.

I alle tilfælde fremlægges tilstrækkelig og pålidelig dokumentation.«

Sagens baggrund

11 Bisphenol A (2,2-bis(4-hydroxyphenyl)propan eller 4,4'-isopropylidenediphenol, EF nr. 201-245-8, CAS-nr. 0000080-05-7) er et stof, der hovedsageligt anvendes som mellemprodukt, dvs. monomer ved fremstillingen af polymerer, såsom polycarbonat og epoxyharpikser. Endvidere kan bisphenol A anvendes til formål, hvor stoffet ikke er et mellemprodukt, bl.a. ved fremstillingen af termopapir.

12 Den 4. januar 2017 vedtog ECHA afgørelse ED/01/2017, hvorved agenturet fandt, at bisphenol A skal opføres på listen over stoffer, der skal optages i bilag XIV til REACH-forordningen (herefter »kandidatlisten«), med den begrundelse, at dette stof var blevet identificeret som et »reproduktionstoksisk stof« som omhandlet i denne forordnings artikel 57, litra c).

13 Den 6. juli 2017 traf ECHA afgørelse ED/30/2017, hvorved den eksisterende indgang vedrørende stoffet bisphenol A på kandidatlisten blev suppleret. Dette stof blev således ligeledes identificeret som et stof, der henhører under artikel 57, litra f), dvs. et stof med hormonforstyrrende egenskaber, der kan

have alvorlige virkninger for menneskers sundhed, der er problematiske i samme grad som virkningerne af de andre stoffer, der er anført i den nævnte forordnings artikel 57, litra a)-e).

14 Den 29. august 2017 forelagde Umweltbundesamt (forbundsmiljøstyrelsen, Tyskland) i henhold til REACH-forordningens artikel 59, stk. 3, et dossier i overensstemmelse med forskrifterne i bilag XV til denne forordning (herefter »det i henhold til bilag XV udarbejdede dossier«), hvori den anbefalede, at bisphenol A blev identificeret som et hormonforstyrrende stof, for hvilket der foreligger videnskabelig dokumentation for sandsynlige alvorlige virkninger på miljøet som omhandlet i den nævnte forordnings artikel 57, litra f).

15 Den 5. september 2017 offentliggjorde ECHA det i henhold til bilag XV udarbejdede dossier.

16 Samme dag opfordrede ECHA i overensstemmelse med REACH-forordningens artikel 59, stk. 4, alle berørte parter til at fremsætte deres bemærkninger til dette dossier.

17 Den 20. oktober 2017 fremsatte appellanten på vegne af sine medlemmer bemærkninger til det nævnte dossier.

18 Derpå udfærdigede Umweltbundesamt (forbundsmiljøstyrelsen, Tyskland) et dokument, som var dateret den 14. december 2017, og som indeholdt dens svar på alle de kommentarer vedrørende identifikationen af bisphenol A, som ECHA havde modtaget i forbindelse med den offentlige høring.

19 ECHA forelagde dossieret indeholdende kommentarerne vedrørende identifikationen af bisphenol A for Medlemsstatsudvalget i overensstemmelse med REACH-forordningens artikel 59, stk. 7. Udvalget modtog det i henhold til bilag XV udarbejdede dossier, et udkast til Medlemsstatsudvalgets aftale og et arbejdsdokument, der indeholdt en vurdering af bisphenol A's iboende egenskaber med henblik på dets identifikation i henhold til nævnte forordnings artikel 57, litra f) (herefter »støttedokumentet«).

20 På Medlemsstatsudvalgets 57. møde, der blev afholdt den 11.-15. december 2017, nåede udvalget frem til en enstemmig aftale om at identificere bisphenol A som et stof, der opfylder disse kriterier. Fire medlemsstater undlod at stemme. Begrundelsen for identifikationen af bisphenol A er anført i en ændret version af støttedokumentet, som vedtaget den 14. december 2017.

21 I støttedokumentet i dets endelige affattelse konkluderes det først på grundlag af en analyse af en lang række studier, at bisphenol A opfylder definitionen på hormonforstyrrende stoffer som fastsat af Verdenssundhedsorganisationen (WHO) og som fortolket af Kommissionens rådgivende ekspertgruppe om hormonforstyrrende stoffer. Det konkluderes nærmere bestemt i dette støttedokument, at de analyserede in vitro- og in vivo-data viser, at bisphenol A virker som en østrogen-agonist i visse fiskearter og som en thyroid-antagonist i visse amfibiearter.

22 Derefter konstateres det i dette dokument, at analyserne af de forskellige taksonomiske grupper af hvirvelløse dyr viser, at det er muligt, at de alvorlige virkninger af bisphenol A er en følge af den endokrine virkemåde.

23 Endelig anføres det heri, at virkningerne af bisphenol A på fisk og amfibier anses for at være problematiske i samme grad som virkningerne af de stoffer, der er nævnt i REACH-forordningens artikel 57, litra a)-e), dvs. kræftfremkaldende, mutagene og reproduktionstoksiske stoffer, eller persistente, bioakkumulerende og toksiske stoffer (herefter »PBT-stoffer«) og stoffer, der er meget persistente og meget bioakkumulerende (herefter »vPvB-stoffer«). I denne henseende er det i støttedokumentet i dets endelige affattelse bl.a. anført, at virkningerne for organismerne og populationerne er alvorlige og irreversible, og at det er vanskeligt at fastlægge et sikkert niveau for eksponering for bisphenol A.

24 Den 3. januar 2018 vedtog ECHA – efter enstemmighed i Medlemsstatsudvalget og i overensstemmelse med REACH-forordningens artikel 59, stk. 8 – den omtvistede afgørelse, hvorved den eksisterende indgang vedrørende stoffet bisphenol A på kandidatlisten blev suppleret således, at dette stof af de grunde, der er anført i støttedokumentet i dets endelige affattelse, ligeledes henhører under de stoffer, der fremgår af artikel 57, litra f), dvs. stoffer med hormonforstyrrende egenskaber

med sandsynlige alvorlige virkninger på miljøet, der er problematiske i samme grad som virkningerne af de andre stoffer, der er anført i den nævnte forordnings artikel 57, litra a)-e).

Sagen for Retten og den appellerede dom

25 Ved stævning indleveret til Rettens Justitskontor den 23. marts 2018 anlagde appellanten sag med påstand om annullation af den omtvistede afgørelse.

26 Til støtte for søgsmålet fremførte appellanten fire anbringender. Det første anbringende vedrørte flere åbenbart urigtige skøn ved identifikationen af bisphenol A som et særligt problematisk stof som omhandlet i REACH-forordningens artikel 57, litra f). Med det andet anbringende påberåbte appellanten sig en tilsidesættelse af denne forordnings artikel 59, sammenholdt med den nævnte forordnings artikel 57, litra f). Det tredje anbringende vedrørte en tilsidesættelse af samme forordnings artikel 2, stk. 8, litra b). Med det fjerde anbringende påberåbte appellanten sig en tilsidesættelse af proportionalitetsprincippet.

27 Ved den appellerede dom frifandt Retten ECHA.

Parternes påstande for Domstolen

28 Appellanten har nedlagt følgende påstande:

– Den appellerede dom ophæves.

– Den omtvistede afgørelse annulleres.

– Subsidiært hjemvises sagen til Retten, således at denne kan realitetsbehandle appellantens annullationssøgsmål.

– ECHA tilpligtes at betale sagsomkostningerne, herunder omkostningerne i forbindelse med sagen for Retten og intervenienternes omkostninger.

29 ECHA har nedlagt følgende påstande:

– Appellen forkastes.

– Appellanten tilpligtes at betale sagsomkostningerne.

30 Forbundsrepublikken Tyskland har nedlagt følgende påstande:

– Appellen forkastes.

– Appellanten tilpligtes at betale sagsomkostningerne.

31 Den Franske Republik har nedlagt påstand om, at appellen forkastes.

32 ClientEarth har nedlagt følgende påstande:

– Appellen forkastes.

– Appellanten tilpligtes at bære sine egne omkostninger og at betale de af ECHA, af Den Franske Republik og af ClientEarth afholdte omkostninger, herunder de omkostninger, der er afholdt i første instans.

Om appellen

33 Til støtte for appellen har appellanten fremsat fem anbringender.

34 Det første anbringende vedrører flere retlige fejl, som Retten skulle have begået i forbindelse med den efterprøvelse, den skulle foretage af ECHA's vurdering af den videnskabelige dokumentation med henblik på anvendelsen af REACH-forordningens artikel 57, litra f). Dette anbringende indeholder fire led, der vedrører den efterprøvelse, som Retten foretog for så vidt angår for det første ECHA's manglende hensyntagen til pålidelige og relevante studier, der modsagde agenturets endelige afgørelse, for det andet ECHA's hensyntagen til studier, der havde en svag grad af pålidelighed, som støttede ECHA's endelige afgørelse, for det tredje det forhold, at ECHA tillagde de studier, der støttede agenturets endelige afgørelse, større vægt, og endelig for det fjerde det forhold, at ECHA ikke tog hensyn til studier vedrørende bisphenol A, der var gennemført af andre EU-agenturer og -institutioner.

35 Det andet anbringende vedrører en fejlagtig fortolkning af REACH-forordningens artikel 57, litra f), en urigtig gengivelse af appellantens skriftlige indlæg og en tilsidesættelse af retten til at blive hørt.

36 Det tredje anbringende vedrører retlige fejl, som Retten skulle have begået ved vurderingen af beviserne vedrørende de videnskabelige undersøgelsers troværdighed og en hævdet urigtig gengivelse af beviserne.

37 Det fjerde anbringende vedrører en fejlagtig fortolkning af forsigtighedsprincippet.

38 Det femte anbringende vedrører en fejlagtig fortolkning af REACH-forordningens artikel 2, stk. 8, litra b), og en tilsidesættelse af begrundelsespligten.

Det første anbringende om flere retlige fejl, som Retten begik ved den efterprøvelse, som den skulle foretage af ECHA's vurdering af den videnskabelige dokumentation med henblik på anvendelsen af REACH-forordningens artikel 57, litra f)

Det første anbringendes første led vedrørende den efterprøvelse, som Retten foretog for så vidt angår ECHA's manglende hensyntagen til pålidelige og relevante studier, der modsagde agenturets endelige afgørelse

– *Parternes argumenter*

39 Med det første anbringendes første led har appellanten gjort gældende, at Retten i den appellerede doms præmis 64 foretog en fejlagtig fortolkning og anvendelse af princippet om videnskabelig topkvalitet, af begrebet »bevisers bevisværdi« og af den forpligtelse, der påhviler ECHA til at tage hensyn til alle de relevante oplysninger.

40 Idet Retten i denne præmis 64 fandt, at »et åbenbart urigtigt skøn kun kunne konstateres, hvis ECHA fuldstændigt og fejlagtigt havde set bort fra et pålideligt studie, hvis medtagelse ville have ændret den samlede vurdering af beviserne på en sådan måde, at den [omtvistede] afgørelse ville have været usandsynlig«, tillod Retten ECHA ikke at tage hensyn til pålidelige videnskabelige studier, forudsat at agenturet ikke gjorde det »fuldstændigt og fejlagtigt«. Herved underkendte Retten omfanget af sin retslige prøvelse af ECHA's afgørelser, selv om denne prøvelse er begrænset til en prøvelse af, om der foreligger åbenbart urigtige skøn. Hvis et studie er pålideligt og relevant, skal resultaterne af dette studie tages i betragtning i forbindelse med vurderingen af beviskraften af bevismidler, henset til den forpligtelse, der påhviler ECHA til at tage hensyn til alle de relevante oplysninger.

41 I den appellerede dom fastsattes bevisbyrden for at anfægte beviskraften af bevismidler, som ECHA havde lagt til grund inden for rammerne af agenturets vurdering i henhold til REACH-forordningens artikel 57, litra f), desuden på et uacceptabelt og ugennemførligt niveau, idet appellanten blev pålagt bevisbyrden for at godtgøre for det første, at ECHA fuldstændigt og fejlagtigt havde set bort fra et studie, og for det andet, at det forhold, at der blev taget hensyn til dette studie, ville have ændret den samlede vurdering af beviserne på en sådan måde, at ECHA's endelige afgørelse ville have været usandsynlig.

42 Et sådant krav er ligeledes i strid med formålet og med begrebet »bevisværdi« som defineret i punkt 1.2 i bilag XI til denne forordning. En vurdering af beviskraften af bevismidler finder nemlig pr. definition anvendelse, når der findes mere end ét studie, der begrunder en konklusion, idet et enkelt studie således aldrig er tilstrækkeligt til at afkræfte den konklusion, som ECHA når frem til. Ifølge

appellanten forholder det sig således, at enhver undladelse af at tage hensyn til resultaterne af et pålideligt videnskabeligt studie vedrørende bisphenol A, som er relevante for den egenskab, der er blevet undersøgt inden for rammerne af en vurdering af beviskraften af bevismidlerne, udgør et åbenbart urigtigt skøn, en tilsidesættelse af ECHA's forpligtelse til at tage hensyn til alle de relevante oplysninger og en tilsidesættelse af princippet om videnskabelig topkvalitet.

43 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det første anbringendes første led er ugrundet.

– *Domstolens bemærkninger*

44 Det skal fastslås, at den argumentation, som appellanten har fremført inden for rammerne af det første anbringendes første led, udspringer af en fejlagtig læsning af de relevante begrundelser i den appellerede dom.

45 I den appellerede doms præmis 62 fastslog Retten med rette, at ECHA skal indrømmes et vidt skøn med henblik på identifikationen af særligt problematiske stoffer i henhold til REACH-forordningens artikel 57, litra f), under hensyn til de meget komplekse videnskabelige og tekniske vurderinger, som dette agentur skal foretage i denne sammenhæng (jf. analogt dom af 22.11.2017, Kommissionen mod Bilbaína de Alquitranes m.fl., C-691/15 P, EU:C:2017:882, præmis 34, og af 15.10.2020, Deza mod Kommissionen, C-813/18 P, ikke trykt i Sml., EU:C:2020:832, præmis 40).

46 Herved bemærkes, at når Unionens myndigheder har en bred skønsmargen, navnlig hvad angår de faktuelle forhold af videnskabelig og teknisk meget kompleks karakter til at bestemme karakteren og omfanget af tiltag, som de vedtager inden for denne ramme, bør Unionens retsinstanser begrænse sig til at undersøge, om udøvelsen af dette skøn er behæftet med en åbenbar fejl, om der foreligger magtfordrejning, eller om institutionerne åbenbart har overskredet grænserne for deres skøn. I en sådan situation kan Unionens retsinstanser således ikke sætte deres egen vurdering af de faktiske omstændigheder af videnskabelig og teknisk karakter i stedet for institutionernes, idet institutionerne efter EUF-traktaten varetager denne opgave alene (dom af 21.7.2011, Nickel Institute, C-14/10, EU:C:2011:503, præmis 60, og af 15.10.2020, Deza mod Kommissionen, C-813/18 P, ikke trykt i Sml., EU:C:2020:832, præmis 41).

47 Unionens myndigheders vide skønsbeføjelse, hvis udøvelse er omfattet af en begrænset retslig prøvelse, omfatter ikke udelukkende indholdet og rækkevidden af de bestemmelser, der skal vedtages, men omfatter også i et vist omfang konstateringen af de tilgrundliggende faktiske forhold. Imidlertid fordrer en sådan retslig prøvelse, selv om den har et begrænset omfang, at Unionens myndigheder, der er ophavsmænd til den omhandlede retsakt, er i stand til for Unionens retsinstanser at godtgøre, at retsakten blev vedtaget ved en egentlig udøvelse af deres skønsbeføjelse, hvilket forudsætter, at alle relevante forhold og omstændigheder angående den situation, som retsakten har til formål at regulere, tages i betragtning (kendelse af 4.9.2014, Cindu Chemicals m.fl. mod ECHA, C-289/13 P, ikke trykt i Sml. EU:C:2014:2175, præmis 26 og den deri nævnte retspraksis).

48 I den appellerede doms præmis 63 anførte Retten, at »identifikationen af det omhandlede stof som særligt problematisk [i det foreliggende tilfælde var blevet] foretaget ved hjælp af fremgangsmåden angående [beviskraften af bevismidler]. I henhold til punkt 1.2 i bilag XI til [REACH-forordningen] er denne fremgangsmåde karakteriseret ved den omstændighed, at flere uafhængige oplysningskilder tilsammen kan have tilstrækkelig vægt (»weight of evidence«) til, at man kan formode, at et stof har eller ikke har en bestemt farlig egenskab, mens oplysningerne fra hver enkelt kilde alene kan være utilstrækkelige til at understøtte denne opfattelse eller denne konklusion«.

49 Retten fremhævede endvidere i denne præmis, at »identifikationen af et stof ved hjælp af fremgangsmåden angående [beviskraften af bevismidler] skal foretages på grundlag af fuldstændige oplysninger, der gør det muligt for den kompetente myndighed at udøve det skøn, den råder over i henhold til [denne forordnings] artikel 57 og 59 […], samtidig med at der tages hensyn til alle relevante og tilgængelige beviser på det tidspunkt, hvor myndigheden træffer sin afgørelse«.

50 Det er i lyset af disse principper, som Retten redegjorde for i den appellerede doms præmis 62 og 63, og som appellanten ikke har rejst tvivl om i appellen, at rækkevidden af den appellerede doms præmis

64 skal undersøges. Retten anførte i den nævnte præmis 64 med rette, at det i forbindelse med vurderingen af beviskraften af bevismidler stod ECHA frit for »at se bort fra studier, som [agenturet] ikke anså for relevante af plausible grunde, som er forbundet med den interne sammenhæng i den foretagne vurdering«. Det var ligeledes uden at begå fejl, at Retten udtalte, at den forpligtelse, der påhviler ECHA til at tage hensyn til alle de relevante beviser, der er til rådighed, ikke kan medføre, at alle de studier, der er blevet gennemført, uanset deres pålidelighed eller relevans, nødvendigvis skal omfattes i agenturets vurdering, henset til bl.a. den omstændighed, at bisphenol A er et af de mest undersøgte stoffer i verden.

51 I sidste punktum i den appellerede doms præmis 64 konstaterede Retten, at »[e]t åbenbart urigtigt skøn […] kun [kan] konstateres, hvis ECHA fuldstændigt og fejlagtigt havde set bort fra et pålideligt studie, hvis medtagelse ville have ændret den samlede vurdering af beviserne på en sådan måde, at den endelige afgørelse ville have været usandsynlig«.

52 I modsætning til det af appellanten anførte kan denne sætning ikke fortolkes således, at Retten fandt, at ECHA, henset til den vide skønsbeføjelse, agenturet har, kunne se bort fra relevante oplysninger fra et pålideligt studie, som, hvis de var blevet taget i betragtning, ville have ændret den samlede vurdering af beviserne på en sådan måde, at den endelige afgørelse ikke ville have været sandsynlig. Udtrykkene »fuldstændigt og fejlagtigt«, fortolket i lyset af den sammenhæng, hvori de indgår, vedrører netop det tilfælde, hvor ECHA har tilsidesat sin forpligtelse til at tage hensyn til sådanne relevante, pålidelige og afgørende oplysninger ved sin vurdering. Derimod udgør det ikke et åbenbart urigtigt skøn, hvis ECHA har set bort fra irrelevante oplysninger fra et pålideligt studie eller fra oplysninger, der under alle omstændigheder ikke havde kunnet ændre den samlede vurdering på en sådan måde, at den endelige afgørelse ikke havde været sandsynlig.

53 På grundlag af disse betragtninger undersøgte Retten i den appellerede doms præmis 66-70 korrekt, om ECHA, henset til de forskellige studier, som appellanten havde fremlagt, havde set bort fra relevante oplysninger fra et pålideligt studie, som, hvis de var blevet taget i betragtning, ville have ændret den samlede vurdering af beviserne.

54 Som generaladvokaten har fremhævet i punkt 90 i forslaget til afgørelse, anførte Retten i den appellerede doms præmis 67-69, at ECHA, om end indirekte, tog hensyn til de væsentlige oplysninger fra to af de fire studier, som appellanten havde påberåbt sig. Hvad angår oplysningerne fra de studier, som appellanten havde påberåbt sig, og som ECHA ikke tog hensyn til, kontrollerede Retten faktisk i den appellerede doms præmis 66-68 ECHA's vurdering vedrørende spørgsmålet, om disse oplysninger var irrelevante. Herved underkendte Retten ikke omfanget af den retslige prøvelse, der påhviler den i henhold til den retspraksis, der er nævnt i denne doms præmis 45-47.

55 Hvad angår den hævdede retlige fejl, som Retten begik med hensyn til den bevisbyrde, der påhviler appellanten, er det tilstrækkeligt at bemærke, at dette argument udspringer af den samme fejlagtige læsning af de relevante begrundelser i den appellerede dom, som blev identificeret i denne doms præmis 52.

56 Det første anbringendes første led skal følgelig forkastes som ugrundet.

Det første anbringendes andet led vedrørende den efterprøvelse, som Retten foretog for så vidt angår ECHA's hensyntagen til studier, der havde en svag grad af pålidelighed, som støttede agenturets endelige afgørelse

– *Parternes argumentation*

57 Med det første anbringendes andet led har appellanten foreholdt Retten, at denne i den appellerede doms præmis 82 antog, at ECHA kunne påberåbe sig studier, der havde en svar grad af pålidelighed, for at identificere bisphenol A som et særligt problematisk stof. Et studies svage grad af pålidelighed er imidlertid absolut og generelt til hinder for, at det kan tages i betragtning.

58 Appellanten har ganske vist ikke anfægtet det forhold, at der kan tages hensyn til studier, som ikke er standardstudier, som beviser, men har derimod gjort gældende, at Retten begik en retlig fejl, da den

fandt, at ECHA som uomtvistelige beviser kunne lægge svagt pålidelige eller endog upålidelige studier til grund for at underbygge den omtvistede afgørelse.

59 Ved at tildele ECHA en sådan manøvremargen tillod den appellerede dom dette agentur at foretage en vilkårlig udvælgelse af videnskabelige oplysninger og blandt disse vælge dem, der underbygger agenturets hypotese. Ifølge appellanten kan ECHA i intet tilfælde støtte sig på resultaterne fra upålidelige studier eller fra studier med en svag grad af pålidelighed for at validere sin konklusion, idet det kun er nøglestudierne, der kan anvendes til disse formål. Retten fandt imidlertid fejlagtigt, at ECHA kunne tage hensyn til sådanne upålidelige studier eller studier med en svag grad af pålidelighed i den appellerede doms præmis 168, 169, 174 og 184, ikke blot som studier, der »understøttede« agenturets konklusioner, men ligeledes som nøglestudie.

60 Ifølge appellanten er studier, der har en lav grad af pålidelighed, eller upålidelige studier sådanne studier, der ikke opfylder de almindelige videnskabelige kvalitetskrav, der er fastsat af de videnskabelige organer, til at resultaterne fra disse lægges til grund som videnskabelige beviser. Studier, som ikke er standardstudier, skal ikke automatisk udelukkes, men de kan være upålidelige og irrelevante, f.eks. såfremt deres metodologi ikke er passende dokumenteret eller begrundet, eller såfremt de er blevet gennemført på grundlag af et fejlagtigt studiekoncept. Derimod kan ringe videnskabelige oplysninger ikke påberåbes som videnskabelige beviser for at begrunde ECHA's afgørelser.

61 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det første anbringendes andet led er ugrundet.

– *Domstolens bemærkninger*

62 I den appellerede doms præmis 71-90 undersøgte Retten det klagepunkt, hvormed appellanten kritiserede ECHA's hensyntagen til studier, som »ikke var standardstudier«, eller som var »sonderende« studier, dvs. studier, der ikke var blevet gennemført i overensstemmelse med de på nationalt eller internationalt plan godkendte metoder.

63 I den appellerede doms præmis 76 bemærkede Retten, at ECHA [var] nået frem til en identifikation af bisphenol A som et særligt problematisk stof i henhold til [REACH-forordningens artikel 57, litra f),] ved at følge fremgangsmåden angående bevisers beviskraft«, som kræver, at den kompetente myndighed tager hensyn til »alle relevante beviser«.

64 Efter en analyse af de relevante bestemmelser i denne forordning fastslog Retten i den nævnte doms præmis 82 »at data, der ikke er standardiserede eller som ikke er validerede, kan understøtte konklusioner om et bestemt stofs iboende egenskaber, når ECHA følger fremgangsmåden angående bevisers beviskraft ved identifikationen af et stof som særligt problematisk«. Retten præciserede endvidere i denne præmis, at det er »uløseligt forbundet med denne fremgangsmåde, at der ved vægtningen af beviserne med henblik på at fastslå et stofs iboende egenskaber skal tages hensyn til deres karakter af data, som ikke er standarddata, og deres eventuelt ringe pålidelighed, uden at et bestemt studies ringe pålidelighed på absolut og generel vis er til hinder for, at der tages hensyn hertil ved identifikationen af et stof i henhold til [REACH-forordningens] artikel 57, litra f) […]«.

65 Den nævnte præmis skal læses sammenholdt med den appellerede doms præmis 106, hvoraf det fremgår, at støttedokumentet i dets endelige affattelse har identificeret nøglestudierne ud fra deres pålidelighed og relevans. Pålidelige studier, der tilvejebringer flest oplysninger om den endokrine virkemåde og dens virkninger, kvalificeres i støttedokumentet som »nøglestudier«, mens studier med en mindre grad af pålidelighed, der indeholder færre oplysninger om den endokrine virkemåde, alene støtter de konklusioner, der hovedsageligt er draget af nøglestudierne, og de bidrager således til bevisernes beviskraft.

66 Det fremgår af de ovenstående betragtninger, at Retten fandt, at ECHA ved vurderingen af beviskraften af de bevismidler, som agenturet rådede over, kunne tage studier med variable grader af pålidelighed i betragtning, på den udtrykkelige betingelse, at deres grad af pålidelighed blev taget i betragtning ved vægtningen af beviserne, således at de mest pålidelige studier blev tillagt afgørende

betydning. I modsætning til det, som appellanten har anført, begik Retten ikke nogen retlig fejl ved at gøre dette.

67 På grundlag af disse betragtninger bemærkes, at det også var uden at begå en retlig fejl, at Retten i den appellerede doms præmis 168, 169, 174, 175 og 184 anførte, at ECHA kunne tage hensyn til visse studier med en svag grad af pålidelighed, navnlig når disse studier understøttede de konklusioner, der var draget af studier med en større bevisværdi, og som var nøglestudier.

68 Det første anbringendes andet led skal derfor forkastes som ugrundet.

Det første anbringendes tredje led om den retlige fejl, som Retten begik, og den urigtige gengivelse af bevismidler, som den foretog, da den fastslog, at ECHA kunne tillægge videnskabelige studier, der støttede agenturets afgørelse, størst vægt

– *Parternes argumentation*

69 Med det første anbringendes tredje led har appellanten gjort gældende, at Retten i den appellerede doms præmis 106, 116-118, 152 og 208 begik en retlig fejl, da den godkendte ECHA's fremgangsmåde, der bestod i at tillægge videnskabelige studier, der understøttede den hypotese, som dette agentur anlagde, større vægt. Ved at gøre dette gengav Retten ligeledes de beviser, der var blevet fremlagt for det, urigtigt, og den tilsidesatte princippet om videnskabelig topkvalitet og princippet om anvendelse af begrebet »bevisers beviskraft« som defineret i punkt 1.2 i bilag XI til REACH-forordningen samt forpligtelsen til at tage hensyn til alle de relevante oplysninger.

70 Hvad angår den appellerede doms præmis 106 og 208 har appellanten gjort gældende, at Retten konstaterede, at udvælgelsen af nøglestudier ikke var strengt baseret på disse studiers pålidelighed, men ligeledes hvilede på spørgsmålet, om de understøttede den hypotese, som ECHA havde lagt til grund.

71 I den appellerede doms præmis 116-118 anførte Retten, at ECHA, da agenturet vurderede beviskraften af de beviser, som det rådede over, burde støtte sig på oplysningerne fra in vitro-studierne til trods for deres eventuelle mindre pålidelige og lidet overbevisende karakter, for så vidt som disse oplysninger for det første understøttede de virkninger, der var observeret ved in vivo-studier af fisk og amfibier, og for så vidt som de for det andet svarede til de konklusioner, der var draget af observerede virkninger in vivo. Retten begrænsede således de berørte parters mulighed for faktisk at anfægte ECHA's adfærd ved Unionens retsinstanser.

72 I den appellerede doms præmis 152 fastslog Retten desuden, at svaghederne ved studiet fra Chen m.fl. (2015) skulle vurderes under hensyntagen til dette studies evne til ikke desto mindre at underbygge den konklusion, som det skulle understøtte.

73 Retten fastslog desuden med urette, at ECHA kunne beslutte at lægge studierne med en svag grad af pålidelighed til grund eller lade være med dette, alt efter om resultaterne af disse validerede eller tilbageviste agenturets hypotese.

74 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det første anbringendes tredje led er ugrundet.

– *Domstolens bemærkninger*

75 Med det første anbringendes tredje led har appellanten gjort gældende, at Retten har godkendt den fremgangsmåde, som ECHA har fulgt, hvorefter studiers beviskraft skal afhænge af disse sidstnævntes kapacitet til at bekræfte eller tilbagevise den hypotese, som ECHA har lagt til grund. Dette led støttes imidlertid på en fejlagtig læsning af den appellerede doms præmis 106, 116-118, 152 og 208.

76 Som det blev anført i denne doms præmis 65 og 66, beskriver den appellerede doms præmis 106 den sondring, der er opstillet i støttedokumentet i dets endelige affattelse, mellem på den ene side de pålidelige studier, der tilvejebringer flest oplysninger om den endokrine virkemåde og dens virkninger, som kvalificeres som »nøglestudier«, og på den anden side de studier med en mindre grad af

pålidelighed, der indeholder færre oplysninger om den endokrine virkemåde, som alene støtter de konklusioner, der hovedsageligt er draget af nøglestudierne. Med andre ord opstiller den tilgang, der er beskrevet i den nævnte præmis 106, en sondring, ikke mellem studier, der skal bekræfte eller afkræfte ECHA's hypotese, men mellem studier, der er pålidelige, og studier, der er mindre pålidelige.

77 Denne konstatering finder ligeledes anvendelse på den appellerede doms præmis 116-118, 152 og 208.

78 Retten »godkendte« således ikke i den appellerede doms præmis 106, 116-118, 152 og 208 en hævdet fremgangsmåde fra ECHA's side, der bestod i at tillægge videnskabelige studier, der understøttede dette agenturs hypotese, størst vægt.

79 Det første anbringendes tredje led skal derfor forkastes som ugrundet.

Det første anbringendes fjerde led vedrørende den efterprøvelse, som Retten foretog for så vidt angår ECHA's manglende hensyntagen til studier vedrørende bisphenol A gennemført af andre EU-agenturer og -institutioner

– *Parternes argumentation*

80 Med det første anbringendes fjerde led har appellanten gjort gældende, at Retten begik en retlig fejl, da den i den appellerede doms præmis 109 og 176 fastslog, at ECHA ved den vurdering, der førte til vedtagelsen af den omtvistede afgørelse, havde kunnet se bort fra konklusionerne vedrørende de oplysninger, der vedrørte bisphenol A, som var draget af andre EU-agenturer og -institutioner, dvs. Unionens rapport om risikovurdering i forbindelse med bisphenol A, som blev udarbejdet af Det Forenede Kongerige i februar 2010 i overensstemmelse med Rådets forordning (EØF) nr. 793/93 af 23. marts 1993 om vurdering af og kontrol med risikoen ved eksisterende stoffer (EFT 1993, L 84, s. 1), og protokollen om vurdering af de farer, der er forbundet med bisphenol A, som udarbejdet af Den Europæiske Fødevaresikkerhedsautoritet (EFSA).

81 Appellanten har gjort gældende, at der ikke kan ses bort fra videnskabelige konklusioner og/eller fremgangsmåder vedrørende vurderingen af oplysninger, som er relevante på EU-plan vedrørende det samme stof, alene af den grund, at de er blevet vedtaget i en objektivt anderledes ånd. Det forhold, at der blev set bort fra disse, kan tilgodese forskellige reguleringsmæssige forskelle og modsætninger og er uforeneligt med princippet om videnskabelig topkvalitet. Dette ville føre til det absurde resultat, at oplysninger eller bedre praksis fra andre retlige rammer aldrig ville være relevante med henblik på identifikationen af et stof som særligt problematisk stof som omhandlet i REACH-forordningen.

82 Retten fastslog endvidere, at de forskellige formål, der forfølges med flere informationskilder, kunne føre til forskellige konklusioner hvad angår pålideligheden af videnskabelige oplysninger. Pålideligheden af et videnskabeligt studie er imidlertid iboende, idet den afhænger af, at de videnskabelige minimumskrav er overholdt, og den kan ikke variere alt efter den kontekst, hvori det pågældende studie er blevet gennemført.

83 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det første anbringendes fjerde led er ugrundet.

– *Domstolens bemærkninger*

84 Det bemærkes, at i overensstemmelse med artikel 256, stk. 1, TEUF og artikel 58, stk. 1, i statutten for Den Europæiske Unions Domstol er appel begrænset til retsspørgsmål. Det er alene Retten, der har kompetence såvel til at fastlægge og bedømme de relevante faktiske omstændigheder som til at vurdere beviserne. Det følger heraf, at Domstolen i forbindelse med en appel ikke har kompetence til at fastlægge de faktiske omstændigheder og principielt heller ikke til at bedømme de beviser, Retten har lagt til grund ved fastlæggelsen af de faktiske omstændigheder (jf. i denne retning dom af 28.10.2021, Vialto Consulting mod Kommissionen, C-650/19 P, EU:C:2021:879, præmis 58 og den deri nævnte retspraksis).

85 Domstolens prøvelsesret med hensyn til Rettens faktiske konstateringer omfatter således navnlig spørgsmålet, om det fremgår af sagens akter, at disse konstateringer er indholdsmæssigt urigtige, den

retlige kvalifikation af disse, om de faktiske omstændigheder og beviserne er gengivet forkert, samt om reglerne om bevisbyrde og bevisførelse er overholdt (dom af 25.1.2007, Sumitomo Metal Industries og Nippon Steel mod Kommissionen, C-403/04 P og C-405/04 P, EU:C:2007:52, præmis 39, og af 11.5.2017, Dyson mod Kommissionen, C-44/16 P, EU:C:2017:357, præmis 31).

86 Det er i denne henseende tilstrækkeligt at bemærke, at appellanten med sin argumentation, der er fremført inden for rammerne af det første anbringendes fjerde led, reelt tilsigter at opnå en ny prøvelse af Rettens vurdering af de faktiske omstændigheder, hvilket Domstolen ikke har kompetence til i forbindelse med en appelsag, således som det følger af den retspraksis, der er nævnt i denne doms præmis 84 og 85 (jf. i denne retning dom af 21.12.2021, PlasticsEurope mod ECHA, C-876/19 P, ikke trykt i Sml., EU:C:2021:1047, præmis 80).

87 Det første anbringendes fjerde led skal derfor afvises.

88 Det følger heraf, at det første anbringende skal forkastes, idet det delvist er ugrundet, delvist skal afvises.

Det andet anbringende om en urigtig gengivelse af appellantens skriftlige indlæg, en fejlagtig fortolkning af REACH-forordningens artikel 57, litra f), og en tilsidesættelse af retten til at blive hørt

Parternes argumentation

89 Med det andet anbringende har appellanten gjort gældende, at Retten i den appellerede doms præmis 220-226 vedrørende kriteriet om, at virkningerne af stoffet skal være problematiske i samme grad som virkningerne af de øvrige stoffer, der er anført i REACH forordningens artikel 57, litra a)-e), som omhandlet i denne artikels litra f), har gengivet appellantens skriftlige indlæg urigtigt, fortolket denne sidstnævnte bestemmelse fejlagtigt og tilsidesat appellantens ret til at blive hørt.

90 I den appellerede doms præmis 224 forvekslede Retten kriteriet om, at virkningerne af stoffet skal være problematiske i samme grad som virkningerne af andre stoffer, med kriteriet om, at stoffet skal have de samme egenskaber. Retten gengav således de argumenter, som appellanten havde fremført, urigtigt, for så vidt som den lagde til grund, at appellanten anførte, at et stof skulle have PBT-egenskaber og/eller vPvB-egenskaber for at kunne være omfattet af REACH-forordningens artikel 57, litra f).

91 Appellanten har imidlertid gjort gældende, at den for Retten anførte, at et stof kun kan være omfattet af denne bestemmelse, hvis det er problematisk for miljøet i samme grad som PBT-stofferne og/eller vPvB-stofferne, der er omhandlet i denne forordnings artikel 57, litra d), og e), uden at dette stofs egenskaber nødvendigvis skal svare til egenskaberne ved PBT-stofferne og/eller vPvB-stofferne.

92 Appellanten har endvidere gjort gældende at have påvist de fejl, der svækker ECHA's vurdering om, at stoffet skal være problematisk i samme grad. I denne henseende har appellanten anført, at denne påvisning fremgår af appellantens svar på Rettens spørgsmål. For det første konstaterede appellanten i punkt 63 i dette svar, at det fremgår af bilag XIII til REACH-forordningen og af forarbejderne hertil, at det særligt problematiske niveau for miljøet, fra hvilket niveau et stof skal kvalificeres som PBT-stof og/eller vPvB-stof, er uløseligt forbundet med den uoprettelige karakter af virkningerne af sådanne stoffer efter en akkumulering i miljøet.

93 For det andet vedrørte appellantens argument i punkt 65 i det nævnte svar spørgsmålet, om ECHA havde godtgjort, at bisphenol A, der er hurtigt nedbrydeligt og har et lavt potentiale for bioakkumulering, er problematisk for miljøet i samme grad som stoffer med PBT-egenskaber og/eller vPvB-egenskaber.

94 For det tredje har appellanten i punkt 66-75 i samme svar gjort gældende, at ECHA ikke havde godtgjort, at virkningerne af andre egenskaber end persistens og bioakkumulation – hvilke egenskaber er specifikke for stofferne PBT-stofferne og vPvB-stofferne – er problematiske, og at ECHA's henvisning til alvorligheden af virkningerne, den oprettelige karakter og vanskelighederne ved definitionen af et sikkert niveau ikke opfyldte dette kriterium.

95 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det andet anbringende er ugrundet.

Domstolens bemærkninger

96 Hvad for det første angår argumentet om, at Retten i den appellerede doms præmis 224 skulle have gengivet appellantens skriftlige indlæg urigtigt, skal det fastslås, at appellanten i stævningen med påstand om annullation, replikken og svaret på Rettens spørgsmål anførte, at ECHA, fordi bisphenol A er let og umiddelbart bionedbrydeligt, fejlagtigt havde konkluderet, at dette stof var »problematisk i samme grad« som virkningerne af de andre stoffer som omhandlet i REACH-forordningens artikel 57, litra f).

97 Til støtte herfor henviste appellanten flere gange til det forhold, at bisphenol A ikke har de persistente og bioakkumulerende egenskaber, der karakteriserer PBT-stofferne og vPvB-stofferne, og som begrunder, at disse sidstnævnte er problematiske. Som illustration kan anføres, at appellanten i punkt 83 i replikken udtrykkeligt anførte, at der med henblik på at påvise, at et stof er »problematisk i samme grad« som virkningerne af de andre stoffer som omhandlet i REACH-forordningens artikel 57, litra f), skulle »henvises til egenskaber, der er relevante for identifikationen af PBT-stofferne og vPvB-stofferne, dvs. persistens og bioakkumulation«, idet det skulle tages i betragtning, at »[b]isphenol A i det foreliggende tilfælde hverken er persistent i miljøet (eftersom det nedbrydes hurtigt) eller bioakkumuleres (fordi det har en svag bioakkumulationsgrad)«.

98 I den appellerede doms præmis 224 gengav Retten – på ingen måde urigtigt –appellantens skriftlige indlæg i overensstemmelse med sin begrundelsespligt og fremhævede indlæggets selvmodsigende karakter.

99 Hvad for det andet angår appellantens argumenter vedrørende den vurdering, som ECHA foretog, hvorefter bisphenol A var »problematisk i samme grad« som omhandlet i REACH-forordningens artikel 57, litra f), bemærkes, at appellanten har begrænset sig til at resumere de bemærkninger, som denne indgav i denne henseende til Retten, idet den har foreholdt Retten at have forkastet den fortolkning, som appellanten havde foreslået.

100 Det bemærkes, således som det fremgår af den retspraksis, der er nævnt i denne doms præmis 46, at Rettens skal begrænse sig til at kontrollere, om den vurdering, som ECHA har foretaget, ikke er behæftet med en åbenbar fejl eller magtfordrejning, eller om ECHA ikke åbenbart har overskredet grænserne for sit skøn.

101 I den appellerede doms præmis 229 fastslog Retten efter en detaljeret analyse af de argumenter, som appellanten havde fremført, at appellanten ikke havde godtgjort, hvorledes ECHA havde anlagt et åbenbart urigtigt skøn ved påvisningen af, at stoffet var »problematisk i samme grad«. Ingen af de argumenter, som appellanten har fremført til støtte for sin appel, gør det muligt at afsvække denne vurdering, og de kan ikke føre til den antagelse, at Retten har begået en retlig fejl ved at finde, at ECHA ikke havde anlagt et åbenbart urigtigt skøn.

102 Det skal følgelig konstateres, at det andet anbringende skal forkastes som ugrundet.

Det tredje anbringende om retlige fejl ved vurderingen af beviserne vedrørende de videnskabelige studiers pålidelighed og en urigtig gengivelse af beviserne

Parternes argumentation

103 Med det tredje anbringende har appellanten gjort gældende, at Retten har begået flere retlige fejl ved vurderingen af beviserne vedrørende visse videnskabelige studiers pålidelighed, og at den desuden har gengivet visse af disse beviser urigtigt.

104 Appellanten har for det første foreholdt Retten, at den gengav beviserne forkert, da den i den appellerede doms præmis 66 fastslog, at ECHA ikke havde anlagt et åbenbart urigtigt skøn ved ikke at finde, at studiet fra Bjerregaard m.fl. (2008) udgjorde et relevant bevis, for så vidt som ophavsmændene til dette studie ifølge ECHA ikke havde observeret større ændringer i udviklingen af

fisks gonader efter at have eksponeret æg og yngel for bisphenol A. Retten nåede frem til denne konklusion på grundlag af spekulative observationer foretaget af ophavsmændene til dette studie, hvorefter en længere eksponeringsperiode havde kunnet medføre virkninger på gonaders kønsdifferentiering.

105 Appellanten har for det andet gjort gældende, at Retten i den appellerede doms præmis 69 fejlagtigt fastslog, at ECHA ikke havde undladt at tage hensyn til studiet fra Rhodes m.fl. (2008), som offentliggjort i Mihaich m.fl. (2012). Appellanten har anført, at hvis ECHA havde taget hensyn til dette studie, burde agenturet have konkluderet, at der ikke deraf fremgik en relevant skadelig virkning af bisphenol A for bestanden af fathead minnow (*Pimephales promelas*).

106 For det tredje har appellanten foreholdt Retten, at denne gengav de beviser, som den rådede over, urigtigt, da den fandt, at studiet Sumpter m.fl. (2001) underbyggede ECHA's konklusioner, med den begrundelse, at dette studie ligeledes konstaterede en vittellogenin-induktion som følge af eksponeringen for bisphenol A, mens forhøjelsen af vittellogenin ikke i sig selv skaber en skadelig virkning.

107 For det fjerde har appellanten foreholdt Retten i den appellerede doms præmis 140-144 at have fortolket ECHA's udøvelse af sin skønsbeføjelse fejlagtigt og at have gengivet beviserne forkert, da den fastslog, at både studiet fra Heimeier m.fl. (2009) og studiet fra Iwamuro m.fl. (2003), to in vivo-studier om amfibier af arten *xenopus laevis*, kunne opnå en pålidelighedscore på 2, dvs. »pålidelig med begrænsninger« på Klimischs bedømmelsesskala og således indgå i ECHA's videnskabelige beviser som nøglestudier.

108 For det femte har appellanten foreholdt Retten, at den i den appellerede doms præmis 152-163 fastslog, at ECHA ikke havde anlagt et åbenbart urigtigt skøn, da den fandt, at studiet fra Chen m.fl. (2015) var pålideligt og udgjorde et nøglestudie, og således gengav beviserne urigtigt og tilsidesatte princippet om videnskabelig topkvalitet.

109 For det sjette har appellanten gjort gældende, at Retten begik en fejl, da den konkluderede, at studiet fra Chen m.fl. (2015) var pålideligt, under henvisning til studiet fra Segner m.fl. (2003A), studiet fra Keiter m.fl. (2012) og studiet fra Yokota m.fl. (2000), og undlod at besvare appellantens argument, hvorefter studiet fra Segner m.fl. (2003) og studiet fra Keiter m.fl. (2012) ikke havde taget højde for kønsfordelingen. Retten konstaterede nemlig i den appellerede doms præmis 158, at der i disse to sidstnævnte studier henvises til andre indikatorer, der bekræfter, at bisphenol A har – eller i det mindste sandsynligvis har – en endokrin virkemåde, nemlig navnlig en vittellogenin-induktion, selv om en vittellogenin-induktion ikke er en indikator for skadelige virkninger.

110 For det syvende og endelig bekræftede Retten fejlagtigt i den appellerede doms præmis 159 og uden at besvare appellantens argumenter, at studiet fra Chen m.fl. (2015) og studiet fra Yokota m.fl. (2000) samlet set bidrog til bevisernes beviskraft for så vidt angår bisphenol A's virkninger på kønsfordelingen i fiskebestandene. Studiet fra Yokota m.fl. (2000) blev gennemført med en koncentration, der var mere end fire gange højere end studiet fra Chen m.fl. (2015), således som Retten anførte i den appellerede dom, og den enkelte koncentration i studiet Yokota m.fl. (2000), hvori der blev observeret en ændring af kønsfordelingen, befandt sig i spektret for dødelig toksicitet.

Domstolens bemærkninger

111 Det fremgår af Domstolens faste praksis, at når en appellant under en appelsag gør gældende, at Retten har gengivet beviserne forkert, skal appellanten i henhold til artikel 256 TEUF, artikel 58, stk. 1, i statutten for Den Europæiske Unions Domstol og artikel 168, stk. 1, litra d), i Domstolens procesreglement præcist angive, hvilke beviser der er blevet urigtigt gengivet af Retten, og påvise de fejl i undersøgelsen, der efter appellantens opfattelse har foranlediget Retten til at foretage denne urigtige gengivelse. En urigtig gengivelse skal i øvrigt fremgå på åbenbar vis af sagsakterne, uden at det skal være fornødent at foretage en fornyet vurdering af de faktiske omstændigheder og beviserne (dom af 12.5.2022, Klein mod Kommissionen, C-430/20 P, EU:C:2022:377, præmis 23 og den deri nævnte retspraksis).

112 I det foreliggende tilfælde skal det konstateres, at ingen af de urigtige gengivelser, som appellanten har anført, fremgår på åbenbar vis af sagsakterne som omhandlet i den retspraksis, der er nævnt i denne doms præmis 111.

113 Med sin argumentation ønsker appellanten herved reelt at opnå en fornyet prøvelse fra Domstolens side af de beviser, der blev fremlagt for Retten, hvis vurdering henhører under sidstnævntes enekompetence i overensstemmelse med den retspraksis, der er nævnt i denne doms præmis 84.

114 Det følger af det ovenstående, at det tredje anbringende må afvises i det hele.

Det fjerde anbringende om en fejlagtig fortolkning af forsigtighedsprincippet

Parternes argumentation

115 Med det fjerde anbringende har appellanten gjort gældende, at Retten i den appellerede doms præmis 88 og 223 foretog en fejlagtig fortolkning af forsigtighedsprincippet for at gøre det muligt for ECHA – ved agenturets vurdering af beviserne – at støtte sig på ikke godkendte upålidelige videnskabelige studier og på hævdede usikkerheder vedrørende fastlæggelsen af et sikkert niveau for eksponering. Dette princip, der ligger til grund for alle REACH-forordningens bestemmelser, kunne ikke påberåbes af ECHA for ikke at efterkomme den forpligtelse, der påhviler agenturet i medfør af REACH-forordningens artikel 57, litra f), og ikke at overholde princippet om videnskabelig topkvalitet.

116 Ifølge appellanten fremgår det af dom af 1. oktober 2019, Blaise m.fl. (C-616/17, EU:C:2019:800, præmis 43 og 46), at forsigtighedsprincippet kun tillader vedtagelse af beskyttelsesforanstaltninger, når der er usikkerhed vedrørende eksistensen eller omfanget af risici. Dette princip betyder derimod ikke, at Unionens agenturer kan vedtage foranstaltninger på grundlag af upålidelige videnskabelige oplysninger.

117 Appellanten har endvidere påberåbt sig afsnit 5.1 i meddelelse fra Kommissionen om forsigtighedsprincippet med overskriften »Faktorer, som udløser anvendelse af forsigtighedsprincippet«, hvoraf det følger, at anvendelsesområdet for forsigtighedsprincippet begrænser sig til den usikkerhed, der er omkring spørgsmålet om og i hvilket omfang et stof frembyder en risiko. Dette princip kan til gengæld ikke påberåbes for at afhjælpe utilstrækkelige – i det foreliggende tilfælde upålidelige – oplysninger, der beviser, at et stof har en iboende egenskab, dvs. en fare, hvilket er en etape forud for vurderingen af spørgsmålet, om stoffet reelt frembyder en risiko for menneskers sundhed eller miljøet.

118 ECHA, Forbundsrepublikken Tyskland, Den Franske Republik og ClientEarth har anfægtet appellantens argumentation og har gjort gældende, at det fjerde anbringende er ugrundet.

Domstolens bemærkninger

119 Hvad angår den appellerede doms præmis 88 bemærkes, at denne præmis indgår i en række af begrundelser, som Retten anførte i den appellerede doms præmis 71-90 for at besvare et klagepunkt, hvorved appellanten kritiserede ECHA's hensyntagen til studier, som »ikke var standardstudier«, eller som var »sonderende studier«, dvs. studier, der ikke var blevet gennemført i overensstemmelse med de på nationalt eller internationalt plan godkendte metoder.

120 Selv hvis det antages, at Retten havde begået en retlig fejl i den appellerede doms præmis 88, derved at den havde fortolket forsigtighedsprincippet fejlagtigt, har denne fejl dog ingen betydning for konstateringen om, at der ikke findes et principielt forbud for ECHA mod at tage hensyn til studier, der »ikke er standardstudier«, eller som er »sonderende« studier. I denne henseende bemærkes, at Retten forkastede appellantens klagepunkt, idet den støttede sig på de argumenter, der fremgår af den appellerede doms præmis 87 og 89, som appellanten ikke har rejst tvivl om i forbindelse med denne appel.

121 For så vidt som det fjerde anbringende vedrører den appellerede doms præmis 88, må det følgelig forkastes som uvirksomt.

122 Den appellerede doms præmis 223 indgår for sit vedkommende i en række af begrundelser, som Retten anførte i den appellerede doms præmis 211-230 med henblik på at besvare et klagepunkt, hvorved appellanten hævdede, at der forelå et åbenbart urigtigt skøn foretaget af ECHA ved identifikationen af, om stoffet var »problematisk i samme grad« som omhandlet i REACH-forordningens artikel 57, litra f).

123 Den appellerede doms præmis 221-223 vedrører særligt den vurdering, der blev foretaget af ECHA, og appellantens tvivl herom i forbindelse med spørgsmålet, om det var umuligt at godtgøre et sikkert niveau for eksponering for bisphenol A, og appellantens tvivl herom.

124 I den appellerede doms præmis 222 konstaterede Retten, at ECHA havde taget hensyn til usikkerheden i forbindelse med fastlæggelsen af et sikkert niveau for eksponering, som fulgte for det første af, at visse virkninger kun kan observeres i bestemte livsfaser, bestemte perioder eller bestemte sæsoner, og for det andet af, at bisphenol A påvirker en lang række organismer gennem forskellige endokrine virkemåder.

125 Det var i denne sammenhæng, at Retten i den appellerede doms præmis 223 anførte, at ECHA, henset til disse usikkerheder, som i det mindste var sandsynlige, med forsigtighed havde behandlet spørgsmålet om muligheden for at fastsætte et sikkert niveau for eksponering for bisphenol A, og denne forsigtighed var »navnlig« begrundet i lyset af det forsigtighedsprincip, som bestemmelserne i REACH-forordningen er baseret på i henhold til denne forordnings artikel 1, stk. 1. Retten udledte deraf, at ECHA ikke kunne kritiseres for at have begrundet, i hvilken grad virkningerne af bisphenol A var problematiske på grund af stoffets endokrine virkemåde, bl.a. ved at påberåbe sig de usikkerheder, som ECHA havde identificeret med henblik på at fastlægge et sikkert eksponeringsniveau for bisphenol A.

126 Ved en læsning af de relevante begrundelser i den appellerede dom ses det ikke – i modsætning til det, som appellanten har hævdet – at Retten fortolkede forsigtighedsprincippet således, at ECHA kunne støtte den omtvistede afgørelse på upålidelige videnskabelige oplysninger. I den appellerede doms præmis 223 anførte Retten nemlig, at ECHA, da der var usikkerheder, havde behandlet spørgsmålet om muligheden for at fastsætte et sikkert niveau for eksponering for bisphenol A med forsigtighed, og denne forsigtighed var begrundet i lyset af dette princip.

127 Det bemærkes desuden, at forsigtighedsprincippet indebærer, at der, når der er usikkerhed med hensyn til, om og i givet fald i hvilket omfang der er risiko for menneskers sundhed, kan træffes beskyttelsesforanstaltninger uden at afvente, at det fuldt ud påvises, at der er en risiko, og hvilket omfang denne har. Hvis det viser sig ikke at være muligt med sikkerhed at fastslå, om og i givet fald i hvilket omfang den hævdede risiko foreligger, som følge af, at resultaterne af de foretagne undersøgelser ikke er overbevisende, men at sandsynligheden for en reel skade på den offentlige sundhed varer ved, dersom risikoen indtræder, begrunder forsigtighedsprincippet restriktive foranstaltninger (dom af 16.6.2022, SGL Carbon m.fl. Kommissionen, C-65/21 P og C-73/21 P – C-75/21 P, EU:C:2022:470, præmis 96 og den deri nævnte retspraksis).

128 Henset til de usikkerhederne i forbindelse med fastsættelsen af et sikkert eksponeringsniveau for bisphenol A var det med rette, at Retten fandt, at ECHA's forsigtighed i denne henseende bl.a. var begrundet i lyset af forsigtighedsprincippet som fortolket i den retspraksis, der er nævnt i denne doms præmis 127.

129 Det følger heraf, at det fjerde anbringende skal forkastes som delvist uvirksomt, delvist ugrundet.

Det femte anbringende om en fejlagtig fortolkning af REACH-forordningens artikel 2, stk. 8, litra b), og en tilsidesættelse af begrundelsespligten

Parternes argumentation

130 Med det femte anbringendes første led har appellanten foreholdt Retten at have begået en retlig fejl i den appellerede doms præmis 243-271, idet den fastslog, at mellemprodukter såsom bisphenol A ikke var undtaget fra identifikationen i henhold til REACH-forordningens artikel 57-59, med den

begrundelse, at disse bestemmelser ikke vedrører et stofs iboende egenskaber og heller ikke dets anvendelse, og at det ikke var uforholdsmæssigt for ECHA at opføre bisphenol A på kandidatlisten.

131 I denne henseende har appellanten indledningsvis, idet denne har påberåbt sig dom af 25. oktober 2017, PPG og SNF mod ECHA (C-650/15 P, EU:C:2017:802, præmis 59), gjort gældende, at Rettens fortolkning er i strid med en ordlydsfortolkning af REACH-forordningens artikel 2, stk. 8, litra b), der undtager alle mellemprodukterne i denne forordnings afsnit VII, for så vidt som de kun eksisterer midlertidigt og i henhold til REACH-forordningens artikel 3, nr. 15), skal omdannes til et andet stof.

132 Herefter begrundede Retten i den appellerede doms præmis 255 sin fortolkning med bl.a. behovet for at sikre, at mellemprodukterne ikke falder uden for identifikationsproceduren som særligt problematiske stoffer. De krav, der er fastsat i REACH-forordningens artikel 7, stk. 2, og i artikel 33, blev imidlertid ikke udformet for at dække mellemprodukterne. Anvendelsen af disse bestemmelser udløses af tilstedeværelsen af stoffer, der opfylder kriterierne i denne forordnings artikel 57, i genstande, som er fremstillet af kemiske stoffer. De nævnte bestemmelser skal følgelig ikke omfatte mellemprodukterne, da disse pr. definition skal omdannes til andre stoffer, således at de ikke længere kan opfattes som værende »til stede«.

133 Endelig har appellanten gjort gældende for det første, at Retten begik en retlig fejl, da den i den appellerede doms præmis 252 fandt, at begrebet »mellemprodukt« henviser til anvendelserne af et stof, og for det andet, at anvendelserne af et stof ikke er relevante med henblik på identifikationen som særligt problematisk stof. Der skal sondres mellem »anvendelsen af et mellemprodukt«, som er det begreb, der korrekt er anvendt i stævningen, og »mellemprodukt som anvendelse«, hvilket begreb ECHA har taget udgangspunkt i, og som Retten også i den appellerede dom og i dens tidligere domme har fortolket som bestående af en bestemt form for anvendelse af et stof.

134 Med det femte anbringendes andet led har appellanten gjort gældende, at Retten tilsidesatte sin begrundelsespligt, idet den ikke besvarede en række argumenter, der fremgik af stævningen med påstand om annullation, som var forskellige fra de argumenter, der blev fremført i den sag, der gav anledning til dom af 25. oktober 2017, PPG og SNF mod ECHA (C-650/15 P, EU:C:2017:802), som Retten henviste til i den appellerede dom.

135 For det første svarer Rettens konstatering i den appellerede doms præmis 252, hvorefter »det er en bestemt type anvendelse af stoffer, der er omfattet af bl.a. artikel 17, stk. 3, og artikel 18, stk. 4, i [REACH-forordningen]«, ikke til appellantens observationer, der er redegjort for i punkt 144 i appellantens stævning med påstand om annullation, vedrørende de særlige bestemmelser i denne forordning om de oplysninger, der skal meddeles for at registrere mellemprodukter.

136 For det andet har Retten ligeledes undladt at besvare de argumenter, der er anført i punkt 149 i stævningen med påstand om annullation, hvorefter den juridiske fortolkning af begrebet »mellemprodukt« ikke må være påvirket af den særlige omstændighed, at kravene vedrørende de begrænsede oplysninger, der fremgår af REACH-forordningens artikel 17 og 18, ikke finder anvendelse på en monomer, som i tilfældet med registreringen af bisphenol A som mellemprodukt.

137 Appellanten har fremhævet, at til trods for alle de ovennævnte argumenter, der underbygger den konklusion, at mellemprodukter har en særlig retlig status i REACH-forordningen og ikke blot må anses for at være en »bestemt form for anvendelse af et stof«, har Retten blot anvendt Domstolens fortolkning i dom af 25. oktober 2017, PPG og SNF mod ECHA (C-650/15 P, EU:C:2017:802).

138 Med det femte anbringendes tredje led har appellanten anført, at Retten begik en retlig fejl i den appellerede doms præmis 258, idet den foretog en fejlagtig fortolkning af appellantens skriftlige indlæg, for så vidt som disse vedrørte REACH-forordningens artikel 49.

139 Appellanten havde nemlig i punkt 148 i stævningen om annullation fremhævet, at ikke alene de mellemprodukter, der fremstilles og/eller anvendes under strengt kontrollerede betingelser, kunne være registreret ved fremlæggelse af begrænsede oplysninger, men at isolerede mellemprodukter anvendt på produktionsstedet, som anvendes under strengt kontrollerede betingelser, ligeledes var særligt undtaget fra vurderingen af stoffet i henhold til REACH-forordningens artikel 49.

140 I den appellerede dom fortolkede Retten dette argument fejlagtigt, idet den bekræftede, at REACH-forordningens artikel 49 havde et »helt andet formål« end identifikationen i henhold til denne forordnings artikel 57. Retten tog herved ikke hensyn til den omstændighed, at den nævnte forordnings artikel 49 særligt finder anvendelse, når en medlemsstats kompetente myndighed mener, at en risiko udgør en risiko i samme grad som brugen af stoffer, der opfylder kriterierne i samme forordnings artikel 57. Det fremgår således klart af overtagelsen af ordene »risiko i samme grad« og af den udtrykkelige henvisning til REACH-forordningens artikel 57, at EU-lovgiver havde til hensigt for isolerede mellemprodukter anvendt på produktionsstedet at anvende denne forordnings artikel 49 som en anden procedure til håndtering af risici end den, der var fastsat under overskriften »Godkendelse« i den nævnte forordning.

141 ECHA, Forbundsrepublikken Tyskland og ClientEarth har anfægtet appellantens argumenter og har sammen med Den Franske Republik gjort gældende, at det femte anbringende er ugrundet.

Domstolens bemærkninger

142 Hvad angår det femte anbringendes første led er det tilstrækkeligt at bemærke, at Retten i den appellerede doms præmis 251-257 med rette anvendte dom af 25. oktober 2017, PPG og SNF mod ECHA (C-650/15 P, EU:C:2017:802), hvad angår omfanget af den undtagelse, der er fastsat i REACH-forordningens artikel 2, stk. 8, litra b). I den nævnte doms præmis 63 fastslog Domstolen nemlig efter en ordlydsfortolkning samt en kontekstuel og teleologisk fortolkning af denne bestemmelse, der også tog hensyn til bestemmelsens tilblivelseshistorie, at denne undtagelse ikke finder anvendelse på bestemmelserne i REACH-forordningens afsnit VII, der regulerer stofferne efter deres iboende egenskaber, idet den præciserede, at denne forordnings artikel 2, stk. 8, litra b), således ikke var til hinder for, at et stof kan være identificeret som værende et særligt problematisk stof på grundlag af de kriterier, der er fastsat i den nævnte forordnings artikel 57, og dette selv om det ikke anvendes som isoleret mellemprodukt, der bliver på produktionsstedet, eller som isoleret mellemprodukt, der transporteres.

143 Følgelig skal det femte anbringendes første led forkastes som ugrundet.

144 Hvad angår dette anbringendes andet led bemærkes, at det følger af fast retspraksis, at den pligt til at begrunde domme, der påhviler Retten i medfør af artikel 36 og artikel 53, stk. 1, i statutten for Den Europæiske Unions Domstol, ikke pålægger den at foretage en udtømmende gennemgang af hvert enkelt af de argumenter, der er fremført af parterne i sagen. Begrundelsen kan således fremgå indirekte, forudsat at de berørte parter kan få kendskab til den begrundelse, som Retten støtter sig på, og således at Domstolen kan råde over de oplysninger, der er nødvendige for, at den kan udøve sin prøvelsesret inden for rammerne af en appel (dom af 9.12.2020, Groupe Canal + mod Kommissionen, C-132/19 P, EU:C:2020:1007, præmis 45 og den deri nævnte retspraksis).

145 I det foreliggende tilfælde skal det fastslås, at den begrundelse, som Retten gav i den appellerede doms præmis 251-257, opfylder de krav, der er nævnt i denne doms præmis 144, idet de berørte parter kan få kendskab til den begrundelse, som Retten støttede sig på, og Domstolen kan råde over de oplysninger, der er nødvendige for, at den kan udøve sin prøvelsesret inden for rammerne af en appel.

146 Følgelig skal dette andet led forkastes som ugrundet.

147 Hvad angår det femte anbringendes tredje led, der vedrører en hævdet retlig fejl, som Retten skulle have begået i den appellerede doms præmis 258, bemærkes, at det hviler på den forudsætning, at bestemmelserne i REACH-forordningens artikel 49, der finder anvendelse på isolerede mellemprodukter anvendt på produktionsstedet, udelukker, at denne forordnings artikel 57 kan finde anvendelse på sådanne stoffer.

148 Som det fremgår af den appellerede doms præmis 258, er denne forudsætning imidlertid fejlagtig. Den ordning, der er fastsat i REACH-forordningens artikel 49, vedrører nemlig det tilfælde, at der er en risiko, som følger af anvendelsen af stoffer som isolerede mellemprodukter på produktionsstedet under strengt kontrollerede betingelser, uden at det – for at denne artikel finder anvendelse – er nødvendigt, at disse stoffer opfylder kriterierne i denne forordnings artikel 57. Den nævnte artikel 49 har således ganske rigtigt, som Retten anførte, et helt andet formål end den nævnte artikel 57, og den udelukker på

ingen måde anvendeligheden af denne sidstnævnte, når et stofs iboende egenskaber begrunder en senere optagelse i bilag XIV til den nævnte forordning.

149 Henvisningen til REACH-forordningens artikel 57, der fremgår af denne forordnings artikel 49, fører ikke til en anden konklusion. Denne henvisning tilsigter nemlig ikke at indføre en undtagelse til den nævnte artikel 57, men alene at fastlægge det risikoniveau, der er krævet for, at den nævnte artikel 49 finder anvendelse, idet denne risiko skal udgøre en risiko for menneskers sundhed eller miljøet »i samme grad som brugen af stoffer, der opfylder kriterierne i artikel 57«.

150 Følgelig skal det femte anbringendes tredje led forkastes som ugrundet.

151 Under disse omstændigheder skal det femte anbringende forkastes som ugrundet, og som følge heraf skal appellen forkastes i sin helhed.

Sagsomkostninger

152 I henhold til procesreglementets artikel 184, stk. 2, træffer Domstolen afgørelse om sagsomkostningerne, såfremt appellen ikke tages til følge. I henhold til dette reglements artikel 138, stk. 1, der i medfør af dets artikel 184, stk. 1, finder anvendelse i appelsager, pålægges det den tabende part at betale sagsomkostningerne, hvis der er nedlagt påstand herom.

153 Procesreglementets artikel 184, stk. 4, fastsætter, at en intervenient i første instans, som ikke selv har iværksat appel, kun kan pålægges at betale sagsomkostninger i appelsagen, hvis den pågældende har deltaget i den skriftlige eller den mundtlige del af retsforhandlingerne for Domstolen. Deltager en intervenient i første instans i appelsagen, kan Domstolen bestemme, at den pågældende skal bære sine egne omkostninger.

154 Da ECHA og ClientEarth har nedlagt påstand om, at PlasticsEurope tilpligtes at betale sagsomkostningerne, og da PlasticsEurope har tabt sagen, bør det pålægges sidstnævnte at betale sagsomkostningerne.

155 Forbundsrepublikken Tyskland, der var intervenient i første instans, bærer sine egne omkostninger.

156 Den Franske Republik, der var intervenient i første instans, og som har deltaget i den skriftlige del af retsforhandlingerne for Domstolen, men som ikke har nedlagt påstand om, at PlasticsEurope tilpligtes at betale sagsomkostningerne, bærer sine egne omkostninger.

På grundlag af disse præmisser udtaler og bestemmer Domstolen (Fjerde Afdeling):

1) Appellen forkastes.

2) PlasticsEurope AISBL bærer sine egne omkostninger og betaler de af Det Europæiske Kemikalieagentur (ECHA) og ClientEarth afholdte omkostninger.

3) Forbundsrepublikken Tyskland og Den Franske Republik bærer hver deres egne omkostninger.

Underskrifter

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* Processprog: engelsk.