Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

20 September 2019*

(REACH — Establishment of a list of substances identified with a view to their eventual inclusion in Annex XIV of 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 — Legal certainty — Legitimate expectations — Proportionality)

In Case T-636/17,

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

applicant,

v

European Chemicals Agency (ECHA), represented by M. Heikkilä, W. Broere, C. Buchanan and A. Hautamäki, acting as Agents, and initially by S. Raes, lawyer,

defendant,

supported by

French Republic, represented initially by D. Colas, E. de Moustier and J. Traband, and subsequently by D. Colas, J. Traband and A.-L. Desjonquères, 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 Decision ED/30/2017 by the Executive Director of ECHA of 6 July 2017, 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 that substance is also identified as a substance with endocrine disrupting properties

* Language of the case: English.

that may have serious effects on human health which give rise to a level of concern equivalent to that raised by the use of other substances listed in Article 57(a) to (e) of that regulation, within the meaning of Article 57(f) thereof,

THE GENERAL COURT (Fifth Chamber),

composed of D. Gratsias, President, I. Labucka and A. Dittrich (Rapporteur), Judges,

Registrar: F. Oller, Administrator,

having regard to the written part of the procedure and further to the hearing on 11 April 2019,

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 In 2012, a research programme called 'Consortium Linking Academic and Regulatory Insights on Bisphenol A Toxicity' ('the Clarity-BPA programme') was launched 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 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 human health effects of exposure to low levels of endocrine active agents, and take into account a wide range of doses and new relevant 'parameters' ('endpoints') which have never been used before. More specifically, the programme combines, in particular, a core perinatal 2-year chronic toxicity study, which is compliant with guidelines or recommendations and with good laboratory practices and is performed at FDA premises, on the one hand, with additional mechanistic endpoints and studies conducted by academic researchers, on the other. In the latter regard, 13 university-based research projects were selected by the NIEHS.

3 Also in 2012, in accordance with Article 44 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1, and corrigendum at OJ 2007 L 136, p. 3), bisphenol A was included in the Community Rolling Action Plan for the evaluation of that substance.

4 On 23 December 2013, the European Chemicals Agency (ECHA) adopted a decision on the evaluation of bisphenol A ('the evaluation decision') pursuant to Article 46(1) of Regulation No 1907/2006. The section of that decision devoted to 'Procedure' reads as follows:

'The [competent evaluating authority] did not evaluate [endocrine disrupting] properties related to human health in the Substance Evaluation in detail, yet acknowledged the information currently available with respect to [that] endpoint. The [competent evaluating authority] took note of other ongoing studies [the NIEHS, NTP and FDA rodent study (the Clarity-BPA programme; see Schug et al. 2013)], which are currently performed by American laboratories. Therefore, the need for further data requirements was not assessed at this stage. Any need for further testing may depend on the results from these studies and on other relevant new information which might become available. Hence, endocrine disruption for human health may be considered at a later stage. The registrants are reminded that they have the obligation to include the results of any new relevant information in the considerations for the risk characterisation and to update the [Chemical Safety Report] accordingly once such results become available.'

5 The conclusions of the evaluation and the evaluation report produced by the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Federal Institute for Occupational Health and Safety, Germany), as the competent authority within the meaning of Article 45 of Regulation No 1907/2006, dated May 2017, were published on 31 August 2017.

6 On 12 January 2017, ECHA published on its website its decision ED/01/2017 of 4 January 2017 on the inclusion of bisphenol A in the 'Candidate List', that is, the list of substances identified with a view to their eventual inclusion in Annex XIV to Regulation No 1907/2006 on the ground that that substance had been identified as a substance toxic for reproduction within the meaning of Article 57(c) of Regulation No 1907/2006.

7 On 21 March 2017, the applicant, PlasticsEurope, brought an action for annulment in respect of that decision, registered by the Registry of the General Court under Case T-185/17. By judgment of 11 July 2019, the Court dismissed that action (*PlasticsEurope* v *ECHA*, T-185/17, EU:T:2019:492). 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. Four of the applicant's member undertakings, which are part of the applicant's 'Polycarbonate/Bisphenol A' group, are active in placing bisphenol A on the market in the European Union. The members of that group market bisphenol A for both intermediate and non-intermediate uses.

8 On 2 March 2017 the relevant French competent authority, that is to say, the Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (National Agency for Food, Environmental and Occupational Health and Safety, Anses, France; 'the French competent authority'), submitted, pursuant to Article 59(3) of Regulation No 1907/2006, a dossier consistent with Annex XV to that regulation ('the dossier prepared in accordance with Annex XV'), in which it proposed that bisphenol A be identified as an endocrine disrupting substance for which there was scientific evidence of probable serious effects on human health. More specifically, that dossier was intended to supplement the entry relating to bisphenol A on the Candidate List, which had been included in that list since 12 January 2017 (see paragraph 6 above), with a view to that substance also being identified as a substance of very high concern under Article 57(f) of Regulation No 1907/2006.

9 On 9 March 2017, ECHA published the dossier prepared in accordance with Annex XV, as submitted by the French competent authority.

10 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.

11 On 21 April 2017 the applicant submitted comments, on behalf of its members, on the dossier prepared in accordance with Annex XV.

12 The French competent authority subsequently produced a document ('the RCOM Document'), dated 14 June 2017 and containing that authority's responses to all the comments received by ECHA in the course of the public consultation.

13 On 14 June 2017, at its 54th meeting, ECHA's Member State Committee unanimously agreed on the identification of bisphenol A as a substance which fulfils the criteria laid down in Article 57(f) of Regulation No 1907/2006 'because it [was] a substance with endocrine disrupting properties for which there [was] scientific evidence of probable serious effects to human health … which [gave] rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of [Regulation No 1907/2006]'. The dossier prepared in accordance with Annex XV served as the basis for the creation of the document upon which the Member State Committee relied before reaching unanimous agreement ('the Support Document').

14 On 6 July 2017, the Executive Director of ECHA adopted Decision ED/30/2017 ('the contested decision'), whereby the existing entry relating to the substance bisphenol A on the list of substances identified with a view to their eventual inclusion in Annex XIV to Regulation No 1907/2006, in accordance with Article 59 thereof, 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 a level of concern equivalent to that raised by the use of other substances listed in Article 57(a) to (e) of that regulation, within the meaning of Article 57(f) thereof.

15 On 7 July 2017 the Candidate List published on ECHA's website was updated in accordance with the contested decision.

II. Procedure and forms of order sought

16 By application lodged at the Court Registry on 15 September 2017, the applicant brought the present action.

17 By documents lodged at the Court Registry on 21 and 27 December 2017, respectively, the French Republic and ClientEarth applied for leave to intervene in support of the form of order sought by ECHA.

18 The defence was lodged at the Court Registry on 5 December 2017.

19 By separate documents, lodged at the Court Registry on 29 January 2018, the applicant submitted two requests for confidential treatment of certain information communicated in the application vis-à-vis the French Republic and ClientEarth, respectively.

20 The reply was lodged at the Court Registry on 29 January 2018.

21 By two orders of 5 March 2018, the President of the Fifth Chamber of the Court granted the French Republic and ClientEarth leave to intervene.

22 Since 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 29 January 2018, that request was granted in relation to that Member State in accordance with the Rules of Procedure of the Court.

23 On 12 March 2018 the rejoinder was lodged at the Court Registry.

24 By written submission lodged at the Court Registry on 23 March 2018, ClientEarth opposed the request for confidential treatment, lodged by the applicant on 29 January 2018 vis-à-vis ClientEarth.

25 By document lodged at the Court Registry on 29 March 2018, the applicant asked the Court, pursuant to Article 85(3) of the Rules of Procedure, to accept new evidence in the form of a document, dated February 2018, entitled 'Draft [United States] NTP Research Report on the Clarity-BPA Core Study: A Perinatal and Chronic Extended-Dose-Range Study of Bisphenol A in Rats'. The applicant attached that document as an annex to the document lodged on 29 March 2018.

26 On 19 April 2018, the French Republic and ClientEarth lodged their respective statements in intervention, drafted on the basis of a confidential version of the application, at the Court Registry.

27 By written submission of 25 April 2018, ECHA stated that, in its view, the evidence produced by the applicant on 29 March 2018 was inadmissible. ECHA added that, in any case, that evidence did not add anything new to the arguments already put forward in that case. ECHA therefore claimed that it should be rejected.

28 By order of 18 May 2018, the President of the Fifth Chamber of the Court granted the request for confidential treatment vis-à-vis ClientEarth.

29 On 4 June 2018 ClientEarth lodged a supplementary statement in intervention at the Court Registry.

30 By documents lodged at the Court Registry on 19 and 20 July 2018, respectively, ECHA and the applicant each submitted their observations on the statements in intervention.

31 The applicant claims that the Court should:

– annul the contested decision;

– order ECHA to pay the costs;

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

32 ECHA contends that the Court should:

– dismiss the action;

– order the applicant to pay the costs.

33 ClientEarth contends that the Court should:

– dismiss the action in its entirety;

– order the applicant to bear the costs.

34 The French Republic contends, for its part, that the Court should dismiss the action.

III. Law

A. The claim for annulment of the contested decision

35 In support of the action, the applicant relies on six pleas in law. By its first and third pleas, the applicant alleges infringement of the principles of legal certainty and protection of legitimate expectations. The second plea alleges that ECHA committed manifest errors of assessment and breached its duty of care. The fourth plea refers to an alleged infringement of Article 57(f) and Article 59 of Regulation No 1907/2006. By the fifth and sixth pleas, the applicant alleges infringement of Article 2(8)(b) of that regulation and of the principle of proportionality.

36 The Court considers it appropriate to begin by examining the second plea.

1. Second plea in law: manifest errors of assessment and a breach by ECHA of its duty of care

37 The second plea alleges that ECHA committed manifest errors of assessment and breached its duty of care. This plea is divided into two branches, the first of which is subdivided into several complaints.

(a) First branch of the second plea in law: error of law and manifest errors of assessment

38 The first branch of the second plea alleges, in essence, that the identification by ECHA of bisphenol A as an endocrine disruptor of very high concern which fulfils the criteria laid down in Article 57(f) of Regulation No 1907/2006 is vitiated by an error of law and manifest errors of assessment.

(1) The first complaint in the first branch of the second plea: error of law on the ground that ECHA failed to establish the 'level of concern' referred to in Article 57(f) of Regulation No 1907/2006

39 In the context of the first complaint of the first branch of the second plea, the applicant submits that ECHA infringed Article 57(f) of Regulation No 1907/2006 by failing to establish that, in addition to the alleged endocrine disrupting properties of the substance, there was scientific evidence of its probable serious effects on human health which gave rise to the level of concern referred to in that provision. It is claimed that, in the Support Document, ECHA concluded that '[bisphenol A was] identified as a [substance of very high concern] according to Article 57(f) [of Regulation No 1907/2006] for probable serious effects on human health, due to its endocrine disrupting properties, which are of [an equivalent level of concern]'. According to the applicant, it is apparent from that statement that ECHA considered the alleged endocrine disrupting properties to be, per se, of an equivalent level of concern.

40 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

41 It should be observed that the first complaint in the first branch of the second plea proceeds on the assumption that the fact that a substance is an endocrine disruptor does not suffice per se to demonstrate that it is of an equivalent level of concern. In that connection, it should be borne in mind 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. As regards the condition related to establishing serious effects on human health or the environment, this requires an analysis of the hazards linked to the intrinsic properties of the substance under consideration. As regards the condition related to the existence of a certain level of concern, it requires that the demonstration that the serious effects on

human health or the environment of the substance under consideration give rise to an equivalent level of concern to those of other substances referred to in Article 57(a) to (e) of the same regulation, be based on the analysis of the hazards arising from the intrinsic properties of the substances concerned, without prohibiting the taking into consideration of other data (see, to that effect, judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA*, C-324/15 P, EU:C:2017:208, paragraphs 26, 27 and 40). In particular, in order for a substance to be identified as an endocrine disruptor of very high concern, it is necessary that it be established, on a case-by-case basis, on the basis of scientific evidence, that (i) a substance with endocrine disrupting properties can have serious effects on human health or the environment, and (ii) those effects give rise to an equivalent level of concern to the substances referred to in Article 57(a) to (e) of Regulation No 1907/2006.

42 There is no factual basis for the applicant's statement — in the context of the first complaint in the first branch of the second plea in law — that ECHA confined itself to finding that bisphenol A was merely an endocrine disruptor and failed to establish that that endocrine disruptor gave rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006.

43 That statement is in fact contradicted by the Support Document (Annex A.13 to the application, page 160 et seq.). More specifically, as is apparent from Section 6.3.2 of that document, following on from the French competent authority's assessments, ECHA distinguished very clearly between (i) the nature of bisphenol A as an endocrine disruptor as such and (ii) the question whether that endocrine disruptor gave rise to the level of concern referred to in Article 57(f) of Regulation No 1907/2006. In the wake of that distinction, ECHA, again following on from the French competent authority's assessments, also stated the specific criteria used in examining the question of which level of concern was to be attributed to bisphenol A. Those criteria were the effects on health, impact on quality of life, societal concern and the question whether a safe concentration could be established. More specifically, with regard to effects on health, the following were taken into account: the type of possible effects on health, the irreversibility of effects on health, and the delay in the manifestation of effects on health.

44 Having regard to those factors, the first complaint in the first part of the second plea in law must be rejected.

(2) The second complaint in the first branch of the second plea in law: manifest error of assessment in that ECHA failed to meet the criteria laid down in Article 57(f) of Regulation No 1907/2006 and comply with certain general principles of EU law

45 In the context of the second complaint in the first branch of the second plea, the applicant calls into question, in essence, the scientific assessment conducted by ECHA to demonstrate that bisphenol A is a substance which may have adverse effects giving rise to a level of concern equivalent to that raised by the use of other substances listed in Article 57(a) to (e) of Regulation No 1907/2006.

46 In the first place, according to the applicant, ECHA relied on a series of studies in a manner inconsistent with the principle of excellence.

47 It is claimed, first, that some of the studies relied on by ECHA in support of the contested decision and identified in the dossier prepared in accordance with Annex XV as the most informative studies have been recognised, by other expert committees, as having obvious limitations and as being unreliable. For example, concerning mammary gland development, all the studies highlighted as the most informative in the dossier prepared in accordance with Annex XV had already been included in a review conducted by the European Food Safety Authority (EFSA) in 2015, which had reported notable limitations for those studies. This is the case with the Jenkins (2009), Tharp et al. (2012) and Ayyanan (2011) studies. ECHA considered that those studies permitted the conclusion that there was a serious effect on health.

By contrast, in a document entitled 'Scientific Opinion on the risks to public health related to the presence of Bisphenol A (BPA) in foodstuffs' of 25 March 2015 (Executive Summary: EFSA Journal 2015;13(1):3978. DOI: 10.2903/j.efsa.2015.3978; 'the EFSA Opinion of 25 March 2015'), the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids ('the EFSA CEF Panel') considered the three studies mentioned above 'supportive' only in order to take them into account in its safety assessment. Concerning cognitive function, it is argued that EFSA took the view that, according to some of the studies referred to as the most informative in the dossier prepared in accordance with Annex XV, exposure of mice to bisphenol A had showed, in those animals, an 'inconsistent change' in the hippocampal NMDA receptors and that, therefore, no conclusion could be drawn from those results. This is the case with the Xu (2010b) study. With regard to another study, namely the Inagaki (2012) study, EFSA concluded, inter alia, that its design, the doses and the number of animals used in the various tests appeared unclear. Moreover, concerning that study, ECHA itself identified the following limitations:

'Weaknesses: — Single dose acute administration — Test performed in one sex only; Insufficient study report; Inappropriate statistics.'

48 Secondly, it is claimed that ECHA did not give appropriate weight in its assessment to data recognised as scientifically valid and reliable by other regulatory bodies of the European Union. For example, concerning reproductive function, the Tyl (2002), Tyl (2008), Ema (2001) and Delclos (2014) studies, which are acknowledged as key studies by other regulatory bodies such as ECHA's Risk Assessment Committee, EFSA and the Scientific Committee on Occupational Exposure Limits ('SCOEL'), are not mentioned in the dossier prepared in accordance with Annex XV amongst the 'most informative' studies. With particular regard to the oestrous cyclicity endpoint, the applicant observes that several studies are not cited in the Annex XV dossier even though they contain research carried out regarding oestrous cyclicity at different life stages. The majority of those studies show no effect on oestrous cyclicity using a human relevant exposure level (Goodman (2009, 2006), Gray (2004), C[enter for the] E[valuation of] R[isks to] H[uman] R[eproduction] (2008), EFSA (2015), SCOEL (2014)). The applicant takes the view that if all the relevant data had been taken into account as part of an assessment based on the weight of evidence approach, bisphenol A could not have been considered an endocrine disruptor in relation to oestrous cyclicity. Concerning mammary gland development, the comprehensive study by Delclos (2014) was not considered by ECHA as 'most relevant' even though EFSA considered that it was relevant. Concerning cognitive function, studies conducted by the FDA and the NCTR were available and evaluated by EFSA, but not considered by ECHA.

49 Thirdly, it is argued that the studies relied upon by ECHA do not support the conclusions reached by that body. For example, concerning reproductive function, it is true that the dossier prepared in accordance with Annex XV did indeed state, in essence, that, according to the Lee (2013a) study, tests on adult female Sprague-Dawley rats showed that 'one clear cut primary target of [bisphenol A] [was] the reduction of the expression of aromatase'. According to the applicant, in other words, bisphenol A is an aromatase inhibitor. However, the applicant claims that, according to the Organisation for Economic Cooperation and Development (OECD) Task Force on Endocrine Disruptors Testing and Assessment of the Test Guidelines Programme, one of the several severe effects of the aromatase inhibitor is the dramatic increase in body weight in female rats. However, in the applicant's view, the Lee (2013a) study did not report body weight increase in the results and does not therefore confirm the hypothesis proposed by ECHA. Furthermore, the Yamasaki (2002) study, a comprehensive study performed in accordance with the OECD Guidelines for the Testing of Chemicals No 407 called 'OECD TG 407' was available concerning bisphenol A. According to the applicant, no increase in body weight had been reported at any dose tested in that study. Since no consistent effect on fertility is reported at a dose of between 1 and 100 µg/kg (that is to say, the dose level investigated by the Lee (2013a) study) in in-depth multi-generation studies dosing adult animals (generation F0), experts concluded in their evaluations that there was no consistent or reproducible effect at those dose levels (Hengstler (2011), EFSA (2015), ECHA (2014)). Concerning mammary gland development, the studies by one research group mentioned in the dossier to support this conclusion used an inappropriate study

design. Concerning metabolism, the author of the dossier prepared in accordance with Annex XV stated that, 'even if available epidemiological studies [were] inconclusive, these effects [were] [nevertheless] considered relevant for humans because similarities [existed] … between animals and humans'. According to the applicant, it is not comprehensible that inconclusive human data was considered relevant because similarities exist between animals and humans.

50 Fourthly, studies that are scientifically considered as better conducted, more comprehensive or more complete were not, it is argued, taken into account, or were taken into account only partially. Concerning reproductive function, the dossier prepared in accordance with Annex XV does not take into account OECD document No 150 entitled 'Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption' and considered level 3 in vivo experiments in ovariectomised rodents as 'most informative studies', although level 4 studies and comprehensive level 5 multi-generation studies were available. Lastly, concerning mammary gland development, it is claimed that the dossier prepared in accordance with Annex XV mentions the publications by one research group to support the hypothesis that alterations in EZH2 gene-expression is crucial in the bisphenol A-dependent mammary gland carcinogenesis mode of action (Bhan (2014a), Bhan (2014b), Hussain (2015)). However, the dossier prepared in accordance with Annex XV did not mention that gene expression of EZH2 and other genes were investigated in other studies, for example in the NCTR one-generation 90-day study conducted by Delclos (2014) under the auspices of the NTP. In addition, where that dossier cites studies with exposure of adult animals, no mention is made of the fact that comprehensive chronic carcinogenicity studies were available for two species, namely F344 rats and B6C3F1 mice. The report entitled 'The EU Risk Assessment Report' produced in 2008 concluded from those studies that '[bisphenol A] was not carcinogenic … in both species'. Concerning cognitive function, a study conducted by Stump in 2010 investigated brain histopathology and developmental neurotoxicity endpoints. No developmental neurotoxicity effects were reported in respect of any dose tested in any endpoint investigated. Finally, other comprehensive level 5 studies, such as the Tyl (2002), Tyl (2008) and Ema (2001) studies, also do not indicate effects on neurotoxicity.

51 In the second place, the applicant submits that, with regard to the endocrine disrupting properties of bisphenol A, ECHA came, in part, to different conclusions from those reached by EFSA. In its opinion of 25 March 2015, EFSA concluded that scientific knowledge of how bisphenol A behaved in humans was still unclear and that there was no single explanation as to how it potentially affects humans. The applicant states that, according to EFSA, bisphenol A is 'as likely as not' to have effects on the functions 'relevant for this assessment'. In essence, EFSA took the view that it was not possible to conclude that bisphenol A was an endocrine disruptor. It is argued that ECHA failed to give any explanation as to the reasons why its findings differed from those of other scientific bodies of the European Union, such as the conclusions expressed in the EFSA opinion of 25 March 2015, using the procedure provided for in Article 95(3) of Regulation No 1907/2006 in order to do so.

52 Lastly, 'major inconsistencies' in the selection and scoring of individual studies conducted by ECHA and by EFSA render the dossier prepared in accordance with Annex XV inconsistent and non-transparent, and the 'ToxRTool' applied by ECHA for the purposes of analysing the studies used and, in particular, the most recent studies, could not rectify those inconsistencies. In that connection, the applicant observes, and is not challenged in this regard by ECHA, that 'ToxRTool' is a software-based protocol developed by the Commission's Joint Research Centre ('the JRC') to provide comprehensive criteria and guidance in order to guarantee the reliability of evaluations of toxicological data. It applies to various types of experimental data, endpoints and studies (study reports, peer-reviewed publications) and leads to a classification which takes account of an internationally recognised methodology called the Klimisch scoring system (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, vol. 25, pp. 1-5). The applicant states, and is not challenged in this regard by ECHA, that the ToxRTool assigns the studies used to three categories: Klimisch 1 (reliable without restrictions),

Klimisch 2 (reliable with restrictions) and Klimisch 3 (not reliable). However, the applicant submits that the use of the ToxRTool in the present case was not transparent because there was no protocol to follow, no indication of expert evidence and no background information on the assessment used.

53 In the third place, the applicant takes the view that the information upon which ECHA based its conclusion that bisphenol A has an endocrine disrupting mode of action does not meet the standard of evidence provided for in Article 57(f) of Regulation No 1907/2006.

54 First, as is clear from the 62nd row of the full version of the RCOM Document, according to the French competent authority, the 'association between adverse effects and the mode of action was defined as a biologically plausible link'. According to the applicant, since ECHA endorsed the assessments contained in the RCOM Document, the 'plausibility' test added by ECHA to the definition of endocrine disruptor given by the World Health Organisation (WHO), as drawn up in the context of the 'International Programme on Chemical Safety' ('the WHO definition'), does not meet the criteria in Article 57(f) of Regulation No 1907/2006 concerning the standard of evidence. The standard of evidence laid down in that provision requires that the adverse effects be 'probable'. However, the 'plausibility' threshold is lower than the 'probability' threshold provided for in Article 57(f) of Regulation No 1907/2006.

55 Secondly, in the applicant's view, the evidence produced by ECHA in support of an endocrine disrupting mechanism or mode of action in relation to bisphenol A does not provide any detailed description of a consistent endocrine-related mode of action. In reality, '"associating" an effect to an endocrine-related [mode of action]' is not sufficient to conclude that there is scientific evidence that an endocrine disruptor has adverse effects on human health. To fulfil the criteria of Article 57(f) of Regulation No 1907/2006 for the identification of a substance of very high concern taking account of its endocrine disrupting properties, a conclusive demonstration of a respective mode of action or mechanism of action that is relevant for the observed adverse effect is needed. In that connection, only an observation accompanied by proof of a consistent, defined biological response is specific enough to be linked to a specific mode of action or mechanism of action. Furthermore, according to the applicant, since the endocrine mechanism is not established, ECHA has failed to demonstrate that the substance had endocrine disrupting properties and/or that it met the criteria of Article 57(f) of Regulation No 1907/2006 with respect to any of the four alleged effects, namely effects on the reproductive system, the mammary gland, cognitive function or metabolism. According to the applicant, the evidence does not provide any detailed description of a consistent, specific endocrine-related mode of action. In the overall conclusion of the human health hazard assessment, contained in Chapter 4.6 of the dossier prepared in accordance with Annex XV, it is stated that the primary target of bisphenol A is still unknown, that multiple modes of action may interact and that other findings point to the involvement of other factors in bisphenol A-mediated effects. It is submitted that ECHA acknowledges that there are uncertainties when it concludes that, 'when considering the definition of an [endocrine disruptor], the association between adverse effects and [mode of action] is defined as a biologically plausible link and not a causal relationship'. In that context, the applicant adds that ECHA committed a manifest error of assessment when it stated that it was relying on the 'qualitative weight of expert judgment' without using a rigorous method that provides criteria to substantiate the underlying analysis and to disqualify scientific evidence. It is argued that the phrase 'qualitative weight of expert judgment' does not actually mean anything. According to the applicant, ECHA ought to have used a protocol developed for the hazard assessment of bisphenol A in order to establish its effect, a protocol similar to the one developed by EFSA for the assessment of bisphenol A in food contact applications.

56 In the fourth place, according to the applicant, ECHA failed to demonstrate that the alleged adverse effects of bisphenol A gave rise to an 'equivalent concern' to that raised by the effects of substances which fulfil the criteria laid down in Article 57(a) to (e) of Regulation No 1907/2006. In principle, the criteria for the classification of substances as carcinogenic, mutagenic or toxic for reproduction as category 1A or 1B should be taken into account in the assessment of the equivalency of the level of

concern. More specifically, it is apparent from a combined reading of Article 57 of Regulation No 1907/2006 and the criteria set out in 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 2008 L 353, p. 1) that a finding of an equivalent level of concern, as required in Article 57(f) of Regulation No 1907/2006, must be based on human data or on evidence from animal studies providing a strong presumption of effects. In the present case, in the 67th row of the RCOM Document, the French competent authority stated, inter alia, that, 'based on animal data and without any good argument to exclude that this could happen in humans … the adverse effects observed in rodents are also relevant for humans'. It is argued that those findings do not demonstrate that the adverse effects of bisphenol A give rise to a level of concern equivalent to that raised by the substances referred to in Article 57(a) to (e) of Regulation No 1907/2006.

57 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

58 As a preliminary point, it should be observed that, according to settled case-law, in order to establish that an institution 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). 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).

59 Moreover, the EU authorities' broad discretion, which implies limited judicial review of their exercise of that discretion, applies not only to the nature and scope of the measures to be taken but also applies, 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).

60 It is in the light of those considerations that it is necessary to consider whether ECHA's assessment of the properties of bisphenol A as a substance fulfilling the provisions of Article 57(f) of Regulation No 1907/2006 is vitiated by a manifest error of assessment.

61 In the first place, contrary to the applicant's claims (see paragraph 46 above), ECHA did not rely on a series of studies which do not comply with the principle of excellence.

62 First, concerning the studies which, according to the applicant, EFSA considered unreliable, whereas ECHA found them 'instructive' (see paragraph 47 above: the Jenkins (2009), Tharp et al (2012) and Ayyanan (2011) studies on mammary gland development and the Xu (2010b) and Inagaki (2012) studies on cognitive functions), it is clear that the purpose of EFSA's examination of the data relating to bisphenol A was in no way to determine whether that substance was an endocrine disruptor of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006. More specifically, the EFSA opinion of 25 March 2015 does not contain any specific conclusion as to the question whether bisphenol A possesses endocrine disrupting properties which give rise to the level of concern referred to in that provision.

63 By contrast, EFSA's analysis is generally based on the evaluation of the risk connected to a particular use, namely the risk created by consumer exposure to a substance, in particular dietary exposure through materials in contact with foodstuffs. In particular, EFSA's analysis was intended to determine the tolerable daily intake of bisphenol A, that is to say, the intake that can be ingested daily by a consumer for the duration of his life without it presenting a risk to his health. In that connection, EFSA concluded that, at current exposure levels, the presence of bisphenol A in foodstuffs did not present a risk to human health because those levels were below the tolerable daily intake.

64 In that regard, first, it should be observed that the EFSA opinion of 25 March 2015 does not contain any analysis of the hazards linked to the intrinsic properties of bisphenol A, or any clear conclusion as to the identification of that substance as an endocrine disruptor meeting the criteria referred to in Article 57(f) of Regulation No 1907/2006.

65 Moreover, as regards the studies used for the purposes of drafting its opinion of 25 March 2015, EFSA neither excluded nor sought to exclude the relevance of those studies in so far as concerns the properties of that substance in the light of Article 57(f) of Regulation No 1907/2006. As the French Republic, in essence, rightly contends, the spheres of activity and the duties of ECHA and EFSA are different, with the result that the findings of one of those agencies with regard to a study do not necessarily call into question the findings of the other agency with regard to the same study. Moreover, even if EFSA had wished — quod non — to draw up observations as to the intrinsic properties of bisphenol A as an endocrine disruptor meeting the criteria referred to in Article 57(f) of Regulation No 1907/2006, that would not have bound ECHA in that regard, or exempted it from conducting its own assessment of the properties of that substance.

66 Consequently, EFSA's findings concerning the risk to the health of consumers resulting from dietary exposure to bisphenol A cannot call into question ECHA's findings based on the same studies concerning the intrinsic properties of that substance as an endocrine disruptor of very high concern.

67 Secondly, it should be observed that, in its opinion of 25 March 2015, EFSA admittedly found that there was no risk to the health of consumers of all age groups following dietary exposure to bisphenol A and a low level of concern following overall exposure to that substance. However, EFSA's finding does not mean that bisphenol A does not present, per se, any danger to human health, only that consumer exposure to that substance, at the levels considered by EFSA, is not sufficient to conclude that there is a risk to health. In that connection, it is pertinent to recall and emphasise again that the identification by EFSA, in accordance with Article 59 of Regulation No 1907/2006, of a certain substance as satisfying the two conditions referred to in Article 57(f) of that regulation must be based on an analysis of the hazards arising from the intrinsic properties of the substance concerned, and not on an analysis of the uses of the substance.

68 Thirdly, it is clear that, while it is true that the EFSA opinion of 25 March 2015 does not contain any specific conclusions concerning the question whether bisphenol A has endocrine disrupting properties, the fact remains that it confirms, albeit indirectly, ECHA's conclusion that bisphenol A has an effect on the human endocrine system.

69 More specifically, as the French Republic contends and is not challenged in that regard by the applicant in a substantiated manner and by means of evidence, according to the EFSA opinion of 25 March 2015, a series of studies published since 2010 on the mechanism of action of bisphenol A show that that substance modifies the hormonal system through the action of biochemical receptors that transmit specific hormonal signals to cells, among other signalling pathways. As ECHA stated in its defence, on page 449 of the EFSA review report on bisphenol A, the EFSA CEF Panel considered that those studies contained relevant evidence. Concerning the Jenkins (2009) study, the EFSA CEF Panel found 'that [that] study cannot be used for the assessment of cancer risk but as supporting evidence of the induction of proliferation by [bisphenol A] following lactational as well as in utero

exposure'. Similarly, as regards the Tharp et al (2012) study, that panel was of the view that 'the results of this study can be used as supportive evidence of the induction of proliferation by [bisphenol A]'. Lastly, as for the Ayyanan (2011) study, the panel stated the following:

'Several of the studies (e.g. Markey et al., 2001; Murray et al., 2007; Ayyanan et al. 2011, Vandenberg et al., 2013c) were reported to show a non-monotonic dose-response curve for proliferation (Section 4.3). The [EFSA] CEF Panel considered the effects nonetheless supportive of a [bisphenol A] induced effect on the mammary gland.'

70 It is apparent from the foregoing that, inasmuch as the applicant refers to the conclusions expressed by EFSA in its opinion of 25 March 2015, that reference fails to demonstrate in any way that there is a manifest error of assessment.

71 Secondly, the applicant's argument alleging that ECHA failed to take into account certain data which had been recognised as scientifically valid and reliable by other regulatory bodies of the European Union, or that ECHA gave insufficient weight to those studies (see paragraph 48 above), must be rejected.

72 In that connection, it should be observed, as has been set out in paragraph 65 above, that, generally, regulatory bodies and scientific committees other than ECHA, including EFSA and SCOEL, do not have the same duties as ECHA and draw up their scientific opinions for purposes other than those envisaged by ECHA. Consequently, the mere fact that those bodies and committees considered that some studies written on the subject of the properties of bisphenol A and cited by ECHA in the Support Document deserved to be given greater weight than ECHA attached to them does not necessarily call into question the plausibility of that agency's findings concerning those studies, or the appraisal conducted by that agency in the wake of the conclusions which the competent French authority had already reached.

73 Moreover, it is true that it follows from the observations set out on page 24 of the Support Document that the Tyl (2002) and Ema (2001) studies did not identify any significant differences in the oestrous cyclicity diagram. However, contrary to what the applicant appears to submit — and as observed by ECHA, which was not challenged in that regard — there are numerous other studies, including the Tyl (2008) and Delclos (2014) studies relied upon by the applicant, which, conversely, demonstrate that bisphenol A has adverse effects on oestrous cyclicity. The applicant makes no reference to the results of the other studies and does not explain what specific conclusions, different to ECHA's own findings, the regulatory bodies and scientific committees allegedly drew from those other studies.

74 Thirdly, the applicant's argument that ECHA's findings are not supported by the studies that the agency considered convincing (see paragraph 49 above) must be rejected as unfounded.

75 The criticism levelled by the applicant at the Lee (2013a) study, which has been highlighted by ECHA concerning reproductive function, cannot succeed. The thesis underpinning that criticism is that, according to the OECD Working Group mentioned in paragraph 49 above, increase in body weight is an observable effect in all aromatase inhibitors. The applicant has failed to substantiate that allegation by any reference to a relevant scientific study other than that developed by that working group, with the result that that allegation cannot be verified. It is therefore not certain that increase in body weight is an observable effect in all aromatase inhibitors, as the applicant claims. Moreover, the applicant suggests that the Lee (2013a) study demonstrated that there was no increase in the body weight of the animals tested. On account of the applicant's failure to provide that study, it is impossible to know whether it mentions the body weight of animals after exposure to bisphenol A and whether, in the context of that study, body weight had in fact increased.

76 Similarly, inasmuch as the applicant refers, with regard to the effects of bisphenol A as an aromatase inhibitor, to the Yamasaki (2002), Hengstler (2011), EFSA (2015) and ECHA (2014) studies, the Court is also not in a position to verify the data that they contain. Those studies were not in fact added to the case file, or summarised in a comprehensible and conclusive manner in the pleadings submitted by the applicant in the context of the present action. To the extent that the applicant complains that ECHA used 'a protocol which was not appropriate' concerning the effects of bisphenol A on mammary gland development, the Court is not in a position to ascertain how the protocol referred to by the applicant was not 'appropriate'.

77 Lastly, as regards metabolism, the applicant's claim that it is not comprehensible that inconclusive human data was considered relevant is in no way persuasive. The applicant's claim is based in that regard on a reductive misinterpretation of the content of Section 4.5.4 of the Support Document (Annex 13 to the application, page 139). Contrary to the interpretation advocated by the applicant, that section merely acknowledges that the epidemiological data available for humans are not conclusive. There is no claim in that section as to whether or not the data concerning humans are relevant, but rather that the effects observed in studies in animals are also relevant for humans on account of similarities between animals and humans, even though the effects have not been conclusively demonstrated in humans. On that basis, it is a common approach in science to consider that, on account of the existence of a certain number of uncertainties surrounding epidemiological studies in general, negative or merely inconclusive epidemiological studies cannot invalidate positive studies in animals. That was rightly observed by the competent French authority in Comment No 67 on page 62 of the full version of the RCOM Document, made in the following terms, which are furthermore not disputed by the applicant:

'However, negative results (i.e. no significant association) of epidemiological studies are not sufficient to conclude on the lack of effects in humans. That is why, based on animal data and without any good argument to exclude that this could happen in humans, we consider that the adverse effects observed in rodents are also relevant for humans.'

78 Fourthly, the argument alleging that certain studies which deserved to be scientifically considered as better conducted, more comprehensive or more complete were not taken into account or were taken into account only in part by ECHA (see paragraph 50 above), is also not persuasive. As is clear from the RCOM Document, the criticisms set out by the applicant with regard to the studies mentioned in paragraph 50 above were each the subject of a clear reply from the competent French authority. In the present action, the applicant neither explains nor demonstrates how those replies were incorrect or insufficient.

79 To the extent that the applicant submits that, in respect of the effects of bisphenol A on reproductive functions, both the competent French authority and ECHA wrongly deemed the level 3 in vivo experiments conducted on ovariectomised rodents to be 'most informative studies', whereas level 4 studies and comprehensive level 5 multi-generation studies were available, it is clear that there is nothing to indicate which level 4 and level 5 studies the applicant is referring to. Moreover, concerning the applicant's claim that the competent French authority's dossier failed to take into consideration OECD document No 150, it should be observed that that French authority replied in Comment No 70 set out on page 63 of the full version of the RCOM Document that 'it [was] fully justified that studies using ovariectomised animals are identified as very informative in particular for [mode of action] considerations' and that 'it [was] also noted that the studies by Xu (2015b) and Inagaki (2012) also include intact animals in their protocol in addition to ovariectomised animals'. The applicant neither explains nor demonstrates how that reply was incorrect or insufficient in the light of the guidelines contained in OECD Document No 150.

80 To the extent that the applicant claims that ECHA failed duly to take into account the expression of EZH2 and other genes, as mentioned in other studies, for example in the NCTR's one-generation 90-day study, conducted by Delclos (2014) under the auspices of the NTP, it should be observed that

(i) in Comment No 83 set out on page 78-79 of the full version of the RCOM Document, the competent French authority replied to the applicant's concerns that 'results on EZH2 [were] well reported in the supplementary data (Table Excel supplement table 5) but appears to be related to an evaluation conducted at [post-natal day] 4 and not at [post-natal day] 90'; and (ii) the applicant does not make any mention of that very specific reply in the context of the present action.

81 To the extent that the applicant alleges that the Support Document cites studies on the exposure of adult animals without mentioning that comprehensive chronic carcinogenicity studies were available for two species, namely F344 rats and B6C3F1 mice, whereas the report entitled 'The EU Risk Assessment Report' produced in 2008 concluded that '[bisphenol A] was not carcinogenic … in both species', it should be observed that that argument proceeds on the assumption that a carcinogenic substance is automatically an endocrine disruptor of very high concern. The applicant has failed to demonstrate that this is necessarily the case. In particular, it has failed to exclude the possibility of there being substances which cause a certain type of cancer, but which do not cause harmful changes in endocrine function.

82 Lastly, as regards neurotoxicity studies, it should be noted at the outset that the applicant has failed to clarify the link between neurotoxicity and the nature of endocrine disruptors of very high concern. Moreover, it should be observed that the competent French authority stated in reply to Comment No 86 set out on page 86-87 of the full version of the RCOM Document that 'the study of Stump (2010) [was] included in the … dossier [prepared in accordance with Annex XV] and considered in the weight of evidence', that 'it [was] however noted that animals were fed with a diet containing phytoestrogens which may therefore compromise the interpretation of results at low doses' and that 'the studies by Tyl (2002) and Tyl (2008) did not investigate any specific parameters related to neurobehaviour and it [was] therefore not relevant to include and discuss these studies in the Neurobehavioural section of the [dossier prepared in accordance with] Annex XV …'. The applicant has failed to clarify how that reply is unsatisfactory.

83 In the second place, inasmuch as the applicant submits that, with regard to the properties of bisphenol A as an endocrine disruptor, ECHA in part arrived at different conclusions to those of EFSA and that it failed to give any explanation as to the disparity between its opinions and those of EFSA (see paragraphs 51 and 52 above), it should be recalled that, as has already been observed in paragraph 64 above, those two agencies have different duties and conduct assessments carried out in the pursuit of different objectives. The examination carried out by EFSA in 2015 did not have the same scope as the assessment conducted by ECHA for the purposes of adopting the contested decision. In those circumstances, the mere fact that, according to EFSA, bisphenol A is 'as likely as not' to have effects on the functions relevant 'for this assessment' does not suffice to deprive the study selection and appraisal, as carried out by ECHA for the purposes of adopting the contested decision, of plausibility. In the absence of further explanations from the applicant, the alleged 'major inconsistencies' affecting the selection and appraisal of the individual studies carried out by ECHA and EFSA in their assessments have no bearing on what should happen to the contested decision.

84 Furthermore, the applicant's supplementary argument that those alleged 'major inconsistencies' render the dossier drawn up in accordance with Annex XV inconsistent and non-transparent, and that the ToxRTool protocol followed by ECHA for the purposes of analysing the studies used could not rectify those inconsistencies (see paragraph 52 above), is also not persuasive.

85 The applicant's complaint that the use of the ToxRTool in the present case was not transparent because there was no protocol to follow, no indication of expert evidence and no background information on the assessment used (see paragraph 52 above), is ineffective. The results of the ToxRTool protocol were in fact used solely to supplement the results of the weight-of-evidence approach. It was therefore in no way the sole factor or, at the very least, the determining factor, on

which the assessment at issue in the present case was founded, so that any lack of 'transparency' associated with the use of that software has no bearing on what should happen as regards the merits of the contested decision.

86 In the third place, by all the arguments mentioned in paragraphs 53 to 55 above, the applicant calls into question ECHA's finding that it is scientifically proven that bisphenol A presents a mode of action which allows it to be considered that that substance is an endocrine disruptor of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006.

87 In doing so, the applicant challenges two different things: (i) the question whether ECHA took as its starting point the standard of proof effectively required under Regulation No 1907/2006, it being implied that it is, in that regard, a question of principle; and (ii) the question whether ECHA applied that standard of proof correctly in the present case, bearing in mind that, in that context, more specifically, the applicant calls into question ECHA's assessments relating to the mode of action specific to bisphenol A and, accordingly, the effects of that substance on human health.

88 First, when it claims that ECHA 'added' the 'plausibility' threshold to the 'probability' threshold allegedly contained in Article 57(7) of Regulation No 1907/2006 (see paragraph 54 above), the applicant starts from the premiss that the standard of proof required by that provision corresponds to the latter threshold. That argument, which appears expressly in paragraph 77 of the application, is based on confusion which calls for the following clarifications.

89 Under Article 57(f) of Regulation No 1907/2006, as is clear, inter alia, from the French version of that regulation, substances for which it is '*scientifiquement prouvé*' (literally, 'scientifically proven') that they '*peuvent*' (literally, 'can') have 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), may be included in Annex XIV of that regulation. Similarly, according to the Spanish version of Article 57(f), substances inter alia for which there is scientific evidence that they have '*posibles efectos graves*' (literally, 'possible serious effects') to human health or the environment, provided that they give rise to a level of concern equivalent to that referred to in Article 57(a) to (e) of Regulation No 1907/2006, may be included in Annex XIV of that regulation. According to the Portuguese version, substances inter alia for which there is scientific evidence that they are '*susceptíveis de provocar*' (literally, 'likely to cause') serious effects to human health or the environment if the condition relating to the level of concern is satisfied, may be included in Annex XIV of that regulation. It must be considered that the phrase 'likely to cause' is the equivalent of the verb 'can' or the adjective 'possible'. By contrast, according to other language versions of that provision, such as the German, English and Italian versions, those serious effects must be 'probable' (German: *wahrscheinlich*; English: *probable*; Italian: *probabilità*).

90 Moreover, it should be noted that while, according to the majority of the language versions of Article 57(f) of Regulation No 1907/2006, there must be 'scientific evidence' that a given substance has possible or probable adverse effects, according to the German version, the answer to the question whether a substance has 'probable effects' must be based on '*wissenschaftliche Erkenntnisse*' (scientific knowledge).

91 Notwithstanding those terminological differences, it should be pointed out that the phrase 'scientific evidence' ('scientific knowledge' in German) refers to the standard of proof which ECHA must meet in order to be able to conclude that a substance has serious effects on human health or the environment.

92 Apart from making the standard of proof dependent on a scientific approach, as is indicated by the wordings 'scientific evidence' or 'scientific knowledge', Article 57(f) of Regulation No 1907/2006 does not stipulate what that approach is to consist in. Neither the General Court nor the Court of Justice has, until now, been called upon to provide further details in that connection. Admittedly, 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' — more specifically, the scientific probability — that a substance 'may' have adverse effects on the environment was sufficient to establish a causal link within the meaning of Article 57(f) of Regulation No 1907/2006. In doing so, the Court confined itself to observing that the finding of the existence of a 'probable' causal link corresponded, in any event, to the standard of proof required by that provision. However, it did not rule definitively on the question relating to the standard of proof.

93 In that connection, first, it should be observed that the expressions 'scientific evidence' and 'scientific knowledge' are synonyms. The existence of scientific knowledge or scientific methods or rules can only be recognised provided that those elements are based on scientific evidence.

94 Secondly, it should be noted that when ECHA conducts an analysis of the intrinsic properties of a substance, it is bound by the principle of scientific excellence, which means that it must comply with the best current scientific standards. The standards applied by scientists in the identification of endocrine disruptors at the time when the contested decision was adopted followed from the recommendations set out in the JRC's report entitled 'Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances — Report of the Endocrine Disrupters Expert Advisory Group'. According to those recommendations, a substance is an endocrine disruptor if it is demonstrated that there is a 'plausible' causal link between the endocrine-related mode of action of that substance and the undesirable effects on health. In other words, the facts and evidence relied upon in the examination of a substance must serve to establish that it is 'plausible' that the mode of action of that substance can lead to certain adverse effects. By contrast, Article 57(f) of Regulation No 1907/2006 does not require absolute proof of a causal relationship.

95 Lastly, the standard of proof and, accordingly, the factors mentioned in paragraphs 91 to 94 above must be clearly distinguished from the question whether it should be found that there exists an endocrine disruptor of very high concern when it is demonstrated that a substance has 'possible' negative effects or that it has 'probable' adverse effects. That second question refers to the nature of the effects observed and, consequently, one of the factors that are the subject of the examination of the intrinsic properties of a substance. It bears no relation to the standard of proof required by Article 57(f) of Regulation No 1907/2006.

96 In that connection, reference must again be made to paragraph 173 of the judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329). According to that case-law, in short, a substance can be considered to be an endocrine disruptor of very high concern when it is demonstrated that it 'may' have adverse effects. The assessment of the intrinsic properties of the substances referred to in Article 57(f) of Regulation No 1907/2006 is not in fact an assessment of the risks arising from the practical use of a substance or exposure to it, but rather an assessment of the hazards of that substance.

97 In that regard, it should be noted that, according to settled case-law, the concept of 'risk' constitutes a function of the 'probability' that use of a product or a procedure will adversely affect the interests safeguarded by the legal order (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 147, and of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 76). In other words, there can be a finding as to the existence of a risk only in so far as it is a question of probable effects.

98 By contrast, it is clear from settled case-law that the concept of 'hazard' describes any product or procedure 'capable' of having an adverse effect on human health (judgments of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 147; of 11 September 2002, *Alpharma* v *Council*, T-70/99, EU:T:2002:210, paragraph 160; of 9 September 2011, *Dow AgroSciences and Others* v *Commission*, T-475/07, EU:T:2011:445, paragraph 147; and of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission*, T-31/07, not published, EU:T:2013:167, paragraph 144). In other words, as regards the hazardous nature of a substance, any finding should be based on the

'possible' undesirable effects of that substance, not the 'probable' effects. The Union legislature's approach on this point is also in line with the precautionary principle referred to, inter alia, in Article 1(3) of Regulation No 1907/2006 (judgment of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 173).

99 In the light of the foregoing, the applicant's complaint that ECHA added a 'plausibility' criterion to the 'probability' criterion referred to in Article 57(f) of Regulation No 1907 cannot succeed. ECHA did not in fact add any additional threshold to that provision. The applicant's argument referred to in paragraph 88 above is actually based on confusion between (i) the question of 'plausibility' as a criterion to be satisfied by all of the evidence gathered by ECHA (see paragraphs 91 to 94 above) and (ii) the question of the possible or probable nature of the effects of a substance (see paragraphs 95 to 98 above).

100 Moreover and lastly, it should be observed that, in the present case, in recitals 9 and 12 of the contested decision, ECHA qualified the effects attributable to bisphenol A as 'probable'. The same term also appears in the very first paragraph of the summary included on page 13 of the Support Document, as well as in the first paragraph of Section 6.3.3 of that document. On account of the fact that the language of the case was English and that all the stakeholders had in mind the English version of Regulation No 1907/2006, which requires that there be 'probable' effects, it must be found that the choice, made by ECHA and the competent French authority, of that term was a conscious and deliberate choice. That finding arises, inter alia and similarly, from the reply to Comment No 64 set out in the full version of the RCOM Document (Annex B1 to the defence), which states that bisphenol A 'first decreases estradiol levels by disturbing P450arom protein expression' and that it is 'likely' that 'the prolonged status of reduced estradiol subsequently provokes decreased feedback regulation of [gonadostimulin] LH [, that is, lutenising hormone], lengthening of the [oestrous] cycle as well as ovarian cell apoptosis'.

101 Moreover, the observations contained in the Support Document describe the specific effects of bisphenol A on reproductive function, mammary gland development, cognitive function and metabolism, in part, as being definite and unequivocal effects. The author of that document uses language intended to leave no scope for doubt as to bisphenol A's endocrine disrupting properties of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006. It is a wording which strives to demonstrate not only that the effects observed are 'possible' but also that the findings made take 'likely' effects into account. Although, from a strictly legal perspective, it is not required to establish the probable nature of the serious effects on health or the environment, ECHA has made such a finding in the present case. In doing so, it has, in any event, complied with the standard of proof required by the regulation in question.

102 In the light of the foregoing, the applicant's argument referred to in paragraph 54 above must be rejected.

103 Secondly, as to whether ECHA correctly applied the standard of proof referred to in Article 57(f) of Regulation No 1907/2006 in the present case in the light of the mode of action of bisphenol A and the effects of that substance on human health (see paragraph 87 above), the following should be noted.

104 First, in paragraphs 75 and 79 to 81 of the application, the applicant starts from the premiss that there is a distinction between the endocrine mode of action and the endocrine mechanism of action of a substance, without stating what it means by those terms or whether, in its view, regard must be had to one or the other in order to ascertain the extent to which it is possible to speak of an endocrine disruptor of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006. The applicant's arguments concerning the mode and mechanism of action, which are vague, call for the following clarifications.

105 On pages 19 and 20 of the Support Document, ECHA provides a detailed explanation, which is not disputed by the applicant and should be upheld, on the difference between a mode of action and a mechanism of action. According to that agency:

'The mechanism of action is typically defined as the totality of mechanistic steps, whereas the [mode of action] refers to a less detailed sequence of key events. [The mode of action] is not intended to build a comprehensive model of a chemical mechanism of action. This is also in line with definitions proposed in the OECD guidance document on adverse outcome pathways (AOP) (OECD 2013): "[The mode of action] differs from [the mechanism of action], in that the [mode of action] requires a less detailed understanding of the molecular basis of the toxic effect". For the purposes of the present analysis, the following definition is retained for [mode of action]: "A sequence of key cellular and biochemical events with measurable parameters that result in a toxic effect."'

106 Secondly, it is correct that it is noted in the second paragraph of Section 4.6 of the Support Document (page 152 of that document) that the 'primary target of [bisphenol A] is however still not known with certainty'. However, setting aside the fact that the applicant has failed to cite the phrase 'with certainty', it has also omitted the conclusion of the overall assessment stated just above, according to which:

'[The Support Document contains] the available evidence showing that [bisphenol A] can affect a number of physiological functions and systems of a mammal organism through [endocrine disrupting] pathways. More specifically, [bisphenol A] alters the reproductive function, mammary gland development, cognitive functions and metabolism through an [endocrine-disrupting mode of action]. Most importantly, although the steps of the respective mechanisms of action are specific for each effect, the disruption of the estrogenic pathways is a common [mode of action] consistently involved in each of the four effects.'

107 Moreover, it should be observed that the applicant has failed to support in any way its claims that, in essence, ECHA has failed conclusively to demonstrate that there was 'a respective [mode of action] or mechanism of action that [was] relevant for an observed adverse effect' (see paragraph 55 above and paragraph 80 of the application). According to the applicant, as evidence of the endocrine mechanism has not been adduced, ECHA has failed to demonstrate that the substance at issue had endocrine disrupting properties or that it met the criteria under Article 57(f) of Regulation No 1907/2006 in so far as concerns any of the four alleged effects, namely the effects on the reproductive system, mammary glands, cognitive functions and metabolism (see paragraph 55 above and paragraph 81 of the application).

108 In that connection, it should be observed that Table 6 on page 46 of the Support Document describes the endocrine disruption-mediated mode of action of bisphenol A on alteration of oestrous cyclicity using a description of underlying cellular and molecular events and a description of the associated alteration of organs or certain functions. Table 7 provides an overview of the elements supporting the identification of an alteration of oestrous cyclicity as an endocrine disruption-mediated effect of bisphenol A. So far as concerns the alteration of mammary gland development, Sections 4.3.4 and 4.3.5, and in particular figures 13 and 14, on pages 67 and 68 of the Support Document, describe the mode of action of bisphenol A having regard to that adverse effect. The relevance in humans of the mode of action is discussed in Sections 4.3.6 and 4.3.7 and the 'plausible' link between adverse effects on mammary glands and the endocrine-related mode of action is summarised in Section 4.3.8 (see pages 70 and 71 of the Support Document). Concerning the alteration of brain development and cognitive function, in Section 4.4.2 of the Support Document on adverse effects (see page 95 of the Support Document), contextual information is provided concerning learning, memory and underlying cellular and molecular mechanisms. Section 4.4.3 provides information on the endocrine-related mode of action, the plausible link between that mode of action and adverse neurological effects, and the relevance in humans. Table 19 on page 107 of the Support Document defines the endocrine disruption-mediated mode of action of bisphenol A on learning and memory, by providing a description of underlying cellular and molecular events and the associated alteration of organs and

certain functions. Table 20 gives an overview of the elements supporting identification of alteration of learning and memory as an endocrine disruption-mediated effect of bisphenol A. The effects on metabolism and obesity are described in Section 4.5 of the Support Document, in which detailed information is provided on the way in which biochemical pathways can be affected (see in particular Sections 4.5.2.2 and 4.5.3.2). A description of the link between the mode of action and adverse effects observed is presented in Sections 4.5.2.3 and 4.5.3.3. The relevance in humans is discussed and summarised in Sections 4.5.4 and 4.5.5.

109 In the light of those elements, as is apparent from the summary contained in Section 4.6 of the Support Document, ECHA found that it had been demonstrated that the disruption of oestrogen pathways was a common mode of action, consistently involved in each of the four effects, and that the sequence of essential cellular and biochemical events had been presented with measurable endpoints which had given rise to toxic effects. In particular, ECHA found that the available evidence showed that bisphenol A affected various physiological functions, including, in particular, the hormonal functions of oestrogens. Moreover, as is apparent, in essence, from Section 6.3.1 of the Support Document (page 153 thereof), the endocrine disruptor mode of action affecting oestrogen pathways is known with sufficient certainty, but there is, furthermore, enough evidence to suspect that bisphenol A possesses other endocrine disruptor modes of action in addition to that which has already been identified. In the sixth paragraph on page 159 of the Support Document, it is stated that:

'It is also noted that some evidence points towards a disruption by [bisphenol A] of the Hypothalamo-Pituitary-Thyroid axis. Thyroid hormones are known to regulate sex steroid synthesis and action in both brain and gonads as well as fat metabolism. The crosstalk between the sex steroid and the thyroid endocrine axes was recently reviewed by Duarte-Guterman *et al* (2014).'

110 The applicant has failed to address those assessments specifically. Its complaints are of a general nature, although this does not deprive them of plausibility.

111 Consequently, the mere claim that ECHA confines itself to '"associating" an effect to an endocrine-related [mode of action]' (see paragraph 55 above) does not prove the existence of a manifest error of assessment. In order to deprive ECHA's assessments as to the mode of action of bisphenol A of plausibility, the applicant ought to have supported that claim with specific evidence drawn from the Support Document or other documents which served as the basis for the reasoning behind the contested decision. However, this is not the case. Similarly, rather than simply confining itself to recalling the criterion according to which only a 'defined and consistent biological response is sufficiently precise to be linked to a mode of action' — which is, furthermore, a classic and well-known criterion in the scientific world — the applicant ought to have demonstrated that the studies relied on by ECHA did indeed fail to apply that criterion or that, in order to prove the effects brought about by the mode of action of bisphenol A, ECHA had, in complete disregard of that criterion, taken into account studies which used a different criterion. Lastly, the mere fact of claiming that, in order to assess the risks linked to bisphenol A, ECHA used a protocol similar to that developed by EFSA for assessing that substance in the context of the uses of the substance involving contact with foodstuffs, can in no way support the criticisms put forward by the applicant with regard to the findings to be made as to the endocrine mode of action of bisphenol A.

112 In the light of the foregoing, the arguments referred to in paragraphs 53 to 55 must be rejected.

113 In the fourth place, as regards the applicant's argument alleging that ECHA failed to demonstrate that the alleged adverse effects of bisphenol A gave rise to 'an equivalent level of concern' to that arising from the effects of substances meeting the criteria in Article 57(a) to (e) of Regulation No 1907/2006 (see paragraph 56 above), it should be noted that the applicant has failed to explain how the assessment of the equivalent level of concern conducted by ECHA, set out in Section 6.3.2 of the Support Document, does not demonstrate that the adverse effects of bisphenol A give rise to an equivalent level of concern. Nowhere in the application or the reply is reference made to the

assessment of the equivalent level of concern conducted by ECHA in Section 6.3.2 of the Support Document. To submit, as the applicant does, that the finding of an equivalent level of concern required under Article 57(f) of Regulation No 1907/2006 ought to be based on human studies or on data from studies in animals establishing a strong presumption of the existence of effects is admittedly not, per se, an irrelevant argument. However, the applicant has failed to demonstrate on the basis of specific and verifiable elements that ECHA failed to comply with that criterion in the light of the studies on which its assessments were based. Moreover, concerning the applicant's argument regarding the determination of the equivalent level of concern, ECHA observes, in its defence, that the applicant has not once referred to the part of the Support Document where it is allegedly established that the adverse effects were of an equivalent level of concern or where the reasons for that situation were referred to (see paragraphs 106 and 107 of the defence). There is also no such reference in the reply. It must therefore be concluded that the applicant has failed to prove that ECHA committed a manifest error of assessment on that point, so that the arguments referred to in paragraph 56 above must be rejected as unfounded.

114 It follows from the foregoing that the matters raised by the applicant seeking to contest the scientific assessment conducted by ECHA do not render implausible the assessments on which the contested decision is based. Consequently, the second complaint in the first branch of the second plea in law must be rejected as unfounded.

(3) The third complaint in the first branch of the second plea: manifest error of assessment in that ECHA failed to consider the safe level for the use of bisphenol A required in other provisions of EU law

115 In the context of the third complaint in the first branch of the second plea, the applicant criticises ECHA for having failed to consider the safe level for the use of bisphenol A, as required in certain provisions of EU law, as a relevant factor for the assessment of bisphenol A in the light of the criteria laid down in Article 57(f) of Regulation No 1907/2006.

116 According to the applicant, EU legislation provides for a safe level for the use of bisphenol A, in particular under the legislation concerning contact with food and toys. More specifically, the use of bisphenol A as a monomer in the production of plastic materials and articles used in contact with food is authorised subject to a specific migration limit of 0.6 mg of bisphenol A per kilogramme of food. It is argued that this is clear from Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ 2011 L 12, p. 1). Pending the anticipated outcome of the Clarity-BPA programme, EFSA recently established a temporary tolerable daily intake ('t-TDI') of 4 µg/kg body weight/day. Lastly, in relation to the use of bisphenol A in toys, a specific limit value was set by Commission Directive (EU) 2017/898 of 24 May 2017 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards bisphenol A (OJ 2017 L 138, p. 128). According to the applicant, under that directive, the 'limit reflecting current scientific knowledge' must be set at 0.04 mg/l to ensure the safety of bisphenol A when used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. None of those levels was taken into account by ECHA for the purposes of the contested decision, even though they were established in relation to bisphenol A vis-à-vis the most sensitive applications for human health, namely food contact materials.

117 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

118 As a preliminary point, inasmuch as the applicant refers to the safe level for the use of bisphenol A developed, inter alia, in the context of legislation relating to contact with food and toys, it is clear that the applicant is referring to the use of bisphenol A as a monomer, namely as a substance capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process (Article 3(6) of Regulation

No 1907/2006). In doing so, the applicant refers to bisphenol A as a substance which, through a polymerisation reaction, is converted into a repeating unit of the polymer sequence. Any substance used as a monomer in the manufacture of a polymer is, by definition, an intermediate (see Article 3(15) of Regulation No 1907/2006).

119 First, it is common ground that bisphenol A is also used for non-intermediate purposes. This is the case where it is used in the manufacture of thermal paper (see paragraph 1 above). To the extent that that substance is used as a non-intermediate, in the light of the clarifications set out in paragraph 118 above, the argument which the applicant derives from the legislation on the specific safe level developed for the use of bisphenol A in toys and items in contact with food is ineffective. As is apparent from Entry 151 in Table 1 of Annex I to Regulation No 10/2011, the safe level referred to by the applicant as regards plastic items intended to come into contact with food, namely the specific migration limit of 0.6 mg of bisphenol A per kilogramme of food, applies to intermediate uses only. That is the case for the migration limit of bisphenol A in toys, which is 0.04 mg/l, as laid down in Article 1 of Directive 2017/898.

120 Secondly, to the extent that that substance is used as an intermediate, it should be observed that, admittedly, establishing the safe level provided for the use of bisphenol A in the legislation relating to contact with food and toys is one of the relevant factors which may be taken into account by ECHA in the examination of the 'equivalent level of concern' referred to in Article 57(f) of Regulation No 1907/2006.

121 Generally, by providing that substances can be identified, on a case-by-case basis, if their serious effects on human health give rise to 'an equivalent level of concern' to that for those substances meeting the criteria for classification in the hazard classes carcinogenicity, mutagenicity or reproductive toxicity, Article 57(f) of Regulation No 1907/2006 does not prohibit the taking into consideration of data other than those relating to the hazards arising from the intrinsic properties of the substances concerned (judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA*, C-324/15 P, EU:C:2017:208, paragraph 40). Regulation No 1907/2006 seeks to reserve the authorisation procedure to certain substances, identified as being of very high concern, not only on account of the seriousness of their dangerous effects on health or on the environment, but also having regard to other factors. The latter 'may include', inter alia, the difficulty of adequately assessing the risks posed by those substances when it is impossible to determine, with the necessary certainty, a 'derived no-effect level' or a 'predicted no-effect concentration' (judgment of 15 March 2017, *Hitachi Chemical Europe and Polynt* v *ECHA*, C-324/15 P, EU:C:2017:208, paragraph 39). It follows that the migration limit of bisphenol A in certain objects, such as items intended to be in contact with food or toys, is a factor which ECHA can take into account for the purposes of identifying substances of very high concern, without that factor being decisive in that respect, and without it therefore being possible to conclude that the decision referring to such an identification is vitiated by a manifest error of assessment merely on account of a failure to take the permitted migration limit into account.

122 However, contrary to what the applicant appears to be relying on in Section 6.3.2 of the Support Document (pages 165 and 166 thereof), ECHA did indeed examine the possibility of establishing a safe level of concentration and concluded that that was difficult, as there were significant uncertainties surrounding the establishment of a quantitative dose-response relationship and because certain studies had detected effects at doses lower than the starting point used for establishing the derived no-effect level.

123 In particular, it is noted on pages 165 and 166 of the Support Document that, with regard to the effects on metabolism, recently published studies had reported effects of bisphenol A at doses equivalent to or below the doses used in previous regulatory assessments. Whilst noting that the level of sensitivity also depended on the window of exposure and the susceptibility of the exposed population, it is asserted in the Support Document that it would be difficult to define a safe level with a sufficient level of confidence, as the new data would cast doubt on current limits. It is also stated in the Support

Document that collective knowledge of the endocrine disrupting effects of bisphenol A may not be complete, as there is emerging evidence of an effect of bisphenol A on the immune function which raises concerns as to possible effects at doses lower than the starting point used for establishing the derived no-effect level.

124 The applicant has failed to dispute those elements in a substantiated manner and through the submission of evidence. By referring simply to certain specific limits laid down, in the relevant legislation, in respect of materials in contact with foods and toys, the applicant therefore fails to rebut the conclusions set out in the Support Document demonstrating that, overall, there are uncertainties in establishing a quantitative dose-response and safe levels. That being the case, the argument referred to in paragraph 115 above does not render ECHA's assessments implausible on that point.

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

(b) Second branch of the second plea in law: breach of the duty of care

126 In the context of the second branch of the second plea, the applicant claims that, when it identified bisphenol A as a substance of very high concern, ECHA failed to take into account all the relevant information carefully and impartially. More specifically, ECHA failed to take into consideration the fact that, on the date of adoption of the contested decision, bisphenol A was still undergoing specific tests, such as those which were to be conducted as part of the Clarity-BPA programme mentioned in paragraphs 2 and 4 above. The applicant claims that by knowingly identifying bisphenol A as a substance of very high concern on the basis of incomplete evidence, and by basing its decision on an incomplete dossier prepared in accordance with Annex XV, ECHA not only committed a manifest error of assessment but also breached its duty of care.

127 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

128 As a preliminary point, it should be observed that the argument relied upon in support of the second branch of the second plea has no independent scope in the present action, but rather supplements the line of argument claiming the existence of a manifest error of assessment (see paragraph 126 above). Having regard to the fact that the applicant has failed to demonstrate the existence of such an error, there is no longer any need to address the argument alleging breach by ECHA of its duty of care.

129 Moreover, were there a need to address that argument, it would be recalled that the guarantees afforded by the EU legal order in administrative proceedings include, in particular, the principle of sound administration, enshrined in Article 41 of the Charter of Fundamental Rights of the European Union, which entails the duty of care, that is, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case (judgments of 27 September 2012, *Applied Microengineering* v *Commission*, T-387/09, EU:T:2012:501, paragraph 76, and of 16 September 2013, *ATC and Others* v *Commission*, T-333/10, EU:T:2013:451, paragraph 84).

130 In the present case, the applicant has not demonstrated that ECHA failed to examine carefully and impartially all the relevant aspects of the present case. In particular, as noted in paragraph 163 above, it was not for ECHA to postpone the adoption of the contested decision pending the publication of the results of the Clarity-BPA Programme. Those results therefore do not form part of the aspects to be taken into account for the purposes of adopting the contested decision.

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

2. First plea in law: infringement of the principle of legal certainty

132 By its first plea, the applicant claims that ECHA infringed the principle of legal certainty by (i) using a series of allegedly inconsistent criteria in the contested decision, and (ii) failing to establish a clear and precise set of criteria for assessing endocrine disruptors under Article 57(f) of Regulation No 1907/2006. All the arguments relied on in support of the first plea may be grouped into two separate branches.

(a) First branch of the first plea: alleged inconsistency in the criteria used during the assessment that served as the basis for the contested decision

133 In support of the first branch of the first plea, the applicant claims that the Support Document, which served as the basis for the discussions of the Member State Committee and is based on the dossier prepared in accordance with Annex XV, is vitiated by an 'internal inconsistency', as is the contested decision.

134 On the one hand, the Support Document refers to the WHO definition of 'endocrine disruptor'. According to that definition, an 'endocrine disruptor' is 'an exogenous substance or mixture that alters functions of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations'. The applicant argues that that definition requires a causal link to be established between the alteration of the functions of the endocrine system and the adverse effects on health.

135 On the other hand, the Member State Committee's Support Document also states that it is assumed that, in order to be identified as an endocrine disruptor, a substance must fulfil the recommendations from the European Commission's Expert Advisory Group on Endocrine Disruptors. Those recommendations stem from a JRC report entitled 'Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances — Report of the Endocrine Disrupters Expert Advisory Group'. According to the applicant, under those recommendations, a substance can be identified as an endocrine disruptor only if the adverse health effects resulting from the alteration of the functions of the endocrine system have a 'biologically plausible' causal link to an endocrine disrupting mode of action ('the JRC definition').

136 The WHO and JRC definitions, it is claimed, differ from each other to such an extent that the applicant could not have foreseen how it might be affected.

137 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

138 As a preliminary point, it should be recalled that, according to settled case-law, the principle of legal certainty, which is part of the general principles of EU law, requires that legal rules be clear and precise and aims to ensure that situations and legal relationships governed by EU law remain foreseeable (judgments of 22 October 1998, *Jokela and Pitkäranta*, C-9/97 and C-118/97, EU:C:1998:497, paragraph 48, and of 15 September 2005, *Ireland* v *Commission*, C-199/03, EU:C:2005:548, paragraph 69). That principle requires that the binding nature of any act intended to produce legal effects be derived from a provision of EU law which must be expressly indicated as its legal basis and which prescribes the legal form to be taken by that act (see judgment of 19 June 2015, *Italy* v *Commission*, T-358/11, EU:T:2015:394, paragraph 123 and the case-law cited; see also, to that effect, judgment of 23 January 2019, *Deza* v *ECHA*, C-419/17 P, EU:C:2019:52, paragraphs 69 and 72). The principle of foreseeability is an integral part of the principle of legal certainty (judgment of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 135; see also, to that effect, judgment of 11 December 2003, *AMOK*, C-289/02, EU:C:2003:669, paragraph 30).

139 In the present case, in the first place, the binding force of the contested decision arises from a provision of EU law, which was expressly indicated. That decision refers in fact to Article 59(8) of Regulation No 1907/2006 as its legal basis. Furthermore, that decision sets out all necessary parameters for identifying its legal effects, in a clear and precise manner, thus allowing the applicant to ascertain unequivocally the scope of that decision. More specifically, it is clear from that decision that it is intended to supplement the existing entry relating to bisphenol A on the Candidate List of substances with an identification as an endocrine disruptor of very high concern for which there is scientific evidence of probable serious effects on human health within the meaning of Article 57(f) of Regulation No 1907/2006. Furthermore, it defines why bisphenol A was identified as a substance having endocrine disrupting properties within the meaning of Article 57(f) of Regulation No 1907/2006.

140 In the second place, to the extent that the applicant complains that ECHA applied different scientific criteria in the Support Document — which reflects the clarifications supplied by the competent French authority in the dossier drawn up in accordance with Annex XV, which allegedly led to an infringement of the principle of legal certainty — it should be observed that the WHO and JRC definitions, as referred to in the Support Document, both contain a multitude of criteria which cannot be placed on the same footing as legal rules within the meaning implied by the principle of legal certainty, which is intended to ensure that situations and legal relationships governed by EU are foreseeable (see paragraph 138 above). Those definitions are scientific elements.

141 Without it being necessary to determine if and how the two definitions referred to by the applicant — which, in any event, share the concept of a causal link — are different, and without there being a need to determine the cases in which the application, by an EU institution, of a series of allegedly inconsistent or insufficient scientific criteria can give rise to uncertainty at a legal level, of such seriousness that it can be found that there is infringement of the principle of legal certainty itself, it is clear that, contrary to what the applicant suggests, neither the Support Document nor, accordingly, the contested decision is vitiated by any 'internal inconsistency'. ECHA did not apply two allegedly different series of criteria at the same time. On the contrary, a closer examination shows that the approach taken in the Support Document consists in simply giving precedence to the JRC definition.

142 In Section 4 of the Support Document, and more specifically page 18 thereof, ECHA stated that the WHO definition was 'widely accepted'. However, that finding and the list of subcriteria which serve to define endocrine disruptors, as envisaged by the WHO, are immediately followed by an explanation of how to define an endocrine disruptor, according to the European Commission's Endocrine Disrupters Expert Advisory Group, as noted in the JRC Report referred to in paragraph 135 above. That is the definition proposed by that group of experts in 2013.

143 Contrary to what the applicant appears to argue, ECHA did not confine itself to referring to those factors. On the contrary, it is stated unequivocally in Section 4 of the Support Document:

'It is assumed in [that] report that a substance should fulfil the recommendations from the European Commission's Endocrine Disrupters Expert Advisory Group … in order to be identified as an endocrine disruptor, and available information has accordingly been assessed based on:

– Adverse health effects

– Endocrine mode of action (MoA)

– Plausible link between adverse effects and [endocrine mode of action]

– Human relevance'.

144 That finding is sufficient to reject the first branch of the first plea in law.

(b) Second branch of the first plea in law: failure to lay down in writing a set of criteria for the identification of endocrine disruptors under Article 57(f) of Regulation No 1907/2006

145 The second branch of the first plea alleges that a set of scientific criteria has not been laid down that ECHA may apply in order to identify endocrine disruptors under Article 57(f) of Regulation No 1907/2006. It is claimed that in the absence of any clearly defined criteria, it was impossible for the applicant to predict how ECHA would define endocrine disruptors in the light of that provision.

146 In the first place, that impossibility results from the current regulatory state of flux surrounding the identification of endocrine disrupting properties. No consensus has been reached at EU level thus far as regards the definition of an endocrine disruptor. Since 2016, the Commission has presented four alternative options for the development of criteria enabling endocrine disruptors to be defined and three different options for the development of the regulatory decision-making procedure to be followed. Nor do the various pending initiatives within the European Union vis-à-vis the identification of bisphenol A as an endocrine disruptor allow a clear conclusion to be drawn in that regard. In its technical report of 30 November 2017, entitled 'Bisphenol A (BPA) Hazard Assessment Protocol', EFSA stressed that 'it [was] essential that well-defined and transparent scientific criteria concerning the selection of the new scientific studies [be] laid down in advance of the re-evaluation'. The specific aim of that report was to ensure an efficient, transparent and methodologically rigorous re-evaluation of bisphenol A. The draft report was published before the contested decision was adopted.

147 In the second place, the applicant claims that it follows from paragraph 120 of the judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329), that ECHA may draw up its own criteria for the identification of a substance as an endocrine disruptor within the meaning of Article 57(f) of Regulation No 1907/2006. However, ECHA has not, to date, produced any guidance on the correct way of identifying endocrine disruptors within the framework of Regulation No 1907/2006 in a systematic and foreseeable manner. In other words, ECHA has not adopted 'its own criteria' for the identification of endocrine disruptors under Article 57(f) of Regulation No 1907/2006. Since ECHA has not established a transparent and rigorous methodology for the evaluation of bisphenol A in particular, it was impossible for the applicant to foresee how ECHA would apply Article 57(f) of Regulation No 1907/2006 to its situation.

148 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

149 In the first place, by the complaints referred to in paragraphs 146 and 147 above, the applicant submits in essence that EU law guarantees, in the sphere covered by Regulation No 1907/2006, the right for stakeholders, such as the applicant's members, to be fully in a position to anticipate the exact content of the scientific criteria which allow ECHA to identify endocrine disruptors for the purposes of applying Article 57(f) of Regulation No 1907/2006.

150 Leaving aside the fact that that is not the meaning of 'foreseeability' covered by the principle of legal certainty, it should be observed in that connection that it is common ground that ECHA has used the JRC definition in its settled practice since 2014. ECHA's established use of the JRC definition since 2014 may be considered to be a consistent and foreseeable approach for all stakeholders active in the field of substances that may be identified as being endocrine disruptors of very high concern. Both the applicant and its members were perfectly aware — or ought to have been aware — of the existence of that definition, well before the date of adoption of the contested decision.

151 Those grounds are sufficient to reject all of the arguments referred to in paragraphs 146 and 147 above.

152 In the second place, it should be pointed out that it was held in paragraph 120 of the judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329) that it is permissible for ECHA to draw up its own criteria for the identification of a substance as an endocrine disrupting substance of very high

concern within the meaning of Article 57(f) of Regulation No 1907/2006. Within the edifice of European bodies and institutions, that agency is the central entity responsible for ensuring the effective management, inter alia, of the scientific aspects of Regulation No 1907/2006 at European Union level (see recital 15 of that regulation). As regards the criteria for identifying a substance as an endocrine disruptor within the meaning of Article 57(f) of Regulation No 1907/2006, ECHA can not only develop such criteria itself, but it can also fully rely in that respect on criteria developed by other scientists. Whether it sets down its own criteria or aligns itself with criteria developed by other scientists, ECHA must, in the context of any scientific assessment, comply with the principles of excellence, transparency and independence (see, by analogy, judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 172). In paragraph 61 of the judgment of 23 January 2019, *Deza* v *ECHA* (C-419/17 P, EU:C:2019:52), the Court of Justice upheld the approach taken by the General Court in paragraph 120 of the judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329).

153 By contrast, contrary to the applicant's submissions, ECHA is not itself required to develop such criteria beforehand or lay them down in writing. No provision of Regulation No 1907/2006 provides for a specific obligation for ECHA to provide methodological guidance containing the criteria for identifying endocrine disruptors generally, let alone methodological guidance including the criteria for assessing bisphenol A in particular. Furthermore, it should be observed that, in its judgment of 11 May 2017, *Deza* v *ECHA* (T-115/15, EU:T:2017:329), the Court did not hold that it was for ECHA to lay down in writing scientific criteria for the identification of endocrine disruptors of very high concern. On appeal against that judgment, the Court of Justice also did not find, for its part and furthermore, that ECHA was under such an obligation (judgment of 23 January 2019, *Deza* v *ECHA* C-419/17 P, EU:C:2019:52).

154 Moreover, admittedly, pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ 2012 L 167, p. 1), the Commission was to adopt measures specifying scientific criteria for the determination of endocrine disrupting properties by 13 December 2013 at the latest. However, that article does not lay down the same obligation for ECHA.

155 In those circumstances, the second branch of the first plea in law must be rejected as unfounded, as must the first plea in its entirety.

3. Third plea in law: infringement of the principles of legal certainty and protection of legitimate expectations on the ground that ECHA did not await the publication of the results of the Clarity-BPA programme

156 By its third plea, the applicant submits that the best way of ensuring legal certainty in the present case would have been for ECHA to await and take into account the publication of the results of the Clarity-BPA programme mentioned in paragraph 2 above. Moreover, in the applicant's view, by failing to take into account all the relevant information with a view to adopting the contested decision, even though it had expressly stated in the decision on the assessment that it was necessary to take such matters into account, ECHA infringed the principle of protection of legitimate expectations.

157 In the first place, according to the applicant, the contested decision places all its members in a situation of legal uncertainty which cannot be resolved until the results of the Clarity-BPA programme are delivered. According to the applicant, if that programme provides evidence against the inclusion of bisphenol A in the Candidate List, its members will not be in a position to foresee what ECHA will do, since Regulation No 1907/2006 does not provide for any formal procedure to remove a substance — in the present case, an entry — from the Candidate List.

158 In the second place, the applicant claims that it could legitimately have expected that ECHA would take the results of the Clarity-BPA programme into account for the purposes of assessing the properties of bisphenol A as an endocrine disruptor. It is argued that by adopting the contested decision when the Clarity-BPA study had yet to be published, ECHA infringed the principle of protection of legitimate expectations.

159 First, the applicant claims that, in the Evaluation Decision (see paragraph 4 above), the Clarity-BPA programme was recognised as being a relevant study in relation to the effects of bisphenol A, as an endocrine disruptor, on human health. ECHA therefore failed to take into consideration all relevant information in the contested decision, even though it expressly stated in the Evaluation Decision that it was necessary to do so. According to the applicant, in view of the assessments contained in the Evaluation Decision on bisphenol A, it had a legitimate expectation that ECHA would await the results of the Clarity-BPA programme.

160 Secondly, the guidelines drafted by ECHA entitled 'Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern' (see Annex A.3 to the application) makes clear that, as the first of five steps, ECHA was to 'collect the relevant information' and then assess it. Given ECHA's position on producing a dossier prepared in accordance with Annex XV, the applicant takes the view that it had a legitimate expectation that ECHA would await the results of the Clarity-BPA programme.

161 Thirdly, in paragraph 105 of the application, the applicant raises the following argument:

'Similarly, the Applicant had legitimate expectations based on the Equivalent Level of Concern Guidance that the derivation of a safe concentration is taken into account. By not doing so, the Agency frustrated such expectations.'

162 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

163 In the first place, by the argument alleging that ECHA was under an obligation to await the publication of the results of the Clarity-BPA programme before adopting a decision on the identification of bisphenol A as an endocrine disruptor of very high concern within the meaning of Article 57(f) of Regulation No 1907/2006, the applicant seeks to secure greater legal protection than that arising from the principle of legal certainty. That principle does not in fact require that a European Union institution await the preparation of a specific scientific study before taking a decision.

164 The applicant's argument that, in essence, in the event that the results of the Clarity-BPA programme 'do not justify the [inclusion] of bisphenol A in the Candidate List of substances', the applicant's members will not be in a position to foresee what ECHA will do, since Regulation No 1907/2006 does not provide for a formal procedure for withdrawing a substance from the Candidate List (see paragraph 157 above), must be rejected.

165 As ECHA rightly contends, as a general rule, all decisions can be reviewed subsequently in the light of new available information, without any provision expressly provided for in secondary legislation being required. It cannot be considered that a decision which is withdrawn following an internal review was, at the time of its adoption, contrary to the principle of legal certainty, as defined by case-law (see paragraph 138 above). The possibility that, at a future date, information will emerge which calls into question the merits of an EU measure can, admittedly, constitute the starting point for discussions as to the appropriateness of maintaining that act from that future date onwards. That possibility does not, however, call into question the answer to the matter of whether the effects of the measure referred to were foreseeable. Lastly, the fact that the regulation does not provide for a formal procedure for removing a substance from the Candidate List does not prevent ECHA from taking a decision according to Article 59(8) of Regulation No 1907/2006 when, at a certain point, the evidence is sufficient and the conditions under Article 57(f) of that regulation are satisfied. Even if it were to be

considered that the absence of an explicit rule allowing ECHA to withdraw a substance from the Candidate List of substances effectively prevents the inclusion of a substance in that list, ECHA would never be able to make such an inclusion.

166 In the second place, as regards the principle of the protection of legitimate expectations, it is clear from settled case-law that the right to rely on that principle extends to any person with regard to whom an institution of the Union has given rise to justified hopes and that a person may not plead a breach of that principle unless the administration has given him precise assurances (see judgment of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 137 and the case-law cited). In whatever form it is given, information which is precise, unconditional and consistent and comes from authorised and reliable sources constitutes assurances capable of giving rise to such expectations (see judgment of 14 March 2013, *Agrargenossenschaft Neuzelle*, C-545/11, EU:C:2013:169, paragraph 25 and the case-law cited).

167 In the present case, the applicant has failed to adduce evidence that it or one of its members received specific, unconditional and consistent assurances from ECHA or other reliable sources that the results of the Clarity-BPA programme would undoubtedly be taken into account when the contested decision was adopted.

168 First, the appraisals carried out by ECHA in the context of the assessment decision, as referred to in paragraph 4 above, cannot be understood as meaning that ECHA gave unconditional assurances that the Clarity-BPA programme would be taken into account. The remark contained in that decision that the need to obtain further information — from the industry in the context of the assessment procedure — could depend on the outcome of the Clarity-BPA programme is a recital, set out by ECHA, which is intended neither to be binding on the competent authority responsible for assessing bisphenol A, nor to announce which factors would be taken into account in the identification of bisphenol A as an endocrine disruptor of very high concern. That remark was therefore not an unconditional assurance in which the applicant or one of its members could legitimately base its expectations.

169 Moreover, even if it were to be found that it was a factor on which the applicant or one of its members could base its expectations, the fact remains that the remark in question could have an influence only in the context of the procedure for adopting the assessment decision pursuant to Article 46 of Regulation No 1907/2006. By contrast, it has no influence on the assessment of the question whether there is sufficient information to arrive at a viable conclusion so far as concerns the properties of bisphenol A as an endocrine disruptor which reaches the level of concern referred to in Article 57(f) of Regulation No 1907/2006. The procedure for evaluating a substance, referred to in Articles 44 to 48 of Regulation No 1907/2006, and the procedure for identifying a substance as a substance of very high concern, referred to in Article 57 to 59 of that regulation, pursue different objectives and provide for different timeframes. It is not apparent from Regulation No 1907/2006 that the legislature intended to make the identification procedure subject to the evaluation procedure that is carried out on the basis of the dossier submitted by a registrant in the context of the registration of a substance (see, to that effect, judgment of 30 April 2015, *Hitachi Chemical Europe and Others* v *ECHA*, T-135/13, EU:T:2015:253, paragraphs 63 and 107 and the case-law cited). The appraisals conducted simply for the purposes of the assessment procedure cannot therefore be deemed from the outset to constitute specific and unconditional assurance given in the context of the procedure for identifying a substance as being of very high concern.

170 Lastly, it cannot be excluded that the Clarity-BPA programme may not be the final stage of debate concerning the possibility that bisphenol A possesses endocrine disrupting properties. In fact, 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 (judgment of 30 April 2015, *Hitachi Chemical Europe and Others* v *ECHA*, T-135/13, EU:T:2015:253, paragraph 112).

171 Secondly, in so far as concerns the applicant's argument relating to the relevance of the guidance on preparing a dossier consistent with Annex XV to Regulation No 1907/2006, it is sufficient to note that, as ECHA rightly claims, the need to 'collect relevant information', as stated in the '[ECHA] Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern' can only be interpreted as specific and unconditional assurance that a scientific research study or programme will be expected. In that connection, that guidance describes only what it is for ECHA to do by virtue of its duty of care generally and pursuant to Regulation No 1907/2006 specifically.

172 Thirdly, to the extent that the applicant claims that ECHA 'frustrated its expectations' by failing to take into account the 'establishment of a safe concentration' of bisphenol A in mixtures or articles (see paragraph 161 above), it is clear that the issue of the acceptable concentration level of bisphenol A is not per se a factor on which the applicant or one of its members could base its legitimate expectations within the meaning of the case-law referred to in paragraph 166 above. ECHA in fact did not at any time indicate to the applicant or any of its members, in the form of a specific and unconditional assurance, that the decision on the identification of bisphenol A as an endocrine disruptor which meets the conditions under Article 57(f) of Regulation No 1907/2006 would be based on the taking into account of a certain level of concentration of that substance in mixtures or articles.

173 In the light of all the foregoing, the third plea must be rejected.

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

174 According to the applicant, 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 the latter provision, 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 an exception: as a 'catch-all' provision, it covers all other 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 a level of concern equivalent to that raised by the substances listed 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.

175 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. The requirement of an 'equivalent' level of protection, 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.

176 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

177 In response to the fourth plea, 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.

178 None of the applicant's other arguments can cast doubt on that finding. Those arguments must therefore be rejected as unfounded.

179 First, without there being any need to rule generally on the question of the substances in respect of which Article 57(f) of Regulation No 1907/2006 could be considered to be a 'catch-all provision', 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 sole provision in that regulation to do so. So far as concerns endocrine disruptors of very high concern, Article 57(f) of Regulation No 1907/2006 does not constitute a 'catch-all provision'.

180 Secondly, 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.

181 Thirdly, 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.

182 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 applicant's interpretation of that provision is based on a formalism which runs counter to the aim pursued by Regulation No 1907/2006, which consists, according to Article 1(1), in ensuring a high level of protection of human health and the environment.

183 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 points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59"' 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).

184 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 simple — and fairly cursory — description of the overall scheme of Article 57 of Regulation No 1907/2006, 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). 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.

185 Under those circumstances, the fourth plea must be rejected as unfounded.

5. Fifth plea in law: infringement of Article 2(8)(b) of Regulation No 1907/2006

186 In the context of the fifth 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' (see paragraph 1 above), whereas 'intermediates' are exempt from Title VII of that regulation in its entirety, and are thus outside the scope both of Articles 57 and 59 thereof and of the authorisation procedure.

187 In the applicant's view, first, according to the clear wording of Article 2(8)(b) of Regulation No 1907/2006, all isolated intermediates are exempt from Title VII of that regulation without exception and, therefore, also from the application of Articles 57 and 59 which form part of Title VII of that regulation. The wording of Article 2(8)(b) of the regulation at issue is in sharp contrast, for example, to the wording of Article 2(8)(a) of that regulation, which exempts intermediates from Chapter 1 of Title II 'with the exception of Articles 8 and 9'.

188 Secondly, the title of Article 57 of Regulation No 1907/2006, 'Substances to be included in Annex XIV', shows, in the applicant's view, 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 and establishing a Candidate List for eventual inclusion in Annex XIV'. 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.

189 Thirdly, 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 in its entirety would fall short of a high level of protection because intermediates could not be identified under Article 59 of Regulation No 1907/2006, it would have applied a correction to the exemption laid down in Article 2(8)(b) similar to the reference to 'strictly controlled conditions' in Articles 17(3) and 18(4) of that regulation. By not applying such a correction, the legislature clearly meant, in the applicant's view, for all intermediates to be exempt from Title VII in its entirety, with no exceptions or special conditions.

190 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

191 As a preliminary point, it should be pointed out that bisphenol A is used both as an intermediate and for non-intermediate purposes, and that the contested decision does not distinguish between those different types of use. In the context of its fifth 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 hypotheses 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.

192 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'.

193 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 that definition of an intermediate that a substance will or will not be classified as an intermediate depending on the intended purpose of its manufacture and use (judgment of 25 September 2015, *PPG and SNF* v *ECHA*, T-268/10 RENV, EU:T:2015:698, paragraph 66). 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. Preference is therefore given to a certain type of use of substances, inter alia, in Article 17(3) and Article 18(4) of that regulation.

194 Moreover, Article 3(15) of the regulation divides the uses of a substance for 'intermediate' purposes into three categories. The first category, '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, 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, '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).

195 In the present case, it is common ground that bisphenol A is used primarily as an on-site isolated intermediate or as a transported isolated intermediate.

196 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 be noted 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 stated in essence that 'on a literal interpretation …, the latter provision should lead to the conclusion that any substance used as an on-site isolated intermediate or as a transported isolated intermediate is, for that reason, automatically exempted from all the provisions of Title VII of [Regulation No 1907/2006]', that 'such a substance accordingly would 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', and that 'the authorisation procedure governed by Chapters 2 and 3 of Title VII of that regulation would thus be inapplicable to such a substance'.

197 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 noted, 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] concerns only the authorisation procedure laid down in Chapters 2 and 3 of Title VII of that regulation'.

198 It follows from paragraph 63 of the judgment of 25 October 2017, *PPG and SNF* v *ECHA* (C-650/15 P, EU:C:2017:802) that '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'.

199 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.

200 In those circumstances, without it being necessary to address each of the applicant's other arguments in turn, referred to in paragraphs 187 to 189 above, the fifth plea must be rejected as being, in part, ineffective (see paragraph 191 above) and, in part, unfounded (see paragraphs 192 to 199 above).

6. Sixth plea in law: infringement of the principle of proportionality

201 In the context of the sixth plea, the applicant claims that the contested decision exceeds the limits of 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.

202 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 (see Article 3(15) of Regulation No 1907/2006), those substances pose a much lower risk than other substances. 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. However, according to the applicant, the inclusion of intermediate uses of bisphenol A in the Candidate List will not contribute in any way 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, the inclusion of bisphenol A in the Candidate List is even less appropriate for the purposes of achieving the objectives of Title VII of Regulation No 1907/2006, considering 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.

203 In the second place, according to the applicant, ECHA had a choice between several measures and could have acted in such a way as to avoid confusion and mitigate the effects of lawful use of bisphenol A as an intermediate following its 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. According to the applicant, that solution allows substances used as both intermediates and non-intermediates to be included in the Candidate List, whilst respecting the provisions of Article 2(8)(b) of the regulation by clarifying that the inclusion in the Candidate List does not apply to bisphenol A when used as an 'intermediate', and ensuring better legal certainty with regard to the need to apply for authorisation under Article 60 of Regulation No 1907/2006 for intermediate uses.

204 ECHA, supported by the French Republic and ClientEarth, contests those arguments.

205 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).

206 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 (see paragraph 202 above), it should be observed that the applicant proceeds on a false premiss. As has already been noted in paragraph 193 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.

207 That being the case, it must be found 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 chiefly 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 on 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.

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

209 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. Case-law has already confirmed that 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).

210 In the second place, as regards the argument seeking to prove infringement of the principle of proportionality by reason of the failure to refer, in the Candidate List of substances, to the intermediate uses of a substance which may be used for intermediate and non-intermediate purposes, it should be observed that that argument was also raised in the case which gave rise to the judgment of 25 October 2017, *PPG and SNF* v *ECHA*, (C-650/15 P, EU:C:2017:802).

211 In respect of that argument, the Court stated, in paragraph 79 of the judgment of 25 October 2017, *PPG and SNF* v *ECHA*, (C-650/15 P, EU:C:2017:802), that a measure intended to '[accompany] 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'.

212 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.

213 In the light of the foregoing, the sixth plea must be dismissed as unfounded.

B. Further evidence

214 In its request relating to the lodging of the draft report of the Clarity-BPA programme referred to in paragraph 25 above as further evidence, the applicant states that that evidence is very relevant in support of several pleas in the application. More specifically, according to the applicant, it is intended to substantiate the pleas alleging infringement of the principles of legal certainty and protection of legitimate expectations on account of the failure to examine the ongoing Clarity-BPA study (third plea in law), and the existence of a manifest error of assessment and a breach, by ECHA, of its duty of care by not taking into consideration the fact that the Clarity-BPA study was ongoing (second plea in law).

215 Pursuant to Article 85(3) of the Rules of Procedure, the main parties may, exceptionally, produce or offer further evidence before the oral part of the procedure is closed or before the Court's decision to rule without an oral part of the procedure, provided that the delay in the submission of such evidence is justified.

216 Admittedly, the research programme's draft report submitted in evidence on 29 March 2018 could not be added to the case file concomitantly with the lodging of the application and the reply (see paragraphs 16 and 20 above), with the result that it must be regarded as admissible.

217 However, it should be observed that, as ECHA rightly contends, the draft report, which was submitted by the applicant and drafted subsequent to the adoption of the contested decision, cannot usefully be taken into consideration in connection with the review of the lawfulness of that decision. The applicant relies, in essence, on new analyses which were not available at the time when the contested decision was adopted and which were therefore not brought to ECHA's attention in the pre-litigation procedure which led to the adoption of that decision. According to case-law, in an action for annulment brought under Article 263 TFEU, the lawfulness of European Union measures must be assessed on the basis of the facts and the law as they stood at the time when those measures were adopted (see, to that effect, judgment of 21 May 2015, *Rubinum* v *Commission*, T-201/13, not

published, EU:T:2015:311, paragraph 84 and the case-law cited). Moreover, as has in essence been observed in response to the first and second pleas, ECHA was not required to take into account the results of the Clarity-BPA programme.

218 It is apparent from the considerations set out in paragraph 217 above that the draft report submitted by the applicant on 29 March 2018 must be regarded as ineffective.

219 In any event, aside from the fact that, as ClientEarth states without being challenged on that point by the applicant, the data contained in the research programme's draft report referred to in the letter of 29 March 2018 have not yet been the subject of peer review and therefore do not appear to be the final conclusions to be drawn from the programme, the applicant has failed to demonstrate how those data could have contributed to dispelling the alleged scientific uncertainty which it complains of. Similarly, the applicant has failed to establish how those data would have altered the assessment carried out by ECHA in the light of all of the evidence on which that agency based the contested decision.

220 Accordingly, the applicant's request to submit further evidence must be rejected.

C. On the request that appropriate measures be ordered

221 The outcome of the third head of claim, whereby the applicant requests that the Court 'take such other or further measure as justice may require' depends in essence on the Court annulling the contested decision on the grounds raised in the application.

222 Given that the contested decision is not to be annulled, the third head of claim must be rejected from the outset.

IV. Costs

223 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.

224 In accordance with Article 138(1) of the Rules of Procedure, the institutions which have intervened in the proceedings are to bear their own costs. It follows that the French Republic must bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth 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 French Republic to bear its own costs.**

Gratsias Labucka Dittrich

Delivered in open court in Luxembourg on 20 September 2019.

E. Coulon
Registrar

D. Gratsias
President

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