MRF 2023.196

EU-Domstolens dom af 9. november 2023, 4. afd., sag C-558/21 P, Global Silicones Council m.fl. mod Kommissionen m.fl.

Ikke grundlag for at underkende det i Kommissionens forordning 2018/35 fastsatte forbud mod at markedsføre silikone med stoffet octamethylcyclotetrasiloxan eller decamethylcyclopentasiloxan, når udvaskning af de to stoffer overstiger 0,1 %, da begrænsningen var begrundet i en risikovurdering i overensstemmelse med forsigtighedsprincippet efter den i REACH-forordningen fremsatte fremgangsmåde og ikke var udtryk for en 0-risikotilgang.

Sagen var anlagt af producenter af silikoneprodukter. Baggrunden var, at de to stoffer octamethylcyclotetrasiloxan (D4) og decamethylcyclopentasiloxan (D5) på baggrund af en risikovurdering fra Storbritannien og en efterfølgende procedure efter REACH-forordningen var blevet begrænset med Kommissionens forordning 2018/35, hvorefter D4 og D5 ikke må markedsføres i kosmetiske produkter, der vaskes af i en koncentration på eller over 0,1 % ud fra vægten af hvert stof efter den 31. januar 2020. Global Silicones Council og flere silikoneproducenter anlagde annullationssøgsmål vedr. forordningens bestemmelser om de to stoffer, men Retten fandt i sag T-226/18 ikke grundlag for at annullere denne begrænsning af anvendelsen af D4 og D5 i forordningen. Dommen blev anket til EU-Domstolen, hvor silikoneproducenterne for det første gjorde gældende, at forordningens begrænsninger af de to stoffer ikke var tilstrækkelig begrundet, da det ikke af forordningen fremgik, at de to stoffer udgjorde en uacceptabel risiko, hvilket Rettens frifindelse ikke havde taget højde for. EU-Domstolen afviste indsigelsen, da det fremgik af de forudgående vurderinger, hvilke forhold der var lagt til grund for begrænsningerne. For det andet gjorde appellanterne gældende, at restriktionerne i forhold til de to stoffer var sket uden, at der forudgående var fastsat en acceptabel risikotærskel i overensstemmelse med dommen i sag T-13/99, Pfizer. EU-Domstolen medgav, at dette kræves efter "det almindelige forsigtighedsprincip", men anførte herefter, at dette i relation til REACH-forordningen var udmøntet i en særlig fremgangsmåde, og at der under hensyn hertil ikke var tale om overtrædelse af forsigtighedsprincippet (præmis 65-69). For det tredje gjorde appellanterne gældende, at begrænsningerne var baseret på en 0-risikovurdering i modstrid med forsigtighedsprincippet, da den tog udgangspunkt i, at emission af de to stoffer i sig selv udgjorde en risiko, men at risikoen ikke kunne kvantificeres. EU-Domstolen afviste denne indsigelse med, at det af de gennemførte undersøgelser fremgik, at emission af de to stoffer kan udgøre en risiko grundet stoffernes udvaskning i vandet. EU-Domstolen afviste derfor, at Rettens dom var udtryk for anerkendelse af en 0-risikotilgang. EU-Domstolen afviste endvidere appellanternes anbringende om omvendt bevisbyrde med hensyn til biomanificering og bioakkumulation og forkastede dermed i det hele appellen af Rettens dom i sag T-226/18.

Kommentar: *Dommen understreger, at Rettens tidligere dom i sag T-13/99 Pfizer, hvor forsigtighedsprincippet blev udfoldet mere principielt og operativt fortsat er gældende, men med den modifikation, at det almindelige krav om, at risikotærsklen skal fastsættes forud for risikovurderingen skal anvendes under hensyn til den særlige fremgangsmåde, der er fastsat i REACH-forordningen, hvor bestemte stoffer er taget ud til undersøgelse pga. af deres mulige farlighed. Om dommen i sag T-13/99, Pfizer, og dens betydning for forsigtighedsprincippet se Pagh: U 2003B.153. I relation til forholdet mellem kvantitative og kvalitative risikovurderinger er dommen på linje med sag C-119/21 P, PlasticsEurope mod ECHA (**MRF 2023.7**).*

JUDGMENT OF THE GENERAL COURT (Eighth Chamber, Extended Composition)

30 June 2021 (*)

(REACH – Updating of Annex XVII to Regulation (EC) No 1907/2006 concerning restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles – Restrictions concerning octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) – Manifest error of assessment – Annex XIII to Regulation No 1907/2006 – Weight-of-evidence determination – Article 68 of Regulation No 1907/2006 – Unacceptable risk – Proportionality – Essential procedural requirements)

In Case T-226/18,

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

Wacker Chemie AG, established in Munich (Germany),

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

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

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

represented by A. Kołtunowska and R. Semail, lawyers,

applicants,

supported by

American Chemistry Council, Inc. (ACC), established in Washington, represented by K. Nordlander and C. Grobecker, lawyers,

intervener,

v

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

defendant,

supported by

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

by

United Kingdom of Great Britain and Northern Ireland, represented by S. Brandon, acting as Agent, and by C. Banner and A. Parkinson, Barristers,

by

European Parliament, represented by L. Darie and A. Tamás, acting as Agents,

by

Council of the European Union, represented by M. Moore and A. Maceroni, acting as Agents,

and by

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

interveners,

APPLICATION under Article 263 TFEU for annulment of Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane (‘D4’) and decamethylcyclopentasiloxane (‘D5’) (OJ 2018 L 6, p. 45),

THE GENERAL COURT (Eighth Chamber, Extended Composition),

composed of S. Papasavvas, President, J. Svenningsen, R. Barents, T. Pynnä and J. Laitenberger (Rapporteur), Judges,

Registrar: B. Lefebvre, Administrator,

having regard to the written part of the procedure and further to the hearing on 29 September 2020,

gives the following

Judgment

I. Legal context

1 On 1 June 2007, 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) entered into force.

2 Annex I to Regulation No 1907/2006 (‘Annex I’) provides the following:

‘4. PBT AND VPVB ASSESSMENT

4.0. Introduction

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

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

Step 1: Comparison with the Criteria.

Step 2: Emission Characterisation.

…

4.1. Step 1: Comparison with the criteria

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

4.2. Step 2 Emission Characterisation.

If the substance fulfils the criteria or it is considered as if it is a PBT or vPvB in the registration dossier an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance. …'

3 Annex I also provides the following:

'6. RISK CHARACTERISATION

…

6.3. The risk characterisation consists of:

– a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL,

– a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs, and

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

…

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

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

4 Annex XIII to Regulation No 1907/2006 ('Annex XIII') lays down the criteria for the identification of persistent ('P'), bioaccumulative ('B') and toxic ('T') substances (together, 'PBT'), and very persistent ('vP') and very bioaccumulative ('vB') substances (together, 'vPvB').

5 On 15 March 2011, the European Commission adopted Regulation (EU) No 253/2011 amending Regulation No 1907/2006 as regards Annex XIII (OJ 2011 L 69, p. 7). That regulation amended the former Annex XIII, taking into account experience acquired at international level.

6 The preamble to Annex XIII now states:

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

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

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

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

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

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

7 Annex XIII provides, inter alia:

‘1.1.2. Bioaccumulation

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

…

1.2.2. Bioaccumulation

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

8 Annex XIII also states the following:

‘3.2. Assessment Information

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

…

3.2.2. Assessment of B or vB properties

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

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

– Results from a bioaccumulation study in terrestrial species;

…

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

II. Background to the dispute

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

10 On 1 October 2014, the competent authority of the United Kingdom of Great Britain and Northern Ireland submitted to the European Chemicals Agency (ECHA) parts of a dossier based on Annex XV to Regulation No 1907/2006 (‘Annex XV’) relating to the PBT and vPvB properties of D4 and D5.

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

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

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

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

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

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

17 On 11 March 2016, the ECHA Committee for Socio-economic Analysis (‘the SEAC’) in turn adopted a draft opinion. A public consultation took place between 16 March and 16 May 2016. On 9 June 2016, the SEAC adopted its final opinion, indicating that the proposed restriction was the most appropriate Union-wide measure for reducing the discharge of D4 and D5 to waste water in terms of its socio-economic benefits and costs (‘the opinion of the SEAC’). The SEAC nevertheless recommended that the application of the restriction be deferred for 24 months to allow stakeholders to take the measures necessary to comply with it.

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

19 On 10 May 2017, the Commission submitted its proposal for a regulation for consideration by the Committee established by Article 133 of Regulation No 1907/2006.

20 On 10 January 2018, the Commission adopted Regulation (EU) 2018/35 amending Annex XVII to Regulation (EC) No 1907/2006 as regards D4 and D5 (OJ 2018 L 6, p. 45; ‘the contested regulation’). That regulation provides that neither D4 nor D5 is to be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0.1% by weight of either substance, after 31 January 2020.

III. Procedure and forms of order sought

21 By application lodged at the Court Registry on 2 April 2018, the applicants brought the present action.

22 On 5 July 2018, the Commission lodged its defence at the Court Registry.

23 On 12 July 2018, the applicants, by separate document lodged at the Court Registry, requested that certain information in the file be treated as confidential vis-à-vis the public.

24 By documents lodged at the Court Registry on 16, 26, 27 July and 2 August 2018 respectively, the Council of the European Union, the Federal Republic of Germany, ECHA, the European Parliament and the United Kingdom applied to intervene in support of the form of order sought by the Commission.

25 By document lodged at the Court Registry on 2 August 2018, the American Chemistry Council Inc. ('ACC') applied to intervene in support of the form of order sought by the applicants.

26 By decision of 5 September 2018, the President of the Fifth Chamber of the General Court granted the Council, the Federal Republic of Germany, the Parliament and the United Kingdom leave to intervene.

27 On 22 September 2018, the applicants lodged their reply at the Court Registry.

28 On 25 September, 9 and 23 November 2018, the applicants, by separate documents lodged at the Court Registry, requested that certain information in the file be treated as confidential vis-à-vis ACC.

29 On 17 October 2018, the Council, the Federal Republic of Germany, the Parliament and the United Kingdom lodged their statements in intervention at the Court Registry.

30 By order of 25 October 2018, the President of the Fifth Chamber of the General Court granted ECHA's application to intervene.

31 On 12 December 2018, the Commission lodged the rejoinder at the Court Registry.

32 On 12 December 2018, ECHA lodged its statement in intervention at the Court Registry.

33 By order of 13 December 2018, the President of the Fifth Chamber of the General Court granted ACC leave to intervene. He also ordered the Court Registry to provide ACC with a non-confidential version of the pleadings and documents lodged by all the parties. Finally, he decided it necessary to set a deadline for ACC, first, to submit its statement in intervention and, second, to provide its observations on the applicants' request that the file be treated as confidential in its regard. By decision of 18 December 2018, those two deadlines were set at 30 January and 14 January 2019 respectively.

34 By documents lodged at the Court Registry on 17 and 18 January 2019 respectively, the Commission and the applicants submitted their observations on the statements in intervention of the Council, the Federal Republic of Germany, the Parliament and the United Kingdom. With regard, in particular, to the United Kingdom, the applicants requested that, after the withdrawal of that State from the European Union, it be denied any further involvement in the present case, as an intervener or otherwise. According to the applicants, at that date, that Member State would no longer have any specific rights as intervener or any legal interest in the result of the case.

35 On 30 January 2019, ACC lodged its statement in intervention at the Court Registry.

36 By documents lodged at the Court Registry on 1 and 4 February 2019 respectively, the Commission and the applicants each submitted their observations on ECHA's statement in intervention.

37 By documents lodged at the Court Registry on 12 and 13 March 2019, respectively, the Commission and the applicants submitted their observations on ACC's statement in intervention.

38 By letter of 2 April 2019, the applicants confirmed, at the Court's request, that they were not requesting confidential treatment for the Commission's observations on ACC's statement in

intervention. In addition, in anticipation of the withdrawal of the United Kingdom from the European Union, the applicants requested the Court to revoke, before the end of the written procedure, that Member State's status as intervener and not to take its statement in intervention into account. Furthermore, as that Member State could no longer, according to the applicants, be regarded as a privileged applicant, it had to demonstrate an interest in bringing proceedings, which it failed to do. Finally, the applicants requested that that Member State be ordered to bear its own costs and to pay those incurred by the applicants in connection with its intervention in the proceedings.

39 By letter of 30 April 2019, the applicants requested that a hearing be held.

40 By decision of 23 October 2019 and following a change in the composition of the Chambers of the Court, the case was reassigned to a new Judge-Rapporteur sitting in the Eighth Chamber.

41 On 8 April 2020, the Court (Eighth Chamber), on a proposal from the Judge-Rapporteur and by way of the measures of organisation of procedure provided for in Article 89 of the Rules of Procedure of the General Court, put questions to the parties to be answered in writing. The parties complied with that request within the period prescribed.

42 On 20 April 2020, on a proposal from the Eighth Chamber, the Court decided, pursuant to Article 28 of the Rules of Procedure, to refer the case to a Chamber sitting in extended composition.

43 By measure of organisation of 7 May 2020, the main parties were asked whether or not, in the light of the health situation connected to COVID-19, they were maintaining their request to be heard at a hearing. By letter of 29 May 2020, the applicants stated that they were maintaining that request.

44 On 7 August 2020, the Court (Eighth Chamber, Extended Composition), acting on a proposal from the Judge-Rapporteur and by way of the measures of organisation of procedure provided for in Article 89 of the Rules of Procedure, invited each of the parties to submit its observations on the other parties' replies to the Court's written questions of 8 April 2020. The main parties, as well as the United Kingdom and ECHA, complied with that request within the period prescribed.

45 On a proposal from the Judge-Rapporteur, the Court (Eighth Chamber, Extended Composition) decided to open the oral part of the procedure.

46 The parties, with the exception of the United Kingdom, which did not participate in the hearing, presented oral argument and answered the questions put to them by the Court at the hearing on 29 September 2020.

47 At the hearing, the applicants withdrew two of their heads of claim based on a plea of illegality, which was recorded in the minutes of the hearing, such that they now claim that the Court should:

– annul the contested regulation;

– order the Commission to pay the costs;

– take any other measure as justice may require.

48 The Commission contends that the Court should:

– declare the action inadmissible in so far as it concerns preparatory and non-binding acts;

– dismiss the action as unfounded as to the remainder;

– order the applicants to pay the costs.

49 The Council contends that the Court should:

– dismiss the action as unfounded;

– order the applicants to pay the costs.

50 The Federal Republic of Germany requests the Court to dismiss the action.

51 The Parliament, having taken note of the applicants' withdrawal of the head of claim based on the plea of illegality in respect of Annex XIII or certain of its provisions, states that it no longer has any claims.

52 The United Kingdom claims that the Court should:

– declare the action inadmissible in so far as it concerns preparatory and non-binding acts;

– dismiss the remainder of the action as unfounded.

53 ECHA contends that the Court should:

– declare the action inadmissible in so far as it concerns preparatory and non-binding acts;

– dismiss the action as unfounded as to the remainder;

– order the applicants to pay the costs.

54 ACC requests the Court to uphold the action as well founded.

IV. Law

A. Intervention of the United Kingdom

55 In their observations on the United Kingdom's statement in intervention of 18 January 2019 and in their letter of 2 April 2019, the applicants, in essence, requested the Court to revoke the status as intervener accorded to that former Member State given that it had withdrawn from the European Union.

56 In that regard, it should be noted that, until the date of delivery of the present judgment, the United Kingdom had a right to intervene.

57 Indeed, when it was authorised to intervene by decision of the President of the Chamber of 5 September 2018, the United Kingdom was still a Member State of the European Union. Consequently, its right to intervene stemmed from a direct application of the first paragraph of Article 40 of the Statute of the Court of Justice of the European Union.

58 After its withdrawal from the European Union and during the transition period, as defined by Article 126 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, as approved by Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ 2020 L 29, p. 1) ('the Withdrawal Agreement'), ending on 31 December 2020, the first paragraph of Article 40 of the Statute of the Court of Justice of the European Union continued to apply to the United Kingdom in accordance with Article 127(1) and (6) of the Withdrawal Agreement, according to which, during that transition period, EU law was applicable to the United Kingdom and according to which, unless otherwise provided in the Withdrawal Agreement, any reference to Member States in that law was to be understood as including the United Kingdom.

59 Thus, during the written and oral part of the procedure, the United Kingdom continued to enjoy intervener status under the first paragraph of Article 40 of the Statute of the Court of Justice of the European Union.

60 Contrary to what the applicants claim in their observations on the replies of the Commission and of the United Kingdom to a question from the Court, a breach of the Withdrawal Agreement by the United Kingdom, if established, would not prevent that State from invoking the rights arising from that agreement. Neither EU law nor, more specifically, the Withdrawal Agreement contains a general

provision according to which one of the parties automatically loses its rights under EU law and the Withdrawal Agreement in the event of breach of one of its obligations.

61 So far as concerns the period after the transition period, it must be held that, as the United Kingdom submits, even assuming that, since 1 January 2021, that State – now a third country – can no longer rely on the first paragraph of Article 40 of the Statute of the Court of Justice of the European Union, that State would, in any event, establish an interest in the result of the case within the meaning of the second paragraph of Article 40 of that statute, given that it was the competent authority of that State which had submitted to ECHA parts of an Annex XV dossier relating to the PBT and vPvB properties of the substances D4 and D5.

B. Substance

62 Following the withdrawal, at the hearing, of two of their heads of claim, the applicants rely, in support of their action, in essence, on eight pleas in law.

63 The first plea alleges manifest errors of assessment.

64 The second plea alleges breach of the principle of proportionality, in that the contested regulation is not appropriate or necessary to address the purported concern, does not constitute the least onerous measure and causes disadvantages which are disproportionate to the aims pursued.

65 The third plea alleges breach of essential procedural requirements, in particular in that the Commission 'never adequately or sufficiently considered or reviewed the fundamental basis for the contested [regulation]'. Moreover, according to the applicants, it is the RAC – and not the MSC – that should have assessed all the underlying factors and justifications for the restriction established by the contested regulation.

66 The fourth plea alleges breach of the principle of legal certainty and of the principle of legitimate expectations.

67 The fifth plea alleges breach of the institutional balance of powers, in that ECHA 'made law' in reaching a conclusion on the B and vB properties of D4 and D5, outside and independently of the applicable law.

68 The sixth plea alleges breach of the principle of good administration, in particular in that the Commission and ECHA breached the requirement to ensure that administrative procedures in risk assessments ensure scientific objectivity and preclude arbitrary measures.

69 The seventh plea alleges breach of the rights of the defence and of the right to be heard.

70 Finally, the eighth plea alleges breach of the obligation to state the reasons for the contested regulation.

1. First plea in law: manifest errors of assessment

71 The applicants, supported by ACC, submit in essence that, in adopting the contested regulation, the Commission committed a number of manifest errors of assessment.

72 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, contends that the first plea should be rejected as unfounded.

73 It should be noted that the contested regulation was adopted on the basis of Article 68(1) of Regulation No 1907/2006. As is apparent from Article 1(1) of Regulation No 1907/2006, the purpose of that regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. According to recitals 87, 89 and 91 of Regulation No 1907/2006, the EU legislature set as the main purpose of the introduction of new restrictions and the amendment of existing restrictions, as provided for in Title VIII of that regulation, the first of those three objectives, namely ensuring a high level of

protection of human health and the environment (see judgment of 1 February 2013, *Polyelectrolyte Producers Group and Others* v *Commission*, T-368/11, not published, EU:T:2013:53, paragraph 62 and the case-law cited).

74 In order to be able to pursue those objectives effectively, it must be emphasised that, in an area of evolving and complex technology such as that of the present case, the competent EU authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts, in order to determine the nature and scope of the measures which they adopt. Thus, in that area, review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the authorities of the European Union on which alone the FEU Treaty has placed that task (see judgment of 30 April 2015, *Polynt and Sitre* v *ECHA*, T-134/13, not published, EU:T:2015:254, paragraph 52 and the case-law cited).

75 Moreover, the broad discretion of the authorities of the European Union, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken but also, to some extent, to the finding of the basic facts. However, even though such judicial review is of limited scope, it requires that the European Union authorities which have adopted the act in question must be able to show before the European Union judicature that in adopting the act they actually exercised their discretion, which presupposes that they took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see judgment of 30 April 2015, *Polynt and Sitre* v *ECHA*, T-134/13, not published, EU:T:2015:254, paragraph 53 and the case-law cited).

76 It is thus for the European Union judicature to establish inter alia whether the evidence relied on contains all the information which must be taken into account in order to assess the complex situation at issue (see judgment of 9 September 2011, *France* v *Commission*, T-257/07, EU:T:2011:444, paragraph 87 and the case-law cited).

77 In essence, the present plea can be broken down into four parts. The first part refers to the existence of errors allegedly committed in the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII. In the second part, the applicants claim that the contested regulation does not comply with one of the conditions laid down for the adoption of a restriction, defined in Article 68(1) of Regulation No 1907/2006, namely that unacceptable risk results from ‘the manufacture, use or placing on the market’ of a substance. In the third part, they argue that a number of errors were made in the risk assessment. The fourth part of the first plea concerns the arguments of the applicants raised also under the plea alleging breach of essential procedural requirements according to which the Commission ‘never adequately or sufficiently considered or reviewed the fundamental basis for the contested [regulation]’.

(a) First part of the first plea: manifest error of assessment in the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII

78 The applicants, supported by ACC, claim that the application of the weight-of-evidence determination according to the rules laid down in Annex XIII is vitiated by manifest errors. D4 and D5 do not present any hazards and are neither PBT substances nor vPvB substances. The identification of D4 as a PBT and vPvB substance and of D5 as a vPvB substance is vitiated by manifest errors of assessment.

(1) The allegedly insufficient consideration of factors other than the bioconcentration factor

79 The applicants claim, first of all, that ECHA and the Commission committed a manifest error of assessment in relying, in the identification of the vB properties of D4 and D5, solely on the bioconcentration factor (‘BCF’), to which Sections 1.1.2 and 1.2.2 of Annex XIII refer, and ignoring other factors, such as the trophic magnification factor (‘TMF’) and the biomagnification factor (‘BMF’). The Executive Director of ECHA requested an opinion from the MSC ‘on whether the relevant properties of D4 and D5 [met] the criteria for being persistent or very persistent or bioaccumulative or very bioaccumulative in Annex XIII of REACH’. Thus, the Executive Director did not request the MSC to provide a scientifically objective, valid, robust and independent opinion on the basis of a weight-of-evidence assessment.

80 According to the applicants, even if it were to be considered that the TMF and the BMF were taken into account, the fact remains that they were attributed less importance than the BCF, even though TMF and BMF are critical factors in determining the B and vB properties of a substance. The importance of information on the TMF and the BMF is reflected in Section 3.2.2(c) of Annex XIII. In the applicants' opinion, trophic magnification and biomagnification up the food chain were the most reliable factors for assessing whether D4 and D5 were B or vB substances. Consequently, the legal or scientific weight attributed to TMF, BMF and bioaccumulation factor data was insufficient in relation to their actual scientific importance. ACC argues that, in accordance with recitals 5 and 6 of Regulation No 253/2011, a weight-of-evidence determination was particularly relevant in the present case because TMF data and other data have shown that D4 and D5 do not biomagnify to unpredictable concentrations in the food web.

81 According to the applicants, in complying with its guidance, whereby an 'indication of a biomagnification potential can on its own be considered as a basis to conclude that a substance meets the B or vB criteria', ECHA did not attribute to the scientific data weight commensurate with their actual scientific validity. ECHA attributed weight to studies that could indicate biomagnification potential when it attributed 'lesser weight, and/or not relevant legal weight, to studies such as, for example, the Powell et al study'.

82 According to the applicants, due to the importance of the BMF, it was important to determine a threshold limit by using the TMF/BMF metric to identify a substance as B or vB. That was not done by the MSC. In their view, therefore, there was no system for comparing, on the one hand, the 'strength' of the TMF and BMF data and, on the other hand, the BCF and other data.

83 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, disputes those arguments.

84 As regards, in the first place, the applicants' assertion that the MSC did not take into account data other than the BCF, in particular TMF and BMF data, it is clear from the file and from the opinion of the MSC that the MSC did indeed take other data into account. After all, the MSC inter alia examined data relating to the BMF, noted variable results concerning the field data on biomagnification and the TMF, considered the reasons for those variations and concluded that those data were inconclusive, but that certain of the trophic magnification studies supported the conclusion that D4 and D5 were bioaccumulative. The MSC found that the information on the BMF and the TMF available on the ground, which indicated that biodilution had occurred in some food chains, did not invalidate the other lines of evidence. Last, the MSC concluded that D4 and D5 were vB substances on the basis of BCF data supported by multiple sources of data on biomagnification.

85 Consequently, it is appropriate to reject that argument of the applicants on the ground that it is factually incorrect.

86 As regards, in the second place, the applicants' arguments that too much legal weight was attributed to the BCF when the TMF and the BMF are the crucial factors for determining the B property, it must be stated that the EU legislature chose to lay down, in Sections 1.1.2 and 1.2.2 of Annex XIII, the criteria for identifying B or vB substances by reference to their BCF in aquatic species. According to the third paragraph of the preamble to Annex XIII, the information listed in Section 3.2, in particular the results of a study on the bioconcentration or bioaccumulation of a substance in aquatic species and the information on the ability of that substance to biomagnify in the food chain, where possible expressed by biomagnification factors or trophic magnification factors, is to be compared with the criteria set out in Section 1 of that annex on the basis of a weight-of-evidence determination using expert judgement.

87 According to the second paragraph of the preamble to Annex XIII, the weight-of-evidence determination is to be applied in particular where the criteria set out in Section 1 cannot be applied directly to the available information. A BCF resulting from a reliable study on the bioconcentration of a substance in aquatic species, such as that at issue in the present case, may be directly – that is to say, numerically – compared with the criteria laid down in Sections 1.1.2 and 1.2.2 of Annex XIII. While recognising that this does not preclude the application of the weight-of-evidence determination in cases like the present one, in which BCF data are available and relevant, it is clear that the information and data referred to in Section 3.2.2 of Annex XIII gain in importance in particular when the criterion

defined by reference to the BCF cannot be applied directly to the information available. Contrary to what ACC suggests in its statement in intervention, it is not apparent from recitals 5 and 6 of Regulation No 253/2011 that the weight-of-evidence determination is particularly relevant when the TMF data and other data show that a substance does not biomagnify to unpredictable concentrations in the food web. Recital 6 of that regulation, like the second paragraph of the preamble to Annex XIII, refers to the impossibility of directly applying the criteria in Section 1 to the information available. Where reliable BCF information is available, the criteria established by reference to the BCF may be applied to that information directly.

88 It follows from those provisions that the legislature chose to give a certain priority to the results of reliable studies on the BCF of a substance in aquatic species or, at the very least, that the MSC, without committing a manifest error of assessment, considered that the BCF values had, in the case at hand, greater weight than the other data cited by the applicants.

89 By contrast, the arguments raised by the applicants, based on the alleged greater importance of other information in the case, such as TMF and BMF information, find no support in the text of Annex XIII and, in particular, do not take that priority into account. They are thus based on a misinterpretation of the relevant provisions of that annex.

90 Moreover, the applicants have not demonstrated that the assessment and conclusion of the MSC on the vB properties of D4 and D5 in the present case were not in conformity with those provisions or were vitiated by manifest errors of assessment. It has already been noted that the MSC inter alia examined data relating to the BMF, noted variable results concerning the field data on biomagnification and the TMF, considered the reasons for those variations and concluded that those data were inconclusive, but that certain of the trophic magnification studies supported the conclusion that D4 and D5 were bioaccumulative. The MSC found that the information on biomagnification and the TMF available on the ground, indicating that biodilution had occurred in some food chains, did not invalidate the other lines of evidence. Furthermore, the MSC referred to Chapter R.11 on the evaluation of the PBT properties of November 2014 of ECHA's 'Guidance on Information Requirements and Chemical Safety Assessment' ('the ECHA Guidance'), as a consolidated source of expert opinion, according to which the absence of biomagnification cannot be used to disregard a valid assessment based on reliable BCF data indicating that a substance meets the criteria for B and vB substances set out in Annex XIII. Last, the MSC concluded that D4 and D5 were vB substances on the basis of BCF data supported, inter alia, by multiple lines of evidence on biomagnification resulting from dietary testing. Thus, the MSC did indeed apply a weight-of-evidence determination using expert judgement, as provided for in Annex XIII, by comparing the available and relevant information referred to in Section 3.2.2 of that annex to the criterion laid down in Section 1.2.2.

91 The fact that the MSC thus attributed greater weight to the BCF values in the case at hand does not constitute a manifest error of assessment. On the contrary, that committee acted in accordance with Annex XIII and complied with the order set out by the EU legislature.

92 ECHA, the United Kingdom and the Federal Republic of Germany also state – rightly – that that also corresponds to the greater scientific weight of the BCF. Thus, BCF is given the 'greatest weight' as the preferred metric because it follows, as the main result, from a standard test for bioaccumulation in fish, namely Guideline No 305 of the Organisation for Economic Cooperation and Development (OECD) Guidelines for the Testing of Chemicals ('OECD Guideline No 305'), which is recognised as the most robust test for measuring bioaccumulative potential in general.

93 With regard to the applicants' arguments, set out in their observations on the statement in intervention submitted by ECHA, according to which neither that guideline nor the other arguments advanced by the Commission and ECHA demonstrate that BCF was an appropriate metric for measuring the bioaccumulative potential of D4 and D5 since those two substances have unique physicochemical properties, the following must be stated. First, OECD Guideline No 305 is of general application and does not provide for any exceptions to application for substances such as D4 or D5. Second, it is apparent from Annex XIII, in particular from Sections 1.1.2 and 1.2.2 thereof, that the BCF in aquatic species is, in general, not only an appropriate instrument, but also the main instrument prescribed by Regulation No 1907/2006 for measuring bioaccumulative potential. Third, the question whether

Annex XIII, in particular Sections 1.1.2 and 1.2.2 thereof, was applicable in the present case and whether the allegedly unique properties of D4 and D5 call into question the conclusion on the vB properties of those substances will be examined in paragraph 99 et seq. below and in paragraph 113 et seq. below, respectively.

94 Likewise, the fact that the MSC found that the information indicating biodilution in certain food chains did not invalidate the other lines of evidence does not constitute a manifest error of assessment. As was indicated in Chapter R.11 of the ECHA Guidance, to which the MSC referred:

'… as dietary and trophic biomagnification represent different processes than bioconcentration in aquatic organisms, BMF and/or TMF values <1 cannot be used to disregard a valid assessment based on reliable BCF data indicating that a substance meets the numerical B/vB criteria in Annex XIII. … In principle, BMF values are not directly related to the BCF values, and in fact BMFs and BCFs represent complementary bioaccumulation pathways. Food chain transfer and secondary poisoning are basic concerns in relation to PBT and vPvB substances, therefore an indication of a biomagnification potential can on its own be considered as a basis to conclude that a substance meets the B or vB criteria but absence of such a biomagnification potential cannot be used to conclude that these criteria are not fulfilled. …'

95 That assessment does not depart from the provisions of Annex XIII. Given that bioconcentration and biomagnification are two different pathways to bioaccumulation, both explicitly recognised by Annex XIII, it is clear that the mere absence of biomagnification does not mean that there is no bioaccumulation. Consequently, even the existence of biodilution does not necessarily, according to Annex XIII, dispel the concerns arising from bioconcentration. Thus, and contrary to what the applicants submit, even the identification of a vB substance on the basis of reliable BCF data meeting the criteria laid down in Sections 1.1.2 and 1.2.2 of Annex XIII in the absence of studies proving biomagnification or trophic magnification does not constitute a manifest error of assessment.

96 Moreover, the applicants have failed to prove that the existence of biodilution in certain food chains rules out biomagnification in other food chains.

97 In any event, in the case at hand, the MSC found that the field data on biomagnification and on the trophic magnification of D4 and D5 were inconclusive. Therefore, it is without committing a manifest error of assessment that the MSC was able to find that a conclusion on bioconcentration, based on reliable studies showing BCF values meeting the criteria of vB substances laid down in Annex XIII and which were therefore conclusive, was not invalidated by data which, for their part, did not allow for any definitive conclusion to be drawn on biomagnification and on the trophic magnification of those substances.

98 Last, contrary to what the applicants suggest, the mere fact that the MSC presented certain considerations and conclusions relating to the bioaccumulation of D4 and D5 together does not mean that data and studies relating to D5 were considered applicable to D4 despite the differences between the two substances. That assertion – in support of which the applicants do not provide any concrete examples – is, moreover, undermined by the fact that the MSC, in its opinion of 22 April 2015, clearly distinguishes between the two substances.

(2) Application of the criteria laid down in Sections 1.1.2 and 1.2.2 of Annex XIII

99 The applicants claim that factors other than the BCF were particularly important and that the criteria laid down in Sections 1.1.2 and 1.2.2 of Annex XIII, which specifically refer to the BCF, should therefore have been adjusted in this case for their application to D4 and D5. That follows more particularly, according to the applicants, from the fact that those substances have inorganic backbones, which drives unique properties. Moreover, it is apparent, in their view, from the last paragraph of the preamble to Annex XIII, according to which that annex 'shall apply to all organic substances, including organo-metals', that Section 1 of Annex XIII was not intended to apply and does not apply to inorganic or predominantly inorganic substances, such as D4 and D5.

100 In the reply, the applicants state that neither D4, D5 nor, more generally, siloxanes are listed in the Blue Book of the International Union of Pure and Applied Chemistry (IUPAC) on organic substances

('the Blue Book'), a collection of recommendations on the nomenclature of organic compounds. D4 and D5 are no different from polysiloxanes, since they exhibit the same basic chemical structure (Si-O inorganic backbone) and the same organic (methyl) lateral chains. Polysiloxanes are defined in the Gold Book, a collection of definitions of chemical terms, as 'inorganic polymers' and are considered by ECHA to be inorganic substances. Moreover, ISO standards distinguish between polymers and silicone plastic. However, in their observations on the report for the hearing, the applicants indicate that, even though it is incorrect to state that D4 and D5 are no different from polysiloxanes, D4 and D5 belong to the same family as siloxanes and polysiloxanes.

101 The applicants are of the view that there are substantial data on the inorganic nature of D4 and D5.

102 The Commission, supported by the Federal Republic of Germany and ECHA, disputes those arguments and contends that the provisions of Annex XIII were applicable to D4 and D5.

103 In that regard, it should be recalled that the sixth paragraph of the preamble to Annex XIII states that that annex is to apply to all organic substances, including organo-metals. In contrast to its previous version, the version of Annex XIII applicable in the present case no longer contains an express declaration concerning its non-application to inorganic substances, as the Commission rightly points out.

104 Moreover, it is appropriate to reject the applicants' line of argument according to which the scope of that annex was not changed and could not be changed by the Commission without having due regard to the need to change also the criteria for B and vB substances owing to the broadening of that scope. First, the current wording of the preamble to Annex XIII defines the applicability of that annex to organic substances, including organo-metals, in a positive manner, whereas its previous wording explicitly excluded its applying to inorganic substances. Second, the change in the wording of the preambular paragraph in question would be difficult to understand, as to the legislature's intention, if no change to its scope were to result from it. Third, the allegedly limited competence of the Commission to amend that annex is in no way apparent from the applicable provisions, in particular those of Articles 131 and 133(4) of Regulation No 1907/2006.

105 Consequently, even a substance with a 'hybrid' structure, namely an organic-inorganic or 'principally inorganic' structure, which, according to the applicants, is the case for D4 and D5, would not necessarily be excluded from the scope of that annex.

106 Furthermore, it should be noted that the Blue Book states that structures 'containing at least one carbon atom and no element from Groups 1-12' are organic compounds. D4 and D5 contain multiple carbons and elements from Groups 14 and 16 of the periodic table, as the Commission contends, without being contradicted on that point by the applicants. Cyclosiloxanes, such as D4 and D5, are also defined in the Gold Book as compounds having rings of alternating silicon and oxygen atoms. The entry relating to cyclosiloxanes in the Gold Book contains a reference to the 'Glossary of class names of organic compounds and reactive intermediates based on structure (IUPAC Recommendations 1995)'.

107 It is apparent from those publications that the classification of D4 and D5 as organic substances appears to be consistent with internationally recognised terminology.

108 None of the arguments raised by the applicants is capable of demonstrating that D4 and D5 are inorganic substances, or that Annex XIII or the criteria for vB substances which are defined therein did not apply to those substances.

109 First, as regards the arguments alleging that polysiloxanes are recognised in the Gold Book as being inorganic polymers, it must be held that none of the evidence submitted supports the view that D4 and D5 are polysiloxanes or that the classification of those two substances must correspond to that of polysiloxanes. The applicants have merely provided extracts making reference to polysiloxanes or to hybrid or inorganic polymers. However, it is apparent from the definition of polysiloxanes according to which they constitute 'inorganic polymers', to which the applicants refer, that polysiloxanes are defined in the international nomenclature as polymers. As the Commission submits, D4 and D5 are not defined as polymers either according to the definition in Article 3(5) of Regulation No 1907/2006 or according to the IUPAC nomenclature, which is not disputed by the applicants. Consequently, it must be held that,

according to that nomenclature, D4 and D5 are not regarded as polysiloxanes. Likewise, the fact that polysiloxanes are inorganic polymers does not mean that D4 and D5 must be regarded as hybrid or even inorganic substances.

110 Second, in their replies to the questions put by the Court, the applicants claimed that the fact that a substance was mentioned in the Blue Book could not mean that all substances belonging to that family were to be regarded as organic substances. In that regard, suffice it to note that that argument also fails to demonstrate that D4 and D5 should not be regarded as organic substances. More generally, the fact that the applicants disagree with the terminology and nomenclature established in the Blue Book and the Gold Book to which the Commission has referred is irrelevant. In any event, the European Union authorities cannot be criticised for relying on that terminology established by the IUPAC, the task of which is, inter alia, to define a generally recognised nomenclature and terminology.

111 Third, in their replies to the questions put by the Court, the applicants assert that the designation of the substances at issue in the Blue Book has no impact on the behaviour of those substances, which is determined by their organic chain. In that regard, suffice it to note that, according to the sixth paragraph of the preamble to Annex XIII, that annex is to apply to organic substances and that that argument is not such as to call into question the classification of D4 and D5 as such substances. The question whether the allegedly unique properties of D4 and D5 ought to have had an impact on the conclusion relating to their vB properties is examined in paragraph 118 et seq. below.

112 It follows that the applicants' arguments relating to the application of Annex XIII and the criteria laid down in Sections 1.1.2 and 1.2.2 thereof must be rejected.

(3) The allegedly inadequate assessment of the allegedly unique properties of D4 and D5 such as their volatility, their low water solubility, their metabolisation by certain organisms and their trophic dilution

113 The applicants claim that D4 and D5 are not bioaccumulative, given that they are volatile, poorly soluble in water and not found in natural surface waters. The applicants stated before the adoption of the contested regulation that, inter alia for those reasons, the numeric criteria provided for in Annex XIII were not suitable for assessing the real-life behaviour of the substances at issue. The applicants maintain in the reply, by reference to certain studies annexed to it, that, due to those physicochemical properties, the reversibility of D4 and D5 is shorter than that of PBT and vPvB substances.

114 Moreover, D4 and D5 are metabolised by benthic organisms and terrestrial and other air-breathing organisms, which prevents accumulation.

115 Consequently, D4 and D5 do not biomagnify in food webs and are more subject to trophic dilution.

116 At the hearing, the applicants stated that the BCF tests relating to D4 and D5 did not take into account either those intrinsic properties or the environmental conditions in which organisms interacted with those substances, in particular in that any possibility of the substance of leaving water had wrongly been excluded. Consequently, the data were not obtained under 'relevant conditions'.

117 The Commission, supported by the Federal Republic of Germany and ECHA, disputes those arguments.

118 In the first place, it should be emphasised that Annex XIII describes the criteria for the identification of PBT and vPvB substances for all organic substances, including organo-metals. The EU legislature chose to establish the criteria for identifying a substance as a vB substance by reference to its BCF in aquatic species, while taking international standards into account. By their arguments, according to which those rules were not appropriate for measuring the real-life bioaccumulation of D4 and D5, the applicants are in fact arguing that the criteria as defined by the legislature, in general terms, should not have been applied in this case, in view of its particularities.

119 In the second place, it is appropriate to reject the applicants' contention that, due to the allegedly unique properties of D4 and D5, those substances, once discharged into the environment, are not found

in water, which excludes any bioaccumulation in real-life situations. Without it being necessary to rule on the question whether a given degree of presence in the environment constitutes an aspect relevant to the assessment provided for in Annex XIII, that contention is not supported by any element in the file. It is apparent from the file and in particular from pages 20 and 21 of the opinion of the MSC that D4 and D5 are found in a wide range of organisms, particularly in fish and aquatic invertebrates, but also in birds and mammals up and down various aquatic food chains, including in large predators. As the Commission rightly submits, a low water solubility does not mean that a substance is not at all present in water or that there is no bioconcentration in aquatic species.

120 In the third place, as regards the argument based on the allegedly unrealistic conditions under which the BCF tests were carried out, it should be recalled that, according to Article 13(3) of Regulation No 1907/2006, where tests on substances are required to generate information on intrinsic properties of substances, they are to be conducted in accordance with the test methods laid down in a Commission regulation or in accordance with other international test methods recognised by the Commission or ECHA as being appropriate. Thus, the concept of 'relevant conditions' under which the data must be obtained, in accordance with the fourth paragraph of the preamble to Annex XIII, covers, inter alia, testing conditions as provided for in the test methods referred to in Article 13(3) of Regulation No 1907/2006.

121 The applicants do not claim that the BCF tests were not carried out in accordance with the requirements arising from OECD Guideline No 305, but they do assert that those tests are not in conformity with best scientific practice in that they do not take into account the properties of the substances at issue and do not reproduce environmental conditions. However, the reliability of the studies at issue cannot be invalidated solely on the basis of that criticism by the applicants, which in fact calls into question, without any tangible evidence, the scientific validity of OECD Guideline No 305. As regards the alleged failure to take into account intrinsic properties, as ECHA has explained, it is necessary to maintain a stable concentration in water during the test in order to be able to calculate the BCF. Moreover, ECHA cannot be criticised for following the OECD guidance document on the testing of difficult substances. As regards, more generally, the allegedly unrealistic conditions recommended for testing, OECD Guideline No 305 does not require the same conditions to be reproduced in a laboratory as those which exist in the environment. First, there are a multitude of conditions in the environment which may differ considerably from one place to another. Second, such environmental conditions may make it more difficult to measure the intrinsic property in question in order to compare it with results concerning other substances or a relevant threshold, for example the criterion laid down for the identification of vB substances, as is set out in Annex XIII. The very reason for establishing standards such as that guideline is to ensure the objectivity and comparability of results relating to a specific intrinsic property of a substance, such as the vB property. In particular, the fact that the concentration of a substance in water during testing may differ from its concentration in certain places in the environment has no bearing on the reliability of the results. What is more, as has been stated by ECHA, the BCF is a ratio comparing concentrations in the organism with those in its environment and not an absolute value. Thus, the presence of a substance in the environment is sufficient for bioconcentration to occur, even if the concentration of the substance at issue is low, or even lower than during testing.

122 In the fourth place, it should be noted that all the physicochemical properties of D4 and D5 mentioned by the applicants were taken into account in the MSC's assessment of P and vP properties and of B and vB properties. First, it is stated on pages 3 and 5 of the opinion of the MSC, for example, that D4 and D5 are poorly soluble, volatile substances and that they have high adsorption potential. Second, it is apparent from the opinion of the MSC that the low water solubility of D4 and D5 was taken into account during the laboratory tests, in accordance with the scientific requirements and OECD Guideline No 305, as the Commission submits in its replies to the Court's questions. Third, as the Commission rightly points out, the MSC, in its opinion, examined in detail the role of metabolism in bioaccumulation potential (see pages 16 and 17 of the opinion).

123 The applicants have not shown how that consideration is vitiated by manifest errors of assessment.

124 As regards, more specifically, the argument based on the metabolism and trophic dilution of D4 and D5, the applicants again appear to claim that the information relating to biomagnification and trophic

magnification should have prevailed over the information relating to the BCF in aquatic species. In that regard, it is appropriate to recall that it has already been established (in paragraph 86 et seq. above) that it is in accordance with the provisions of Annex XIII and without committing a manifest error of assessment in that regard that the MSC based its conclusion on data of the BCF in aquatic species supported by information on biomagnification resulting from dietary testing. It should be emphasised that the MSC acknowledged the existence of information indicating the existence of biodilution in certain food chains. Nevertheless, it concluded, without committing a manifest error of assessment and in accordance with the provisions of Annex XIII, that that information did not invalidate the other evidence. It also found that certain studies on trophic magnification supported the conclusion that D4 and D5 were bioaccumulative. Consequently, that argument of the applicants must be rejected.

125 In the fifth place, as regards the studies provided by the applicants in annex to the reply, first, it must be pointed out that the applicants do not state how those studies support their argument that, due to their unique nature, D4 and D5 are more reversible in the environment, particularly in sediment, than PBT and vPvB substances. They merely make a general reference to those annexes. It is not for the Court, however, to seek and identify in the annexes the pleas and arguments on which it may consider the action to be based, since the annexes have a purely evidential and instrumental function (judgment of 17 September 2007, *Microsoft* v *Commission*, T-201/04, EU:T:2007:289, paragraph 94). In any event, the EU legislature laid down clear criteria in Annex XIII for the identification of PBT and vPvB substances. That annex reflects the legislature's view that a substance which meets the criteria for identifying PBT or vPvB substances is of very high concern. The legislature did not provide for any additional assessment for substances meeting those criteria with a view to ascertaining whether they are more or less 'reversible' than other PBT and vPvB substances. Incidentally, ECHA has indicated, without being contradicted on the point by the applicants, that the Xu and Wania (2013) study was indeed taken into account by the RAC, that the study by Mackay et al. (2014) had not been submitted during the public consultation and that the two Kim et al. studies were published after the opinions of the MSC and of the RAC and thus could not be taken into account. ECHA has also stated the reasons for which, in its view, the study by Mackay et al. (2014) and the two Kim et al. studies do not support the applicants' argument. On that point, the applicants merely reiterate their argument that the volatility and degradation of the substances at issue mitigate the persistency of those substances in all environments, without indicating how those studies support that argument.

126 In the light of the foregoing and having regard to the findings in paragraphs 74 and 75 above, it cannot be held that the contested regulation is vitiated by a manifest error of assessment on account of the allegedly unique physicochemical properties of D4 and D5.

(4) The fact that PBT and vPvB properties were identified in different compartments

127 The applicants claim that ECHA committed a manifest error of assessment in examining the alleged P, B and T properties of D4 and D5 in isolation instead of examining them together. They submit, inter alia, that B properties were not identified in the same compartment as P properties. The information used for the purposes of the assessment was thus not based on relevant data, which is contrary to the requirements of the fourth paragraph of the preamble to Annex XIII. In particular, the assessment of the vP and vB properties of D4 and D5 did not observe the requirements provided for in the fourth paragraph of Annex XIII, such that vP properties, on the one hand, and vB properties, on the other, were identified on the basis of information falling within different compartments.

128 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, disputes those arguments.

129 In that regard, it must be stated that Annex XIII, as the Commission rightly contends, does not require the two or three criteria all to be met in one and the same compartment for the following reasons.

130 First, only the criteria for identifying P and vP properties set out in Sections 1.1.1 and 1.2.1 of Annex XIII expressly refer to specific compartments, such as the various types of water, the sediments of different water types and soil, and define different criteria and alternative criteria for various compartments. Sections 1.1.2, 1.1.3 and 1.2.2 of Annex XIII, which define the criteria for identifying B, vB or T substances, do not make any express reference to a specific compartment and, above all, do not establish a link between such a compartment and the compartment in which P properties were

identified. Furthermore, the criteria for identifying B and vB substances laid down in Sections 1.1.2 and 1.2.2 of Annex XIII are established by reference to the BCF in aquatic species and therefore fall within a specific compartment which does not correspond to all the compartments by reference to which the criteria for identifying P and vP substances are laid down in Sections 1.1.1 and 1.2.1 of that annex. The applicants' line of argument would obviate, for example, the criteria for identifying P and vP substances established by reference to the persistency of a substance in soil.

131 Second, the interpretation advocated by the applicants, as the Commission rightly points out, does not take into account transfers of substances between compartments, such that a substance which is persistent in one compartment, sediment for example, may be transferred to another compartment, for example sea water, where it may bioaccumulate or have toxic effects.

132 Third, according to the second paragraph of the preamble to Annex XIII, the weight-of-evidence determination using expert judgement compares 'all relevant and available information listed in Section 3.2 [of that annex] with the criteria set out in Section 1'. It is clear that this refers in particular to information based on data which are obtained from different compartments or which concern animals living in different compartments (for example, aquatic and terrestrial species and birds). Similarly, Section 3 of Annex XIII refers to factors which in themselves may fall within several compartments, such as the BMF, by reference to which the Commission emphasises that predators and prey can live in different compartments or in multiple compartments.

133 It follows that the applicants' argument that PBT and vPvB properties were identified in different compartments must be rejected.

(5) The alleged failure to take into account all relevant and available information

134 The applicants claim that the opinion of the MSC did not consider certain studies (such as the Bridges and Solomon studies, the Gobas study and the information provided on it, the Ruus study, the Sanchis study, the Hong et al. study, the Jia et al. study and the Krogseth et al. study). They assert that considering them would have materially affected the weight-of-evidence determination and the conclusion. The applicants add that, contrary to what is provided in the second and third paragraphs of the preamble to Annex XIII, the data were not considered and assessed together.

135 In that context, they assert that the RAC did not reassess P, vP, B and vB properties as part of its opinion of 10 March 2016, and that the data which were examined by the RAC were examined separately and in isolation from the full weight of the evidence.

136 The Commission disputes those arguments.

137 As a preliminary point, it should be noted that the applicants' argument that the information was not taken into account together is linked to their plea alleging breach of essential procedural requirements and, in particular, to the argument that the RAC evaluated the T properties of the two substances, without re-evaluating their vP and vB properties. In that regard, reference is therefore made to the assessment of that plea.

138 Next, it must be stated that it is apparent from the file that the majority of the studies listed by the applicants – or their draft versions – were either taken into account during the evaluation process or were not yet available at the time of the evaluation of the PBT properties of the substances at issue by the MSC, which issued its opinion on 22 April 2015, as the Commission rightly points out.

139 First, the United Kingdom, in documents entitled 'Comments 2nd round of call for evidence' relating to D4 and D5 respectively, responded to the draft versions of the Bridges and Solomon studies (comment No 67) and to the Gobas articles submitted in the public call for evidence issued in the context of the opinion of the MSC (comment No 71). Annexes 2 and 3 to the opinion of the MSC contain references to the Hong et al. and Jia et al. studies and indicate a conclusion of them while noting that they have not been evaluated. As regards the Jia et al. study in particular, a summary of it was taken into account in order to highlight the difficulty in determining the current level of trophic magnification. It is found that that study indicates a probability of 94.7% or of 99.8% of observing a TMF value of higher than 1 for D4 and D5, respectively. The Sanchis (2015) study was mentioned and

summarised by the RAC in the reference document accompanying its opinion. Second, the Krogseth et al. (2017) and Ruus (2017) studies were not submitted during the public call for evidence and were not available until 2017 and therefore could not be taken into account either by the MSC in 2015 or by the RAC in 2016.

140 As is apparent from the applicants' observations to a question from the Court, the applicants do not dispute that finding, but criticise the fact that the assessment of the Bridges and Solomon studies and the Gobas articles is to be found not in the opinion of the MSC, but in a document prepared by the United Kingdom, and that the references in the annexes to that opinion to the Hong et al. and the Jia et al. studies indicate that those studies were not evaluated. Thus, according to the applicants, that information was not considered 'in the MSC's so-called weight-of-evidence determination'.

141 That argument must be rejected since there is no provision of Annex XIII requiring that the evaluation of all available information be described in detail in one specific document. In the context of a lengthy administrative procedure such as the one that preceded the adoption of the contested regulation and in the face of a considerable amount of information to be evaluated as in the case at hand, it may be appropriate, inter alia, to describe the evaluation of the information in various documents and annexes and in a summary manner, in particular according to the relevance and importance of that information. In that regard, it should also be noted that the second paragraph of the preamble to Annex XIII applies only to 'relevant … information' and that the third paragraph of that preamble applies only to 'available information bearing on the identification of a PBT or a vPvB substance'. There is inter alia no obligation for the MSC to describe the evaluation of the information which has been considered not to be relevant and not having such a bearing, or even for it to list it in its opinion exhaustively.

142 In any event, it should be pointed out that the applicants, in the application, merely assert that the studies which, according to them, were not considered would have 'materially affected the weight-of-evidence determination and [the] conclusion'. The applicants do not specify how such consideration could have had a bearing on the conclusion that D4 and D5 have vB properties. Nor do the applicants make any distinction between the two substances or, in particular, indicate what impact each study could have had on the evaluation and on the conclusion relating to the vB properties of D4, on the one hand, and of D5, on the other hand.

143 It is only at the stage of their observations on the Commission's replies to the questions from the Court and only as regards certain publications prior to the Ruus study on the monitoring of siloxanes in the Oslo fjord between 2014 and 2017 that the applicants indicated how, in their view, the taking into account of those specific publications could have had an impact on the evaluation of the PBT and vPvB properties of D4 and D5. The applicants specified in those observations that certain of those publications indicate a biodilution of D4 and D5.

144 In that regard, it is appropriate to recall that the MSC noted variable results concerning the field data on biomagnification and the TMF and that certain studies on trophic magnification supported the conclusion on the bioaccumulation of D4 and D5. The MSC also found that the information on the BMF and the TMF available on the ground, which indicated that biodilution had occurred in some food chains, did not invalidate the other lines of evidence. The MSC took into account the ECHA Guidance according to which the absence of biomagnification cannot be used to disregard a valid assessment based on reliable BCF data indicating that a substance meets the criteria for B and vB substances set out in Annex XIII. Therefore, even if one or more additional studies had indicated biodilution in certain other food chains, that would not have changed either the overall assessment described by the MSC, according to which there were variable results in that regard, or its conclusion that the information indicating that biodilution had occurred in some food chains did not invalidate the other lines of evidence, in particular those relating to bioconcentration.

145 As regards the other studies referred to by the applicants, it should be noted that the Jia et al. study, for example, even indicates, according to what is stated in the annexes to the opinion of the MSC, a high probability of trophic magnification. The applicants do not state how the references to that study are erroneous or irrelevant. Likewise, the applicants do not indicate how the references to the Hong et al. study contained in the annexes to the opinion of the MSC, the reference to the Sanchis study appearing

in the annex to the opinion of the RAC and the United Kingdom's replies to the draft versions of the Bridges and Solomon studies and to the Gobas articles are erroneous or irrelevant.

146 Accordingly, their line of argument according to which certain relevant studies were not duly taken into consideration must be rejected.

(6) The importance placed on the data

147 The applicants, supported by ACC, argue that the application of a weight-of-evidence determination using expert judgement in the present case was not 'credible', because no quantitative weight was apportioned to each piece or body of evidence. ACC submits that the failure by the MSC to assign quantitative weights to the available information goes against the ECHA Guidance. A weight-of-evidence determination involves the assessment of the relative weights or values of the available information. It is not sufficient to review a large number of studies. The applicants add that a quantitative approach is necessary for reasons of transparency and in order to prevent arbitrary decisions.

148 It must be pointed out that Annex XIII does not require, in the context of a weight-of-evidence determination, that each item of evidence be given a quantitative value, as the Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, rightly contends.

149 It is apparent from the preamble to Annex XIII that 'appropriate weight' is to be given to the quality and consistency of the data, that the available results are to be assembled together in a single weight-of-evidence determination and that it is necessary to compare the information listed in Section 3.2.2 with the criteria mentioned in Sections 1.1.2 and 1.2.2 of that annex. In order for 'appropriate weight' to be given to the quality and consistency of the data, it is not essential that an exact numerical value be given to each item of evidence. It follows from the use of the words 'by comparing' that the information listed in Section 3.2.2 must be examined in the light of its similarities with and differences from the criteria. That does not necessarily imply a purely quantitative approach. Thus, the rules set out in Annex XIII allow the competent EU authorities to apply a quantitative or qualitative weight-of-evidence determination. The choice of the competent authorities between those options in a given case depends on the circumstances of the case, in particular on the nature of the available information to be compared.

150 The ECHA Guidance encourages a quantitative approach for either all or part of the available information. ECHA also states in that document that the establishment of a conclusion property by property requires expert judgement, especially where different types of information are available and cannot be compared directly – that is to say, numerically – with the criteria.

151 Consequently, the description of that approach in the ECHA Guidance and the application of the weight-of-evidence determination without giving a precise value to each item of evidence in the case at hand are consistent with the provisions of Annex XIII, such that the applicants' line of argument in that respect must be rejected.

(7) Certain other errors allegedly committed during the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII

152 It is necessary to reject as out of time and therefore inadmissible, under Article 84(1) of the Rules of Procedure, the applicants' line of argument, raised for the first time in their observations on the statements in intervention of ECHA and ACC, according to which ECHA misinterpreted certain data relating to the BMF in finding that they demonstrated the existence of bioconcentration after having misapplied a lipid correction and a growth-dilution correction. According to the applicants, other data related to the BMF were interpreted as indicating the existence of bioaccumulation. According to the applicants, those data demonstrate, in reality, the opposite, namely the existence of biodilution. The Court must also reject as out of time the arguments set out in the applicants' observations on the Commission's replies to the questions from the Court, according to which BCF values were also poorly corrected for growth.

153 Those arguments, after all, do not constitute an amplification of a complaint made in the application and the applicants have neither alleged nor demonstrated that they are based on matters of law or of fact which came to light in the course of the procedure.

154 In any event, as the Commission and ECHA indicate in their replies to the questions put by the Court, the correction at issue was applied in accordance with OECD Guideline No 305 and Section C.13 of the annex to Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods in accordance with Regulation No 1907/2006 (OJ 2008 L 142, p. 1). The applicants have not demonstrated that errors were made in applying that correction, but rather merely criticise the fact that a correction was applied. The application of the methodology recognised by the OECD and provided for in Regulation No 440/2008, however, cannot be regarded, in itself, as manifestly erroneous on the basis of the applicants' general statement in the reply.

155 Similarly, the applicants' assertion of a misinterpretation of a BMF value of 0.31 as indicating the existence of bioaccumulation must, in any event, be rejected as factually incorrect. As ECHA and the Commission contend in their replies to the questions put by the Court and as is apparent from the file, in particular from the opinion of the MSC, the study by Inoue et al. (2012) was used only to support the conclusion according to which the BCF value of a substance could meet the criterion of vB substances even where its BMF value was lower than 1. Contrary to what the applicants claim, the MSC did not interpret the fact that a BMF value was lower than 1 as indicating the existence of bioaccumulation, but only as not contradicting a high BCF value. Consequently, the applicants' claim stems from a misinterpretation of the opinion of the MSC. Moreover, that assessment by the MSC is consistent with what has been noted in regard to the relationship between bioconcentration and biomagnification in paragraph 95 above.

156 Consequently and in the light of what has been found in paragraphs 74 and 75 above, the first part of the first plea, alleging a manifest error of assessment in the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII, must be rejected.

(b) Second part of the first plea: absence of unacceptable risk arising from the manufacture, use or placing on the market of D4 and D5 in wash-off cosmetic products

157 In the second part of the first plea, the applicants claim that the contested regulation does not comply with one of the conditions laid down for the adoption of a restriction defined in Article 68(1) of Regulation No 1907/2006, namely the condition that unacceptable risk must result from 'the manufacture, use or placing on the market' of a substance.

158 First, the contested regulation does not aim to address a purported concern which arises from the manufacture, use or placing on the market of a substance, but relates to waste. The applicants refer to Article 2(2) of Regulation No 1907/2006, as well as to Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ 2000 L 327, p. 1) and to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2008 L 312, p. 3).

159 Second, the contested regulation covers an alleged risk arising from the disposal of wash-off cosmetic products and not from the manufacture, use or placing on the market of such products. Nor does the contested regulation restrict the use of products, contrary to what was originally proposed. In omitting a restriction on use in favour of a prohibition on placement on the market, that regulation fails to comply with the requirements arising under Section II 3 of Annex XV, according to which a restriction 'must be targeted to the effects or exposures that cause the risks identified', even if it were true that the risks at issue arise from the use of the cosmetic products in question.

160 Third, the applicants maintain that wash-off cosmetic products containing D4 and D5 can be used with water in a manner which does not pose any risk.

161 The Commission disputes those arguments.

162 In that regard, it should be recalled that Article 68(1) of Regulation No 1907/2006 provides for the adoption of new restrictions for the manufacture, use or placing on the market of substances when there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Union-wide basis.

163 As regards the applicants' first argument, it should first of all be stated that, according to Article 1(2) of Regulation No 1907/2006, Regulation No 1907/2006 lays down provisions on substances and mixtures within the meaning of Article 3 of that regulation, applicable to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures. According to the definition set out in Article 3(1) of that regulation, a substance is a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. It is undisputed that D4 and D5 are substances within the meaning of that definition.

164 It is admittedly true that, according to Article 2(2) of Regulation No 1907/2006, waste as defined in Directive 2008/98 is not a substance within the meaning of Article 3 of that regulation. Thus, a substance can cease to be a substance for the purposes of Article 3 of Regulation No 1907/2006 when it becomes waste as defined in EU law (see, to that effect, judgment of 10 September 2015, *FCD and FMB*, C-106/14, EU:C:2015:576, paragraph 52).

165 However, it must be stated that the fact that a substance can lose its status as a substance at the end of its lifecycle for the purposes of Article 3 of Regulation No 1907/2006 is not such as to call into question its status as a substance before that event. That is not apparent either from the definition of the term 'substance' contained in Article 3(1) or from Article 2(2) of that regulation.

166 The contested regulation concerns the placing on the market of D4 and D5 in certain products and not the management of waste containing D4 and D5. It should be stated that, at the stage of their being placed on the market, D4 and D5 constitute substances under Article 3(1) of Regulation No 1907/2006.

167 Accordingly, the applicants' line of argument according to which the contested regulation relates to waste must be rejected.

168 As regards the applicants' second argument concerning the target of the contested regulation, it must be stated that the placing on the market of D4 and D5 is the origin of their use, which gives rise to the risk at issue. There is nothing in the wording of Article 68(1) of Regulation No 1907/2006 to indicate that the restriction should apply exclusively to the point in the lifecycle of the substance in question at which the risk concerned by the restriction immediately and directly materialises.

169 In that regard, it should be noted, as the Commission rightly contends, that risks rarely arise from the placing on the market – in the strict sense of the term and including, in accordance with Article 3(12) of Regulation No 1907/2006, import – of substances, mixtures or articles. Their intended subsequent use and their lifecycle should be considered.

170 A restriction on the placing on the market – including, in accordance with the definition in Article 3(12) of Regulation No 1907/2006, import – of a substance is often the most effective measure for achieving the objective pursued by that regulation, which is to ensure a high level of protection of human health and the environment. If a substance is not placed on the market, it may not be used. On the contrary, hypothetical restrictions prohibiting the use of such products by consumers and final users who are professionals without restricting their being placed on the market would not always enable the risk to be managed effectively.

171 Thus, an interpretation whereby a restriction could apply only at the final stage following which the risks materialise would considerably weaken the effectiveness of the restriction tool provided for in Article 68 of Regulation No 1907/2006 in order to ensure a high level of protection of human health and the environment.

172 It must consequently be held that the contested regulation concerns, in accordance with Article 68(1) of Regulation No 1907/2006, the placing on the market of D4 and D5 in wash-off cosmetic products.

173 Accordingly, and subject to the examination of the other arguments of the applicants concerning the alleged alternatives to the restriction adopted by the contested regulation, in the context of the second plea, the second part of the first plea must also be rejected.

(c) Third part of the first plea: errors allegedly committed in the risk assessment

174 In the third part of the first plea, the applicants, supported by ACC, claim that the risk assessment in this case is vitiated by manifest errors in the assessment of the facts and by errors in law and that it contains an inadequate statement of reasons.

175 They maintain that the United Kingdom, which submitted the Annex XV dossier proposing the restriction at issue, made a manifest error of assessment in considering that any emissions of D4 and D5 were a proxy for ‘unacceptable risk’. According to that interpretation, which ECHA and the Commission subsequently adopted, any emissions of D4 and D5 automatically constitute an ‘unacceptable risk’. Consequently, only zero emissions would have been judged acceptable. That is impossible to achieve in practice. Moreover, again according to that interpretation, the hazard properties alone of a substance constitute an unacceptable risk, which is not consistent with the legislature’s intention.

176 The need to quantify the risks arises also under Section II 3 of Annex XV, according to which, to justify a restriction at Union level, it is necessary to establish that that restriction is capable ‘of reducing these risks to an acceptable level within a reasonable period of time’ and that it is ‘proportional to the risk’. Section 6.5 of Annex I should not be interpreted to mean that it is not possible to control the risks of PBT and vPvB substances and that, consequently, all potential and actual emissions must be minimised regardless of whether the emissions and adverse effects are sufficiently controlled. The applicants, supported by ACC, assert that such a hypothetical approach seeking to reduce the risk to zero is not in accordance with EU law.

177 The applicants also assert that a threshold level of emissions or exposure applies, below which there is no ‘relevant effect or … adverse effect’. Emissions below that threshold do not constitute a risk or an unacceptable risk within the meaning of Article 68(1) of Regulation No 1907/2006. It follows from that provision that only an ‘unacceptable risk’ justifies the adoption of a restriction, which indicates that there is a tolerance of exposure.

178 In addition, the applicants, supported by ACC, argue, relying on the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209, paragraph 151), that it was necessary to establish a ‘critical probability threshold for adverse effects on human health [and the environment] and for the seriousness of those possible effects – which … is [judged as] no longer acceptable for society [and/or the environment] and above which it is necessary, in the interests of protecting human health [and the environment], to take preventive measures’. However, in the case at hand, no critical probability threshold was established.

179 Moreover, in this case, there are no ‘relevant adverse effects’. Persistency and bioaccumulation per se, taken in isolation or together, do not constitute ‘adverse effects’ on human health or the environment. The applicants maintain in the reply, referring to certain studies annexed to it, that, due to those physicochemical properties, the reversibility of D4 and D5 is shorter than that of PBT and vPvB substances.

180 The applicants dispute that Annexes I and XV set out the risk assessment to be undertaken in the context of the adoption of a restriction under Title VIII of Regulation No 1907/2006.

181 With regard, first, to Annex I, it sets out the general provisions for assessing substances and preparing safety reports and does not seek to limit the risk assessment under Title VIII of Regulation No 1907/2006. Moreover, ‘Section [II] 3 of Annex XV relates to information on “hazard and risk”’ and ‘Section 4.0.1 of Annex I REACH states that “a hazard assessment … cannot be carried out with sufficient reliability”’. According to the applicants, ‘Section 4.0.1 [of] Annex I therefore cannot be

interpreted to preclude a valid risk assessment from being conducted in the context of the Title VIII REACH Restriction provisions'.

182 With regard, second, to Annex XV, it rather determines the general principles applicable to the proposal and initial justification of a restriction but should not limit the RAC's risk assessment in accordance with Article 70 of Regulation No 1907/2006. This follows from that provision, according to which the RAC itself is to formulate its opinion 'as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment' and according to which it must form its opinion 'based on its consideration of the relevant parts of the dossier'. In this case, the RAC failed to respect its obligations by limiting itself to the issues set out in the Annex XV dossier and by not assessing the risk, as it believed that it was not possible to assess the risk and exposure.

183 The applicants assert that the outcome would have been different had a risk assessment been done, first, because it is apparent from an assessment of the hazards relating to D4 and D5 and exposure to those substances that the risks are negligible owing to their unique properties, second, due to that incorrect use of any emission as a proxy for risk, third, because that presumption prevented the Commission and ECHA from considering the proportionality of the contested regulation and, fourth, because the Commission and ECHA did not assess the varying degrees of risk relating to the variety of products covered by the contested regulation.

184 The Commission, supported by the Federal Republic of Germany and the United Kingdom, disputes those arguments.

185 As a preliminary point, it is appropriate to clarify the scope of the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209), in which the Court ruled on the interpretation of the Commission's communication on the precautionary principle of 2 February 2000. The Court held in that judgment that that communication could be taken as a codification of the law as it stood at the time when the regulation at issue in the case giving rise to that judgment was adopted (judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 149).

186 However, it must be pointed out that the contested regulation in the present case was adopted on the basis of Article 68(1) of Regulation No 1907/2006 and had to comply with the conditions that were set out therein.

187 Consequently, and in accordance with Article 70 and Article 68(1) of Regulation No 1907/2006, the adoption of the contested regulation presupposed that the Commission was right to take the view that the placing on the market of D4 and D5 in wash-off cosmetic products in a concentration equal to or greater than 0.1% by weight of either substance involved an unacceptable risk to human health or the environment which needed to be addressed on a Union-wide basis.

188 In the light of the line of argument put forward by the applicants in relation to the alleged absence of a risk assessment, it must be stated that it is based on a misinterpretation of Annexes XV and I and on a failure to take into account the specific features of the assessment of the risks associated with PBT and vPvB substances.

189 According to Section II 3 of Annex XV, under the heading 'Information on hazard and risk', the risks to be addressed with the restriction are to be described 'based on an assessment of the hazard and risks according to the relevant parts of Annex I'.

190 Annex I lays down a number of specific provisions applicable to PBT and vPvB substances which are an embodiment of the precautionary principle, as the Commission and the Federal Republic of Germany rightly submit. It is apparent in particular from the provisions of Annex I that the standard approach for the risk assessment described in Section 6.4 of that annex, according to which an environmental risk can be considered to be adequately controlled if the estimated exposure levels do not exceed the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur (Predicted No-Effect Concentrations; 'PNECs'), does not apply to PBT and vPvB substances. According to Section 4.0.1 of Annex I, neither a hazard assessment addressing all the long-term effects, including the establishment of PNECs according to Section 3 of

that annex, nor the estimation of the long-term exposure of the environment is sufficiently reliable for PBT and vPvB substances. Section 6.5 of Annex I provides that a ‘qualitative assessment of the likelihood that effects are avoided’ for substances, such as PBT and vPvB substances, for which it is not possible to establish PNECs, is to be carried out. Moreover, the same section mentions the aim of minimising exposures to PBT and vPvB substances and emissions to humans and the environment.

191 It is apparent from those provisions that it is not possible to address with sufficient reliability and in a quantitative manner the risks associated with PBT and vPvB substances. That finding is also confirmed by the fact that, according to Article 60(3)(b) of Regulation No 1907/2006, the granting of an authorisation on the ground that the risk to the environment is adequately controlled is not possible for PBT and vPvB substances. Such an authorisation may be granted under Article 60(4) of Regulation No 1907/2006 only if it is shown that the socio-economic benefits outweigh the risks and if there are no suitable alternative substances or technologies.

192 Contrary to what the applicants claim, those principles established in Annex I apply not only to the Annex XV dossier, but also in the context of the subsequent steps of the process of adopting a restriction. First, the argument that the legislature laid down principles applicable to the risk assessment for one step of the process leading to the adoption of a restriction, namely for the proposal of such a restriction, and chose to amend those principles for the subsequent steps of that process, is in no way corroborated. Second, the reasons why Annex I sets out specific rules applicable to PBT and vPvB substances, in particular owing to the uncertainty as to the long-term effects of those substances for which the concern is that concentrations in the environment and organisms will continue to increase even after emissions have ceased, are valid and applicable during all steps of the process leading to the adoption of a restriction.

193 The risk assessment in this case followed those rules.

194 The United Kingdom, in its Annex XV dossier, noted the PBT and vPvB properties of D4 and D5. It acknowledged that ‘the risk from PBT/vPvB substances [could] not be adequately addressed in a quantitative way’ and that ‘a qualitative risk assessment should be carried out’ in accordance with Section 6.5 of Annex I. Emissions and exposure could be considered as a proxy for (unacceptable) risk. The United Kingdom inter alia found that the key concerns with D4 and D5 related to their persistence and bioaccumulation in the aquatic environment, such that the aim of the restriction at issue was to reduce releases to surface waters. The contribution of personal care products to emissions to waste water was recorded at 97% for D5 and at 78% for D4, which was why that use was considered to represent the greatest risk to the environment. On the other hand, the United Kingdom found that air emissions were not a source of concern.

195 The RAC, in its opinion, acknowledged the broad concerns arising from PBT and vPvB substances, noted that those substances had effects that were unpredictable in the long term and difficult to reverse, and concluded that a qualitative assessment was necessary, in accordance with Section 6.5 of Annex I. In that opinion, the RAC stated that the aim was to minimise any releases as far as technically and practically possible. The RAC found that wash-off personal care products accounted for a significant amount of emissions of D4 and D5 to the aquatic environment and that emissions from the use phase of those products seemed to be greater than from the formulation stage. The RAC concluded that the risks associated with D4 and D5, as PBT and vPvB substances, could not be quantified adequately and that, therefore, their emissions to the environment could be considered as a proxy for risk. Considering the uncertainty as to the potential significance of emissions of D4 and D5 into the air, the RAC recommended a revision no later than five years after the entry into force of the restriction.

196 Consequently, and in view of what has been noted in paragraphs 74 and 75 above, it cannot be argued that the contested regulation is vitiated by a manifest error of assessment on the ground that, like the United Kingdom, in its Annex XV dossier, the RAC, in its opinion, concluded that the risks associated with D4 and D5 could not be quantified adequately and that their emissions could be considered as a proxy for risk.

197 In view of the line of argument put forward by the applicants concerning the Commission’s failure to identify a threshold of risk considered unacceptable in the absence of establishment of a critical

probability threshold for adverse effects, it is appropriate first of all to recall the procedure and the provisions governing the adoption of a new restriction.

198 First, according to Article 68(1) of Regulation No 1907/2006, the adoption of a new restriction depends on an unacceptable risk which needs to be addressed on a Union-wide basis. Second, and again according to Article 68(1) of that regulation, any decision on the adoption of a restriction must take into account the socio-economic impact of the restriction, including the availability of alternatives. Third, according to Article 69 of Regulation No 1907/2006, the process of adopting a restriction starts with the preparation of an Annex XV dossier if one of the stakeholders mentioned therein considers there to be a risk that is not adequately controlled and needs to be addressed. Fourth, according to Article 70 of that regulation, the RAC's opinion is to take a view on whether the restriction is appropriate in reducing the risk to human health or the environment and, according to Article 71(1) of that regulation, the SEAC, in its opinion, is to state its view inter alia on the socio-economic impact. According to Article 72(1) of Regulation No 1907/2006, ECHA is to submit those opinions to the Commission, which, finally, according to the first subparagraph of Article 73(1) of that regulation, is to prepare the draft amendment to Annex XVII.

199 It is apparent from those provisions that the notion of 'unacceptable risk' in Article 68(1) of Regulation No 1907/2006 is different from that of 'risk that is not adequately controlled and needs to be addressed' in Article 69 of that regulation. It is apparent more specifically from those provisions and, in particular, from the content to be covered by the opinions of the RAC, on the one hand, and of the SEAC, on the other, which guide the Commission in preparing the draft amendment to Annex XVII and in deciding whether or not a risk is unacceptable, that that risk depends on several factors. Those factors include, in particular, the risk assessment, in accordance with the relevant rules set out in Annexes XV and I, the appropriateness of a restriction in reducing the risks assessed and the socio-economic impact of such a restriction.

200 In the case at hand, the Commission was entitled to take account of all those factors when adopting the contested regulation, factors which had been examined in the Annex XV dossier and in the opinions of the ECHA committees referred to in, inter alia, recitals 1 to 5 of the contested regulation.

201 In addition, it should be recalled that, in the present case, unlike the case which gave rise to the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209), the restriction covers PBT and vPvB substances. It must be stated that the relevant provisions of Annex I set out specific rules for the assessment of the risks associated with such substances, as is indicated in paragraph 190 et seq. above.

202 Consequently, the assessment of the existence of an 'unacceptable risk', such as that which was made in the present case in accordance with the terms of Article 68 of Regulation No 1907/2006, is not the same as that of the existence of a 'level of risk deemed unacceptable', such as that which was carried out in the case giving rise to the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209). In the present case, the determination of a critical probability threshold for adverse effects, as required by the applicants, was not necessary, inter alia, by virtue of the specific rules of Annex I relating to PBT and vPvB substances. It is therefore necessary to reject the applicants' line of argument according to which, in order to determine whether there was an 'unacceptable risk' under Article 68(1) of Regulation No 1907/2006, a critical probability threshold for adverse effects should have been established in this case, on the ground that that line of argument is based on a misinterpretation of Article 68(1) of that regulation.

203 Lastly, it is also necessary to reject the line of argument of the applicants and ACC according to which the Commission's assertion that it was entitled to determine the risk implicitly is not in accordance with the case-law of the Court. According to ACC, the implicit determination of risk favours a purely hypothetical approach and precludes the Commission from taking into account the impact of the restriction on free circulation on the internal market.

204 In that regard, it should be stated that the absence of the word 'unacceptable' in the contested regulation does not prove that the Commission considered that the risk at issue was not unacceptable or indeed that it disregarded the conditions allowing the adoption of a restriction or the objectives of Regulation No 1907/2006. With regard to ACC's argument relating to the objective of free circulation,

it should be noted that that objective does not rule out the adoption of restrictions. The contested regulation pursues that objective in that it provides, in accordance with Title VIII of Regulation No 1907/2006, for a harmonised restriction applicable to the placing on the market of the products at issue. It does not follow from the case-law that the Commission should have used the expression 'unacceptable risk'. The case-law relied on in that regard by ACC concerns, for example, the necessity of an evaluation of the risks (judgment of 14 November 2013, *ICdA and Others* v *Commission*, T-456/11, EU:T:2013:594, paragraph 50), the definition of judicial review by the EU judicature (judgment of 1 February 2013, *Polyelectrolyte Producers Group and Others* v *Commission*, T-368/11, not published, EU:T:2013:53, paragraph 29), and the obligation of the institutions to ensure a high level of protection of public health, without basing their decisions on a 'zero risk' (judgments of 17 May 2018, *Bayer CropScience and Others* v *Commission*, T-429/13 and T-451/13, EU:T:2018:280, paragraph 123, and of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 152). On the contrary, the Court, in the judgment of 12 April 2013, *Du Pont de Nemours (France) and Others* v *Commission* (T-31/07, not published, EU:T:2013:167, paragraph 277), also relied on by ACC, found that the fact that a certain active substance had been included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1) for four crops and a duration of 18 months indicated that, for those crops and that duration, the Commission had deemed the risk acceptable. In any event, in the case at hand, it is apparent from that regulation, and in particular from recitals 8 and 9 thereof, and from the legal basis of the contested regulation, to which the second introductory paragraph of that regulation refers, that the Commission implicitly, but necessarily, regarded the risks associated with D4 and D5 in certain cosmetic products as constituting an unacceptable risk to the environment.

205 In the light of those considerations and having regard to what has been noted in paragraphs 74 and 75 above, it must be held that none of the arguments put forward by the applicants, supported by ACC, prove that the contested regulation is vitiated by a manifest error committed during the risk assessment.

206 That finding is not called into question by the arguments put forward by the applicants in the alternative – should the Court conclude that substances with persistent or bioaccumulative properties automatically have adverse effects – according to which D4 and D5 have no adverse effects and according to which, in particular, there was no assessment of adverse effects or unacceptable effects, no adequate assessment, and no determination that the effects exceeded the critical threshold. Those unclear arguments, first, are based on the false premiss according to which the assessment of the risks associated with the substances at issue and with PBT and vPvB substances, in general, requires an assessment of adverse effects and, second, constitute a reformulation of their criticisms that have already been rejected above.

207 Nor is that finding called into question by the applicants' assertion in the reply that D4 and D5 have unique physicochemical properties, pass from other compartments to air where they degrade more rapidly and, unlike PBT and vPvB substances, are readily reversible. Because of their unique properties, any risks relating to D4 and D5 can, in the applicants' opinion, be identified, quantified and sufficiently controlled.

208 First, it must be stated that the applicants have demonstrated neither that the substances at issue are easily reversible in the environment despite their persistency and bioaccumulation nor that they are different from the other PBT or vPvB substances, such that the rules applicable to the assessment of the risks associated with those substances are not applicable and the concern generally associated with such substances is dispelled for D4 and D5. So far as concerns the assessment in paragraph 9 of the reply and the studies provided in annex, reference is made to paragraph 125.

209 Second, similar arguments have already been raised and rejected in the first part of the first plea. It is necessary, for the same reasons, to reject them also in the present part of the plea relating to the risk assessment for similar considerations. The allegedly unique properties of the substances at issue were taken into account during the administrative procedure and the applicants have not demonstrated how the assessment made in the present case is manifestly erroneous. None of the applicants' arguments is capable of dispelling the concerns relating to emissions of the substances at issue on account of their persistency and their bioaccumulation.

210 Accordingly, the third part of the first plea must be rejected.

(d) Fourth part of the first plea: alleged failure to review the 'fundamental basis' for the contested regulation

211 It is appropriate to examine, in the fourth part of the first plea, the arguments raised by the applicants in support of their plea alleging breach of essential procedural requirements according to which the Commission itself 'never reviewed or considered whether D4 or D5 had th[o]se purported hazardous properties, nor reviewed the scientific evidence or information regarding th[at] issue'. The applicants submit that 'the Commission never adequately or sufficiently considered or reviewed the fundamental basis for the contested act', that 'it never sufficiently stated the reasons for the adopt[ion] of the contested act' and that, 'by failing to assess, consider or review the fundamental basis and purported legal justification for the contested act, and/or sufficiently stating the reasons, the Commission committed a manifest error in the exercise of its discretionary powers; and/or misused its powers; and/or committed an act manifestly exceeding the limits of its discretionary powers'.

212 The Commission disputes those arguments.

213 It should first of all be noted that, according to the second subparagraph of Article 73(1) of Regulation No 1907/2006, where the draft amendment prepared by the Commission diverges from the original proposal or if it does not take ECHA's opinions into account, the Commission is to annex a detailed explanation of the reasons for the differences. It is apparent from that provision that, first, the Commission is not bound by the opinions of the committees and, second, that the obligation to provide a detailed explanation is necessary only where the Commission diverges from the draft amendment to the proposal or from ECHA's opinions. On the contrary, such a detailed explanation is not necessary when the Commission follows the proposal and ECHA's opinions.

214 Moreover, it should be pointed out that the Commission takes its decision at the end of a long administrative procedure described in Title VIII of Regulation No 1907/2006, during which the various stakeholders prepare opinions of a scientific nature, after a public consultation, in order to prepare the final Commission decision. It is apparent from Article 73 of Regulation No 1907/2006, read in conjunction with recital 94 of that regulation, that the Commission is required to prepare its draft amendment in order to speed up the amendment procedure, within three months of either receipt of the opinion of the SEAC or by the end of the deadline established under Article 71 of the same regulation for the adoption of that opinion.

215 In the case at hand, the Commission states that it examined ECHA's underlying opinions and adhered to them, as the contested regulation attests. It is apparent inter alia from recitals 2 and 3 of that regulation that the Commission took into account the opinions of the MSC and of the RAC as to the vPvB properties of D4 and D5 and as to the PBT and vPvB properties of D4 and the vPvB properties of D5, respectively. In addition, it is apparent from recital 8 of the contested regulation that the Commission itself considered that a risk arose from the presence of D4 and D5 in wash-off cosmetic products because of the hazard properties of those substances.

216 As follows from the considerations set out in paragraph 213 above, the Commission was not required to explain in detail why it followed ECHA's conclusions. Thus, it does not follow from the absence of such an explanation that the Commission felt bound by the restriction proposal or by ECHA's opinions, or that it did not examine those opinions.

217 Moreover, the Commission, while adhering to ECHA's opinions and the proposal for restriction, was not required to carry out a new scientific assessment, comparable to that carried out by the stakeholders to which Regulation No 1907/2006 expressly entrusted that task in view of their respective powers. The procedure provided for in Title VIII of Regulation No 1907/2006, in particular the preparation of an Annex XV dossier and the opinions of the ECHA committees, is intended to provide the Commission with the necessary scientific information to enable it to determine, in full knowledge of the facts, whether or not there is an unacceptable risk to health and the environment and restrictions in order to address such a risk. First, it follows from Articles 69 to 71 and 73 of Regulation No 1907/2006, governing the procedure for adopting a restriction, that the Annex XV dossier prepared by a Member State or by ECHA and the opinion of the SEAC are to be prepared within 12 months, and the opinion of

the RAC within 9 months, whereas the Commission is to prepare a draft amendment within 3 months. Second, it is apparent from Article 69(1) of Regulation No 1907/2006, read in conjunction with recital 91 thereof, that the Commission is to entrust ECHA with the preparation of an Annex XV dossier when it considers there to be a risk under Article 69(1) of Regulation No 1907/2006. Third, according to recital 95, ECHA should be central in ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility; for that reason, that agency is ensured inter alia a high scientific capacity.

218 It follows from all the foregoing that the last part of the first plea must also be rejected, as must, therefore, the first plea in its entirety.

2. Second plea in law: breach of the principle of proportionality

219 The applicants argue that the contested regulation is not in conformity with the principle of proportionality. It is not appropriate or necessary to address the purported concern, does not constitute the least onerous measure and causes disadvantages which are disproportionate to the aims pursued.

220 In the first place, given that the purported concern relates, according to the applicants, to the waste phase of certain cosmetic products, the contested regulation, which concerns placement on the market, is disproportionate. According to the applicants, a risk-management measure addressing the purported concern, namely the disposal of waste products, would have been more appropriate and less onerous than the restriction on the placement on the market of the cosmetic products at issue and would not have caused disadvantages disproportionate to the aims pursued.

221 In the second place, the applicants maintain that they had already stated, before the adoption of the contested regulation, that there was no unacceptable risk which was not adequately controlled. They assert that there were risk-management measures already in place and that the risks at issue were able to be identified and managed using the ‘standard PEC/PNEC approach’.

222 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the second plea should also be rejected as unfounded.

223 According to settled case-law, the principle of proportionality, which is one of the general principles of EU law, requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see judgments of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124 and the case-law cited, and of 1 February 2013, *Polyelectrolyte Producers Group and Others* v *Commission*, T-368/11, not published, EU:T:2013:53, paragraph 75).

224 With regard to judicial review of the conditions referred to in the previous paragraph, the Commission must be allowed a broad discretion in a sphere which entails political, economic and social choices on its part and in which it is called upon to undertake complex assessments. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the legislature is seeking to pursue (see judgments of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 125 and the case-law cited, and of 1 February 2013, *Polyelectrolyte Producers Group and Others* v *Commission*, T-368/11, not published, EU:T:2013:53, paragraph 76).

225 In the present case, it is apparent from recitals 1, 3 and 8 of the contested regulation that that regulation was adopted in order to address the risks to the environment associated with the use of D4 and D5 in wash-off cosmetic products.

226 That objective is consistent with the objectives pursued by Regulation No 1907/2006. Indeed, the purpose of that regulation, pursuant to Article 1(1) thereof, is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Having regard to recitals 87, 89 and 91 of Regulation

No 1907/2006, the Court finds that the legislature set as the main purpose of the introduction of new restrictions and the amendment of existing restrictions, as provided for in Title VIII of that regulation, the first of those three objectives, namely ensuring a high level of protection of human health and the environment (see paragraph 73 above).

227 The restriction of the placing on the market of wash-off cosmetic products containing D4 and D5 in a concentration equal to or greater than 0.1% by weight of either substance is appropriate having regard to that objective. That restriction, after all, limits the use of such products to minimal quantities. It is the intended use of those products, however, that causes emissions of D4 and D5 to the aquatic environment. It is without committing a manifest error of assessment that the Commission found that that posed an unacceptable risk to the environment (see paragraph 185 et seq. above).

228 In the light of the line of argument put forward by the applicants, it is therefore appropriate to examine whether or not, in the case at hand, there was another appropriate, but less onerous, measure.

229 In that regard, in a proportionality test consideration may be given to possible less restrictive means than the measure adopted by the Union institution only if they are equally suitable for achieving the objective pursued by the EU measure in question (see, to that effect, judgments of 14 December 2004, *Arnold André*, C-434/02, EU:C:2004:800, paragraph 55; of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802, paragraph 56; and of 4 May 2016, *Philip Morris Brands and Others*, C-547/14, EU:C:2016:325, paragraph 180).

230 It should be noted that different options for limiting the environmental risks associated with D4 and D5 in wash-off cosmetic products were examined in detail during the administrative procedure leading to the adoption of the contested regulation. It is apparent, in particular, from the Annex XV dossier and from the ECHA document relating to the opinion issued on that dossier that the removal efficiency of existing treatment plants and the measures under Directive 2000/60, that the possibility of granting an authorisation under Regulation No 1907/2006 and the possibility of voluntary measures by the industry were examined. It was considered that those options were limited in various ways, and that only the restriction at issue could achieve the targeted removal of a key use that dominates aquatic emissions. In the light of those considerations and of what has been stated in paragraph 224 above, it must be held that the assessment in this case according to which there was no other measure as appropriate as the restriction established by the contested regulation was not manifestly erroneous.

231 None of the arguments put forward by the applicants is capable of calling that finding into question.

232 As regards, first of all, the applicants' line of argument according to which the restriction provided for in the regulation is disproportionate since it concerns the placing on the market of D4 and D5 in the products in question and not waste disposal, it is necessary to recall the considerations set out in paragraph 168 et seq. above and in particular the fact that a restriction on placement on the market appears to be more effective than other alternatives. In addition, Article 68(1) of Regulation No 1907/2006 provides for the amendment of the restrictions applicable to manufacture, placement on the market and use without establishing a hierarchy between those three options. Thus, the mere fact that the contested regulation concerns the placing on the market of the products in question and not their use could not imply that it is disproportionate, unless there were a restriction on use which was both equally suitable, but less onerous than the contested regulation. The applicants, however, have failed to prove, convincingly, that that was the case. The applicants' line of argument in that regard must therefore be rejected.

233 So far as concerns, next, the applicants' line of argument concerning the alleged existence of less onerous alternative measures, it should be noted that the contested regulation is the result of a long administrative procedure during which various options for limiting the risks to the environment associated with the use of D4 and D5 in wash-off cosmetic products were examined, by the United Kingdom in particular, in the Annex XV dossier.

234 As regards the line of argument according to which the risks associated with the use of D4 and D5 in wash-off cosmetic products can be addressed by following the 'standard PEC/PNEC approach', it must be recalled that it has already been held in paragraph 190 above that, according to Annex I, the PNEC does not apply to PBT and vPvB substances and a hazard assessment addressing all the long-term

effects or the estimation of the long-term exposure of the environment are not sufficiently reliable for those substances. Consequently, the measures proposed by the applicants cannot be regarded as appropriate for addressing the risks associated with D4 and D5 used in wash-off cosmetic products.

235 As regards, moreover, the applicants' line of argument, raised in the first plea, according to which wash-off cosmetic products containing D4 and D5 can be used with water in a manner which does not pose any risk, it must be stated that the applicants do not provide any precise description of that alleged use or of how it would be possible to impose and control that specific use by users. Thus, it is not possible to verify whether the measure advocated by the applicants is appropriate or whether it would have been less onerous than the restriction laid down by the contested regulation.

236 In any event, in order for such an allegedly safe use of the products at issue to be able to reduce emissions of D4 and D5 to the aquatic environment with the same effectiveness as the restriction on placement on the market as provided for by the contested regulation, it would have to be implemented by all users of wash-off cosmetic products within the European Union, including consumers. Given the difficulty of ensuring compliance with a very specific way of using a cosmetic product by all consumers, it is clear that such a measure would be less appropriate for achieving the legitimate objective of reducing emissions of D4 and D5 to the aquatic environment.

237 In terms of the possibility of not prohibiting certain products but of restricting their sale or use so that only specifically trained professional users may use them, it is sufficient to note that a restricted and controlled use of wash-off cosmetic products containing D4 and D5 would not be as effective as the restriction on the placing on the market of those products provided for by the contested regulation with a view to reducing emissions of D4 and D5 to the aquatic environment. Such a measure would make it possible only to reduce the emissions of D4 and D5 contained in wash-off cosmetic products, whereas the contested regulation prevents the placing on the market of such products and, therefore, the emissions linked to the use of those products.

238 Lastly, as regards the applicants' line of argument according to which a measure relating to waste disposal would have been more appropriate and less onerous, it should be stated once again that the applicants do not provide any details concerning the implementation of such a measure. Nor is it possible, therefore, to verify whether such a measure would have been more appropriate or whether it would have been less onerous than the restriction provided for by the contested regulation, chosen on the basis of the examination of proportionality carried out by the United Kingdom in the Annex XV dossier. The application, after all, does not contain any detailed elements liable to call into question the exercise of discretion underlying the adopted restriction. At the very least, the application should have contained concrete elements illustrating the feasibility of an alternative approach that would have enabled the difficulties identified in the abovementioned proportionality examination to be addressed.

239 In any event, the Annex XV dossier had already taken into account inter alia removal efficiency in respect of D4 and D5 by existing treatment plants and the measures under Directive 2000/60. It is stated in that dossier that those plants are usually efficient at removing D4 and D5, but that removal efficiency varies between the different plants. The dossier specifies that it is difficult to estimate the costs of upgrading existing treatment plants, which will depend on several unknown factors, and that information on improving efficiency at removing other substances suggests that those costs could be significant. Furthermore, according to that file, in some cases, waste water might not be treated in treatment plants. In that regard, the United Kingdom also examined, in that dossier, the effects of an increase in the proportion of waste water treated within the European Union, which would reduce emissions to a certain extent. The United Kingdom concluded that measures taken under Directive 2000/60 could be useful as a supplement to the proposed restriction. However, according to the United Kingdom, even if D4 and D5 were identified under that directive as priority hazardous substances and the Commission established an environmental quality standard, Member States would have to adopt measures under that standard only where it was feasible and not disproportionately costly. Thus, according to that State, measures aimed at controlling supply, such as the proposed restriction, are more cost-effective than national measures aimed at improving water-treatment plants. Furthermore, the latter type of measure would place the burden of monitoring on Member States rather than on the industry.

240 In view of the uncertainties described by the United Kingdom in terms of the implementation and efficiency of those measures potentially alternative or supplementary to the proposed restriction, as well as the fact that waste waters within the European Union are not necessarily all treated at treatment plants (see, inter alia, Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ 1991 L 135, p. 40) and the Eighth Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation status and the programmes for implementation (as required by Article 17) of that directive), and having regard to what has been noted in paragraph 224 above, it must be stated that the fact that the measures relating to the treatment of waste water were rejected as alternative, less onerous measures does not constitute a breach of the principle of proportionality.

241 That is all the more so since the alternative suggested by the applicants would mean that the cost of minimising the risks associated with D4 and D5 would be borne entirely by the taxpayer in order for the applicants to be able to continue to market them.

242 No socio-economic element justifying, or even requiring, such a distribution of the cost of the risks associated with the substances in question has been put forward in the present case, however. On the contrary, the costs associated with the adopted restriction were analysed in detail during the administrative procedure. More specifically, the United Kingdom analysed in the Annex XV dossier the costs caused by the restriction. It considered them to be relatively low, compared them with the benefits generated and concluded that the proposed restriction was proportionate. The opinion of the SEAC also analysed those costs, compared them with the benefits and did not conclude that there was a proportionality problem. Since the applicants have not claimed that there is any specific disadvantage which is disproportionate to the objectives pursued and having regard to the considerations set out in paragraph 224 above, it must be held that it has not been established that the contested regulation causes any disadvantages which are disproportionate to the aims pursued.

243 In addition, the decision to restrict placement on the market in order to prevent the emissions of the substances in question and not to accept those emissions or to use public money to remove the substances discharged is consistent with the principle laid down in the first subparagraph of Article 191(2) TFEU, according to which EU policy on the environment is, inter alia, to be based on the principle that environmental damage should as a priority be rectified at source and on the principle that the polluter should pay.

244 Consequently, none of the arguments raised by the applicants demonstrates that the contested regulation exceeds the limits of what is appropriate and necessary in order to achieve the objective pursued.

245 Accordingly, the second plea must be rejected.

3. Third plea in law: breach of essential procedural requirements

246 The applicants maintain, in essence, that the process leading to the adoption of the contested regulation is affected by a breach of essential procedural requirements. By a first complaint, the applicants claim that the Commission ‘never reviewed or considered whether D4 or D5 had th[o]se purported hazardous properties, nor reviewed the scientific evidence or information regarding th[at] issue’, that it ‘never adequately or sufficiently considered or reviewed the fundamental basis for the contested act’, that ‘it never sufficiently stated the reasons for the adopt[ion] of the contested act’ and that, ‘by failing to assess, consider or review the fundamental basis and purported legal justification for the contested act, and/or sufficiently stating the reasons, [it] committed a manifest error in the exercise of its discretionary powers; and/or misused its powers; and/or committed an act manifestly exceeding the limits of its discretionary powers’.

247 By a second complaint, the applicants argue that it was for the RAC, and not the MSC, to assess all the underlying factors and justification for the restriction set by the contested regulation. The adoption of an opinion by the MSC therefore constitutes a procedural step which is neither envisioned nor allowed by Regulation No 1907/2006 where a restriction is being decided. Finally, the hazard assessment carried out by the MSC was deficient, to the extent that it was necessary to address it in the preparation of the opinion of the RAC.

248 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the third plea should also be rejected as unfounded.

249 As regards the first complaint and the alleged obligation on the Commission to re-examine itself whether D4 and D5 had dangerous properties, it must be pointed out that it has already been examined and rejected as unfounded in the fourth part of the first plea, to which reference is therefore made.

250 As to the second complaint, first, the applicants' argument that the hazard assessment carried out by the MSC was deficient must be rejected as inadmissible under Article 76(d) of the Rules of Procedure. Indeed, as the Commission notes, that argument is not substantiated in any way in the present plea. The applicants have not explained what the deficiencies or gaps in that opinion are. Moreover, if that argument were to be understood as a reference by the applicants to their arguments relating to the alleged errors committed during the hazard assessment raised in the first part of the first plea, it must be noted that the applicants have not demonstrated the existence of such errors.

251 Second, the applicants submit that the procedure set out in Articles 69 to 73 of Regulation No 1907/2006 was flawed because the MSC was consulted, although such consultation is not provided for by that procedure.

252 It must be stated that Article 77(3)(c) of Regulation No 1907/2006 allows the Executive Director of ECHA to obtain the opinion of the MSC concerning the safety of substances on their own, in mixtures or in articles. There is therefore a legal basis for intervention by the MSC in such a context. What is more, no provision of Articles 68 to 73 of Regulation No 1907/2006, or even of Article 77 thereof, excludes the possibility of such intervention by the MSC in addition to the requirements set by the procedure for adopting a restriction.

253 As for the rest, the Commission has explained – again without being contradicted by the applicants – that this additional opinion was requested in order to avoid possible conflicts of opinion or approach regarding the assessment of PBT properties between the RAC, which, as part of the restriction procedure, performs the risk-assessment part based on the Annex XV dossier, and the MSC, which is responsible for the identification of, inter alia, PBT and vPvB substances, as substances of very high concern within the procedure set out in Article 59 of Regulation No 1907/2006.

254 Next, it is common ground between the parties that the RAC relied on the opinion of the MSC and that it did not re-evaluate the P and B properties of D4 and D5. Moreover, it should be noted that the parties do not dispute that the T properties of D4 and D5, for their part, were examined by the RAC.

255 With regard to the argument raised by the applicants in the sixth plea, alleging breach of the principle of good administration, according to which P, vP, B and vB properties, on the one hand, and T properties, on the other, were examined by different committees, it should be noted that Article 70 of Regulation No 1907/2006 provides that the RAC is to formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health or the environment, based on its consideration of the relevant parts of the dossier. Contrary to what the applicants claim, that provision does not therefore require that, in order to formulate its opinion, the RAC itself must assess the P, vP, B, vB and T properties of the substances for which a restriction is suggested. On the contrary, that provision explicitly states that that opinion is to be formulated on the basis of all the relevant parts of the dossier, which include, in this case, the opinion of the MSC.

256 An obligation whereby information relating to a property should be assessed at the same time or by the same ECHA committee as other information follows neither from Article 70 of Regulation No 1907/2006 nor from the third paragraph of the preamble to Annex XIII, according to which 'all available information bearing on the identification of a PBT or a vPvB substance is considered together'. Sections 3.1 and 3.2 of Annex XIII make an explicit distinction, on the contrary, between the data to be taken into consideration for the screening of each of those properties and the information to be examined for the assessment of each of those properties.

257 Furthermore, there is no direct link between the information on which a conclusion on the T property is to be based (such as, in this case, the information on toxicity for reproduction) and the information on which a conclusion on the P and vP properties (the degradation half-life in particular) is to be based,

and B and vB properties (the bioconcentration factor in particular). The applicants have inter alia not indicated what impact an examination of the T property by the same committee or at the same time as P, vP, B and vB properties would have had on the conclusion relating to one or all of the properties.

258 Consequently, contrary to what the applicants claim, there is nothing to indicate that the procedure for adopting the restriction was vitiated on the ground that the assessment of the P, vP, B and vB properties of D4 and D5 was carried out by the MSC and not by the RAC.

259 Accordingly, the second complaint and, therefore, the third plea in its entirety must be rejected.

4. Fourth plea in law: breach of the principle of legal certainty and of the principle of legitimate expectations

260 The fourth plea consists of two parts.

261 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the fourth plea should also be rejected as unfounded.

(a) First part of the fourth plea: breach of the principle of legal certainty

262 By the first part of this plea, the applicants invoke a breach, by the Commission, of the principle of legal certainty. They submit, in essence, that they do not know how the hazard assessment in respect of the substances D4 and D5 was carried out, how the TMF and BMF data were weighted and how those data were compared to the BCF data. In short, Sections 1.1.2 and 1.2.2 of Annex XIII lack clarity and precision.

263 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).

264 In the case at hand, it should be noted that the contested regulation sets out all necessary parameters for identifying its legal effects, in a clear and precise manner, thus giving the applicants the opportunity to ascertain unequivocally the scope of that regulation.

265 The applicants maintain, however, that they are unaware of the manner in which the hazard assessment in respect of the substances D4 and D5 was carried out, in which the TMF and BMF data were weighted and in which those data were compared to the BCF data. According to them, there is no clear or precise rule in Sections 1.1.2 and 1.2.2 of Annex XIII governing the way in which ECHA conducts or applies the weight-of-evidence determination using expert judgement and, in particular, the manner in which ECHA attributes weight to specific evidence, especially to non-BCF data.

266 That reasoning must be rejected. On the one hand, it reiterates, in essence, the same arguments as those put forward by the applicants in the first plea, alleging manifest errors of assessment, reference to which is therefore made.

267 Second, even if it were accepted, as the applicants maintain, that the rules contained in Sections 1.1.2 and 1.2.2 of Annex XIII are neither clear nor precise, the applicants have in any event not explained in what way that alleged lack of clarity and precision – again, assuming it were established – created a situation of legal uncertainty for them.

268 The application does not contain any information in that regard and, in the reply, the applicants merely claim that, due to the lack of clarity and precision in Sections 1.1.2 and 1.2.2 of Annex XIII, they were unable ‘to ascertain what their rights and obligations were and take steps accordingly’, but also that they ‘could not assert their rights to good administration, to be heard, and/or of defence’. It is clear, however, that those claims are not substantiated in any way and are not specifically developed under the present plea. In addition, the arguments relating, first, to breach of the principle of good administration and, second, to breach of the rights of the defence and of the right to be heard are rejected below under the sixth and seventh pleas.

269 Thus, even assuming that those arguments, set out for the first time at the stage of the reply, are admissible despite their being out of time, it must be stated that the applicants have not explained in any way whatsoever how, in concrete terms, the alleged lack of clarity and precision, if proven to be true, infringed those rights or created a situation of legal uncertainty for them.

270 The first part of the fourth plea must therefore be rejected as unfounded.

(b) Second part of the fourth plea: breach of the principle of legitimate expectations

271 By the second part, the applicants argue that the principle of legitimate expectations was breached, to the extent that the ECHA Guidance, which constitutes a precise assurance by ECHA as to the course of conduct that it follows, was substantially amended in June 2017, with the addition of new sections on the assessment of bioaccumulation and on the conclusions relating to PBT or vPvB properties.

272 As a preliminary point, it should be recalled that, according to settled case-law, 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 or her precise assurances. In that regard, 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, to that effect, judgment of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraphs 137 and 138 and the case-law cited).

273 In the present case, first, it is clear that the applicants have neither demonstrated nor even argued that ECHA or the Commission provided them with precise assurances, with regard to the outcome of the hazard assessment or the outcome of the restriction procedure for the products concerned.

274 At most, the applicants submit that the ECHA Guidance constituted a precise assurance within the meaning of the case-law cited above. On that point, the applicants criticise the MSC for having issued its opinion on the B and vB properties of D4 and D5 on the basis of the 2014 version of the ECHA Guidance and not on the basis of the 2017 version of that document. According to the applicants, that 2017 version includes substantial changes compared to the 2014 version. The older version was, moreover, characterised by manifest errors and outdated scientific understanding.

275 That argument cannot succeed. When the MSC adopted its opinion on 22 April 2015, it relied on the texts in force at that date. In so doing, far from departing from the rules by which the ECHA voluntarily limited its discretion, the MSC fully applied the provisions contained in the 2014 version of that guidance. Furthermore, and in any event, the MSC, the RAC and the SEAC cannot logically be criticised for not having taken into account, in 2015 and in 2016 respectively, a text, namely the new edition of the ECHA Guidance, which was adopted only afterwards, namely in 2017.

276 Second, as is apparent from paragraph 15 above, it is equally clear that the applicants participated in the public consultation, organised between 18 June and 18 December 2015, providing comments and submitting evidence. The applicants were therefore perfectly aware of the existence of the procedure liable to culminate in the adoption of a restriction then in progress and they could anticipate the adoption of the contested regulation.

277 It is apparent from the case-law that, if a prudent and alert economic operator can foresee the adoption of an EU measure likely to affect his or her interests, he or she cannot plead the principle of protection of legitimate expectations if that measure is adopted (see judgment of 23 January 2019, *Deza* v *ECHA*, C-419/17 P, EU:C:2019:52, paragraph 71 and the case-law cited).

278 In the light of those considerations, the second part of the fourth plea and, therefore, the fourth plea in its entirety must also be rejected.

5. Fifth plea in law: breach of the institutional balance of powers

279 The applicants argue that, in the absence of coherent legal criteria, ECHA itself determined that D4 and D5 were B and vB substances, outside and independently of the applicable law. However, ECHA, as an administrative agency of the European Union, has no legal authority or powers to make law or decide what legal provisions should and should not apply to a specific substance. The delegation of such powers to ECHA constitutes a breach of the institutional balance of powers.

280 The opinions of ECHA, even though they were not legally binding, were extremely important in the present case, especially given that the Commission argued that it was not envisioned that it would reassess the scientific basis of the proposed restriction and that it was fully entitled to rely on those opinions. The opinions of ECHA as provided for in Title VIII of Regulation No 1907/2006 set out processes and conclusions from which the 'administration cannot depart in a particular case without giving reasons that are compatible with the principles of legal certainty and legitimate expectations, [and] the right to good administration, including the obligation … to state reasons'.

281 Given that it is not possible to understand ECHA's assessment, that the legal provisions lack clarity, precision and consistency, and that the Commission does not intend to reassess the scientific basis of the decision to be made, ECHA's decision-making is unconstrained by clear rules or implementable law and free of relevant regulatory oversight. According to the applicants, this amounts to an administrative agency's making – not implementing – law, in breach of the institutional balance of powers.

282 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the fifth plea should also be rejected as unfounded.

283 It should be recalled that ECHA was established under Article 75 of Regulation No 1907/2006 for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of that regulation and to ensure consistency at Union level in relation to these aspects.

284 Annex XIII lays down, inter alia, criteria for the identification of PBT and vPvB substances as well as the information that must be considered for the purposes of assessing the P, vP, B, vB and T properties of a substance. According to Article 59(8) and (9) of Regulation No 1907/2006, the MSC is to deliver an opinion on the identification of substances which, in accordance with Article 57 of that regulation, may be included in Annex XIV to that regulation (see also paragraph 253 above). That includes in particular substances such as those provided for in Article 57(c) and (d) of Regulation No 1907/2006, namely PBT or vPvB substances in accordance with the criteria set out in Annex XIII.

285 It is apparent from those provisions that the EU legislature itself laid down in Annex XIII the criteria for identifying PBT and vPvB substances and the information to be considered, whereas, in the context of the identification of substances of very high concern, it entrusted the MSC, inter alia, with the task of assessing whether a given substance was a PBT or vPvB substance by applying the rules laid down in Annex XIII.

286 It should be recalled that, in the case at hand, the MSC delivered its opinion on the vB properties of D4 and D5 in accordance with the provisions of Regulation No 1907/2006, and with the provisions of Annex XIII in particular. It has already been found in paragraph 213 et seq. above that the Commission examined the opinions of ECHA, in particular the opinion of the MSC, adhered to those opinions and then adopted the contested regulation. Moreover, it is apparent from the second subparagraph of Article 73(1) of Regulation No 1907/2006 that the Commission is not bound by those opinions, which are merely preparatory acts for the contested regulation.

287 As regards, more specifically, the opinion of the MSC, it should be noted that, in that opinion, the MSC compared all available information with the criteria for identifying B and vB substances, as laid down in Sections 1.1.2 and 1.2.2 of Annex XIII. A direct comparison of the BCF data for D4 and D5 observed in certain studies was possible and carried out. Nevertheless, the MSC analysed the other available information and compared it with those criteria and thus applied a weight-of-evidence

determination based on expert judgement. Thus, the MSC applied the rules laid down by the legislature. There is nothing in the opinion of the MSC to suggest that it had disregarded the rules set out by the legislature in Annex XIII or that it had itself laid down rules which were not provided for by the legislature.

288 The applicants do not provide any concrete examples in support of their line of argument, but merely state in general terms that, in the absence of clear rules, ECHA's assessment of the B and vB properties of D4 and D5 was not sufficiently circumscribed by the legislator, meaning that the task of drafting the legislation was left to ECHA.

289 The applicants' line of argument in that regard is, moreover, contradictory. On the one hand, the applicants claim on several occasions in the application that the contested regulation is vitiated by manifest errors of assessment, given that ECHA and the Commission applied the Annex XIII criteria directly to D4 and D5 when, in their view, those criteria were not applicable or should have been adjusted, while, at the same time, they claim that ECHA acted outside and independently of the applicable law.

290 In the light of those considerations, the fifth plea must be rejected as unfounded.

6. Sixth plea in law: breach of the principle of good administration

291 The applicants submit that the Commission and ECHA, in carrying out an assessment of the purported B and vB properties of D4 and D5, were required to ensure that a scientific risk assessment was carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence, which is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude arbitrary measures.

292 The applicants argue, in the first place, that the Commission and ECHA breached the principle of good administration and the requirement to ensure that administrative procedures in risk assessments ensure scientific objectivity and preclude arbitrary measures. They maintain that there was no transparency, in particular regarding the assessment of BCF data and non-BCF data. In the absence of clear criteria on how non-BCF data were valued and compared to BCF data, the contested regulation constitutes an arbitrary exercise of the Commission's and ECHA's discretionary powers.

293 The applicants argue, in the second place and referring to their argument raised under the third plea, alleging breach of essential procedural requirements, that the Commission breached the principle of good administration because it 'never adequately or sufficiently considered or reviewed the fundamental basis' for the contested regulation.

294 The applicants argue, in the third place, that the contested regulation was adopted arbitrarily and in breach of the right to good administration, of the correct procedure, as set out in Regulation No 1907/2006 because it was the MSC and not the RAC which assessed the P and vP and B and vB properties of D4 and D5.

295 In the reply, the applicants argue that the adoption of the decisions by ECHA was arbitrary given that neither the restrictions procedure as laid down by Regulation No 1907/2006, nor the Title VIII provisions, nor those of Annex XIII were respected.

296 In support of their argument alleging failure to respect the provisions of Annex XIII, the applicants maintain that there was no hazard assessment, but that a flawed weight-of-evidence determination was applied. The information on the P, vP, B, vB and T properties was not assessed together, the information listed in Section 3.2 of Annex XIII was not compared with the criteria set out in Section 1 of that annex and the information used was not obtained under relevant conditions. Finally, the P, vP, B, vB and T properties were assessed separately and, in the case of the T property, by a different committee.

297 In support of their argument alleging failure to respect the provisions of Title VIII of Regulation No 1907/2006, the applicants refer to the fact that the opinion of the MSC was initiated before the restriction procedure began and pursuant to Article 77(3)(c) of that regulation, and therefore outside the

context of the provisions of Title VIII of Regulation No 1907/2006. The RAC did not assess the P and vP or B and vB properties of D4 and D5 nor did it assess the risks relating to those substances.

298 In addition, the applicants argue that there was an arbitrary use of discretionary powers as the decisions were not scientifically valid. By way of example, with regard to the alleged arbitrary decisions, the applicants reiterate certain arguments raised in support of the first plea. They add, referring to the defence, that the RAC limited the assessment to parts of the Annex XV dossier, but that it should have assessed all relevant aspects relating to whether the restriction was appropriate in reducing risk, as is laid down in Article 70 of Regulation No 1907/2006.

299 Finally, the applicants dispute, in the reply, the independence and transparency of the scientific assessment. There was no transparency in the weight-of-evidence determination, in particular regarding the weight that was attributed to information and regarding certain other alleged flaws referred to in the context of the first plea. The applicants also refer to the absence of transparency regarding the significant evolution in scientific techniques used to assess bioaccumulation. In support of the latter argument, they refer to a document submitted by the CES, a regional association of the applicants, as part of the public consultation on the Annex XV dossier regarding the identification of D4 as a substance of very high concern in 2018.

300 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the sixth plea should also be rejected as unfounded.

301 As a preliminary point, it should be noted that most of the arguments relied on in support of the sixth plea have no independent scope in the present action, but rather supplement the line of argument put forward in support of the other pleas.

302 First, the arguments raised by the applicants concerning the hazard assessment, the application of the weight-of-evidence determination and the lack of risk assessment supplement the line of argument concerning the existence of a manifest error of assessment. Given that the applicants have not demonstrated the existence of such an error, it is also not possible for a breach of the principle of good administration to be breached on the basis of those arguments, either.

303 That finding is not called into question by the applicants' argument, raised at the hearing, relating to the judgment of 7 March 2019, *Sweden* v *Commission* (T-837/16, EU:T:2019:144). In the case giving rise to that judgment, the Commission conditionally authorised the use of certain substances under Article 60(4) and (5) of Regulation No 1907/2006 even though the lack of availability of technically feasible alternatives had not been fully established for all the uses covered by the application due to the difficulties in ascertaining such a lack of availability. In response, the Court found that, first, it was for the Commission, in accordance with its duty of care, to examine the condition concerning the lack of availability of alternatives in greater depth if the evidence provided by the applicant for authorisation in its analysis of alternatives was contradicted by the evidence submitted by third parties or Member States, and that, second, if there remained uncertainties relating to the scientific assessment which could not be dispelled, it had to be concluded that in principle that condition was not fulfilled and that the Commission was therefore not entitled to grant an authorisation, even one which was conditional (judgment of 7 March 2019, *Sweden* v *Commission*, T-837/16, EU:T:2019:144, paragraphs 84 and 85). In the case at hand, the Commission did not leave open, due to difficulties, the question of whether such a necessary condition for the adoption of the contested regulation had been met. The applicants have moreover not proved the existence of contradictions in the file which the Commission failed to examine.

304 This is also true of the argument that there was no transparency concerning the significant evolution in the scientific techniques used to assess bioaccumulation. After all, the document submitted by the CES to which the applicants make reference reiterates the assertion that the Annex XIII criteria were not suitable for determining whether D4 was a vB substance. In addition, that document cites, as regards the alleged significant evolution, almost exclusively articles published between 2016 and 2018, which rules out the possibility of such an evolution having been taken into account in full transparency by the MSC in 2015. In any event, ECHA and the Commission were obliged to apply the rules as defined in Annex XIII and which were in force. Incidentally, those rules were amended in 2011 to take account of the experience gained in identifying PBT and vPvB substances.

305 Second, the arguments raised by the applicants concerning the lack of transparency in the weight-of-evidence determination also supplement their line of argument raised in support of the first plea. The argument based on an alleged lack of transparency refers to the errors allegedly committed in the weight-of-evidence determination. Given that none of the arguments raised by the applicants is capable of demonstrating the existence of such errors, the arguments alleging breach of the principle of good administration cannot succeed, either.

306 Third, the arguments raised by the applicants concerning the referral of the matter to the MSC supplement the line of argument put forward in support of the third plea alleging breach of essential procedural requirements. Having regard to the fact that the applicants have failed to demonstrate the existence of such a breach, it cannot be held that there has been a breach of the principle of good administration.

307 Even if the applicants' line of argument relating to the lack of independence of the scientific assessment, raised for the first time at the stage of the reply, were admissible despite the fact that it does not appear in the application, and therefore in spite of being out of time, it must be pointed out that it is not supported by any specific evidence. Consequently, the line of argument based on the alleged lack of independence of the scientific assessment must be rejected.

308 It follows from all the foregoing that the sixth plea must also be rejected.

7. Seventh plea in law: breach of the rights of the defence and of the right to be heard

309 The applicants maintain that their rights of defence, and in particular their right to be heard, have been breached. Specifically, the applicants take the view that, before and during the assessment stage, it was not possible for them to know the means and criteria by which ECHA would determine whether the substances D4 and D5 had B and vB properties. More precisely, the weighting system and the weight-of-evidence approach applied in the context of bioaccumulation were unclear, to the extent that the applicants were in no position to assert their rights of defence.

310 The applicants emphasise that the matter was referred to the MSC pursuant to Article 77 of Regulation No 1907/2006. That provision does not appear in Title VIII of that regulation, relating to restrictions, but in Title X, on agency. Given that the RAC and the SEAC did not reassess the P and vP and B and vB properties assessed by the MSC, the public consultation regarding the contested regulation, adopted under Title VIII of Regulation No 1907/2006, excluded discussions of issues which were the subject of the opinion of the MSC. Consequently, the applicants' right to submit comments and to be heard was not respected, 'in particular within the context of the relevant REACH process'.

311 In the reply, the applicants add that, since the first applicant, Global Silicones Council, represents the interests of the silicone industry worldwide, the restrictions process leading to the adoption of the contested regulation constituted de facto proceedings initiated against it. In those circumstances, the rights of the defence and the right to be heard, as guaranteed, inter alia, by Article 41 of the Charter of Fundamental Rights of the European Union ('the Charter'), should have been respected.

312 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, disputes that there was any denial of the rights of the defence and of the right to be heard in the present case. It argues that the seventh plea should also be rejected as unfounded.

313 In this connection, it should be recalled that, according to settled case-law, observance of the rights of the defence is a general principle of EU law, which is to be applied where the authorities are minded to adopt in respect of a person a measure that will adversely affect him or her. In accordance with that principle, the addressees of decisions which significantly affect their interests must be placed in a position in which they can effectively make known their views as regards the information on which the authorities intend to base their decision (see judgment of 16 October 2019, *Glencore Agriculture Hungary*, C-189/18, EU:C:2019:861, paragraph 39 and the case-law cited; see also, to that effect, judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 470 and the case-law cited).

314 It should also be recalled that Article 41 of the Charter, which guarantees the right to good administration, provides for the right of every person to be heard before any individual measure which would affect him or her adversely is taken. Respect for the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of EU law which must be guaranteed even in the absence of rules governing the proceedings in question. That principle requires that the addressees of decisions which significantly affect their interests should be placed in a position in which they can effectively make known their views on the accusation made against them forming the basis of the contested measure (judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 86).

315 By contrast, in the case of acts of general application, neither the process of drafting them nor those acts themselves require, in accordance with the general principles of EU law, such as the right to be heard, consulted or informed, the participation of the persons affected. That is not the case only where an express provision of the legal context governing the adoption of that act confers a procedural right on a person affected (judgment of 19 December 2019, *Probelte* v *Commission*, T-67/18, EU:T:2019:873, paragraph 87).

316 Thus, the rights of the defence, as they are defined by the case-law and Article 41 of the Charter (in so far as it concerns the right to be heard), apply only during the phase of adoption of an act adversely affecting the person concerned and of individual scope. It is common ground, however, that the contested regulation is not an act of individual scope but, on the contrary, is of general application.

317 That conclusion is not called into question by the line of argument of the applicants according to which one of them, namely Global Silicones Council, represents the interests of the silicone industry worldwide, meaning that the restrictions process leading to the adoption of the contested regulation constituted de facto proceedings initiated against it. In short, according to them, the contested regulation, under cover of general application, is of individual scope. Lastly, in specifically but de facto targeting Global Silicones Council, the contested regulation, according to the applicants, affected all the members of that association.

318 That argument is not convincing. The applicants' arguments confirm, on the contrary, the general application of the contested regulation. If Global Silicones Council does in fact represent the interests of the sector on the global level, and thus a significant portion if not all of the operators active on that market, and if all the members of that association are affected by the contested regulation, that demonstrates the general application of that regulation. A rule which applies to all the persons concerned, or to a large majority of them, is a priori a rule of general application.

319 Consequently, the applicants' line of argument according to which the contested regulation was adopted de facto against Global Silicones Council and according to which, therefore, Global Silicones Council could validly invoke a breach of its rights of defence and of its right to be heard must be rejected.

320 Moreover, no provision in Articles 68 to 73 of Regulation No 1907/2006, strictly speaking, guarantees a right to be heard to interested parties. At most, Article 69(6)(a) and Article 71(1) of Regulation No 1907/2006 grant those parties the right to submit 'comments' which ECHA (the RAC and the SEAC) is to 'take into account'.

321 The public consultation provided for in Article 69(6)(a) and Article 71(1) of Regulation No 1907/2006, after all, does not confer specific procedural rights on interested parties. Those articles provide only for the right to submit comments. In addition, the fact that those two provisions provide for a public consultation does not call into question the fact that neither ECHA nor the Commission is required, under those two articles, to hear an individual who might be concerned by the contested regulation in addition to that public consultation (see, to that effect and by analogy, judgment of 25 September 2015, *VECCO and Others* v *Commission*, T-360/13, EU:T:2015:695, paragraphs 81 and 82 and the case-law cited).

322 Lastly and in any event, it must be stated that, in paragraph 26 of the application, the applicants explicitly acknowledge that, between 18 June and 18 December 2015, a public consultation 'took place

pursuant to Article 69(6) [of Regulation No 1907/2006]' and that, in that connection, they 'submitted comments and evidence'.

323 As has been noted above, however, under Article 70 and Article 71(2) of Regulation No 1907/2006, the opinions of the RAC and of the SEAC must take account of comments made and information provided by interested parties in accordance with Article 69(6)(a) and (b) of that same regulation. Their right to submit comments in the procedure leading to the adoption of the contested regulation was therefore fully respected in this case.

324 In the light of all those factors, the seventh plea must be rejected as unfounded.

8. Eighth plea in law: breach of the obligation to state reasons

325 The applicants argue that the contested regulation fails to provide adequate reasoning for its hazard and risk conclusions, in particular inasmuch as it fails to state the reasons why D4 and D5 were regarded as B and vB substances by the Commission or the reasons why there was a hazard or risk. There is no statement of reasons as to why the conditions laid down in Article 68 of Regulation No 1907/2006 were fulfilled or why the essential requirements were observed. The applicants reiterate a series of arguments raised in the first plea and invoke the lack of a statement of reasons in respect of those alleged shortcomings which vitiate the contested regulation.

326 The Commission, supported by the Federal Republic of Germany, the United Kingdom and ECHA, argues that the eighth plea should also be rejected as unfounded.

327 As a preliminary point, it should be recalled that the obligation to state reasons is an essential procedural requirement which must be distinguished from the question whether the reasons given are correct, the latter being a matter going to the substantive legality of the contested measure (judgments of 22 March 2001, *France* v *Commission*, C-17/99, EU:C:2001:178, paragraph 35, and of 20 September 2019, *ICL-IP Terneuzen and ICL Europe Coöperatief* v *Commission*, T-610/17, EU:T:2019:637, paragraph 47).

328 Under the second subparagraph of Article 296 TFEU, legal acts such as the contested regulation must state the reasons on which they are based. In accordance with settled case-law, the statement of reasons must show clearly and unequivocally the reasoning of the institution which adopted the measure. It must, on the one hand, enable the persons concerned to understand the full significance of and the reasons for the measure at issue in order to enable them to safeguard their rights and, on the other hand, enable the EU judicature to exercise its powers of review of legality. It is not, however, required to go into every relevant point of fact and law. The question whether a statement of reasons satisfies the requirements must be assessed with reference not only to the wording of the measure but also to its context and to the whole body of legal rules governing the matter in question (see, to that effect, judgment of 12 December 2006, *Germany* v *Parliament and Council*, C-380/03, EU:C:2006:772, paragraphs 107 and 108 and the case-law cited).

329 It is also clear from settled case-law that the scope of the obligation to state reasons depends on the nature of the measure at issue and that, in the case of measures of general application, the statement of reasons may be confined to indicating the general situation which led to the adoption of that measure and the general objectives which it is intended to achieve. In that context, the Court of Justice has repeatedly ruled that if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made (see judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 115 and the case-law cited).

330 Moreover, where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed, since they acquire information through their involvement (judgments of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 116, and of 1 February 2013, *Polyelectrolyte Producers Group and Others* v *Commission*, T-368/11, not published, EU:T:2013:53, paragraph 101).

331 In addition, the General Court has decided in pharmaceutical and food cases that, where a decision follows the opinion of a scientific body, the content of that opinion, referred to in the recitals, is an integral part of the statement of reasons on which that decision was based (see, to that effect, judgment of 13 December 2013, *Hungary* v *Commission*, T-240/10, EU:T:2013:645, paragraph 91 and the case-law cited). Incidentally, this Court, in the context of an application for annulment of a regulation amending Annex XIV to Regulation No 1907/2006 on the basis of an ECHA recommendation, took that recommendation into account in the examination of the statement of reasons for that regulation (see, to that effect, judgment of 20 September 2019, *ICL-IP Terneuzen and ICL Europe Coöperatief* v *Commission*, T-610/17, EU:T:2019:637, paragraphs 49 and 139).

332 Lastly, as is mentioned in paragraph 213 above, it follows from an *a contrario* argument, based on the second subparagraph of Article 73(1) of Regulation No 1907/2006, that the Commission was not required to provide a detailed explanation as to why its draft amendment followed the original proposal and ECHA's opinions.

333 In the light of the principles which have just been recalled, it is necessary to examine whether the contested regulation, regard being had also to the content of the opinions of the MSC and of the RAC, meets the requirement to state reasons of Article 296(2) TFEU.

334 The applicants' line of argument according to which, first, none of the committees carried out a risk assessment or an evaluation of whether a risk exceeded the relevant threshold, second, no reasons were given for the lack of a credible weight-of-evidence determination and, third, no reasons were given for numerical thresholds in relation to the TMF and the BMF for establishing bioaccumulation must be rejected. That line of argument is part of the first plea and concerns the substance of the decision rather than its statement of reasons. For the sake of completeness, it should be noted that the considerations set out in the first plea clearly demonstrate that the existing reasoning was sufficient to enable the applicants to formulate their pleas for annulment and to enable the EU judicature to exercise its powers of review of the legality of the contested regulation.

335 Furthermore, it must be borne in mind that the contested regulation was adopted on the basis of Article 68(1) of Regulation No 1907/2006. Under that provision, Annex XVII to that regulation is to be amended, by the adoption of a new restriction or by the adoption of an amendment to an existing restriction for the manufacture, use or placing on the market of substances in accordance with the procedure referred to in Articles 69 to 73 of Regulation No 1907/2006, under three conditions. There must first of all be an unacceptable risk to human health or to the environment. Next, that risk must result from the manufacture, use or placing on the market of the substance. Finally, that risk must need to be addressed on a Union-wide basis.

336 In that regard, in the first place, it should be noted that it is apparent in particular from recital 8 of the contested regulation that the Commission considered that a risk to the environment arose from the presence of D4 and D5 in certain wash-off cosmetic products because of the hazard, PBT and vPvB properties of those substances. It is apparent from the same recital that the Commission considered that that risk had to be dealt with at Union level. In recitals 8 and 9 of the contested regulation, the Commission provided reasoning as to the scope of that regulation, including in relation to maximum content, the products covered and the determination of the period for application of the restriction.

337 It is certainly true that the Commission did not explicitly state that the risk to the environment arising from the presence of D4 and D5 in certain cosmetic products was 'unacceptable' within the meaning of Article 68 of Regulation No 1907/2006. However, the absence of that term does not affect the ability of the persons concerned to understand the full significance and the reasons for the contested regulation in order for them to safeguard their rights, or the ability of the EU judicature to exercise its powers of review of legality. First, it has already been held in paragraph 204 above that it was apparent from that regulation, and in particular from recitals 8 and 9 thereof and from the legal basis of the contested regulation, to which the second introductory paragraph of that regulation refers, that the Commission implicitly, but necessarily, considered that the risks associated with D4 and D5 in certain cosmetic products constituted an unacceptable risk to the environment. Second, the applicants were able to develop detailed considerations in this respect in the application and in the reply.

338 In the second place, having regard to the fact that, in recitals 1, 3, 4, 5 and 7 of the contested regulation, the Commission referred to the Annex XV dossier and to the opinions of the MSC, the RAC and the SEAC, which are moreover available to the public, and to the fact that, in the contested regulation, the Commission followed those documents, it is appropriate to take account of the reasons provided in those documents in accordance with the case-law cited in paragraph 331 above.

339 First, the Annex XV dossier and the opinion of the MSC describe in detail why and on the basis of which information the United Kingdom and the MSC concluded that D4 and D5 were vPvB substances in accordance with Annex XIII, in particular the comparison between non-BCF data and BCF data (see paragraph 84 et seq. above concerning the opinion of the MSC). The United Kingdom, in its Annex XV dossier, and the RAC, in its opinion, explained why they had considered D4 and D5 emissions as a proxy for risk and why they had carried out a qualitative risk assessment in accordance with Annex I (see paragraphs 194 and 195 above).

340 Consequently, the applicants' line of argument according to which the contested regulation does not state the reasons why the Commission considered that D4 and D5 were B and vB substances, or the reasons why there was a hazard or risk must be rejected. The applicants' line of argument according to which the contested regulation does not contain any reasons regarding the weighting of the BCF data in relation to the other data must also be rejected. As regards the alleged lack of statement of reasons in relation to the weight attributed to the evidence, it should be noted that that argument is based on the applicants' false premiss that the provisions of Annex XIII require a quantitative weight-of-evidence determination based on expert judgement. As has already been noted in paragraph 148 et seq. above, the application of a qualitative weight-of-evidence determination in this case was consistent with Annex XIII.

341 Second, the United Kingdom, in its Annex XV dossier, explained that the proposed restriction, which concerned the placing on the market of D4 and D5 in certain products, was the most effective measure for addressing the risk identified, in particular by comparing that measure with potential measures under Directive 2000/60 (see paragraph 239 above). Consequently, the applicants' line of argument according to which the contested regulation does not state why that regulation concerns the placing on the market of the products concerned must also be rejected.

342 In the light of those considerations, it appears that the statement of reasons for the contested regulation is sufficient and, in particular, enables the persons concerned to understand, inter alia, the reasons why the Commission considered that the conditions laid down in Article 68(1) of Regulation No 1907/2006 were satisfied.

343 As regards the applicants' line of argument according to which the contested regulation does not provide any statement of reasons as to the manner in which placement on the market is envisaged, it should be noted that such a statement of reasons was not necessary in order to enable the persons concerned to understand the full significance and the reasons for the contested regulation in order for them to safeguard their rights in that regard, nor was it necessary in order to enable the EU judicature to exercise its powers of review of the legality of the contested regulation. It is clear from the annex to the contested regulation that the products concerned were not to be placed on the market after 31 January 2020.

344 That is also true of the applicants' line of argument according to which the contested regulation should have indicated the reasons why it was considered that essential procedural requirements had been observed. The stages of the procedure are clear, after all, from the recitals of the contested regulation. A more detailed explanation of the procedure was not necessary to enable the persons concerned to understand the full significance and the reasons for the measure at issue.

345 In any event, in relying on those elements, the applicants were able to assert their rights before the Court. This is demonstrated by the fact that, in the present action, they have alleged that the contested regulation was vitiated by a number of manifest errors of assessment in fact and in law, by breach of the principle of proportionality, by breach of essential procedural requirements, by breach of the principles of legal certainty and legitimate expectations, by breach of the institutional balance of powers, by breach of the principle of good administration and by breach of the rights of the defence and

of the right to be heard. Moreover, the Court has been able to exercise its powers of review on the basis of that reasoning, as is apparent from the considerations relating to those various pleas.

346 It follows from all the foregoing and from the applicants' participation in the administrative procedure leading to the adoption of the contested regulation that that regulation sets out clearly and unequivocally the Commission's reasoning and that it enabled the applicants to understand its full significance and the reasons for it in order for them to be able to safeguard their rights to be in a position to defend their rights and the EU judicature to exercise its powers of review of legality.

347 Consequently, the eighth plea must also be rejected and, therefore, the action must be dismissed in its entirety.

V. Costs

348 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 applicants have been unsuccessful, they must be ordered to bear their own costs and to pay those incurred by the Commission, in accordance with the form of order sought by the Commission.

349 Under Article 138(1) of the Rules of Procedure, the Member States and institutions which have intervened in the proceedings are to bear their own costs. Accordingly, the Federal Republic of Germany, the United Kingdom, the Parliament, the Council and ECHA shall bear their own costs.

350 Under Article 138(3) of the Rules of Procedure, the Court may order an intervener other than those referred to in Article 138(1) and (2) of those rules to bear its own costs. In the circumstances of this case, ACC shall bear its own costs.

On those grounds,

THE GENERAL COURT (Eighth Chamber, Extended Composition)

hereby:

1. Dismisses the action;

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

3. Orders the Federal Republic of Germany, the United Kingdom of Great Britain and Northern Ireland, the European Parliament, the Council of the European Union, the European Chemicals Agency (ECHA) and American Chemistry Council, Inc. (ACC) to bear their own costs.

Papasavvas Svenningsen Barents

Pynnä Laitenberger

Delivered in open court in Luxembourg on 30 June 2021.

E. Coulon S. Papasavvas

Registrar President

Table of contents

I. Legal context

II. Background to the dispute

III. Procedure and forms of order sought

IV. Law
A. Intervention of the United Kingdom
B. Substance
1. First plea in law: manifest errors of assessment
(a) First part of the first plea: manifest error of assessment in the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII
(1) The allegedly insufficient consideration of factors other than the bioconcentration factor
(2) Application of the criteria laid down in Sections 1.1.2 and 1.2.2 of Annex XIII
(3) The allegedly inadequate assessment of the allegedly unique properties of D4 and D5 such as their volatility, their low water solubility, their metabolisation by certain organisms and their trophic dilution
(4) The fact that PBT and vPvB properties were identified in different compartments
(5) The alleged failure to take into account all relevant and available information
(6) The importance placed on the data
(7) Certain other errors allegedly committed during the hazard assessment and in the identification of D4 and D5 as PBT and vPvB or vPvB substances pursuant to Annex XIII
(b) Second part of the first plea: absence of unacceptable risk arising from the manufacture, use or placing on the market of D4 and D5 in wash-off cosmetic products
(c) Third part of the first plea: errors allegedly committed in the risk assessment
(d) Fourth part of the first plea: alleged failure to review the ‘fundamental basis’ for the contested regulation
2. Second plea in law: breach of the principle of proportionality
3. Third plea in law: breach of essential procedural requirements
4. Fourth plea in law: breach of the principle of legal certainty and of the principle of legitimate expectations
(a) First part of the fourth plea: breach of the principle of legal certainty
(b) Second part of the fourth plea: breach of the principle of legitimate expectations
5. Fifth plea in law: breach of the institutional balance of powers
6. Sixth plea in law: breach of the principle of good administration
7. Seventh plea in law: breach of the rights of the defence and of the right to be heard
8. Eighth plea in law: breach of the obligation to state reasons

V. Costs

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* Language of the case: English.

Samling af Afgørelser

DOMSTOLENS DOM (Fjerde Afdeling)

9. november 2023*

»Appel – forordning (EF) nr. 1907/2006 (REACH-forordningen) – registrering, vurdering og godkendelse af samt begrænsninger for kemikalier – bilag XVII – ajourføring – begrænsninger for fremstilling, markedsføring og anvendelse af visse farlige stoffer, blandinger og artikler – begrænsninger vedrørende octamethylcyclotetrasiloxan (D4) og decamethylcyclopentasiloxan (D5) – persistente, bioakkumulerende og giftige stoffer – stoffer, der er meget persistente og meget bioakkumulerende – uacceptable risici«

I sag C-558/21 P,

angående appel i henhold til artikel 56 i statutten for Den Europæiske Unions Domstol, iværksat den 8. september 2021,

Global Silicones Council, Washington (De Forenede Stater),

Wacker Chemie AG, München (Tyskland),

Momentive Performance Materials GmbH, Leverkusen (Tyskland),

Shin-Etsu Silicones Europe BV, Almere (Nederlandene),

Elkem Silicones Frankrig SAS, Lyon (Frankrig),

først ved advokát A. Bartl, avocat R. Cana, adwokat A. Kołtunowska og avocate E. Mullier, derefter ved advokát A. Bartl og avocats R. Cana og E. Mullier,

appellanter,

de øvrige parter i appelsagen:

Europa-Kommissionen ved R. Lindenthal og K. Mifsud-Bonnici, som befuldmægtigede,

sagsøgt i første instans,

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

Det Forenede Kongerige Storbritannien og Nordirland,

* Processprog: engelsk.

Europa-Parlamentet,

Rådet for Den Europæiske Union,

Det Europæiske Kemikalieagentur (ECHA) ved W. Broere, A. Hautamäki og M. Heikkilä, som befuldmægtigede,

American Chemistry Council Inc. (ACC), Washington, først ved avocate A. Moroni, advocaat B. Natens og advokat K. Nordlander, derefter ved advocaat S. De Knop, avocate A. Moroni og advocaat B. Natens, og endelig ved advocaat S. De Knop og avocate A. Moroni,

intervenienter i første instans,

har

DOMSTOLEN (Fjerde Afdeling),

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

generaladvokat: J. Kokott,

justitssekretær: A. Calot Escobar,

på grundlag af den skriftlige forhandling,

og efter at generaladvokaten har fremsat forslag til afgørelse i retsmødet den 20. april 2023,

afsagt følgende

Dom

1 Global Silicones Council, Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV og Elkem Silicones France SAS (herefter samlet »appellanterne«) har i appelskriftet nedlagt påstand om ophævelse af Den Europæiske Unions Rets dom af 30. juni 2021, Global Silicones Council m.fl. mod Kommissionen (T-226/18, herefter »den appellerede dom«, EU:T:2021:403), hvorved Retten frifandt Kommissionen i det søgsmål, som de havde anlagt med påstand om annullation af Kommissionens forordning (EU) 2018/35 af 10. januar 2018 om ændring af bilag XVII til Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 om registrering, vurdering og godkendelse af samt begrænsninger for kemikalier (REACH) for så vidt angår octamethylcyclotetrasiloxan (»D4«) og decamethylcyclopentasiloxan (»D5«) (EUT 2018, L 6, s. 45, herefter »den omtvistede forordning«).

Retsforskrifter

REACH-forordningen

2 Artikel 13, stk. 3, i Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 af 18. december 2006 om registrering, vurdering og godkendelse af samt begrænsninger for kemikalier (REACH), om oprettelse af et europæisk kemikalieagentur og om ændring af direktiv 1999/45/EF og ophævelse af Rådets forordning (EØF) nr. 793/93 og Kommissionens forordning (EF) nr. 1488/94 samt Rådets direktiv 76/769/EØF og Kommissionens direktiv 91/155/EØF, 93/67/EØF, 93/105/EF og 2000/21/EF (EUT 2006, L 396, s. 1, berigtiget i EUT 2007, L 136, s. 3), som ændret ved Kommissionens forordning (EU) 2017/1510 af 30. august 2017 (EUT 2017, L 224, s. 110) (herefter »REACH-forordningen«), bestemmer:

»Hvis forsøg er påkrævet til fremskaffelse af oplysninger om stoffers iboende egenskaber, skal disse udføres i henhold til de forsøgsmetoder, der er fastlagt i en [forordning fra Europa-Kommissionen], eller i henhold til andre internationale forsøgsmetoder, som Kommissionen eller [Det Europæiske Kemikalieagentur (ECHA)] har anerkendt som værende hensigtsmæssige. Kommissionen vedtager denne forordning beregnet til at ændre de ikke-væsentlige bestemmelser i nærværende forordning ved at supplere den, efter proceduren i artikel 133, stk. 4.

Oplysninger om stoffers iboende egenskaber kan fremskaffes i henhold til andre forsøgsmetoder, forudsat at betingelserne i bilag XI er opfyldt.«

3 Denne forordnings artikel 57, litra d) og e), har følgende ordlyd:

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

[…]

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

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

4 Den nævnte forordnings afsnit VIII med overskriften »Begrænsninger for fremstilling, markedsføring og anvendelse af visse farlige stoffer, blandinger og artikler« indeholder forordningens artikel 67-73.

5 REACH-forordningens artikel 68 med overskriften »Indførelse af nye og ændring af gældende begrænsninger« bestemmer følgende i stk. 1:

»Når der som følge af fremstilling, anvendelse eller markedsføring af stoffer er en uacceptabel risiko for menneskers sundhed eller miljøet, som det er nødvendigt at imødegå på fællesskabsplan, ændres bilag XVII efter den procedure, der er nævnt i artikel 133, stk. 4, ved vedtagelse af nye begrænsninger eller ved ændring af gældende begrænsninger i bilag XVII for fremstilling, anvendelse eller markedsføring af stoffer som sådan, i blandinger eller i artikler efter proceduren i artikel 69-73. Alle sådanne afgørelser tager hensyn til de socioøkonomiske konsekvenser af begrænsningen, herunder eventuelle disponible alternativer.

[…]«

6 Denne forordnings artikel 69 med overskriften »Udarbejdelse af et forslag« bestemmer:

»1. Hvis Kommissionen mener, at fremstillingen, markedsføringen eller anvendelsen af et stof som sådan, i en blanding eller i en artikel udgør en risiko for menneskers sundhed eller miljøet, der ikke er tilstrækkeligt kontrolleret, og som det er nødvendigt at imødegå, skal den anmode [ECHA] om at udarbejde et dossier, der er i overensstemmelse med kravene i bilag XV.

[…]

4. Hvis en medlemsstat mener, at fremstillingen, markedsføringen eller anvendelsen af et stof som sådan, i en blanding eller i en artikel udgør en risiko for menneskers sundhed eller miljøet, der ikke er tilstrækkeligt kontrolleret, og som det er nødvendigt at imødegå, skal den meddele [ECHA], at den foreslår, at der udarbejdes et dossier, der opfylder kravene i de relevante punkter i bilag XV. […]

[…]«

7 I henhold til ordlyden af den nævnte forordnings artikel 70 med overskriften »[ECHA's] udtalelse: Udvalget for Risikovurdering« »skal Udvalget for Risikovurdering på grundlag af sin gennemgang af de relevante dele af dossieret udarbejde en udtalelse om, hvorvidt de foreslåede begrænsninger er egnede til at nedbringe risikoen for menneskers sundhed og/eller miljøet«.

8 REACH-forordningens artikel 71, der har overskriften »[ECHA's] udtalelse: Udvalget for Socioøkonomisk Analyse«, bestemmer i stk. 1:

»[…] Udvalget for Socioøkonomisk Analyse [skal] udarbejde en udtalelse om de foreslåede begrænsninger på grundlag af sin gennemgang af de relevante dele af dossieret og de socioøkonomiske konsekvenser. […]«

9 Denne forordnings artikel 72 med overskriften »Fremsendelse af en udtalelse til Kommissionen« bestemmer i stk. 1:

»[ECHA] skal straks sende Kommissionen udtalelserne fra Udvalgene for Risikovurdering og Socioøkonomisk Analyse om de foreslåede begrænsninger for stoffer som sådan, i blandinger eller i artikler. […]«

10 Forordningens artikel 73 med overskriften »Kommissionens afgørelse« fastsætter i stk. 1:

»1. Hvis de i artikel 68 fastsatte betingelser er opfyldt, skal Kommissionen udarbejde et udkast til ændring af bilag XVII, […]

Hvis udkastet til ændring afviger fra det oprindelige forslag eller ikke tager hensyn til [ECHA's] udtalelser, vedlægger Kommissionen som bilag en detaljeret redegørelse for grundene til forskellene.

2. Den endelige afgørelse træffes efter proceduren i artikel 133, stk. 4. Kommissionen sender udkastet til ændring til medlemsstaterne mindst 45 dage inden afstemningen.«

11 Bilag I til REACH-forordningen, som ændret ved Kommissionens forordning (EU) nr. 252/2011 af 15. marts 2011 (EUT 2011, L 69, s. 3) (herefter »bilag I«) med overskriften »Almindelige bestemmelser om vurdering af stoffer og udarbejdelse af kemikaliesikkerhedsrapporter«, har følgende ordlyd:

»0. Indledning

[…]

0.6. Trin i en kemikaliesikkerhedsvurdering

0.6.1. Producentens eller importørens kemikaliesikkerhedsrapport for et stof skal omfatte trin 1-4 i overensstemmelse med de respektive punkter i dette bilag:
1. Vurdering af farlighed for menneskers sundhed.
2. Vurdering af de fysisk-kemiske egenskabers farlighed for menneskers sundhed.
3. Vurdering af farlighed for miljøet.
4. PBT- og vPvB-vurdering.

0.6.2. I de i punkt 0.6.3 omhandlede tilfælde skal kemikaliesikkerhedsvurderingen også omfatte følgende trin 5 og 6 i overensstemmelse med punkt 5 og 6 i dette bilag:
5. Eksponeringsvurdering
5.1 Udvikling af eksponeringsscenarie(r) (eller, hvis det er hensigtsmæssigt, identifikation af relevante anvendelses- og eksponeringskategorier).
5.2. Eksponeringsberegning.
6. Risikokarakterisering

0.6.3. Hvis producenten eller importøren som resultat af trin 1-4 konkluderer […], at stoffet […] vurderes at være et [persistent, bioakkumulerende og toksisk (PBT-)] eller [meget persistent og meget bioakkumulerende) (vPvB-stof)], skal kemikaliesikkerhedsvurderingen desuden omfatte trin 5 og 6 i overensstemmelse med punkt 5 og 6 i dette bilag:

[…]

4. PBT- og vPvB-vurdering

4.0. Indledning

4.0.1. Formålet med PBT- og vPvB-vurderingen er at bestemme, om stoffet opfylder kriterierne i bilag XIII, og i bekræftende fald at karakterisere de potentielle emissioner af stoffet. For stoffer, der opfylder PBT- og vPvB-kriterierne i bilag XIII, kan der ikke foretages en tilstrækkeligt pålidelig farevurdering vedrørende alle langtidsvirkninger i overensstemmelse med punkt 1 og 3 i dette bilag og en estimering af langtidsudsættelsen af mennesker og miljø efter punkt 5 (eksponeringsvurdering), trin 2 (eksponeringsberegning). Der må derfor foretages en separat PBT- og vPvB-vurdering.

4.0.2. PBT- og vPvB-vurderingen skal omfatte følgende to trin, der begge skal være tydeligt identificeret i kemikaliesikkerhedsrapportens del B, punkt 8:

Trin 1: Sammenholdelse med kriterierne

Trin 2: Karakterisering af emissioner

[…]

4.1. Trin 1: Sammenholdelse med kriterierne

Denne del af PBT- og vPvB-vurderingen skal bestå af en sammenholdelse af de foreliggende oplysninger med kriterierne i punkt 1 i bilag XIII og en erklæring om, hvorvidt stoffet opfylder kriterierne eller ikke. Vurderingen foretages i overensstemmelse med indledningen til bilag XIII og punkt 2 og 3 i samme bilag.

4.2. Trin 2: Karakterisering af emissioner

Hvis stoffet opfylder kriterierne, eller hvis det i registreringsdossieret anses for at være et PBT- eller vPvB-stof, skal der foretages en karakterisering af emissionerne omfattende de relevante dele af eksponeringsvurderingen som beskrevet i punkt 5. […]

[…]

6. Risikokarakterisering

[…]

6.3. Risikokarakteriseringen skal bestå af:

– en sammenligning af eksponeringen af hver befolkningsgruppe, der med sikkerhed eller sandsynligvis vil blive eksponeret, med de relevante DNEL-værdier [(afledte nuleffektniveauer (Derived No-Effect Levels) – de niveauer for menneskers eksponering for stoffet, der ikke bør overskrides)]

– en sammenligning af den forventede miljøkoncentration i hvert delmiljø med PNEC-værdierne [den beregnede nuleffektkoncentration [(predicted no-effect concentration) – den stofkoncentration, under hvilken der ikke forventes negative virkninger på det relevante delmiljø)], og

– en vurdering af sandsynligheden og alvoren af de hændelser, der kan indtræde som følge af stoffets fysisk-kemiske egenskaber.

6.4. For ethvert eksponeringsscenarie kan risikoen for mennesker og miljø anses for tilstrækkeligt kontrolleret i hele den livscyklus, der følger stoffets fremstilling og identificerede anvendelser, når:

– de i punkt 6.2 beregnede eksponeringsniveauer ikke overskrider de relevante DNEL- eller PNEC-værdier, som bestemt i henholdsvis punkt 1 og 3, og

– sandsynligheden og alvoren af de hændelser, der kan indtræde som følge af stoffets fysisk-kemiske egenskaber som fastlagt i punkt 2, er ubetydelig.

6.5. For de virkninger på mennesker og delmiljøer, for hvilke der ikke har kunnet fastsættes en DNEL eller PNEC-værdi, skal der foretages en kvalitativ vurdering af sandsynligheden for, at virkningerne kan undgås, når eksponeringsscenariet realiseres.

For stoffer, der opfylder PBT- og vPvB-kriterierne, skal producenten eller importøren anvende de i punkt 5, trin 2, opnåede oplysninger, når han i virksomheden gennemfører risikohåndteringsforanstaltninger, der gennem hele den livscyklus, der følger af stoffets fremstilling og identificerede anvendelser, minimerer eksponeringen af mennesker og miljø samt deres udsættelse for emissioner, og anbefaler sådanne foranstaltninger over for downstream-brugere.

[…]«

12 Bilag XIII til REACH-forordningen (herefter »bilag XIII«) med overskriften »Kriterier for identifikation af persistente, bioakkumulerende og giftige stoffer og meget persistente og meget bioakkumulerende stoffer« opstiller kriterierne for identifikation af persistente, bioakkumulerende og giftige stoffer (herefter »PBT-stoffer«) og meget persistente og meget bioakkumulerende stoffer (herefter »vPvB-stoffer«) samt de oplysninger, der skal tages hensyn til ved vurderingen af et stofs P- (persistente), B- (bioakkumulerende) og T- (giftige) egenskaber.

13 Bilag XV til REACH-forordningen (herefter »bilag XV«) med overskriften »Dossierer« »fastlægger de generelle principper for udarbejdelsen af dossierer med henblik på at foreslå og begrunde […] identifikation af stoffer som […] et PBT-stof, et vPvB-stof [og] begrænsninger i fremstilling, markedsføring eller anvendelse af et stof inden for Fællesskabet«.

Forordning (EU) nr. 253/2011

14 Den 15. marts 2011 vedtog Kommissionen forordning (EU) nr. 253/2011 om ændring af bilag XIII til Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 vedrørende registrering, vurdering og godkendelse af samt begrænsninger for kemikalier (REACH) (EUT 2011, L 69, s. 7).

15 Femte og sjette betragtning til forordning 253/2011 har følgende ordlyd:

»(5) Erfaringer viser, at en passende identifikation af PBT- og vPvB-stoffer kun er [mulig], hvis alle relevante oplysninger integreres og vægtes, når de sammenholdes med kriterierne i punkt 1 i bilag XIII.

(6) Det er [særligt] relevant at foretage en vægtning i de tilfælde, hvor de foreliggende oplysninger ikke uden videre kan sammenholdes med kriterierne i punkt 1 i bilag XIII.«

16 I bilag XIII, som ændret ved forordning nr. 253/2011, er følgende anført i præamblen:

»Dette bilag indeholder kriterierne for identifikation af [PBT-stoffer] og [vPvB-stoffer] samt de oplysninger, der skal tages hensyn til ved vurderingen af et stofs P-, B- og T-egenskaber.

Ved identifikation af PBT- og vPvB-stoffer skal der foretages en ekspertvurdering, hvor alle relevante tilgængelige oplysninger under punkt 3.2 vægtes og sammenholdes med kriterierne i punkt 1. Dette gælder navnlig, hvis kriterierne i punkt 1 ikke umiddelbart kan sammenholdes med de foreliggende oplysninger.

Ved vægtning af oplysninger forstås, at alle tilgængelige oplysninger, der har betydning for identifikation af et PBT- eller vPvB-stof, vurderes samlet, som f.eks. resultaterne af overvågning og modelberegning, egnede in vitro-forsøg, relevante data fra dyreforsøg, oplysninger fra anvendelse af kategorisering (gruppering, read-across), (Q)SAR-resultater [(kvalitative eller kvantitative

struktur-aktivitets-relationer (Qualitative or Quantitative structure-activity relationship)], erfaringer fra mennesker, såsom arbejdsmiljødata og data fra ulykkesdatabaser, epidemiologiske og kliniske undersøgelser samt veldokumenterede case-rapporter og observationer. Dataenes kvalitet og konsistens vægtes på passende vis. De tilgængelige resultater skal, uanset hvilke konklusioner de hver for sig har ført til, samles i en enkelt vægtet vurdering.

De oplysninger, der lægges til grund for en vurdering af stoffers PBT- og vPvB-egenskaber, skal baseres på data, der er fremkommet under relevante forhold.

Ved identifikationen skal der også tages højde for PBT- og vPvB-egenskaberne af stoffets relevante bestanddele og relevante omdannelses- og/eller nedbrydningsprodukter.

Dette bilag finder anvendelse på alle organiske stoffer, herunder organiske metalforbindelser.«

17 Punkt 1.1.2 og 1.2.2 i bilag XIII, som ændret ved forordning nr. 253/2011, har følgende ordlyd:

»1.1.2. Bioakkumulering

Et stof opfylder bioakkumuleringskriteriet (B), når biokoncentrationsfaktoren i akvatiske arter er på over 2 000.

[…]

1.2.2. Bioakkumulering

Et stof opfylder kriteriet for at være »meget bioakkumulerende« (vB), hvis biokoncentrationsfaktoren i akvatiske arter er på over 5 000.«

18 Punkt 3.2 og 3.2.2 i bilag XIII, som ændret ved forordning nr. 253/2011, har følgende ordlyd:

»3.2. Oplysninger, der tages i betragtning ved vurderingen af et stofs egenskaber

Følgende oplysninger tages i betragtning ved vurderingen af P-, vP- [(meget persistent)], B-, vB- og T-egenskaber, idet der foretages en vægtning af disse:

[…]

3.2.2. Vurdering af B- eller vB-egenskaber:

a) Resultater af undersøgelser af biokoncentration eller bioakkumulering i akvatiske arter.

b) Andre oplysninger om bioakkumuleringspotentiale, forudsat at deres egnethed og pålidelighed er tilstrækkeligt dokumenteret, såsom:

   – resultater af en undersøgelse af bioakkumulering i terrestriske arter

     […]

c) Oplysninger om stoffets evne til at ophobe sig i fødekæden, om muligt udtrykt ved hjælp af biomagnificeringsfaktorer eller trofiske magnificeringsfaktorer.«

Forordning (EF) nr. 440/2008

19 Den 30. maj 2008 vedtog Kommissionen på grundlag af REACH-forordningens artikel 13, stk. 3, forordning (EF) nr. 440/2008 om fastlæggelse af forsøgsmetoder i henhold til Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 om registrering, vurdering og godkendelse af samt begrænsninger for kemikalier (REACH) (EUT 2008, L 142, s. 1).

20 Punkt C.13 i bilaget til forordning nr. 440/2008, som ændret ved Kommissionens forordning (EU) 2017/735 af 14. februar 2017 (EUT 2017, L 112, s. 1), vedrører »[b]ioakkumulering i fisk: eksponering i vand eller føde«.

21 Første afsnit i introduktionen til dette punkt C.13 er affattet som følger:

»Denne forsøgsmetode svarer til OECD's [Organisationen for Økonomisk Samarbejde og Udvikling] testvejledning (Test Guideline (TG)) 305 (2012). Det overordnede mål med denne revision af forsøgsmetoden er dobbelt. For det første er det hensigten at medtage en test af bioakkumulering i føde […], der kan anvendes til at bestemme bioakkumuleringspotentialet for stoffer med meget lav vandopløselighed. […]«

Sagens baggrund

22 Sagens baggrund er gengivet på følgende måde i den appellerede doms præmis 9-20:

»9 […] Global Silicones Council er en sammenslutning, der er etableret i De Forenede Stater, som repræsenterer virksomheder, der fremstiller og sælger silikoneprodukter i hele verden. […] Wacker Chemie […], Momentive Performance Materials […], Shin-Etsu Silicones Europe […] og Elkem Silicones France […] er virksomheder, der er etableret i Den Europæiske Union, som fremstiller, sælger og leverer silikoneprodukter, og navnlig kemikalierne octamethylcyclotetrasiloxan (herefter »D4«) og decamethylcyclopentasiloxan (herefter »D5«).

10 Den 1. oktober 2014 indgav den kompetente myndighed i Det Forenede Kongerige Storbritannien og Nordirland til [ECHA] dele af et dossier som omhandlet i bilag XV […] vedrørende D4 og D5's PBT- og vPvB-egenskaber.

11 Den 14. oktober 2014 anmodede ECHA's direktør Medlemsstatsudvalget, som er tilknyttet ECHA (herefter »Medlemsstatsudvalget«), om at udarbejde en udtalelse vedrørende D4's og D5's persistens og bioakkumulering i forhold til kriterierne i bilag XIII.

12 Mellem den 15. oktober og den 1. december 2014 blev der afholdt en offentlig høring vedrørende de dokumenter, som Det Forenede Kongerige havde indgivet vedrørende D4 og D5's PBT- og vPvB-egenskaber.

13 Den 17. april 2015 fremsendte Det Forenede Kongerige til ECHA et dossier som omhandlet i bilag XV (herefter »dossieret udarbejdet i henhold til bilag XV«), hvori det foreslog en begrænsning vedrørende D4 og D5 i kosmetiske produkter, der blev vasket af under normale anvendelsesbetingelser. Ifølge dette dossier var det nødvendigt med et tiltag på EU-plan for at imødegå de risici, som anvendelsen af D4 og D5 udgør for miljøet, når de udledes i spildevandet.

14 Den 22. april 2015 vedtog Medlemsstatsudvalget en udtalelse (herefter »Medlemsstatsudvalgets udtalelse«) om, at både D4 og D5 opfyldte kriterierne i bilag XIII for identifikationen af vP- og vB-stoffer.

15 Mellem den 18. juni og den 18. december 2015 blev der afholdt en offentlig høring vedrørende den tilsigtede begrænsning af brugen af D4 og D5. Inden for rammerne af denne offentlige høring fremsatte [appellanterne] deres bemærkninger og fremlagde beviser.

16 Den 10. marts 2016 vedtog ECHA's Udvalg for Risikovurdering (herefter »RAC«) sin udtalelse, der konkluderede dels, at D4 opfyldte kriterierne i bilag XIII for identifikationen af et PBT-stof og et vPvB-stof, dels at D5 opfyldte kriterierne for identifikationen af et vPvB-stof (herefter »RAC's udtalelse«). RAC bekræftede, at de farlige egenskaber ved D4 og D5 gav anledning til særlig bekymring for miljøet, når de fandtes i kosmetiske produkter, som bruges eller fjernes med vand. Udvalget konkluderede også, at den foreslåede begrænsning var en målrettet og passende foranstaltning på EU-plan til at minimere emissionerne forårsaget af produkter, der vaskes af med vand.

17 Den 11. marts 2016 vedtog ECHA's Udvalg for Socioøkonomisk Analyse (herefter »SEAC«) for sit vedkommende et udkast til udtalelse. Der blev afholdt en offentlig høring mellem den 16. marts og den 16. maj 2016. Den 9. juni 2016 vedtog SEAC sin endelige udtalelse, der indikerede, at den foreslåede begrænsning var den mest passende foranstaltning på EU-plan til at reducere udledningen af D4 og D5 i spildevand, når man så på de socioøkonomiske fordele og de socioøkonomiske omkostninger (herefter »SEAC's udtalelse«). […]

18 Den 10. august 2016 forelagde ECHA Kommissionen udtalelserne fra RAC og SEAC.

19 Den 10. maj 2017 fremlagde Kommissionen sit forslag til forordning til udtalelse for det udvalg, der er oprettet ved [REACH-forordningens] artikel 133.

20 Den 10. januar 2018 vedtog Kommissionen [den omtvistede forordning]. Denne forordning fastsætter, at hverken D4 eller D5 må markedsføres i kosmetiske produkter, der vaskes af i en koncentration på eller over 0,1% ud fra vægten af hvert stof efter den 31. januar 2020.«

Sagsbehandlingen for Retten og den appellerede dom

23 Ved stævning indleveret til Rettens Justitskontor den 2. april 2018 anlagde appellanterne sag med påstand om annullation af den omtvistede afgørelse.

24 Ved afgørelse truffet af formanden for Rettens Femte Afdeling den 5. september 2018 fik Forbundsrepublikken Tyskland, Det Forenede Kongerige, Europa-Parlamentet og Rådet for Den Europæiske Union tilladelse til at intervenere til støtte for Kommissionens påstande.

25 Ved kendelse af 25. oktober 2018 gav formanden for Rettens Femte Afdeling ECHA tilladelse til at intervenere til støtte for Kommissionens påstande.

26 Ved kendelse af 13. december 2018 gav formanden for Rettens Femte Afdeling American Chemistry Council Inc. (ACC) tilladelse til at intervenere til støtte for appellanternes påstande.

27 Til støtte for søgsmålet fremsatte appellanterne otte anbringender om for det første åbenbart urigtige skøn, for det andet en tilsidesættelse af proportionalitetsprincippet, for så vidt som den omtvistede forordning ikke var hensigtsmæssig eller nødvendig, ikke udgjorde den mindst bebyrdende foranstaltning og medførte uforholdsmæssige ulemper i forhold til de forfulgte mål, for det tredje en tilsidesættelse af væsentlige formforskrifter, navnlig for så vidt som Kommissionen »aldrig på passende eller tilstrækkelig vis [havde] undersøgt eller kontrolleret det grundlæggende grundlag [for den omtvistede forordning]«, og for så vidt som RAC og ikke Medlemsstatsudvalget burde have vurderet alle de faktorer og begrundelser, der lå til grund for den begrænsning, som er fastsat i den omtvistede forordning, for det fjerde en tilsidesættelse af retssikkerhedsprincippet og princippet om beskyttelse af den berettigede forventning, for det femte en tilsidesættelse af den institutionelle ligevægt mellem beføjelserne, for så vidt som ECHA havde »lovgivet« ved at konkludere, at D4 og D5 havde B-egenskaber og vB-egenskaber uden for og uafhængigt af gældende ret, for det sjette en tilsidesættelse af princippet om god forvaltningsskik, navnlig for så vidt som Kommissionen og ECHA havde tilsidesat forpligtelsen til at sikre, at de administrative procedurer for risikovurdering sikrer videnskabelig objektivitet og udelukker vilkårlige foranstaltninger, for det syvende en tilsidesættelse af retten til forsvar og retten til at blive hørt og for det ottende en tilsidesættelse af begrundelsespligten i den omtvistede forordning.

28 Ved den appellerede dom forkastede Retten alle de fremsatte anbringender og frifandt følgelig Kommissionen i det hele.

Parternes påstande for Domstolen

29 Appellanterne, støttet af ACC, har i appelskriftet nedlagt følgende påstande:

– Den appellerede dom ophæves.

– Den omtvistede forordning annulleres.

– Subsidiært hjemvises sagen til Retten med henblik på, at denne træffer afgørelse i annullationssøgsmålet.

– Kommissionen tilpligtes at betale sagsomkostningerne, herunder omkostningerne i forbindelse med sagen for Retten.

30 Kommissionen, støttet af Forbundsrepublikken Tyskland og ECHA, har nedlagt følgende påstande:

– Appellen forkastes.

– Appellanterne tilpligtes at betale sagsomkostningerne.

Om appellen

31 Appellanterne har til støtte for appellen gjort fem anbringender gældende.

– Det første anbringende vedrører en fejl, som Retten begik dels ved at fastslå, at Kommissionen ikke havde tilsidesat REACH-forordningens artikel 68, stk. 1, ved ikke udtrykkeligt at fastslå, at

der forelå en uacceptabel risiko, dels ved ikke at fastsætte en kritisk tærskel for sandsynligheden for skadelige virkninger, som ikke er acceptable for samfundet.

– Det andet anbringende vedrører en fejl, som Retten begik, idet den fandt, at Kommissionen ikke havde undladt at begrunde sin afgørelse om, at de risici, der var forbundet med anvendelsen af D4 og D5 i de produkter, der vaskes af med vand, var uacceptable.

– Det tredje anbringende vedrører en fejl, som Retten begik, idet den fastslog, at den usikkerhed, der var forbundet med vurderingen af PBT- eller vPvB-stofferne, begrundede en tilgang, der bestod i at anse emissionerne af et stof for at være et tegn på, at der forelå en risiko.

– Det fjerde anbringende vedrører en fejlagtig fortolkning af bilag XIII og af forordning nr. 253/2011, for så vidt som Retten fastslog, at dataene vedrørende biokoncentrationsfaktoren (herefter »BKF«) havde en »vis prioritet« eller en »større beviskraft« i forhold til andre data med henblik på vurderingen af B/vB-egenskaberne.

– Det femte anbringende vedrører en fejlagtig fortolkning af bilag XIII, for så vidt som Retten fastslog, at ECHA ikke havde begået en åbenbar fejl ved ikke at tage hensyn til D4 og D5's hybride natur.

Det andet anbringende

Parternes argumentation

32 Med det andet anbringende, som skal behandles først, har appellanterne, støttet af ACC, gjort gældende, at Retten fejlagtigt fastslog, at Kommissionen ikke havde tilsidesat begrundelsespligten i henhold til artikel 296, andet afsnit, TEUF ved ikke i den omtvistede forordning at nævne, at den risiko, der er forbundet med anvendelsen af D4 og D5 i visse kosmetiske produkter, der vaskes af, var »uacceptabel« som omhandlet i REACH-forordningens artikel 68, stk. 1.

33 Det er appellanternes opfattelse, at selv om ottende og niende betragtning til den omtvistede forordning med hensyn til anvendelsen af D4 og D5 nævner, at der foreligger en risiko, angiver de ikke, at denne risiko er uacceptabel. Henvisningen til dossieret udarbejdet i henhold til bilag XV og til udtalelserne fra Medlemsstatsudvalget, RAC og SEAC kan ikke afhjælpe tilsidesættelsen af denne begrundelsespligt, for så vidt som EU-lovgiver ikke har pålagt disse udvalg som en sidste udvej at afgøre, om risikoen var uacceptabel. Selv hvis det antages, at Kommissionen kan foretage en implicit fastlæggelse af risikoen, er den omtvistede forordning i øvrigt behæftet med en begrundelsesmangel og kan derfor ikke gøres til genstand for domstolsprøvelse.

34 Appellanterne har anfægtet den appellerede doms præmis 187, for så vidt som det kan udledes af denne præmis, at Kommissionen har overholdt sin begrundelsespligt alene på grund af vedtagelsen af den omtvistede forordning.

35 Appellanterne har gjort gældende, at Retten i den appellerede doms præmis 204 med urette fastslog, at »[d]et [ikke] følger […] af retspraksis, at Kommissionen burde have anvendt udtrykket »uacceptabel risiko«, og har hævdet, at forpligtelsen til at anføre en sådan angivelse fremgår direkte af REACH-forordningens artikel 68, stk. 1.

36 Ved at acceptere, at Kommissionen havde ret til at foretage en implicit vurdering, tiltrådte Retten synspunktet om, at når en afgørelse følger et videnskabeligt organs udtalelse, udgør indholdet af denne udtalelse, som er nævnt i betragtningerne til denne afgørelse, en integrerende del af afgørelsens begrundelse. Det er dog fejlagtigt at antage, at ECHA kan foretage en vurdering af, om risikoen er uacceptabel, og at Kommissionen blot kan henvise til denne vurdering implicit.

37 Rettens bemærkning i den appellerede doms præmis 337 om, at den manglende angivelse af ordet »uacceptabel« i den omtvistede forordning ikke har nogen indvirkning på de berørte parters mulighed for at forstå rækkevidden af og begrundelserne for denne forordning, er i åbenbar modstrid med de krav, der følger af begrundelsespligten.

38 Kommissionen, støttet af Forbundsrepublikken Tyskland og ECHA, har gjort gældende, at appellanternes argumentation er ugrundet.

Domstolens bemærkninger

39 Det bemærkes, at appellanterne ved at påberåbe sig en tilsidesættelse af artikel 296, andet afsnit, TEUF har kritiseret den måde, hvorpå Retten bl.a. i den appellerede doms præmis 187, 204 og 337 besvarede kritikken om, at udtrykket »uacceptabel« som omhandlet i REACH-forordningens artikel 68, stk. 1, ikke var nævnt i den omtvistede forordning.

40 I denne henseende bemærkes, at spørgsmålet om, hvorvidt en begrundelse er tilstrækkelig, ikke blot skal vurderes i forhold til ordlyden, men ligeledes i forhold til den sammenhæng, hvori den indgår, samt under hensyn til alle de retsregler, som gælder på det pågældende område (dom af 29.9.2022, ABLV Bank mod Afviklingsinstansen, C-202/21 P, EU:C:2022:734, præmis 193 og den deri nævnte retspraksis).

41 I det foreliggende tilfælde bemærkes, at Retten – efter i den appellerede doms præmis 327-331 at have redegjort for omfanget af den begrundelsespligt, der påhviler den institution, som har udstedt den pågældende retsakt – i denne doms præmis 337 undersøgte det klagepunkt, som appellanterne havde fremført om, at udtrykket »uacceptabel« ikke var nævnt i den omtvistede forordning i forbindelse med den risiko for miljøet, der var forbundet med tilstedeværelsen af D4 og D5 i visse kosmetiske produkter.

42 Retten konstaterede, at det forhold, at dette udtryk ikke var blevet nævnt i denne forordning, hverken havde indvirkning på de berørte parters mulighed for at forstå rækkevidden af og begrundelserne for den nævnte forordning eller på Unionens retsinstansers mulighed for at udøve deres legalitetskontrol. Med henblik herpå henviste Retten til den appellerede doms præmis 204, hvoraf det fremgik, at det følger af ottende og niende betragtning til og retsgrundlaget for den omtvistede forordning, at Kommissionen implicit, men nødvendigvis, anså den risiko, der var forbundet med tilstedeværelsen af D4 og D5 i visse kosmetiske produkter, for at udgøre en uacceptabel risiko for miljøet. Samme betragtning fremgår ligeledes af denne doms præmis 187.

43 Endvidere fastslog Retten i den nævnte doms præmis 338, at der skulle tages hensyn til de begrundelser, der var angivet i dossieret udarbejdet i henhold til bilag XV, og til udtalelserne fra Medlemsstatsudvalget, RAC og SEAC, som var offentlige, og hvis konklusioner Kommissionen fulgte ved udarbejdelsen af den omtvistede forordning, således som det fremgår af første, tredje til femte og syvende betragtning til denne forordning.

44 Retten kunne derfor uden at begå en retlig fejl udlede af de oplysninger, der er nævnt i denne doms præmis 42 og 43, at det forhold, at udtrykket »uacceptabel risiko« ikke er nævnt i den omtvistede forordning, ikke udgjorde en lakune i denne forordnings begrundelse, eftersom det følger af såvel ordlyden af som den sammenhæng, hvori den nævnte forordning indgår, at Kommissionen nødvendigvis skulle anse den risiko, der var forbundet med tilstedeværelsen af D4 og D5 i visse kosmetiske produkter, der vaskes af, for at være en uacceptabel risiko.

45 Det følger heraf, at det andet anbringende skal forkastes som ugrundet.

Det første anbringende

Det første anbringendes første led

– *Parternes argumentation*

46 Med det første anbringendes første led har appellanterne, støttet af ACC, foreholdt Retten, at den tilsidesatte REACH-forordningens artikel 68, stk. 1, da den tiltrådte Kommissionens tilgang, som bestod i implicit at fastslå, at der forelå en uacceptabel risiko for menneskers sundhed eller miljøet som omhandlet i denne bestemmelse, og at bekræfte konklusionerne i udtalelserne fra Medlemsstatsudvalget, RAC og SEAC uden at foretage sin egen vurdering af, om denne risiko var uacceptabel.

47 For det første fremgår det af artikel 68, stk. 1, sammenholdt med artikel 69, stk. 1 og 4, og artikel 70 i REACH-forordningen, at hverken ECHA, RAC eller medlemsstaterne har beføjelse til at kvalificere den nævnte risiko som uacceptabel. Det er appellanternes opfattelse, at selv om indsenderen af dossieret udarbejdet i henhold til bilag XV i det foreliggende tilfælde anførte, at »simple emissioner og den efterfølgende eksponering, når der er tale om et PBT- eller vPvB-stof, kan anses for at være et tegn på en uacceptabel risiko«, er ordet »uacceptabel« hverken nævnt i RAC's udtalelse eller i SEAC's udtalelse, hvilket viser, at disse udvalg ikke anså sig for kompetente til at kvalificere risikoen.

48 En sådan kvalificering følger af en politisk afgørelse vedtaget af Kommissionen i overensstemmelse med proceduren i REACH-forordningens artikel 133, stk. 4. Kommissionen kan ikke støtte sig på bilag I for vurderingen af den »uacceptable risiko«, idet dette bilag ikke vedrører vurderingen af en sådan risiko. Retten begik således en retlig fejl, da den i den appellerede doms præmis 192 fastslog, at »[d]e principper, der er fastlagt i bilag I, […] ikke kun [finder] anvendelse på det dossier, der er udarbejdet i overensstemmelse med bilag XV, men også i forbindelse med de efterfølgende trin i proceduren for vedtagelse af en begrænsning«.

49 Appellanterne har gjort gældende, at der ikke er noget retsgrundlag, der gør det muligt for Retten at fastslå, at Kommissionen er bundet af de principper, der er fastlagt i bilag I i forbindelse med risikovurderingen i henhold til REACH-forordningens artikel 68, stk. 1. Retten tog ikke hensyn til den omstændighed, at det trin, der er fastsat i denne bestemmelse, og det trin, der er fastsat i denne forordnings artikel 69, er to særskilte trin, der hver har et forskelligt retsgrundlag, og i forbindelse med hvilke der anvendes forskellige principper.

50 For det andet modsagde Retten sig selv i den appellerede doms præmis 192, 199 og 217, idet den fastslog, dels at de principper, der er fastlagt i bilag I, finder anvendelse under hele processen for vedtagelse af en begrænsning, dels at begrebet »uacceptabel risiko« i REACH-forordningens artikel 68, stk. 1, adskiller sig fra begrebet »risiko, der ikke er tilstrækkeligt kontrolleret, og som det er nødvendigt at imødegå«, som er omhandlet i forordningens artikel 69, og at Kommissionen ikke var forpligtet til at foretage en ny videnskabelig vurdering, der kunne sammenlignes med den, der blev foretaget af de aktører, som forordningen udtrykkeligt har overdraget denne opgave til.

51 I modsætning til, hvad der fremgår af den appellerede dom, overholdt Kommissionen således ikke den forpligtelse, der påhviler den i henhold til REACH-forordningens afsnit VIII til at afgøre, om anvendelsen af D4 og D5 i kosmetiske produkter, der vaskes af, udgør en uacceptabel risiko som omhandlet i denne forordnings artikel 68, stk. 1, idet en simpel henvisning til den risikovurdering, som RAC har foretaget i henhold til denne forordnings artikel 69, ikke er tilstrækkelig. Retten antog derfor fejlagtigt, at det var tilladt at foretage en implicit fastlæggelse af risikoen.

52 Ifølge Kommissionen, støttet af Forbundsrepublikken Tyskland og ECHA, er appellanternes argumentation ugrundet.

– *Domstolens bemærkninger*

53 Det skal for det første bemærkes, at vedtagelsen af en ny begrænsning med hensyn til fremstilling, anvendelse eller markedsføring af visse stoffer i henhold til REACH-forordningens artikel 68, stk. 1, er baseret på Kommissionens konstatering af, at der foreligger en uacceptabel risiko for menneskers sundhed eller miljøet, som det er nødvendigt at imødegå på EU-plan, og indebærer, at der tages hensyn til de socioøkonomiske konsekvenser af denne begrænsning, herunder eventuelle disponible alternativer.

54 I henhold til denne forordnings artikel 69 indledes proceduren for vedtagelse af en ny begrænsning ved udarbejdelse af et dossier i overensstemmelse med bilag XV, hvis Kommissionen eller en medlemsstat mener, at der er en risiko, der ikke er tilstrækkeligt kontrolleret, og som det er nødvendigt at imødegå. I overensstemmelse med den nævnte forordnings artikel 70 udtaler RAC sig om, hvorvidt begrænsningen er egnet til at nedbringe risikoen for menneskers sundhed eller miljøet, og ifølge samme forordnings artikel 71, stk. 1, udarbejder SEAC en udtalelse om de foreslåede begrænsninger på grundlag af bl.a. de socioøkonomiske konsekvenser af disse. ECHA sender på grundlag af REACH-forordningens artikel 72, stk. 1, Kommissionen RAC's udtalelse og SEAC's udtalelse, og Kommissionen udarbejder i overensstemmelse med denne forordnings artikel 73, stk. 1, første afsnit, udkastet til ændring af bilag XVII til den nævnte forordning.

55 Det fremgår af disse bestemmelser, at selv om fastlæggelsen af den uacceptable risiko for menneskers sundhed eller miljøet som følge af fremstillingen, anvendelsen eller markedsføringen af et stof henhører under Kommissionens skønsbeføjelse, hviler denne afgørelse bl.a. på udtalelserne fra RAC og SEAC. Som Kommissionen har gjort gældende i sit svarskrift, følger den nævnte afgørelse af en enkelt administrativ procedure, hvorunder forskellige aktører udarbejder videnskabelige udtalelser, efter at der har fundet en offentlig høring sted, med henblik på at forberede den endelige afgørelse.

56 Følgelig kunne Retten i den appellerede doms præmis 192 med rette fastslå, at de principper, der er fastlagt i bilag I, ikke alene finder anvendelse på det dossier, der er udarbejdet i overensstemmelse med bilag XV, men også i forbindelse med de efterfølgende trin i proceduren for vedtagelse af en begrænsning som omhandlet i REACH-forordningens artikel 68, stk. 1. Som generaladvokaten ligeledes har anført i punkt 55 i forslaget til afgørelse, kan appellanterne således ikke gøre gældende, at Kommissionen ikke kunne støtte sig på bilag I med henblik på vurderingen af, om risikoen var uacceptabel som omhandlet i denne bestemmelse.

57 For det andet viser læsningen af den appellerede doms præmis 192, 199 og 217 i modsætning til, hvad appellanterne har gjort gældende, ingen selvmodsigelse. Konstateringen i denne doms præmis 192 af, at de principper, der er fastlagt i bilag I, finder anvendelse under hele proceduren for vedtagelse af en begrænsning, modsiges således ikke af den sondring, der er foretaget i den nævnte doms præmis 199, mellem den risiko, der ikke er tilstrækkeligt kontrolleret som omhandlet i REACH-forordningens artikel 69, og den uacceptable risiko som omhandlet i forordningens artikel 68. Udarbejdelsen af et dossier i overensstemmelse med bilag XV og udtalelserne fra Medlemsstatsudvalget, RAC og SEAC tilsigter at give Kommissionen de nødvendige videnskabelige oplysninger, således at denne kan kvalificere risikoen. Selv om Kommissionen er forpligtet til at foretage en sådan kvalificering, følger det ikke af den nævnte forordnings artikel 68, stk. 1 – således som Retten med rette fastslog i den appellerede doms præmis 217 – at den skal foretage en ny videnskabelig vurdering, der kan sammenlignes med den, som de aktører, der ved REACH-forordningen har fået overdraget denne opgave ved REACH-forordningen, forudgående har foretaget.

58 Endelig er det – for så vidt som appellanterne har påberåbt sig den manglende udtrykkelige konstatering i den omtvistede forordning af, at der foreligger en »uacceptabel risiko«, og heraf har udledt, at Kommissionen har undladt at afgøre, om anvendelsen af D4 og D5 i kosmetiske produkter, der vaskes af, udgør en sådan risiko – tilstrækkeligt at bemærke, således som det er anført i denne doms præmis 44, at det fremgår af såvel ordlyden af forordningen som den sammenhæng, hvori denne indgår, at Kommissionen nødvendigvis skulle anse den risiko, der er forbundet med tilstedeværelsen af D4 og D5 i visse kosmetiske produkter, der vaskes af, for at være en uacceptabel risiko.

59 Det følger heraf, at det første anbringendes første led skal forkastes som ugrundet.

Om det første anbringendes andet led

– *Parternes argumentation*

60 Ifølge appellanterne, støttet af ACC, burde Kommissionen, som det fremgår af dom af 11. september 2002, Pfizer Animal Health mod Rådet (T-13/99, herefter »Pfizer-dommen«, EU:T:2002:209, præmis 151), have fastsat en kritisk tærskel for sandsynligheden for skadelige virkninger, som ikke er acceptable for menneskers sundhed eller miljøet, uanset om vurderingen af denne tærskel skal være kvantitativ eller kvalitativ. I den appellerede doms præmis 185 og 202 forkastede Retten imidlertid anvendelsen af Pfizer-dommen.

61 Appellanterne har gjort gældende, at proceduren med henblik på at fastslå en begrænsning i henhold til REACH-forordningen i lighed med vurderingen af risikoen på grundlag af forsigtighedsprincippet, der var omhandlet i den sag, der gav anledning til Pfizer-dommen, omfatter to trin, hvoraf det første vedrører den videnskabelige identifikation af risikoen, og det

andet har til formål at afgøre, om den således identificerede risiko er acceptabel for samfundet. Fastlæggelsen af det »risikoniveau, der anses for uacceptabelt«, som Retten foretog i Pfizer-dommen, kan derfor overføres til fastlæggelsen af, om risikoen er uacceptabel i henhold til REACH-forordningens artikel 68, stk. 1. Ved at nægte at gå frem som i Pfizer-dommen anvendte Retten Unionens retspraksis forkert.

62 Ifølge appellanterne skal Kommissionen, når den fastlægger den »uacceptable risiko« som omhandlet i REACH-forordningens artikel 68, stk. 1, vurdere, om den risiko, som indsenderen af dossieret har identificeret, når den kritiske tærskel for sandsynligheden for skadelige virkninger, der anses for uacceptabel for samfundet.

63 Ifølge Kommissionen, støttet af Forbundsrepublikken Tyskland og ECHA, er appellanternes argumentation ugrundet.

– *Domstolens bemærkninger*

64 Det skal indledningsvis bemærkes, at Retten i Pfizer-dommens præmis 151 fastslog, at »[d]et tilkommer [EU-institutionerne] at fastsætte det beskyttelsesniveau, som de anser for passende for samfundet[, og] at fastlægge det risikoniveau – dvs. den kritiske [tærskel for sandsynligheden for skadelige virkninger] for menneskers sundhed og for omfanget af disse potentielle virkninger – som de ikke […] anser for acceptabelt […], og som, hvis det overskrides, af hensyn til beskyttelsen af menneskers sundhed gør det nødvendigt at gribe til præventive foranstaltninger«.

65 Selv om det er korrekt, at denne præmis vedrører vurderingen af risikoen i forbindelse med anvendelsen af det almindelige forsigtighedsprincip, kan det dog ikke udledes af Pfizer-dommen, der blev afsagt før vedtagelsen af REACH-forordningen, at fastlæggelsen af det risikoniveau, der kan anses for at være »uacceptabelt« som omhandlet i denne forordning, nødvendigvis skal omfatte en kvantificerbar kritisk tærskel for sandsynligheden for skadelige virkninger.

66 Som generaladvokaten har anført i punkt 81 i forslaget til afgørelse, fremgår det nemlig af Domstolens faste praksis vedrørende forsigtighedsprincippet, at de præventive foranstaltninger for det første kræver en fastlæggelse af de potentielt negative konsekvenser og for det andet en overordnet evaluering af risikoen på grundlag af de mest pålidelige videnskabelige data, der er til rådighed, og de seneste internationale forskningsresultater (jf. i denne retning dom af 28.1.2010, Kommissionen mod Frankrig, C-333/08, EU:C:2010:44, præmis 92, og af 1.10.2019, Blaise m.fl., C-616/17, EU:C:2019:800, præmis 46). Domstolen kræver derimod ikke en nøjagtig fastlæggelse af grænsen for, hvornår en risiko stadig er acceptabel.

67 I den særlige sammenhæng, som PBT- og vPvB-stofferne indgår i, har EU-lovgiver, således som Retten ligeledes fastslog i den appellerede doms præmis 190, 191 og 202, fastsat specifikke bestemmelser i bilag I med henblik på at overholde forsigtighedsprincippet.

68 I denne henseende fremgår det af dette bilags punkt 4.0.1, at der for PBT- og vPvB-stoffer ikke kan foretages en tilstrækkeligt pålidelig farevurdering vedrørende alle langtidsvirkninger i overensstemmelse med punkt 1 og 3 i det nævnte bilag og en estimering af langtidsudsættelsen af mennesker og miljø efter punkt 5.2 i bilag I. Dette bilags punkt 6.5 bestemmer, at der for stoffer såsom PBT- og vPvB-stoffer, for hvilke det ikke er muligt at bestemme den stofkoncentration, under hvilken der ikke forventes negative virkninger på det relevante delmiljø (PNEC), foretages en »kvalitativ vurdering af sandsynligheden for, at virkningerne kan undgås«.

69 Retten begik derfor ikke en retlig fejl, da den godkendte fastlæggelsen af den uacceptable karakter af risikoen som omhandlet i REACH-forordningens artikel 68, stk. 1, på grundlag af den risikovurdering, der blev foretaget i overensstemmelse med bilag I og XV af begrænsningens hensigtsmæssighed med henblik på at mindske de vurderede risici og en sådan begrænsnings socioøkonomiske konsekvenser, når der ikke forelå en kvantificeret kritisk tærskel for sandsynligheden for skadelige virkninger.

70 Følgelig må det første anbringendes andet led forkastes som ugrundet.

Det tredje anbringende

Parternes argumentation

71 Med det tredje anbringende har appellanterne, støttet af ACC, gjort gældende, at den appellerede doms præmis 196 er behæftet med en retlig fejl, for så vidt som Retten heri konkluderede, at den usikkerhed, der var forbundet med vurderingen af risikoniveauet for PBT- eller vPvB-stofferne, begrundede en tilgang, der bestod i at anse deres emissioner for at være et tegn på, at der forelå en risiko. Retten foretog således en fejlagtig anvendelse af sin praksis vedrørende begrebet »nulrisiko«, således som denne fremgår af dom af 17. maj 2018, Bayer CropScience m.fl. mod Kommissionen (T-429/13 og T-451/13, EU:T:2018:280, præmis 116 og 123), og Pfizer-dommen (præmis 152) (herefter »retspraksis vedrørende begrebet »nul-risiko««), og foretog en fejlagtig fortolkning af bilag I.

72 Hvad på den ene side angår den fejlagtige anvendelse af retspraksis vedrørende begrebet »nul-risiko« har appellanterne anført, at Kommissionen ikke rådede over andre kriterier for vurderingen af, om risikoen var uacceptabel som omhandlet i REACH-forordningens artikel 68, stk. 1, end den konklusion, som indsenderen af dossieret havde fremført, og som blev støttet af ECHA, hvorefter enhver emission af et stof udgjorde et tegn på, at der forelå en risiko. En sådan konklusion svarer til at kræve, at der foreligger en »nul-risiko«, eftersom det kun er fraværet af emissioner, der kan anses for at være acceptabelt. Den er derfor i strid med den pågældende retspraksis, hvoraf det fremgår, at vedtagelsen, tilbagetrækningen eller lempelsen af en præventiv foranstaltning ved fastlæggelsen af det risikoniveau, der anses for uacceptabelt, ikke kan gøres betinget af, at der føres bevis for, at der ikke foreligger nogen risiko, for så vidt som et sådant bevis generelt er umuligt at føre, eftersom der i realiteten ikke findes et nul-risikoniveau.

73 Hvad på den anden side angår fortolkningen af bilag I har appellanterne fremhævet, at indsenderen af dossieret, RAC og Retten, da den godkendte RAC's konklusioner, anlagde en urigtig fortolkning af dette bilag, eftersom det for det første ikke af den kvalitative risikovurdering, der er fastsat i dettes punkt 6.5, kan udledes, at alle emissionerne udgør et tegn på, at der foreligger en risiko, og for det andet det anførte om, at denne kvalitative vurdering udelukker en kvantificering af risikoen, er ugrundet.

74 Hvad for det første angår den kvalitative risikovurdering, der er fastsat i bilag I, tager punkt 0.1, 0.3 og 0.5 i dette bilag sigte på at vurdere risiciene og på at fastslå, om de er tilstrækkeligt kontrolleret, ved at analysere stoffernes potentielle negative virkninger og sammenligne dem med vurderingen af eksponeringen af mennesker og miljøet for disse stoffer. En sådan sammenligning foretages på grundlag af kvantificerede oplysninger. Det nævnte bilags punkt 0 med overskriften »Indledning« finder generel anvendelse, herunder for PBT- eller vPvB-stoffer. Dette punkt tilbageviser imidlertid i sig selv de betragtninger, som Retten anførte i den appellerede doms præmis 190, 191

og 196, hvorefter den risiko, der er forbundet med PBT- og vPvB-stofferne, ikke gyldigt kan kvantificeres og kontrolleres, hvilket gjorde det muligt for Retten at fastslå, at enhver emission af sådanne stoffer udgør et tegn på, at der foreligger en risiko.

75 Denne konstatering fra Rettens side afkræftes ligeledes af en systemisk fortolkning af bilag I. For så vidt angår PBT- eller vPvB-stofferne kræver dette bilags punkt 4 nemlig til forskel fra andre stoffer, at der foretages en specifik vurdering af disse stoffer og ikke en farevurdering som fastsat i det nævnte bilags punkt 1 og 3 samt en karakterisering af emissionerne (punkt 4.2) i tillæg til den eksponeringsvurdering, der er fastsat i samme bilags punkt 5 (trin 2). Denne eksponeringsvurdering skal foretages for PBT- eller vPvB-stofferne, for så vidt som punkt 7 i bilag I med overskriften »Kemikaliesikkerhedsrapportens format« inkluderer en »eksponeringsvurdering« som et obligatorisk element i kemikaliesikkerhedsrapporten som omhandlet i REACH-forordningens artikel 14, og dette for alle disse stoffer. Da hovedformålet med den nævnte eksponeringsvurdering er at påvise, at risiciene for menneskers sundhed og miljøet er tilstrækkeligt kontrolleret, kræver denne vurdering en kvantificering af risikoen, for at det kan godtgøres, at risikoen er tilstrækkeligt kontrolleret. Hvis man accepterede, at enhver emission af et stof var et tegn på, at der forelå en risiko, var det ikke nødvendigt at vurdere menneskers og miljøets eksponering for PBT- eller vPvB-stoffer, og kemikaliesikkerhedsvurderingen af disse stoffer var begrænset til at afgøre, om et stof er et PBT-stof eller et vPvB-stof.

76 Ifølge appellanterne omfatter den kvalitative risikovurdering, der er nævnt i punkt 6.5 i bilag I, en vurdering fra sag til sag af sandsynligheden for at undgå negative virkninger og dermed for at kontrollere risikoen korrekt. Selv hvis det antages, at enhver emission af et stof er et tegn på, at der foreligger en risiko, er punkt 6 i dette bilag imidlertid ikke anvendeligt, eftersom det alene af den omstændighed, at et stof er blevet identificeret som et PBT-stof eller et vPvB-stof, vil blive udledt, at risikoen ikke kan kvantificeres og kontrolleres tilstrækkeligt, uden at der skal foretages en vurdering.

77 Det fremgår af disse punkter, at hvis emissionerne og sandsynligheden for negative virkninger af sådanne stoffer reduceres til et minimum, kan risikoen anses for at være tilstrækkeligt kontrolleret, selv om disse emissioner ikke udgør nul. På grund af de særlige kendetegn ved D4 og D5 – såsom deres opløselighed, deres fordeling mellem miljøerne, deres biofortynding og manglen på bioforstærkningspotentiale – kan det udledes af risikovurderingen, at der ikke er sandsynlighed for negative virkninger, og at risikoen er tilstrækkeligt kontrolleret, hvilket RAC og Retten så bort fra, idet de begrænsede sig til at anføre, at emissionerne fra de omhandlede stoffer er et tegn på, at der foreligger en risiko.

78 Appellanterne har gjort gældende, at henvisningen i den appellerede doms præmis 191 til REACH-forordningens artikel 60, stk. 3 og 4, hvorefter der ikke kan udstedes en godkendelse for PBT- og vPvB-stoffer med den begrundelse, at risikoen for miljøet er tilstrækkeligt kontrolleret, ikke modsiger de argumenter, der er anført i denne doms præmis 74-77. Denne bestemmelse afspejler alene EU-lovgivers ønske om at begrænse muligheden for at ansøge om godkendelse i henhold til denne forordnings artikel 60, stk. 2, for stoffer, der har en kritisk tærskel for sandsynligheden for skadelige virkninger.

79 Appellanterne har tilføjet, at hvis det blev anerkendt, at enhver emission af et stof er et tegn på, at der foreligger en risiko, ville forpligtelsen til at gennemføre risikohåndteringsforanstaltninger for at minimere emissionerne være uden indhold, da stoffet uanset disse foranstaltninger altid ville være underlagt begrænsninger, eftersom der reelt ikke findes nogen nulemission. Ved at

minimere emission og eksponering i overensstemmelse med punkt 6 i bilag I opfylder registranterne betingelserne for, at et PBT- eller vPvB-stof kan markedsføres lovligt. De bør derfor beskyttes af retssikkerhedsprincippet og sikres, at deres stof ikke vil blive forbudt alene med den begrundelse, at det stadig genererer emissioner.

80 Hvad for det andet angår Rettens udsagn om, at den kvalitative vurdering udelukker en kvantificering af risikoen, er den i strid med indholdet af bilag I. Appellanterne har i denne henseende gjort gældende, at de sagkyndige med henblik på at godtgøre kvantificeringen af risikoen ved PBT- eller vPvB-stofferne anvender den tekniske rapport fra European Centre for Ecotoxicology and Toxicology of Chemicals (Ecetoc) vedrørende »Risikovurdering af PBT-kemikalier«, der blev offentliggjort i 2005, som suppleret og præciseret i den rapport fra Ecetoc, der blev offentliggjort i 2011. Denne rapport indikerer, at trinnet »Risikokarakterisering«, der svarer til det trin, der er fastsat i punkt 6 i bilag I, omfatter »et kvalitativt og/eller kvantitativt skøn over sandsynligheden for og hyppigheden og alvoren af kendte eller potentielle negative virkninger«.

81 Appellanterne har således gjort gældende, at en kvalitativ risikovurdering principielt skal baseres på kvantitative data, der gør det muligt at kvantificere risikoen, således at Retten med urette fastslog, at de risici, der er forbundet med de i den foreliggende sag omhandlede stoffer og med PBT- eller vPvB-stofferne generelt, ikke kunne kvantificeres på passende vis.

82 Kommissionen, støttet af Forbundsrepublikken Tyskland og ECHA, er af den opfattelse, at appellanternes argumentation er ugrundet. Hvad navnlig angår det argument, der er nævnt i denne doms præmis 80, og som støtter sig på henvisningen til Ecetoc-rapporten, der er nævnt i denne præmis, har Kommissionen gjort gældende, at der er tale om et nyt argument, som ikke er blevet fremført for Retten, og at fremsættelsen heraf under appellen ikke kan antages til realitetsbehandling. Under alle omstændigheder er dette argument ugrundet, idet denne rapport fra Ecetoc følger af et privat initiativ finansieret af de virksomheder, der har en interesse i fremstilling og anvendelse af kemikalier.

83 I replikken har appellanterne tilføjet, at Rettens fortolkning af bilag I, som anfægtes inden for rammerne af det tredje anbringende, ligeledes fører til en tilsidesættelse af den grundlæggende ret til frihed til at oprette og drive egen virksomhed, for så vidt som denne fortolkning ikke gør det muligt at udøve nogen levedygtig aktivitet i forbindelse med PBT- eller vPvB-stoffer.

84 Appellanterne har ligeledes gjort gældende, at de argumenter, der er støttet på dokumenterne fra Ecetoc, ikke er nye, og at disse dokumenter skal illustrere, at en kvalitativ risikovurdering i henhold til punkt 6.5 i bilag I gør det muligt at kvantificere risikoen.

85 Kommissionen har i duplikken anført, at den grundlæggende ret til frihed til at oprette og drive egen virksomhed ikke udgør et absolut prærogativ, for så vidt som den offentlige myndighed af hensyn til den almene interesse kan sætte begrænsninger for udøvelsen af erhvervsvirksomhed.

Domstolens bemærkninger

86 Med det tredje anbringende har appellanterne i det væsentlige gjort gældende, at den appellerede doms præmis 196 er behæftet med en retlig fejl, for så vidt som Retten godkendte RAC's udtalelse om, at de risici, der er forbundet med D4 og D5, ikke gyldigt kunne kvantificeres, idet emissionerne af disse stoffer kunne anses for at være et tegn på, at der forelå en risiko. De er af den

opfattelse, at Retten foretog en fejlagtig anvendelse af retspraksis vedrørende begrebet »nul-risiko«, og at den foretog en fejlagtig fortolkning af bilag I for så vidt angår den kvalitative vurdering af risikoen, som ifølge appellanterne ikke udelukker en kvantificering af denne risiko.

87 Hvad for det første angår den angivelige anvendelse af begrebet »nul-risiko« bemærkes, således som generaladvokaten har anført i punkt 91 i forslaget til afgørelse, at appellanternes argumentation udspringer af en urigtig læsning af den appellerede dom. I denne doms præmis 196 anførte Retten blot, at det ikke kunne gøres gældende, at den omtvistede forordning var behæftet med et åbenbart urigtigt skøn, fordi RAC i lighed med Det Forenede Kongerige konkluderede, at »risiciene i forbindelse med D4 og D5 ikke gyldigt kunne kvantificeres, og at deres emissioner kunne anses for at udgøre et tegn på en risiko«.

88 Følgelig skal det for det første konstateres, at det i det nævnte præmis 196 ikke fastslås, at »enhver« emission er et tegn på, at der foreligger en risiko, men at de respektive emissioner af de pågældende stoffer, som RAC undersøgte, dvs. emissionerne i vand som følge af anvendelsen af stofferne i kosmetiske produkter, der vaskes af, således kunne anses for at udgøre en risiko. For det andet skal det bemærkes, at den appellerede doms præmis 196 indgår i den analyse af risikovurderingen, som Retten foretog, som begyndte i denne doms præmis 193, og som i nævnte doms præmis 200 førte til den konklusion, at Kommissionen havde taget hensyn til alle de krævede faktorer ved vedtagelsen af den anfægtede forordning. I samme doms præmis 195 lagde Retten navnlig forklaringerne i RAC's udtalelse til grund for sin konklusion i den appellerede doms præmis 196 om, at risiciene forbundet med D4 og D5 ikke gyldigt kunne kvantificeres, og at deres emissioner til miljøet kunne anses for at udgøre et tegn på, at der forelå en risiko.

89 Det fremgår følgelig ikke af den appellerede doms præmis 196, at Retten godkendte en »nul-risiko«-tilgang.

90 Hvad for det andet angår den påståede fejlagtige fortolkning af bilag I skal det bemærkes, at PBT- og vPvB-stofferne er genstand for særlige regler inden for rammerne af dette bilag.

91 Det nævnte bilags punkt 0 med overskriften »Indledning« bestemmer i underpunkt 0.6.3, at hvis det som resultat af de fire første trin i kemikaliesikkerhedsvurderingen konkluderes, at de pågældende stoffer skal klassificeres som PBT-stoffer eller vPvB-stoffer, skal denne vurdering ligeledes følge trin 5 (eksponeringsvurdering) og trin 6 (risikokarakterisering) i overensstemmelse med samme bilags punkt 5 og 6.

92 Punkt 4 i bilag I har overskriften »PBT- og vPvB-vurdering«. Ifølge dettes underpunkt 4.0.1 har »PBT- og vPvB-vurderingen« til formål at karakterisere de potentielle emissioner af stoffer, der er kvalificeret som PBT- eller vPvB-stoffer. Det fremgår af dette underpunkt, at eftersom de farevurderinger vedrørende de langtidsvirkninger, der er fastsat i punkt 1 og 3 i bilag I, og den estimering af langtidsudsættelsen af mennesker og miljø for stoffer, der er fastsat i dette bilags punkt 5.2, ikke er tilstrækkeligt pålidelige for de nævnte stoffer, må der foretages separate vurderinger, dvs. en sammenholdelse med kriterierne (punkt 4.1) og en karakterisering af emissioner (punkt 4.2). Disse vurderinger er opført i del B, punkt 8, i kemikaliesikkerhedsrapporten som omhandlet i REACH-forordningens artikel 14.

93 Hvis der i henhold til underpunkt 0.6.3 for PBT- og vPvB-stoffer skal foretages en eksponeringsvurdering som omhandlet i punkt 5 i bilag I, skal dette underpunkt derfor sammenholdes med underpunkt 4.0.1, hvorefter de resultater, der er opnået efter det andet trin

af eksponeringsvurderingen (punkt 5.2 – Eksponeringsberegning) ikke er tilstrækkeligt pålidelige, hvorfor punkt 4.2 fastsætter, at der skal foretages en karakterisering af emissionerne, der omfatter de relevante dele af eksponeringsvurderingen som beskrevet i punkt 5.

94 Punkt 6 med overskriften »Risikokarakterisering« indeholder et underpunkt 6.5, der er specifikt for PBT-stoffer, hvorefter der foretages en kvalitativ vurdering af sandsynligheden for, at de negative virkninger kan undgås, når eksponeringsscenariet realiseres for de virkninger på mennesker og delmiljøer, for hvilke der ikke har kunnet fastsættes en PNEC-værdi. Som det med rette blev lagt til grund i den appellerede doms præmis 190, kan PNEC-værdien for de langsigtede virkninger af PBT- eller vPvB-stofferne ikke fastlægges pålideligt.

95 Det fremgår således af opbygningen af bilag I, at der gælder særlige regler for PBT- og vPvB-stoffer. I modsætning til, hvad appellanterne har gjort gældende, fremgår det i øvrigt ikke af dette bilag, at den karakterisering af emissioner, der er fastsat i det nævnte bilags punkt 4.2, supplerer den eksponeringsvurdering, der er beskrevet i det nævnte bilags punkt 5, men at karakteriseringen af de specifikke emissioner til PBT- og vPvB-stoffer omfatter de relevante elementer i den eksponeringsvurdering, der er beskrevet i dette punkt 5, for så vidt som disse stoffers specificitet tillader det. Som Kommissionen ligeledes har gjort gældende i sit svarskrift, er det ifølge punkt 4.2 i bilag I kun de relevante dele af den eksponeringsvurdering, der er beskrevet i det nævnte punkt 5, der finder anvendelse på PBT- eller vPvB-stofferne.

96 Selv om det følger af det ovenstående, at punkt 5 i bilag I, hvis formål det er at fastlægge en kvantitativ og kvalitativ vurdering af den dosis/koncentration af et stof, som mennesker og miljø er eller kan blive eksponeret for, finder anvendelse på »PBT- eller vPvB-vurderingen« af stofferne, indebærer dette ikke, at der nødvendigvis skal foretages en kvantitativ vurdering af risikoen ved disse stoffer.

97 Som Retten rigtigt fastslog i den appellerede doms præmis 191, er det nemlig ikke muligt tilstrækkeligt pålideligt og kvantitativt at afværge de risici, der er forbundet med PBT- og vPvB-stofferne. Denne konstatering understøttes af REACH-forordningens artikel 60, stk. 3 og 4, som er til hinder for, at der meddeles godkendelse til anvendelse af PBT- og vPvB-stoffer med den begrundelse, at risikoen for miljøet kontrolleres tilstrækkeligt, idet en sådan godkendelse kun kan meddeles, hvis det godtgøres, at de socioøkonomiske fordele opvejer risiciene, og at der ikke findes passende alternative stoffer eller teknologier.

98 Hvad angår argumentet om, at Rettens konklusion i den appellerede doms præmis 191 kan afkræftes af konklusionerne i Ecetoc-rapporten, skal det, som Kommissionen har gjort gældende, fastslås, at det er blevet fremført for første gang under appellen, og at appellanterne med dette argument har opfordret Domstolen til at foretage en faktisk vurdering, hvilket overskrider rammerne for dens kontrolbeføjelse (jf. i denne retning dom af 9.3.2023, PlasticsEurope mod ECHA, C-119/21 P, EU:C:2023:180, præmis 84 og den deri nævnte retspraksis). Argumentet skal derfor afvises.

99 Til støtte for det tredje anbringende har appellanterne ligeledes påberåbt sig en tilsidesættelse af retssikkerhedsprincippet og gjort gældende, at de har opfyldt kravene i REACH-forordningen med henblik på at minimere emissionen og eksponeringen i overensstemmelse med punkt 6 i bilag I, og at de således har opfyldt de betingelser, der kræves for, at de pågældende stoffer kan anvendes. I denne henseende bemærkes, at retssikkerhedsprincippet forudsætter, at en EU-retlig bestemmelse giver de berørte mulighed for at få et nøjagtigt kendskab til omfanget af de forpligtelser, der derved pålægges dem, og at de uden at være i tvivl kan kende deres rettigheder

og forpligtelser og handle derefter (dom af 29.3.2011, ArcelorMittal Luxembourg mod Kommissionen og Kommissionen mod ArcelorMittal Luxembourg m.fl., C-201/09 P og C-216/09 P, EU:C:2011:190, præmis 68 og den deri nævnte retspraksis). Påberåbelsen af en tilsidesættelse af REACH-forordningen for Retten og det anførte om, at de pågældende stoffer opfylder de betingelser, der kræves for, at de kan markedsføres, var imidlertid ikke tilstrækkelig til, at appellanterne kunne få medhold. En accept af appellanternes standpunkt ville indebære, at brugen af stoffet er tilladt i alle de situationer, hvor registranterne udviser den nødvendige omhu for at minimere emissionerne af dette, uanset om der foreligger en risiko, der anses for at være uacceptabel, hvilket ikke er i overensstemmelse med EU-lovgivers hensigt.

100 Hvad angår klagepunktet om tilsidesættelse af retten til frihed til at oprette og drive egen virksomhed skal det bemærkes, at dette klagepunkt ikke er blevet fremført i appelskriftet, men først i replikken, således at det skal afvises.

101 Det tredje anbringende skal derfor forkastes i sin helhed, idet det delvis er ugrundet, delvis ikke kan antages til realitetsbehandling.

Det fjerde anbringende

Parternes argumentation

102 Appellanterne har gjort gældende, at det fremgår af andet afsnit i præamblen til bilag XIII og af femte og sjette betragtning til forordning nr. 253/2011, at vurderingen af et stofs B- og vB-egenskaber ikke udelukkende skal baseres på de data om biokoncentration eller bioakkumulering, der er fastsat i bilag XIII, punkt 3.2.2, litra a), men at den ligeledes skal tage hensyn til andre kategorier af oplysninger, såsom biomagnificeringsfaktoren (herefter »BMF«) eller den trofiske magnificeringsfaktor (herefter »TMF«), der udtrykkeligt er nævnt i dette punkts litra c).

103 Ifølge appellanterne begik Retten for det første en retlig fejl, da den i den appellerede doms præmis 88 fastslog, at »lovgiver valgte at give en vis prioritet til resultaterne af pålidelige BKF-undersøgelser af et stof i akvatiske arter, eller at Medlemsstatsudvalget i det mindste uden at anlægge et åbenbart urigtigt skøn fandt, at BKF's værdier i det foreliggende tilfælde havde en større beviskraft end de øvrige data, som [appellanterne] har henvist til«. Denne fejl skyldes den omstændighed, at Retten dels i den appellerede doms præmis 86 med urette fastslog, at EU-lovgiver i punkt 1.1.2 og 1.2.2 i bilag XIII valgte at fastsætte kriterierne for identifikationen af B- eller vB-egenskaberne i forhold til BKF for de omhandlede stoffer i akvatiske arter, hvorved der således blev givet prioritet til data om BKF, dels begrundede denne prioritet i den nævnte doms præmis 87 med den omstændighed, at når pålidelige oplysninger om BKF foreligger, kan de kriterier, der er fastsat i forhold til BKF, anvendes direkte på disse oplysninger.

104 Den fortolkning, der er anlagt i den appellerede dom, er uforenelig med punkt 3.2 i bilag XIII og med ECHA's »Vejledning om informationskrav og kemikaliesikkerhedsvurdering«, hvori det i punkt R.11.4.1.2 anføres, at »der ud over BKF's værdier skal tages hensyn til andre relevante oplysninger«, og at »indledningen af bilag XIII […] således [kræver], at alle andre tilgængelige bioakkumuleringsdata tages i betragtning under ét og ved anvendelse af en tilgang med beviskraft baseret på ekspertudtalelsen for at nå frem til konklusionen«, og som ikke »definerer de forskellige datatypers betydning eller beviskraft«.

105 Retten har ligeledes i den appellerede doms præmis 87 foretaget en fejlagtig fortolkning af andet afsnit i præamblen til bilag XIII og sjette betragtning til forordning nr. 253/2011, hvoraf fremgår, at vægtning er særlig relevant, hvor de foreliggende oplysninger ikke uden videre kan sammenholdes med kriterierne i punkt 1 i dette bilag. Efter appellanternes opfattelse har Retten, idet den fandt, at de data, der er omhandlet i punkt 3.2.2 i det nævnte bilag, får større betydning, når dataene om BKF ikke uden videre kan sammenholdes med de foreliggende oplysninger, i realiteten fastslået, at de data, der er omhandlet i dette punkts litra b) og c), ikke skal tillægges nogen særlig relevans eller virkning, når der foreligger resultater som omhandlet i det nævnte punkts litra a).

106 Denne konklusion støttes imidlertid hverken af andet afsnit i præamblen til bilag XIII eller af femte eller sjette betragtning til forordning nr. 253/2011, hvoraf det ikke fremgår, at vægtning er særligt relevant, når det ikke er muligt uden videre at anvende B/vB-kriterierne på dataene om BKF, men at denne vægtning er særlig relevant, når det ikke er muligt uden videre at sammenholde B/vB-kriterierne på alle de foreliggende oplysninger. Denne fortolkning er ligeledes i overensstemmelse med tredje afsnit i præamblen til dette bilag, hvori det fremhæves, at det er nødvendigt at tage hensyn til alle tilgængelige oplysninger, uanset hvilke konklusioner de hver for sig har ført til. Den appellerede dom giver imidlertid med urette prioritet til dataene om BKF netop på grund af muligheden for at anvende disse data numerisk på de kriterier, der er fastsat i punkt 1 i bilaget. Der burde imidlertid i det foreliggende tilfælde have været anvendt en tilgang baseret på vægtningen for at vurdere de omhandlede stoffers B- og vB-egenskaber, uafhængigt af, om Retten fandt, at dataene om BKF kunne anvendes direkte/numerisk på de kriterier, der er fastsat i dette punkt.

107 Ifølge appellanterne kræver bilag XIII, at der tages hensyn til dataene om BKF og om BMF og/eller TMF uden prioriteringsrækkefølge. Når resultaterne fra disse data er tilgængelige, men de er modstridende, således som det er tilfældet i den foreliggende sag, og når det undersøgte stofs egenskaber viser, at en kategori af data ikke er relevant, således som det også er tilfældet for BKF, er det i overensstemmelse med dette bilags indre sammenhæng, at en vægtning af andre data end BKF, som har samme vigtighed, principielt tillægges særlig betydning.

108 For det andet har appellanterne gjort gældende, at Retten i den appellerede doms præmis 96 vendte bevisbyrden om, idet den konkluderede, at fraværet af biomagnificering af et stof i en fødekæde ikke beviser, at der ikke findes biomagnificering af dette stof i andre fødekæder. Herved så Retten bort fra, at REACH-forordningen ikke kræver, at der føres bevis for, at der ikke findes biomagnificering i alle mulige fødekæder, men derimod pålægger ECHA en forpligtelse til at godtgøre, at et stof opfylder de kriterier, der er fastsat for at blive identificeret som et B-stof eller vB-stof, hvilket ikke er blevet godtgjort i det foreliggende tilfælde.

109 Kommissionen har gjort gældende, at det fjerde anbringende delvist skal afvises og delvist er uvirksomt. For så vidt som appellanterne har anfægtet Rettens vurderinger vedrørende BKF's beviskraft, kan deres argumentation således ikke antages til realitetsbehandling, eftersom den i realiteten tilsigter, at der foretages en ny bedømmelse af de faktiske omstændigheder. For så vidt som appellanternes argumentation derimod vedrører den fortolkningsfejl, som Retten skulle have begået ved at prioritere resultaterne af pålidelige undersøgelser vedrørende BKF, er denne uvirksom. Selv hvis Retten havde begået en retlig fejl ved principielt at prioritere disse resultater, hvilket ikke er tilfældet, kan dens vurdering ikke drages i tvivl, eftersom Medlemsstatsudvalget i det foreliggende tilfælde uden at anlægge et åbenbart urigtigt skøn fandt, at BKF's værdier havde en større beviskraft end de andre data, som appellanterne har henvist til.

110 Ifølge Kommissionen, som støttes af ECHA, er det fjerde anbringende under alle omstændigheder ugrundet, for så vidt som den prioritering, der gives resultaterne af pålidelige undersøgelser af BKF for et stof i akvatiske arter, videnskabeligt set er udtryk for, at dataene om BKF har en højere beviskraft.

111 Forbundsrepublikken Tyskland har i sit svarskrift tilføjet, at det – da BKF'en for D4 og D5 ligger betydeligt højere end de grænseværdier, der er fastsat i bilag XIII – for at begrunde et forbud i sig selv ville være tilstrækkeligt at støtte sig på biokoncentrationen af disse stoffer, selv om Kommissionen og ECHA havde undersøgt andre oplysninger, der er omhandlet i dette bilags punkt 3.2.2.

Domstolens bemærkninger

112 I forbindelse med det fjerde anbringende har appellanterne, støttet af ACC, i det væsentlige gjort gældende, at den appellerede doms præmis 86-88 og 96 er behæftet med retlige fejl vedrørende for det første en fejlagtig fortolkning af bilag XIII for så vidt angår den prioritet, som Retten tillagde oplysningerne fra BKF, og for det andet en omvendt bevisbyrde.

113 Hvad for det første angår den prioritet, der er tildelt resultaterne af pålidelige undersøgelser vedrørende BKF af et stof i akvatiske arter, som Retten har lagt til grund i den appellerede doms præmis 86-88 af, følger det af opbygningen af bilag XIII, som ændret ved forordning nr. 253/2011, at vægtningen af dataene forudsætter, at alle tilgængelige oplysninger, der har indvirkning på identifikationen af et PBT-stof eller et vPvB-stof, tages i betragtning under ét, uanset hvilke konklusioner de hver for sig har ført til, idet dataenes kvalitet og sammenhæng skal tillægges en passende vægt.

114 I henhold til andet afsnit i præamblen til dette bilag skal der med henblik på identifikationen af PBT- og vPvB-stoffer i forbindelse med vægtningen foretages en sammenholdelse af alle relevante og tilgængelige oplysninger under det nævnte bilags punkt 3.2, dvs. bl.a. de relevante og tilgængelige data om BKF, BMF og TMF, med de kriterier, der er fastsat i bilagets punkt 1.

115 I henhold til punkt 1 i bilag XIII vedrørende kriterierne for identifikation af PBT- og vPvB-stoffer defineres bioakkumulering i forhold til BKF i akvatiske arter. Et stof er således »bioakkumulerende«, når BKF er på over 2 000 og »meget bioakkumulerende«, når BKF er på over 5 000.

116 Det fremgår af andet afsnit i præamblen til dette bilag, at der navnlig skal vægtes, hvis kriterierne i punkt 1, i et foreliggende tilfælde BKF, ikke umiddelbart kan sammenholdes med de foreliggende oplysninger. Dette fremgår ligeledes af sjette betragtning til forordning nr. 253/2011, hvorefter det er særlig relevant at foretage en vægtning i de tilfælde, hvor de foreliggende oplysninger ikke uden videre kan sammenholdes med kriterierne i dette punkt 1.

117 Som det ligeledes er anført i punkt 44-50 i generaladvokat Kokotts forslag til afgørelse Global Silicones Council m.fl. mod ECHA (C-559/21 P, EU:C:2023:321), fremgår det af denne præambel, sammenholdt med denne sjette betragtning, at vægtningen under hensyntagen til alle de foreliggende oplysninger, der er opregnet i punkt 3.2 i bilag XIII, i første omgang skal afklare, om de tilgængelige studier beregnede BKF'en på en relevant og pålidelig måde. Hvis dette er tilfældet, indtager de relevante og pålidelige data om BKF'en en privilegeret stilling i opbygningen af bilag XIII, for så vidt som bioakkumulering er direkte forbundet med disse data. Denne fortolkning kan ikke drages i tvivl af indarbejdelsen ved forordning 2017/735, der

ændrede forordning nr. 440/2008, af forsøgsmetoden gennem føden, dvs. gennem biomagnificering eller gennem trofisk magnificering, som er tilpasset stoffer med meget lav vandopløselighed, som en metode, der anvendes til at bestemme bioakkumulering i fisk i lighed med eksponering via vand.

118 Retten kunne følgelig uden at begå en retlig fejl i den appellerede doms præmis 86-88 konkludere, at EU-lovgiver gav resultaterne fra pålidelige studier om BKF af et stof i akvatiske arter prioritet. Som Retten rigtigt fastslog i den appellerede doms præmis 87, berører denne prioritet ikke anvendelsen af vægtningen. Det var i denne sammenhæng, at Retten fastslog, at Medlemsstatsudvalget ikke havde anlagt et åbenbart urigtigt skøn ved at finde, at dataene om BKF havde en større beviskraft end beviskraften for andre data, som appellanterne havde henvist til, nemlig dataene om BMF og TMF. Appellanternes argumentation om, at det fremgår af den appellerede dom, at de data, der er omhandlet i punkt 3.2.2, litra b) og c), i bilag XIII, når der foreligger resultater vedrørende biokoncentrationen, ikke skal tillægges nogen særlig relevans eller virkning, vidner følgelig om en fejlagtig læsning af denne dom og skal derfor forkastes som ugrundet.

119 For så vidt som det fjerde anbringende vedrører Rettens bedømmelse af den konkrete måde, hvorpå der blev vægtet i det foreliggende tilfælde, og af den bevisværdi, der blev tillagt dataene om BKF i forbindelse med vægtningen af forskellige beviser, skal dette anbringende, da der ikke er anført noget om en urigtig gengivelse, i øvrigt afvises af de samme grunde som dem, der er nævnt i denne doms præmis 98.

120 Hvad for det andet angår det hævdede om, at Retten vendte bevisbyrden om i den appellerede doms præmis 96, for så vidt som den implicit fastslog, at appellanterne skulle føre bevis for fraværet af biomagnificering i alle fødekæder, er det tilstrækkeligt at konstatere, at Retten i denne doms præmis 95 med rette anførte, at fraværet af biomagnificering ikke betyder, at der ikke findes bioakkumulation, og ikke nødvendigvis gør det muligt at fjerne de betænkeligheder, der følger af biokoncentrationen. Det var i denne sammenhæng, at Retten i den appellerede doms præmis 96, uden at vende bevisbyrden om, fastslog, at appellanterne ikke havde bevist, at forekomsten af biofortynding i visse fødekæder udelukker biomagnificering i andre fødekæder.

121 Det fjerde anbringende skal derfor forkastes i sin helhed, idet det delvis er ugrundet, delvis ikke kan antages til realitetsbehandling.

Det femte anbringende

Parternes argumentation

122 Appellanterne, støttet af ACC, har gjort gældende, at bilag XIII finder anvendelse på organiske stoffer, herunder organiske metalforbindelser, og ikke på uorganiske stoffer. D4 og D5 har unikke egenskaber på grund af deres hybride natur, som giver sig udslag i forskellige egenskaber med hensyn til opløselighed og fordeling mellem de miljøer, der påvirker deres distribution og tilbliven i miljøet, hvilket ifølge appellanterne forklarer, at oplysningerne om BKF ikke bør prioriteres med henblik på at vurdere disse stoffers B- og vB-egenskaber. Studier vedrørende biokoncentrationen foretages under kunstige forhold, hvorunder stofferne forhindres i at komme ud i luften eller sedimenterne, og hvorunder koncentrationen af disse stoffer i vandet opretholdes konstant. BKF afspejler derfor ikke D4's og D5's adfærd i miljøet under realistiske forhold. Derimod udgør BMF og TMF under disse omstændigheder relevante parametre.

123 Det er appellanternes opfattelse, at der i forbindelse med D4 og D5 – ud over deres egenskaber med hensyn til opløselighed og fordeling mellem miljøerne – indtræder biodilution, fordi deres koncentration mindskes med stigende trofisk niveau, f.eks. ved at de overgår fra organismer, der lever i sedimenter, til fisk, og metaboliseres, når de absorberes af organismerne via føden, dvs. at de ikke akkumuleres i fødekæden. ECHA burde have taget hensyn til D4's og D5's hybride natur og følgelig have tilpasset anvendelsen af de kriterier, der er fastsat i punkt 1.1.2 og 1.2.2 i bilag XIII.

124 Efter appellanternes opfattelse besvarede Retten ikke de argumenter, der er anført i denne doms præmis 122 og 123, og begrænsede sig til i den appellerede doms præmis 105 at anføre, at et stof med hybrid natur ikke er udelukket fra anvendelsesområdet for bilag XIII, eller, i denne doms præmis 108, at ingen af appellanternes argumenter kunne godtgøre, at D4 og D5 er uorganiske stoffer, eller at bilag XIII eller de deri fastsatte kriterier ikke finder anvendelse på disse stoffer.

125 Appellanterne har anført, at Retten imidlertid ikke skulle afgøre, om bilag XIII finder anvendelse på de nævnte stoffer, men om Kommissionen og ECHA havde begået en fejl ved at undlade at undersøge disse stoffers særlige arts indvirkning på den måde, hvorpå kriterierne i bilag XIII kunne anvendes på dem. Da appellanterne har gjort gældende, at de har godtgjort, at ECHA ikke havde taget hensyn til D4 og D5's iboende egenskaber, der fulgte af deres hybride natur, påhvilede det ECHA at bevise det modsatte og Retten at udøve sin kontrol i denne henseende. Den konklusion, som Retten nåede frem til i den appellerede doms præmis 108, fører imidlertid til, at bevisbyrden vendes om, og Retten begik ligeledes en retlig fejl ved at fastslå, at denne undladelse fra ECHA's side ikke udgjorde et åbenbart urigtigt skøn, som behæftede den omtvistede forordnings med en ulovlighed.

126 Kommissionen, støttet af ECHA, har gjort gældende, at det femte anbringende, hvormed appellanterne reelt søger at opnå en ny vurdering af de faktiske omstændigheder og de beviser, som Retten undersøgte, navnlig hvad angår spørgsmålet om, hvorvidt ECHA tog hensyn til D4 og D5's unikke egenskaber eller den hybride natur, ikke kan antages til realitetsbehandling.

127 I lighed med Forbundsrepublikken Tyskland er Kommissionen af den opfattelse, at det femte anbringende under alle omstændigheder er ugrundet med den begrundelse, at Retten, således som det fremgår af den appellerede doms præmis 118 ff., havde forstået appellanternes argumenter korrekt og har besvaret dem.

128 Appellanterne har i replikken præciseret, at de ikke søger at opnå en ny vurdering af en videnskabelig vurdering, men en afgørelse fra Domstolen vedrørende spørgsmålet om, hvorvidt Retten har begået en retlig fejl ved fortolkningen af bilag XIII, hvorvidt Retten har foretaget en urigtig gengivelse af deres anbringender og de beviser, som de havde fremlagt for den, og hvorvidt den tilsidesatte deres ret til at blive hørt.

129 Kommissionen har i duplikken gjort gældende, at argumentationen om en urigtig gengivelse af de af appellanterne fremsatte anbringender og en tilsidesættelse af retten til at blive hørt først blev gjort gældende i replikken og derfor skal afvises af de samme grunde som dem, der er nævnt i denne doms præmis 100.

Domstolens bemærkninger

130 Med det femte anbringende har appellanterne i det væsentlige gjort gældende, at Retten ikke skulle afgøre, om bilag XIII finder anvendelse på D4 og D5, således som den fastslog i den appellerede doms præmis 107 og 108, men skulle vurdere de konsekvenser, der følger af disse stoffers hybride natur med hensyn til anvendelsen af de kriterier, der er fastsat i dette bilag.

131 Hvad for det første angår de betragtninger i den appellerede dom, der vedrører klassificeringen af D4 og D5 som organiske stoffer, der henhører under anvendelsesområdet for bilag XIII – selv om det fremgår det af de processkrifter, der er indgivet til Retten, navnlig af stævningen, at appellanterne bl.a. har gjort gældende, at »kriterierne i bilag XIII, herunder kriterierne i punkt 1.1.2 og 1.2.2 […], skulle tilpasses for at fastlægge […] bioakkumulering ved D4 og/eller D5« – skader Rettens konstatering vedrørende anvendelsen af dette bilag på de pågældende stoffer ikke appellanternes interesser. I denne doms opbygning udgør denne konstatering nemlig et trin, der går forud for analysen af de iboende egenskaber, der følger af disse stoffers hybride natur og deres indflydelse på vurderingen af PBT- eller vPvB-egenskaberne, hvilken analyse Retten ligeledes foretog. Som det i øvrigt fremgår af den appellerede doms præmis 106, 107, 109 og 111, som appellanterne ikke har bestridt, vedrørte deres argumentation for Retten ligeledes de nævnte stoffers organiske/uorganiske karakter, og Retten besvarede den i denne doms præmis 107 og 108.

132 Hvad for det andet angår Rettens angivelige undladelse af at analysere appellanternes argumentation med hensyn til de konsekvenser, der følger af D4 og D5's hybride natur, følger det af den appellerede doms præmis 118-126, som appellanterne ikke har bestridt, at D4 og D5's fysisk-kemiske egenskaber blev undersøgt af Retten, som i den appellerede doms præmis 122 fastslog, at Medlemsstatsudvalget i forbindelse med vurderingen af disse stoffers P- og vP-egenskaber og B og vB-egenskaber havde observeret alle disse egenskaber.

133 Det skal ligeledes bemærkes, at Retten ikke vendte bevisbyrden om i forbindelse med sin efterprøvelse af de konsekvenser, der følger af D4 og D5's hybride natur. Det skal i denne henseende bemærkes, at uden at dette udgør en omvendt bevisbyrde, skal den part, der gør gældende, at det pågældende EU-organ har foretaget en utilstrækkelig analyse af de relevante forhold eller anlagt åbenbart urigtige skøn, fremlægge forhold, der kan rejse betydelig tvivl med hensyn til den vurdering, som dette organ har foretaget, idet det i givet fald påhviler dette organ at fjerne denne tvivl.

134 Hvad for det tredje angår den påståede urigtige gengivelse af anbringender og beviser samt tilsidesættelsen af retten til at blive hørt skal det bemærkes, at disse klagepunkter, der i øvrigt ikke er underbyggede, blev gjort gældende for første gang i replikken og derfor ikke kan antages til realitetsbehandling af de samme grunde som dem, der er nævnt i denne doms præmis 100.

135 Det følger heraf, at det femte anbringende skal forkastes, idet det delvist er ugrundet, delvist skal afvises.

136 Det følger af samtlige ovenstående betragtninger, at appellen skal forkastes i sin helhed.

Sagsomkostninger

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

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

139 I henhold til artikel 140, stk. 1, i dette procesreglement, bærer medlemsstater og institutioner, der er indtrådt i en sag, deres egne omkostninger.

140 Da Kommissionen har nedlagt påstand om, at appellanterne pålægges at betale sagsomkostningerne, og appellanterne har tabt sagen, bør det pålægges dem at betale sagsomkostningerne.

141 Da Forbundsrepublikken Tyskland, ECHA og ACC, der var intervenienter i første instans, har deltaget i den skriftlige del af retsforhandlingerne for Domstolen, bærer de deres egne omkostninger.

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

1) **Appellen forkastes.**

2) **Global Silicones Council, Wacker Chemie AG, Momentive Performance Materials GmbH, Shin-Etsu Silicones Europe BV og Elkem Silicones France SAS bærer deres egne omkostninger og betaler de af Europa-Kommissionen afholdte omkostninger.**

3) **Forbundsrepublikken Tyskland, Det Europæiske Kemikalieagentur (ECHA) og American Chemistry Council (ACC) bærer hver deres egne omkostninger.**

Underskrifter