

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

12 July 2016

*(Substance evaluation – Duty to state reasons – Right to be heard – PBT and vPvB
identification – Endocrine disruption)*

Case number	A-009-2014
Language of the case	English
Appellants	Albemarle Europe Sprl, Belgium Chemical Inspection & Regulation Service Limited, Ireland ICL-IP Europe B.V., the Netherlands
Representatives	Ruxandra Cana and Indiana de Seze Steptoe & Johnson LLP, Belgium
Intervener	The United Kingdom Competent Authority Represented by: The Health and Safety Executive and the Environment Agency, United Kingdom
Contested Decision	Decision of 22 May 2014 on the substance evaluation of 1,1'-(ethane-1,2-diyl)bis [pentabromobenzene] adopted by the European Chemicals Agency pursuant to Article 46(1), and in accordance with the procedure laid down in Articles 50 and 52, of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation') The Decision was notified to the Appellants through the following annotation numbers: SEV-D-2114280690-48-01/F, SEV-D-2114280693-42-01/F, and SEV-D-2114280692-44-01/F

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Rafael López Parada (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the dispute

1. On 22 August 2014, the Appellants lodged the present appeal at the Registry of the Board of Appeal. They request the Board of Appeal to annul the Contested Decision requiring the Appellants to provide additional information to address the persistence, bioaccumulation and toxicity concerns regarding the substance 1,1'-(ethane-1,2-diyl)bis [pentabromobenzene], (CAS No 84852-53-9, EC No 284-366-9; hereinafter 'EBP' or the 'Substance') or, alternatively, to amend the Contested Decision at least insofar as the deadline set to update the registrants' dossiers taking account of the suspensive effect of the appeal.
2. The Appellants also request the Board of Appeal to refund the appeal fee and take such other or further measures as justice may require.

Background to the dispute

3. On the basis of an opinion of the Member State Committee (hereinafter the 'MSC'), and due to initial grounds for concern relating to '*Environment/Suspected [persistent, bioaccumulative and toxic properties] (including unclear bioaccumulation potential and the possibility of [persistent, bioaccumulative and toxic or very persistent and very bioaccumulative] transformation products); Exposure/Wide dispersive use, high aggregated tonnage*', EBP was included in the Community rolling action plan (hereinafter 'CoRAP') for substance evaluation pursuant to Article 44(2) of the REACH Regulation (all references to Articles, Recitals and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The CoRAP was published on the website of the European Chemicals Agency (hereinafter the 'Agency') on 29 February 2012. The Competent Authority of the United Kingdom, which is the evaluating Member State Competent Authority (hereinafter the 'eMSCA'), was appointed to carry out the evaluation.
4. The Contested Decision states that the Substance:
'[...] is likely to be a major substitute for the flame retardant decabromodiphenyl ether (decaBDE), for which the UK has submitted an Annex XV dossier for identification as a Substance of Very High Concern. A previous UK national assessment [...] also identified potential environmental risks based on default scenarios. The purpose of this evaluation is to assess any new data generated since the UK review, and identify specific studies to clarify these concerns based on recent experience with decaBDE.
In the course of the evaluation the following additional concerns were noted with respect to the environment: Information on vitellogenin formation was identified from the academic literature, raising uncertainty for endocrine disrupting effects in fish. Published studies were also identified that suggest effects in fish and aquatic invertebrates, raising some concern that the aquatic toxicity studies included in the registration dossiers might not be fully reliable. In addition a review of the compositional data provided by the Registrant(s) revealed the level of brominated diphenyl ethane congeners present as impurities (which, by analogy with polybromodiphenyl ethers, might have [persistent, bioaccumulative and toxic] properties) in some commercial products was higher than expected [...], requiring further investigation [...].'
5. Following an evaluation of the Substance pursuant to Article 45(4), the eMSCA concluded that further information was required in order to assess the abovementioned concerns. The eMSCA therefore prepared a draft decision pursuant to Article 46(1) which was submitted to the Agency on 26 February 2013.

6. On 4 April 2013, the Agency sent the draft decision to the addressees of the Contested Decision and invited them pursuant to Article 50(1) to provide comments within 30 days of the receipt of the draft decision.
7. The addressees of the Contested Decision provided comments to the Agency on the draft decision by the deadline of 6 May 2013 and the draft decision was modified subsequently by the eMSCA.
8. On 31 October 2013, in accordance with Article 52(1), the eMSCA notified the Competent Authorities of the other Member States (hereinafter the 'MSCAs') and the Agency of its draft decision and invited them, pursuant to Articles 52(2) and 51(2), to submit proposals for amendment within 30 days. Proposals for amendment were subsequently received from two MSCAs and the Agency.
9. On 5 December 2013, the Agency notified the addressees of the Contested Decision of the proposals for amendment to the draft decision and invited them, pursuant to Articles 52(2) and 51(5), to provide comments within 30 days.
10. The eMSCA reviewed the proposals for amendment and further amended the draft decision accordingly (hereinafter the 'amended draft decision').
11. On 16 December 2013, the Agency referred the amended draft decision to the Member State Committee (hereinafter the 'MSC').
12. According to the Contested Decision, on 7 January 2014, the Appellants '*[...] provided comments on the proposals for amendments. In addition, the [Appellants] provided comments on the [amended] draft decision. The [MSC] took the comments on the proposals for amendment of the Registrant into account. The [MSC] did not take into account the Registrants' comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).*'
13. Following discussions in the MSC meeting of 3 to 7 February 2014, at which one of the Appellants was present, a unanimous agreement of the MSC on the amended draft decision, as further modified at the meeting, was reached on 6 February 2014.
14. The Contested Decision was adopted by the Agency on 22 May 2014 requesting the four addressees thereof to submit, by 29 November 2016, information on:
 1. *Analytical confirmation of the test concentrations used in the aquatic toxicity tests reported in the registration dossier. Test solutions shall be prepared in exactly the same way as was done for the acute aquatic toxicity tests and measurements of the dissolved EBP concentrations in relevant test vessels shall be made over 96 hours. The test substance should have the same composition as used in the original aquatic tests, but may be radio-labelled.*
 2. *Long-term toxicity testing on aquatic invertebrates (test method: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 4th ed. October 2002, US EPA 821/R-02-013 Test of Reproduction and Survival Using the Cladoceran ('Ceriodaphnia dubi') EPS1/RM/21 Daphnia magna Reproduction Test EU C.20/OECD TG 211). The study shall be performed with cladocerans, either Ceriodaphnia dubia or Daphnia magna, using suitable pre-conditioned, non-adsorbing vessels. Pending the results of the investigation of test solution stability, test solutions should be prepared in accordance with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances, using the least pure form of the registered substance with analytical verification of the exposure concentration (a limit test can be performed, with further test concentrations only required if effects are observed).*
 3. *Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: Aqueous and Dietary Exposure test, OECD TG 305). Exposure should be via the diet. The test*

material shall be the least pure form of the registered substance, and it may be radiolabelled to overcome problems associated with analytical sensitivity. The study shall also include an assessment of vitellogenin formation in male fish. Sampling and determination of vitellogenin shall follow the guidance for this parameter in OECD TG 229. Vitellogenin induction and sex-determination shall be assessed in individual fish at termination of the uptake phase. At least 16 additional fish (as specified in OECD TG 234), consisting of at least 10 male fish, shall be sampled for this purpose from both the exposure and control groups. The test shall be conducted with one of the following fish species: Japanese medaka (*Oryzias latipes*), zebrafish (*Danio rerio*) or fathead minnow (*Pimephales promelas*). The vitellogenin measurement should be based upon a validated homologous Enzyme-Linked Immunosorbent Assay (ELISA) method, using homologous vitellogenin standard and homologous antibodies. A method capable of detecting vitellogenin levels in whole body homogenate as low as a few parts per billion is requested.

4. Soil simulation testing (test method; Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307 with the following modifications; the study shall be run for at least six months, and include a plant treatment (under aerobic conditions), with the test duration, choice of plant species and growing conditions based on Huang et al. (2010) [...]. Modifications may include the volume of soil (since plants may require more soil for growth over a six-month period than allowed for in the OECD 307 guideline). The substance may be introduced adsorbed to sewage sludge at a relevant but sufficiently high concentration to enable the identification of any relevant transformation products. The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring. The homogeneity of dosing should be checked analytically. The soils should be free from contamination with potential transformation products, and not contain stones. Sufficient replicates should be used to allow appropriate statistical analysis. Suitable controls and precautions will be required to shield the test vessels from dust contamination. The influence of soil organic/inorganic carbon content, pH, clay content and microbial biomass/activity shall be assessed by repeating relevant parts of the test with three additional soils (depending on the results of the main study). The test material should be the purest form of the registered substance, and should be appropriately radiolabelled. The focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1%. The Registrant(s) shall justify the number of sampling intervals, and monitor for volatiles/mineralisation products if considered relevant.

5. Sediment simulation testing (test method; Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD TG 308). The study shall be performed in two different anaerobic sediment types reflecting different microbial activities and adsorption characteristics, and run for at least six months. The test material should be the purest form of the registered substance, appropriately radiolabelled, and may be introduced directly to the sediment using a suitable method (rather than dosed via water). The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring. The homogeneity of dosing should be checked analytically. The sediments should be free from contamination with potential transformation products, and not contain stones. Sufficient replicates should be used to allow appropriate statistical analysis. Suitable controls and precautions will be required to shield the test vessels.

Furthermore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following;

6. A detailed exposure assessment (with sensitivity analysis) for the whole life cycle of EBP. This shall also include consideration of hazards and risks due to transformation

products arising from high temperature processes such as plastic product manufacture and incineration of treated articles at the end of their service life.

Procedure before the Board of Appeal

15. On 22 August 2014, the Appellants lodged the present appeal at the Registry of the Board of Appeal.
16. On 24 October 2014, the United Kingdom Competent Authority applied for leave to intervene in the proceedings before the Board of Appeal in support of the Agency. By Decision of 5 December 2014, the Board of Appeal, having heard the Parties, granted the application for leave to intervene.
17. On 10 November 2014, the Agency submitted its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.
18. On 26 January 2015, the Appellants submitted their observations on the Defence.
19. On 10 February 2015, the Intervener confirmed that it did not wish to use the opportunity granted to it by the Board of Appeal to submit observations on the Notice of Appeal and the Defence.
20. On 7 May 2015, the Agency submitted its observations on the Appellants' observations on the Defence.
21. On 7 May 2015, the Parties to the proceedings and the Intervener were informed of the Board of Appeal's intention to stay, of its own motion, pursuant to the first paragraph of Article 25 of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure'), the present appeal proceedings until 1 September 2015. On 12 and 22 May 2015 respectively, the Agency and the Appellant informed the Board of Appeal that they had no observations on the proposed stay of proceedings. On 16 June 2015, the Board of Appeal decided to stay the proceedings until 1 September 2015 and informed the Parties and the Intervener accordingly.
22. On 10 September 2015, since the position of legally qualified member of the Board of Appeal was vacant and in order to achieve the full composition of the Board of Appeal, the Chairman, pursuant to the first subparagraph of Article 3(2) of the Rules of Procedure, designated an alternate member, Rafael López Parada, to act in the present case as the legally qualified member of the Board of Appeal.
23. On 23 September 2015, following the resumption of the proceedings, the Board of Appeal invited the Parties and the Intervener to provide their observations on the relevance to the present case of the Board of Appeal's Decision of 23 September 2015 in Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*.
24. On 8 and 15 October 2015 respectively, the Intervener and the Appellants provided their observations on the relevance of the decision in *Akzo Nobel Industrial Chemicals and Others*, cited in the previous paragraph. Following a request for an extension of the deadline, the Agency provided its observations on that decision on 13 November 2015.
25. On 25 November 2015, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 2 December 2015, the Appellants requested a hearing to be held.
26. By letter of 12 January 2016, the Appellants requested the Board of Appeal to allow an expert to provide evidence at the hearing regarding the results of a study which had recently been conducted and had not yet been submitted in the proceedings.

27. The Board of Appeal decided in the Summons to the hearing of 29 January 2016 that, having regard to Article 12(1) of the Rules of Procedure, the delay in offering as evidence the results of the study in question, which the Board of Appeal observed were still not available in their final form, was not justified. The Board of Appeal therefore rejected the Appellant's request.
28. In view of the Appellants' request for a hearing to be held, and pursuant to Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 26 February 2016. At the hearing, the Parties and the Intervener made oral submissions and also responded to questions from the Board of Appeal.

Reasons

29. At the hearing the Appellants clarified that they were not contesting the first and the fifth of the information requests set out in the Contested Decision (see paragraph 14 above), namely the requirements to provide '*analytical confirmation of the test concentrations used in the aquatic toxicity tests reported in the registration dossier*' and '*a detailed exposure assessment (with sensitivity analysis) for the whole life cycle of EBP*'. The Board of Appeal will therefore examine the pleas raised by the Appellants contesting the second, third, fourth and fifth information requirements set out in paragraph 14 above, as well as the time-limit prescribed in the Contested Decision for the addressees to provide the requested information.

I. *The alleged failure to state reasons and error of assessment regarding the analogy between decaBDE and the Substance*

Arguments of the Parties

30. The Appellants submit that, in breach of Article 296 of the Treaty on the Functioning of the European Union (hereinafter the 'TFEU') and Article 130 of the REACH Regulation, the Agency does not provide any justification for the statements in the Contested Decision related to the alleged analogy between the Substance and another substance, namely bis(pentobromophenyl) ether (IUPAC name: 1,1'-oxybis(pentabromobenzene), EC No 214-603-9; CAS No 1163-19-5; hereinafter 'decaBDE').
31. The Appellants submit that the scientific differences between the Substance and decaBDE are significant. As a consequence, the justification that there is a concern regarding the Substance – and therefore a need for action – on grounds related to decaBDE are not scientifically robust or scientifically justified. The Appellants argue that any concerns on the Substance triggered by information generated on decaBDE need to be fully justified and that the Contested Decision does not provide such justifications, only presumptions.
32. The Appellants further argue that the Contested Decision does not just fail to explain the relationship, if any, between the Substance and decaBDE, but also unreasonably refers to decaBDE as '*analogue substance*' to the Substance. Given that the two substances are different, their behaviour should be presumed to be different and their similarity should be established through data, rather than be presumed.
33. The Agency states that it did not '*read-across*' data between the Substance and decaBDE within the meaning of Section 1.5 of Annex XI but concluded on the need to investigate further the properties of the Substance based on the findings for decaBDE. The Agency adds that it is not required under substance evaluation to provide a full justification as required by Section 1.5 of Annex XI whenever it refers to concerns triggered by the properties of another substance. According to the Agency, such an

interpretation is in line with the fact that the substance evaluation process is based on the precautionary principle, which acknowledges that an authority's action may already be taken in the absence of scientific certainty on a particular property.

Findings of the Board of Appeal

34. Pursuant to Article 296 TFEU legal acts shall state the reasons on which they are based. Article 130 of the REACH Regulation reiterates that obligation as regards all decisions taken under that Regulation.
35. At the outset, the Board of Appeal observes that the statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Board of Appeal to exercise its powers of review. The requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations. It is not necessary for the reasoning to go into all the relevant facts and points of law since the question of whether the statement of reasons meets the requirements of Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (see Case C-367/95 P, *Commission v Sytraval and Brink's France*, EU:C:1998:154, paragraph 63, and Case A-004-2014, *Altair Chimica and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 127).
36. The Board of Appeal also observes that the duty to state reasons is different from the correctness of those reasons. The duty to state reasons is an essential procedural requirement which must be distinguished from the question of whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue (see Case C-280/08 P, *Deutsche Telekom v Commission*, EU:C:2010:603, paragraph 130; see also the decision in *Altair Chimica and Others*, cited in the previous paragraph, paragraph 128).
37. It is also important to bear in mind that the adequacy of the reasons given in a decision is assessed with reference to the context of the decision. The requirements of the duty to state reasons can be attenuated if the measure in question was adopted in circumstances known to the affected person which enable it to understand the scope of the measure (see, to that effect, C-417/11 P, *Council v Bamba*, EU:C:2012:718, paragraph 54; see also the decision in *Altair Chimica and Others*, cited in paragraph 35 above, paragraph 130). This is the case where a party was closely involved in the process by which the contested decision came about and is therefore aware of the reasons for which the administration adopted it (see, to that effect, Case T-387/09, *Applied Microengineering v Commission*, EU:T:2012:501, paragraph 67 and the case-law cited; see also the decision in *Altair Chimica and Others*, cited in paragraph 35 above, paragraph 130).
38. The Board of Appeal observes that the Substance Evaluation Report of February 2013 prepared by the eMSCA (hereinafter the 'Substance Evaluation Report') shows the similarity in the structural formulae of the two substances regarding the two brominated aromatic rings. The Substance Evaluation Report states that '*[t]here is one registered substance with two linked fully brominated aromatic rings. This is [decaBDE] which has an oxygen atom between the two aromatic rings rather than an ethane bridge. This structural difference means that [the Substance] has greater molecular flexibility but lower polarity [...]*'. The Contested Decision and the Substance Evaluation Report also state that '*[t]he analogue decaBDE has been studied*

intensively, and it has been found to debrominate under a variety of environmental conditions to form small amounts of lower molecular weight homologues that have PBT/vPvB properties'.

39. Furthermore, the Board of Appeal notes that to establish structural similarity for the purposes of identifying a potential concern, under the substance evaluation procedure, the test is different from that needed to justify a read-across adaptation for registration purposes. In the context of the evaluation of the Substance, the consequence of the '*structural similarity*' between the Substance and decaBDE, considered in conjunction with other information, is that there is a potential concern which should be clarified. The requested information may well show that the Substance does not exhibit the same properties as decaBDE. An actual concern is not assumed to exist on the basis of information on decaBDE; rather, this information indicates that there is a concern that needs to be clarified with regard to the Substance.
40. The Board of Appeal observes that, in the case at issue, the Appellants were closely involved in the administrative procedure leading to the adoption of the Contested Decision, received a detailed draft Substance Evaluation Report and had several opportunities to provide comments during the substance evaluation procedure. The Board of Appeal finds that the Appellants are, therefore, in a position to understand the scope of the Contested Decision and to ascertain the reasons behind it.
41. The Board of Appeal therefore considers that for the purposes of establishing a concern under substance evaluation the Agency has provided sufficient reasoning regarding the structural similarity of the two substances.
42. In relation to the Appellants' arguments regarding an error of assessment the Board of Appeal considers that it was clearly set out, in particular in the Substance Evaluation Report and during the present proceedings, that both decaBDE and the Substance are hydrophobic and may partition into aquatic matter. Furthermore, both substances are highly brominated substances with similar structures which could reasonably be expected to act in a similar manner even if their properties are not necessarily the same. The issue of the carbon-bromine bonds is particularly relevant in the present case and, based on the experience with decaBDE, the Substance could reasonably be expected to lose bromide bonds.
43. The Board of Appeal also notes that the expert opinion attached to the Notice of Appeal identifies a number of structural similarities between decaBDE and the Substance. For example, it is made clear that they both have two aromatic rings, 10 bromine atoms with 5 per ring, similar molecular weights, boiling points, melting points and vapour pressures and limited solubility in water. The expert opinion also claims, however, that there are a number of differences between the substances, for example in relation to lower octanol solubility for the Substance when compared to decaBDE, which mean that the two substances will not act in exactly the same way.
44. The Board of Appeal notes that the main difference between the Substance and decaBDE is the bridge between the rings, oxygen for decaBDE and ethane for the Substance. Whilst this difference may lead to differences in properties of the two substances the main concern regarding the breaking of the carbon-bromine bond and what this may mean for the transformation products remains.
45. The Board of Appeal therefore considers that the Agency did not make an error of assessment in reaching its conclusion that the Substance and decaBDE are structurally similar. The Board of Appeal finds therefore that the Agency was justified in reaching the conclusion in the Contested Decision that the evidence on decaBDE is relevant to the assessment of the potential concerns of the Substance.

46. The Appellants' pleas alleging a failure to state reasons and an error of assessment are therefore dismissed.

II. Alleged failure to address a suspected concern

Arguments of the Parties

47. The Appellants submit that the Agency is required, under substance evaluation, and in particular Article 46(1), to request data which is appropriate and necessary to evaluate an identifiable, suspected concern. The Appellants claim that rather than relating to a particular concern the Contested Decision aims at obtaining as much information as possible from the requested tests. In the Appellants' view, no real risk has been identified in the Contested Decision and therefore there is no risk to be clarified. The Appellants add that it follows that the information requested does not have a realistic possibility of leading to improved risk management measures.
48. The Appellants claim that the reason the Agency has requested information on substances not manufactured, supplied or used by the Appellants is because there is no suspected concern related to the Appellants' substances which are of a high degree of purity. The Appellants therefore claim that the Agency has erred in its assessment, misused its powers, and/or acted outside the limits of its discretion.
49. The Appellants further argue that if the Agency had concerns with the Substance at low levels of purity it would have been more appropriate to examine those concerns through a targeted compliance check. Moreover, the Agency has failed to identify immediate, relevant and real concerns justifying recourse to substance evaluation rather than a compliance check.
50. In addition, according to the Appellants, the Agency relied on one flawed study (Nakari, T. and Huhtala, S., 2010, *In vivo and in vitro toxicity of decabromodiphenyl thance, a flame retardant*, Environmental Toxicology, 25, 333-338; hereinafter the 'Nakari and Huhtala study') to justify certain of the information requirements in the Contested Decision. The Agency's evidence is therefore weak and the concern does not need to be clarified based on the results of that study alone.
51. The Appellants claim further that under substance evaluation a concern must be related to risk and that the absence from a registration dossier of the standard information requirements set out in the REACH Regulation is not in itself sufficient to generate a risk-related concern.
52. The Appellants also submit that their registration dossiers for the Substance are fully compliant with the requirements of the REACH Regulation. According to the Appellants, long-term aquatic toxicity testing is not a standard information requirement applicable in all cases but must only be proposed when the chemical safety assessment conducted in accordance with Annex I identifies a need to further investigate the effects on aquatic organisms. The Appellants argue that the chemical safety assessment conducted by the lead registrant for the Substance did not identify the need for such a proposal because the aquatic compartment was not considered the main target compartment when assessing the environmental fate of the Substance.
53. The Appellants also state that in justifying the requests for information in the Contested Decision the Agency draws a number of parallels and similarities between the Substance and decaBDE. The Appellants state that the Agency draws these parallels and similarities while, at the same time, acknowledging in the Contested Decision that *'the substances are different'*. The Appellants argue that the Substance - and in particular the Substance as manufactured, placed on the market, and used by the Appellants - is significantly different from decaBDE. The Appellants state that given that the two substances are different, their behaviour should be presumed to be

- different and any similarity should be established through data, rather than be presumed.
54. The Appellants claim that in finding a concern from information on another substance the Agency transposes concerns from one substance to another and that, according to the Agency, such transposition only needs to abide by the low threshold of 'plausibility'. The Appellants argue that the Agency's interpretation is entirely discretionary and that there is no legal basis that justifies the application of a standard of plausibility, rather than a full justification, in so far as substance evaluation is concerned.
 55. The Appellants submit that the Agency cannot attempt to justify its action taken in regard to one substance on grounds of data relating to another substance without at least understanding the relevant and significant differences between the substances in question. The Appellants submit that this underlying legal and scientific principle is already well acknowledged and accepted by the Agency, as best illustrated in its continued requirement for registrants to provide wholly comprehensive, concrete, and complete justification for any read-across adaptation proposed.
 56. The Agency claims that the information requested in the Contested Decision was based on an actual concern in relation to the Substance and thus targeted to real information needs. In particular, according to the Agency, the concerns were either based (i) on the absence of information for a standard information requirement (long-term toxicity testing on aquatic invertebrates, bioaccumulation in aquatic species), (ii) indications that there is a concern in tests already performed on the Substance (adaptation for vitellogenin determination in the fish feeding bioaccumulation test), or (iii) indications, due to structural similarity, that the Substance will behave similarly to decaBDE in relation to the degradation to hazardous transformation products.
 57. The Agency argues that long-term toxicity testing on aquatic invertebrates and bioaccumulation in aquatic species are standard information requirements for the registration dossiers of some of the Appellants in accordance with Sections 9.1 and 9.3.2 of Annex IX. However, no or insufficient studies addressing these applicable standard information requirements are available in the registration dossiers of the Appellants and there is therefore a concern based on the fact that the minimum requirements imposed by the REACH Regulation cannot be considered as fulfilled. The Agency adds however that it agrees with the Board of Appeal's finding in its decision in *Akzo Nobel Industrial Chemicals and Others*, cited at paragraph 23 above, that the lack of standard information alone cannot justify a request for information and that a potential risk would have to be substantiated further.
 58. The Agency argues that information on long-term aquatic toxicity is relevant for the derivation of a Predicted No-Effect Concentration (hereinafter 'PNEC'), for the hazard classification and for the assessment of the persistent, bioaccumulative and toxic (hereinafter 'PBT') and very persistent and very bioaccumulative (hereinafter 'vPvB') properties of the Substance. The Agency also argues that the waiver contained in the Appellants' registration dossiers is not justified. The Agency states that the Contested Decision sets out why there clearly is a concern triggered by effects that have been observed in the academic literature.
 59. The Agency states that bioaccumulation testing in fish is relevant for hazard classification, the PBT assessment and consideration of secondary poisoning risks. The Agency claims that it considered the aquatic bioaccumulation study submitted in the registration dossier to be invalid as the test was performed above the limit of water solubility using an inappropriate analytical method and too few fish. The Agency states that the available data, even seen together in a weight of evidence approach, do not satisfy the requirements for this endpoint.

60. Moreover, although vitellogenin induction in fish is not a standard information requirement, the Contested Decision clearly explains that this request is based on an actual concern arising from the results of a study. The Agency claims that the results of an *in vitro* screening assay suggest that the Substance has the potential to elicit an oestrogenic effect in fish liver cells, and can induce hepatocyte detoxification enzymes. According to the Agency, it therefore cannot be excluded that the Substance might elicit effects in fish following long-term exposure.
61. The Agency argues that there are a number of differences between the facts underlying the decision in *Akzo Nobel Industrial Chemicals and Others*, cited at paragraph 23 above, and those of the present case. For example, in the present case the standard information at issue was required by all addressees of the Contested Decision and not only for certain of them as in *Akzo Nobel Industrial Chemicals and Others*. In addition, while in that case the experimental study requested was changed by the MSC, the requests for experimental and other data remained the same throughout the decision making procedure in the present case.
62. The Agency argues that it would have been counter-productive for the clarification of suspected PBT/vPvB properties of the Substance to conduct compliance checks on the registration dossiers first. This is because in substance evaluation there are wider possibilities for acquiring and analysing data and employing non-standard test strategies than following a compliance check. In the present case, the data requests and testing strategy were specifically targeted to clarify the identified PBT/vPvB concern in an efficient manner which may limit unnecessary testing if the concern is clarified.
63. According to the Agency, the specification of the form of the Substance to be tested (purest/least pure form) would not normally be addressed under dossier evaluation, while in substance evaluation there is more flexibility in asking for tests on different forms of a substance. This allows obtaining data that are suitable and necessary to clarify the concern identified.
64. The Agency claims further that the compliance check procedure would not have enabled the Agency to obtain all the information it needed to conclude on the PBT/vPvB concern. According to the Agency, this could lead to additional vertebrate animal testing.
65. In addition, the Agency argues that subjecting the registration dossiers concerned to a prior full compliance check would mean delays of up to several years for the substance evaluation process and clarification of the identified concern. In addition, the eMSCA based its evaluation of the Substance on the information in the registration dossiers and available in the literature which goes beyond what dossier evaluation can provide focussing on individual registration dossiers. This approach, which is specific to substance evaluation, allows to obtain a more comprehensive understanding of the information and to conclude accordingly. The Agency also claims that the outcome of the substance evaluation could not be predicted. Therefore, a requirement to ensure compliance of all registration dossiers involved before proceeding to the evaluation of a substance would constitute an artificial separation of the substance and dossier evaluation procedures, which intrinsically aim to meet the same objective.
66. The Agency claims that the requests for soil and sediment testing were triggered by concerns that the Substance may transform to substances that may have PBT/vPvB properties. According to the Agency these concerns were triggered by the fact that the Substance is suspected to have similar properties to decaBDE which transforms to substances that have PBT/vPvB properties.
67. The Agency states that it did not read-across data between the Substance and decaBDE within the meaning of Section 1.5 of Annex XI, but concluded on the need to investigate further the properties of the Substance based on the properties of

- decaBDE. The Agency adds that it is not required under substance evaluation to provide a full justification such as that required by Section 1.5 of Annex XI whenever it refers to concerns triggered by properties of another substance than the one under evaluation. The Agency argues that such an interpretation is in line with the fact that the substance evaluation process is based on the precautionary principle, pursuant to which authorities may take action even in the absence of scientific certainty.
68. The Agency states that, for the purposes of identifying a concern under substance evaluation, it suffices that there are reasons to believe that it is plausible that a substance would behave similarly to an *'analogue'* substance in respect to certain properties. According to the Agency, in the present case, the existence of a concern to be clarified under substance evaluation is plausible based on the properties of decaBDE.
 69. The Agency states that both the Substance and decaBDE have two benzene rings, each having five bromine atoms and that the two substances differ only in the nature of the bridge connecting the two rings (ether or ethyl); decaBDE has an oxygen atom between the two aromatic rings rather than an ethane bridge. The Agency adds that this structural difference means that the Substance has greater molecular flexibility but lower polarity. However, whilst this difference will affect molecular size, steric and physico-chemical properties (e.g. solubility), and it is acknowledged that the two substances are not identical, the main concern linking the two substances is the potential for the carbon-bromine bond to be broken (either by enzymes or abiotic factors).
 70. The Agency adds that there is substantial information on decaBDE showing that the carbon-bromine bond can be broken. Based on the structural similarity, there is a concern that the Substance would undergo similar reactions under similar conditions. In particular, it is plausible that the Substance will lose one or more bromine atoms under certain circumstances, and that these can be replaced by either hydrogen atoms or other functional groups (such as hydroxyl). Since the loss of bromine is likely to make the degradants more bioavailable (and therefore potentially hazardous), there is a need to investigate the identity and rates of formation of transformation products under relevant conditions.

Findings of the Board of Appeal

71. The Board of Appeal has held previously that, under substance evaluation, in order to establish the necessity of a request for additional information the Agency must inter alia be able to demonstrate the necessity of the requested measure by setting out the *'grounds for considering that a substance constitutes a risk to human health or the environment'*. The Agency must also be able to demonstrate that the potential risk needs to be clarified, and that the requested measure has a realistic possibility of leading to improved risk management measures (see Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 76 and the previous decisions cited).
72. The Board of Appeal has also stated that this approach is consistent with the European Union Courts' interpretation of the precautionary principle which states that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time the measure was taken (see Case T-13/99, *Pfizer Animal Health SA v Council*, EU:T:2002:209, paragraph 144; see also the decision in *International Flavors & Fragrances*, cited in the previous paragraph, paragraph 77 and the previous decisions cited).

73. The Appellants argue that the Agency has not demonstrated the necessity of the requested information and that some of that information could not in any case be requested under substance evaluation. With regard to the latter argument the Appellants argue in particular that the adaptations presented in their registration dossiers should have been examined under the compliance check procedure rather than the substance evaluation procedure.
74. The Board of Appeal observes that in the Defence the Agency stated that the information requested in the Contested Decision was justified by concerns based on *'[i] the absence of information for a standard information requirement (long-term toxicity testing on aquatic invertebrates and bioaccumulation in aquatic species), [ii] indications that there is a concern in tests already performed on the Substance (adaptation for vitellogenin determination in the fish feeding bioaccumulation test), and [iii] indications, due to structural similarity, that the Substance will behave similarly to decaBDE in relation to the degradation to hazardous transformation products'*.
75. The Board of Appeal notes that it has not been disputed in the present proceedings that the Substance is produced in large quantities, having been registered by several registrants at the highest tonnage band, and is used as a flame retardant leading to environmental exposure.
76. In light of the above, the Board of Appeal will examine whether the grounds for concern identified by the Agency are sufficient to demonstrate the need for the information requested in the Contested Decision and whether the Agency acted correctly in requesting some of that information under the substance evaluation procedure rather than under the compliance check procedure.

(i) Structural similarity with decaBDE

77. The Board of Appeal observes that the structural similarity with decaBDE is used as a ground for concern to justify the requests for long-term toxicity testing on aquatic invertebrates, bioaccumulation in fish, soil simulation testing and sediment simulation testing. The Board of Appeal notes that the Agency has not claimed that the request for information on vitellogenin induction was justified on the grounds of the structural similarity between decaBDE and the Substance.
78. The Board of Appeal emphasises firstly that the test for establishing structural similarity for the purposes of identifying grounds for concern under substance evaluation is not the same as that for the use of read-across pursuant to Section 1.5 of Annex XI which sets out the rules on grouping of substances and the read-across approach for the purposes of adaptations of the standard testing regime in Annexes VII to X. In any event, both the Agency and the Intervener acknowledge that decaBDE and the Substance are different in certain respects and that it would not therefore be possible to read-across from one to the other for the purposes of satisfying an information requirement. If the Agency was arguing that a read-across applies between decaBDE and the Substance with regard to the identification of properties relevant to a PBT/vPvB assessment there would be no need to perform most of the tests required by the Contested Decision.
79. As explained in paragraphs 42 to 45 above, the structural similarity of the substances is relevant to the identification of grounds for concern. If the Substance does lose bromine atoms under certain conditions it is possible that these will be replaced with hydrogen or other functional groups and that the transformation products may be bioavailable. Whilst there is nothing certain in this regard, the Board of Appeal accepts that the scenario explained in the Substance Evaluation Report, the Contested Decision and the submissions during these appeal proceedings regarding the

- debromination of the Substance is sufficient to demonstrate grounds for concern regarding the PBT and vPvB properties of the Substance which need to be clarified.
80. The Board of Appeal considers that the Agency might be required to provide additional reasoning to justify the grounds for concern if there were evidence to the contrary regarding the PBT and vPvB properties of the Substance. In the present case however the Appellants have argued that the substances are not structurally similar but have not presented evidence indicating the absence of the PBT/vPvB concerns identified.
 81. Whilst the Board of Appeal accepts that there are differences between decaBDE and the Substance, the Board of Appeal finds that the structural similarity between the two substances is sufficient, coupled with the environmental exposure to the Substance (see paragraph 75 above), to demonstrate grounds for concern that the Substance may be a PBT or vPvB, thereby posing a risk to the environment. The structural similarity, coupled with the environmental exposure, is therefore sufficient for requesting additional information by means of long-term toxicity testing on aquatic invertebrates, bioaccumulation testing in fish, soil simulation testing and sediment simulation testing.
 82. The Appellants' claim that the Agency has not demonstrated grounds for concern in relation to those information requirements is therefore dismissed.

(ii) Concern based on the absence of standard information

83. During the proceedings the Agency stated that long-term toxicity testing on aquatic invertebrates required by Section 9.1.5 of Annex IX is *'relevant for all the addressees of the Contested Decision and not only to a certain number of them'*. According to the Contested Decision *'there are no long-term aquatic toxicity tests in the registrations, and the Registrant(s) claim that a study is not technically feasible due to the very low water solubility'*.
84. The Agency argues that as there are no studies addressing the standard information requirements for long-term toxicity testing on aquatic invertebrates in the registration dossiers of the addressees of the Contested Decision there is a concern based on the fact that the minimum requirements imposed by the REACH Regulation cannot be considered as fulfilled. The Agency itself acknowledged however during the present proceedings that under substance evaluation any potential risk would need to be substantiated further by scientific findings.
85. The Appellants claim in particular that there is no missing standard information on long-term aquatic toxicity testing as their chemical safety assessment did not identify a need to further investigate the effects on aquatic organisms pursuant to the second column of Section 9.1.5 of Annex IX (hereinafter the 'adaptation'). The Appellants claim that this conclusion should have been addressed under the compliance check procedure rather than through substance evaluation.
86. The Agency stated that, although bioaccumulation in aquatic species is a standard information requirement pursuant to Section 9.3.2 of Annex IX, there are no or insufficient studies addressing this standard information requirement. The Board of Appeal observes, however, that the Appellants clarified during the proceedings that they *'have not commented on such concerns, but have contested (i) the additional modifications of what is a new testing protocol, and (ii) the ambiguity of the decision with regard to the form of the substance to be tested'*. The Board of Appeal will not therefore consider the issue of concern based on the absence of standard information in relation to the bioaccumulation endpoint.
87. The Board of Appeal considers firstly that in the Contested Decision the Agency did not take a formal decision on the adequacy of the adaptation proposed. This conclusion is

not affected by the fact that the Agency provided certain arguments in the Contested Decision as to why the adaptation presented is insufficient to conclude on the standard information requirement (see, by analogy, Case A-005-2014, *Akzo Nobel Industrial Chemicals and Others*, Decision of the Board of Appeal of 23 September 2015, paragraphs 82 and 83). As a result, the Board of Appeal considers that it is not possible for the Agency to conclude, in the absence of a decision under the compliance check procedure, that the requirements of Sections 9.1.5 and 9.3.2 of Annex IX have not been satisfied by the Appellants in this case.

88. Nonetheless, the Board of Appeal has previously held that the standard information requirements set out in Annexes VII to X may, in certain circumstances, also be requested under substance evaluation (see the decision in *Akzo Nobel Industrial Chemicals and Others*, cited in the previous paragraph, paragraph 87).
89. However, a perceived gap in the standard information requirements cannot, in itself, justify a request to fill such a data gap pursuant to substance evaluation. A data gap does not constitute on its own evidence of a potential risk for human health or the environment. In other words, the Agency's conclusion that the Appellants failed to provide some of the standard information in their registration dossier cannot, on its own, justify a request for that information pursuant to substance evaluation (see the decision in *Akzo Nobel Industrial Chemicals and Others*, cited in paragraph 87 above, paragraph 75).
90. The Board of Appeal has also stated that whilst the REACH Regulation contains no explicit requirement that dossier evaluation should precede substance evaluation, there are a number of indications in the REACH Regulation which suggest that the normal course of action should be for the Agency to carry out a compliance check prior to the performance of a substance evaluation. The Board of Appeal also found that that the substance evaluation procedure should not, ordinarily, be used in place of a compliance check to fill data gaps (see the decision in *Akzo Nobel Industrial Chemicals and Others*, cited in paragraph 87 above, paragraphs 77 to 90).
91. The Board of Appeal has found however, in its decision in *Akzo Nobel Industrial Chemicals and Others*, that the Agency may be able to provide sufficient reasoning to justify in certain cases, in light of the objectives of the REACH Regulation and substance evaluation and in particular the protection of human health and the environment, requesting information under substance evaluation that should have, ordinarily, been requested following a compliance check procedure.
92. The Board of Appeal notes that there are a number of differences between the present case and *Akzo Nobel Industrial Chemicals and Others*. Importantly, in the present case all the addressees of the Contested Decision are subject to the same information requirements for registration purposes. As a result, all information requested in the Contested Decision is relevant for all addressees of the Contested Decision and not only a certain number of them, as was the situation in *Akzo Nobel Industrial Chemicals and Others*.
93. In addition, the Board of Appeal considers that the concerns being investigated in the present case are typical of those effects which should be investigated pursuant to substance evaluation as the Contested Decision is examining environmental effects holistically through the use of modified testing requirements.
94. The Board of Appeal observes that a compliance check considers whether an adaptation for an information requirement is adequate. However a substance evaluation considers a broader set of information in examining whether there are grounds for concern. Without prejudice to a decision under dossier evaluation on an adaptation, a substance evaluation may indicate that information which may be relevant to a standard information requirement is necessary to clarify the grounds for

- concern identified for a substance as a whole and not necessarily for an individual registration dossier.
95. In this particular case, whilst a compliance check should ordinarily have been conducted prior to the substance evaluation, the Board of Appeal finds that the information on the structural similarity of the Substance and decaBDE demonstrates that, irrespective of the validity of the reasons for not supplying the long-term aquatic toxicity data, information is required to clarify the concern identified.
 96. With regard to the long-term aquatic toxicity test requested the Board of Appeal observes that the proposed adaptation in the registration dossier is related to the fact that the Appellants consider that it is technically not possible to conduct the test. The Appellants state that the study is not technically feasible due to the very low water solubility of the substance. However, the Contested Decision takes into account the potential problem of the low water solubility of the Substance by indicating that the performance of the test is *'pending the results of the investigation of test solution stability'*. The Contested Decision states that *'the draft decision has therefore been amended to indicate that further work is needed to establish whether a stable test concentration can be maintained before carrying out the test'*. In other words, if it is impossible to maintain a stable test concentration the test will not need to be carried out. The proposed adaptation has therefore been taken into consideration by the Agency in the Contested Decision.
 97. In this particular case the Board of Appeal finds that it is consistent with the aims and objectives of the substance evaluation process for the Contested Decision to be adopted under substance evaluation without a compliance check being completed first.
 98. The Board of Appeal also finds that the Agency was justified in asking for information to clarify the PBT/vPvB properties of the Substance under substance evaluation without first deciding on the adequacy of the adaptation proposed in the individual registration dossiers.

(iii) Request for information on vitellogenin induction

99. According to the Contested Decision, and the Agency's and Intervener's arguments during the present proceedings, a concern regarding endocrine disrupting effects in fish was triggered by effects observed in tests reported in the Nakari and Huhtala study. The Appellants argue in essence however that the findings of the Nakari and Huhtala study are not sufficient for the Agency to request information on vitellogenin induction.
100. In the Contested Decision it is stated that *'an independent test reported in the academic literature was identified [Nakari and Huhtala] that suggests acute effects may occur in aquatic invertebrates. It is not fully reliable because it was carried out above the water solubility limit without analytical verification of exposure concentrations'* and *'it may be concluded that the study is of unknown reliability'*.
101. During the present proceedings the Agency also accepted that there are concerns regarding the reliability of that publication. The Appellants also provided evidence to this effect in their comments on the draft decision as well as during the present proceedings. In addition, the Substance Evaluation Report identified a number of deficiencies in the study. At the hearing the Intervener also highlighted some of the shortcomings in the Nakari and Huhtala study, for example that the study lacked information on concentrations of solvents, and that it had unsuccessfully attempted to obtain further information from the authors. Nonetheless the Intervener considered that there was a response to the Substance by organisms compared to solvent controls which needs to be investigated further.

102. In view of the above, the Board of Appeal considers that on its own the Nakari and Huhtala study provides weak evidence of a concern for the purposes of requesting additional information under substance evaluation. Whilst a study of unknown reliability may provide grounds for concern it cannot on its own be sufficient to request information under substance evaluation. In order to request this information the Agency would need to further substantiate the grounds for concern.
103. In this respect, the Board of Appeal observes that the vitellogenin induction requirement is not a standard information requirement for registration purposes. The Board of Appeal notes further that the Agency has not claimed that the arguments related to structural similarity between the Substance and decaBDE are applicable to this information requirement.
104. Since no other grounds for concerns have been identified the Board of Appeal considers that the Agency has failed to demonstrate the necessity of the requested measure by setting out the *'grounds for considering that a substance constitutes a risk to human health or the environment'*.
105. In light of the above, the request for information on vitellogenin induction should be annulled and removed from the Contested Decision.

III. Alleged unlawful choice of testing materials: the 'least pure form of the registered substance' and the 'purest form of the registered substance'

106. In relation to long-term toxicity testing on aquatic invertebrates and bioaccumulation in aquatic species the Contested Decision requires testing using *'the least pure form of the registered substance.'*
107. In relation to soil simulation testing the Contested Decision requires that *'the test material should be the purest form of the registered substance, and should be appropriately radiolabelled'*. Similarly, in relation to sediment simulation testing the Contested Decision states that *'the test material should be the purest form of the registered substance, appropriately radiolabelled'*.

Arguments of the Parties

108. First, the Appellants raise several arguments in support of their claim that the Contested Decision is unlawful insofar as it requests the substance to be tested in its least pure form. The Appellants claim that they do not manufacture or place on the market the *'least pure form of the registered substance'*. The requirement to test the least pure form of the registered substance would therefore require the addressees of the Contested Decision to conduct tests on substances of third parties who are not addressees of the Contested Decision. The Appellants submit that the Agency cannot legally require data under Article 46(1) which is outside their control and authority to provide.
109. The Appellants also submit that by adopting a decision containing a request for information with which they cannot themselves ensure compliance, the Agency has committed a manifest error in the exercise of its discretionary powers, misused its powers, and acted outside of the limits of its discretionary powers. The Appellants claim that compliance with the Contested Decision could also raise concerns related to the applicable competition and antitrust laws.
110. The Appellants argue that, given that the Agency's concern relates to the least pure form of the Substance, and given that the addressees of the Contested Decision do not manufacture, place on the market and/or use the least pure form of the

- Substance, the requirements in the Contested Decision regarding the least pure form of the Substance are addressed to the incorrect entities.
111. The Appellants claim that they are, in essence, being required to take on costs associated with the manufacture, placement on the market, and use of third party substances, in addition to incurring the costs relevant to their own substances. The Appellants submit that this is in contradiction with Article 1(1) which states that the purpose of that the REACH Regulation is inter alia to enhance competitiveness and innovation.
 112. The Appellants also submit that the Contested Decision is disproportionate as it requires them to provide information on the Substance in a lower purity than they placed on the market. The Appellants claim that the requested data is unnecessary as it is not relevant to the Substance as manufactured and/or placed on the market by the addressees of the Contested Decision. The Appellants add that the Agency did not have recourse to the least onerous measure and that the disadvantages caused by the Contested Decision clearly outweigh the aims pursued as the Appellants are required to submit data which is outside their control and legal ability to provide.
 113. In addition, the Appellants claim that, in breach of TFEU and Article 130 of the REACH Regulation, the Agency fails to provide an appropriate explanation for the selection of testing materials that are placed on the market by registrants who are not the addressees of the Contested Decision.
 114. The Agency submits that the Appellants allegations are mainly based on a misunderstanding of what is requested in the Contested Decision. According to the Agency, the Contested Decision does not request the Appellants to test a third party substance but merely requires them to test an appropriate sample selected among the compositions registered by them.
 115. The Agency claims that it is clear from the Contested Decision that *'the decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent'*. The Agency states that it sent the draft decision for commenting, pursuant to Article 50(1), to those registrants holding registration dossiers on the day of sending. According to the Agency, any submission by new registrants of a registration dossier for the registered substance after that date cannot lead to the inclusion of those registrants amongst the addressees of the final decision, as those registrants did not have the opportunity to provide comments pursuant to Article 50(1).
 116. The Agency also states that the Contested Decision should be read as meaning *'the least pure form of the Substance among the compositions registered by the addressees'*.
 117. According to the Agency, the reference in the Contested Decision to the other members of the Substance Information Exchange Forum (hereinafter the 'SIEF') for the Substance is merely meant to encourage the involvement of non-addressees in contributing to identifying the test material. The Agency considers, however, that if the involvement of non-addressees is not achieved, the requirements of the Contested Decision will be fulfilled if the Appellants test the least pure/purest form among the compositions they have registered.
 118. Second, the Appellants claim that the requirement to test the *'purest form of the Substance'* is imprecise as it does not allow the addressees of the Contested Decision to determine which form of the Substance should be tested. The Appellants add that an independent and anonymised analysis of the forms of the Substance registered produced by the addressees of the Contested Decision showed that the differences in purity are not significant enough to require testing on the purest form of the Substance.

119. The Appellants further argue that if they are only required to select the least pure and purest form of the Substance amongst those compositions registered by the addressees of the Contested Decision, there is no need to differentiate between them as all of the addressees of the Contested Decision manufacture and/or place on the market the Substance in very similar, high-purity forms.
120. In view of the above, the Appellants claim that the Contested Decision breaches the legal principles regarding good administration, legitimate expectation, and the requirement for clarity.
121. The Appellants submit that, if the requirement to provide data on the purest form of the Substance is to be strictly adhered to, the Appellants would be legally required to carry out a full and comprehensive assessment of each and every addressee and post-April 2013 manufacturer and importer of the Substance to ascertain which entity manufactures, places on the market, and/or uses the purest form. The Appellants submit that this would result in the use of very substantial costs and resources, and be an administrative burden, for no perceivable benefit. The Appellants therefore submit that the requirement is disproportionate in that (i) the requirement is not appropriate or necessary to attain the objectives legitimately pursued, (ii) recourse is not being made to the least onerous appropriate measure, and (iii) the disadvantages caused are disproportionate to the aims pursued.
122. The Appellants also claim that the requirement that *'the test material should be the purest form of the registered Substance, appropriately radiolabelled'* leads to an inherent contradiction as the purest form of the Substance could not be considered the purest form once appropriately radiolabelled.
123. The Agency claims that it is clearly set out in the Contested Decision that the requests for soil and sediment simulation testing aim to determine whether the Substance degrades under the conditions of the test and should allow identification of any transformation products. According to the Agency, the purpose for requiring testing of the purest form of the substance in relation to these tests is aimed to minimise interpretation problems for the registrants should small amounts of degradants be observed.
124. The Agency claims that the determination of the purest form of the testing material would not be disproportionately burdensome as there is no difference between this requirement and the requirement to determine a 'representative sample' which would be the normal way of proceeding if no specification concerning the test material was given in the Contested Decision.
125. The Agency states that, if it is not technically possible to test the purest form, any deviation from the request can always be explained by the registrants when providing the requested information in response to the requests in the Contested Decision.

Findings of the Board of Appeal

(i) Addressees of the Contested Decision

126. During the present proceedings the Agency clarified that the Contested Decision should be read as applying only to the forms of the Substance registered by the addressees of the Contested Decision. In the Defence the Agency acknowledged that *'[i]t is clear that [the Agency] cannot request testing [on] a form that is factually not available to the addressees'*. The Agency further stated that the requirement in the Contested Decision to test the least pure or purest form of the registered substance should be read in light of the Contested Decision as a whole to mean *'purest/least pure form of the substance among the compositions registered by the addressees'*. In

this respect the Agency claims that the Appellants' arguments are based on a misunderstanding of the Contested Decision.

127. It is therefore common ground between the Parties that the addressees of the Contested Decision are not required to perform tests on compositions of the Substance which are not manufactured or imported by them.
128. In this respect, the Board of Appeal considers that the addressees of the Contested Decision are clearly identified. The Contested Decision states that:

'This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an Annex to this decision.'

129. The Board of Appeal considers however that despite the Agency's clarifications during the present proceedings the wording of the Contested Decision does in fact imply that forms of the Substance registered by other registrants of the Substance, who are not addressees of the Contested Decision, due to the fact that they registered the Substance after the draft decision was sent to the registrants for their comments, should also be covered by the Contested Decision. The Agency's interpretation of the Contested Decision during the present proceedings is therefore not consistent with the actual wording of that Decision.

130. For example, the Contested Decision states that:

'However, Registrant(s) who are part of the SIEF but did not have registrations when the Draft Decision was circulated for comment in April 2013 may still supply the substance at a different purity level. Although not bound by the final decision, ECHA believes it is in the interests of all Registrant(s) to support testing that can be applied to their individual registration of [the Substance]. It is also important that risk management decisions are not delayed because of the submission of these additional registrations (which would thereby create uncertainty for the Registrant(s)). Therefore, in the interests of obtaining as much information as possible from the remaining tests, the decision has been amended to specify that some tests are required to use the least or most pure form of the commercial substance registered at the time the Decision is finalised (depending whether the focus of the test is on the transformation of the main constituent or bioaccumulation, respectively), rather than a specially prepared test substance. ECHA considers that this is justified to minimise interpretation problems in the former case (should small amounts of degradants be formed), and to obtain information on relevant impurities in the latter case. The Registrant(s) shall collectively decide on the most appropriate test substance composition in each case. If the Registrant(s) choose not to share relevant information directly, they will need to use a third party. However, ECHA does not consider this to be disproportionate given the concern, as the Registrant(s) would need to agree on the composition of the test substance in any case, and some Registrant(s) have already collaborated by performing analyses in an independent laboratory.'

131. The Agency explained in the Defence that the reference to other members of the SIEF for the Substance is merely intended to encourage the involvement of non-addressees of the Contested Decision in contributing to identifying the test material. The Board of Appeal finds however that in particular the statement in the Contested Decision that the draft was amended during the decision-making procedure *'to specify that some tests are required to use the least or most pure form of the commercial substance registered at the time the Decision is finalised'* can easily be read as meaning that the addressees of the Contested Decision are required to perform tests on compositions other than those which they have registered.

132. The Board of Appeal also considers that the Agency's argument that the section of the Contested Decision quoted in paragraph 130 above is not binding as it is found in Section III of the Contested Decision, the section entitled '*Statement of reasons*', is not convincing. Indeed the Board of Appeal considers that, as the Agency stated during the hearing, due to the nature of the Agency's decisions, it is possible that the distinction between the binding and non-binding parts of a decision may not be absolute. As a result, obligations may also be found in Section III of a decision.
133. Furthermore, in the present case, the Board of Appeal observes that the Statement of reasons is used to explain the meaning of terms such as '*the purest form of the registered substance*' and '*the least pure form of the registered substance*'. With this in mind, whilst the addressees of the Contested Decision are clear, the clarifications set out in Section III of the Contested Decision, in particular those quoted in paragraph 130 above, create uncertainty as to whether the addressees of the Contested Decision are required to perform tests on forms of the Substance not produced by them but rather by later registrants of the Substance.
134. In light of the above and in particular considering the clarifications provided by the Agency on these points, the Board of Appeal finds that, in order to ensure legal certainty for the Appellants, the Contested Decision should be annulled in so far as it is necessary to clarify that only the compositions of the Substance registered by the addressees of the Contested Decision, as listed in the Annex to the Contested Decision, should be subject to the testing required in the Contested Decision.
135. In view of the Agency's clarifications during the present proceedings and the findings of the Board of Appeal above, it is not necessary to examine the Appellants' pleas related to this claim regarding inter alia a manifest error in the exercise of its discretionary powers, misuse of powers, acting ultra vires, infringing the principle of proportionality and failure to state reasons.
136. Since the Contested Decision has not been annulled in its entirety the Board of Appeal will examine the other claims raised by the Appellants.

(ii) Least pure and purest forms of the registered substance

137. The Board of Appeal will next examine the Appellants' claim that it is not necessary to perform tests on the purest and least pure form of the Substance as all the addressees of the Contested Decision have registered the Substance at a similar high degree of purity.
138. The Board of Appeal observes that the Contested Decision itself acknowledges that '*the four Registrant(s) to whom the Decision is addressed now supply the substance at a high degree of purity*'.
139. It is also undisputed that the registration dossiers of the addressees of the Contested Decision were updated several times to amend the level of purity of the Substance. At the hearing, however, the Agency stated that the relevant levels of purities were those in the dossier at the time the Contested Decision was adopted, specifically 22 May 2014.
140. In a table of the results of an impurity analysis of the Substance for the four registrants, attached to the Notice of Appeal, the Appellants indicated that in April 2013 the purity of the Substance amongst the four addressees of the Contest Decision ranged from 97.40 % to 99.11 %. At the hearing the Appellants specified that in September 2013 the range of purity was refined to 98.10 % to 99.11 %.
141. The Board of Appeal also observes that the Contested Decision confirms that the impurities of concern, namely the lower congeners, are not present in the

compositions of the Substance as supplied by the addressees of the Contested Decision. In this respect, the Contested Decision states that:

'In response to this proposal, the Registrant(s) objected to separate testing on several lower brominated diphenyl ethane congener groups that may be present as impurities in the commercial products. Instead, they argued that only testing on the commercial substance as supplied was legally permissible. Where the test substance was proposed to be "as pure as possible", the Registrant(s) also claimed that the lack of specification of an acceptable purity level would place a burden on them. To protect commercially sensitive information, they might also need to involve an independent third party, which would bring disproportionate costs. In response, [the Agency] considers that impurities (or constituents in the case of a substance of undefined or variable composition) are a legitimate subject for consideration under Substance Evaluation where those impurities (or constituents) are suspected of posing a greater hazard than the main component (or whole substance). Nevertheless, [the Agency] notes that the Registrant(s) organised an analysis of each of their commercial products at an independent laboratory and analytical information provided within 60 days of the receipt of the draft decision by the Registrant(s) suggests that the registered substances (as of April 2013) do not contain hepta-, hexa- or pentabromodiphenyl ethanes (at a limit of detection of 0.1% w/w). [The Agency] therefore recognises that the four Registrant(s) to whom the Decision is addressed now supply the substance at a high degree of purity. Assuming that this information is representative of variations in commercial batches of all suppliers and that the method is reliable, then testing on individual congener groups is no longer justified in terms of proportionality.'

142. The Board of Appeal considers therefore that the Agency did not justify in the Contested Decision or during the course of the present proceedings, in light of the level of purity of the form of the Substance registered by the addressees of the Contested Decision, why tests on the Substance should be performed on the purest or least pure form.
143. The Board of Appeal finds that the Agency failed to adequately state reasons for the requirement to test the *'purest form of the substance'* and the *'least pure form of the substance'*.
144. In view of the above, the Board of Appeal finds that the Contested Decision should be annulled insofar as it is necessary to remove all references to the requirement to perform tests on the *'purest form of the substance'* and the *'least pure form of the substance'*. The Contested Decision should be understood as meaning that the tests requested should be conducted on representative samples of the Substance as registered by the addressees of the Contested Decision.

(iii) Radiolabelling of the Substance

145. The Appellants argue that the requirement to radiolabel the Substance for testing is in contradiction with the requirement for testing on the purest form of the Substance. The Board of Appeal notes that the first information request in the Contested Decision, which is not contested in the present proceedings, states that the testing required should be on the Substance and *'may be radio-labelled'*. The Appellants also stated at the hearing that they would use radiolabelling in such testing because of, for example, the very low water solubility of the Substance.
146. The Board of Appeal has already found, at paragraph 144 above, that the requirement to test on the *'purest form of the substance'* must be removed from the Contested Decision. This does not bring into question the value of testing on a radiolabelled form of the Substance.

147. The Board of Appeal observes that the concerns raised by the Appellants in this regard will be resolved by the removal of references to the purity of the test substance (see paragraphs 137 to 144 above) and that as a result no amendments to the Contested Decision are required in relation to the requirement for the substance to be radiolabelled.

IV. Alleged unlawful choice of testing protocols

Arguments of the Parties

148. The Appellants claim that the data produced by the studies required under the Contested Decision will not provide reliable or meaningful data. The Appellants argue that there is a very significant degree of uncertainty regarding whether and how the required studies can be performed in practice and whether the results arising would be reliable and useful. In particular, the Appellants submit that there are fundamental technical uncertainties regarding how to conduct the studies in practice and significant concerns regarding the reliability of the results of such studies and the ability to interpret and draw conclusions from the results.
149. With regard to the requested soil simulation testing (OECD Test Guideline 307; hereinafter 'OECD TG 307') the Appellants claim that:
- The study which was cited as justification for the request for data (Huang, H., Zhang, S., Christie, P., Wang, S. and Xie, M., 2010, *Behavior of decabromodiphenyl ether (BDE-209) in the soil-plant system: uptake, translocation, and metabolism in plants and dissipation in soil*, Environmental Science and Technology, 44 (2), pages 663-667; hereinafter the 'Huang study') is scientifically flawed and unreliable. In particular the Appellants argue that the Huang study was not performed according to an international guideline or Good Laboratory Practice, the raw data are not available, the supplemental data provided with the publication is limited, the study has not been replicated by another laboratory and the findings are inconsistent with previous work.
 - *'There is an unacceptable legal uncertainty over the test conditions of the soil simulation testing as requested in the Contested Decision, i.e. the amended version on the Substance of an already non-standard study conducted on a different substance, decaBDE (the Huang study). In particular, the relevance of the test initially on decaBDE is not sufficiently reasoned.'*
 - *'The Agency has failed to demonstrate that a repeated Huang study on decaBDE would lead to consistent and reliable results. It is all the more questionable whether such a modified Huang study on the Substance could lead to reliable and exploitable results.'*
 - There is no validated protocol for the requested tests. The requested test *'contains major deviations from the original OECD TG 307 protocol. It is required that the soil simulation test be carried out as a reproduction [of the Huang study]. The Huang study, however, does not follow test guidelines and the full details of the protocol are not available [...]. The Appellants are therefore requested to perform a test without certainty that it is technically feasible, since the technical details to perform the test are not available to them.'*
 - The Contested Decision requires that the duration of the test is extended by 50%, i.e. at least 6 months instead of the recommended 120 days. *'Since 4 out of the 6 plants that were tested in the Huang study do not have a life expectancy that is sufficient to cover the requested duration of the test, other plant species will have to be selected, without any assurance that these other species will behave in such a way that the test can be completed successfully, since the test has never been*

- carried out in those conditions. Further the comparability with the Huang study on decaBDE may be highly questioned if test conditions are altered*’;
- The wording of the Contested Decision is ambiguous regarding the exact duration of the test; and
 - Finally, *‘[t]he Contested Decision requires the Appellants to carry out the test at a level of sensitivity unjustifiably ten times higher than the OECD 307 guidelines without adequate reasoning and justification. Further, as there is no certainty that such a level of sensitivity can be reached by the Appellants, the feasibility of the test is put into question.’*
150. With regard to the sediment simulation testing protocol (OECD Test Guideline 308; hereinafter ‘OECD TG 308’) the Appellants argue that:
- *‘There are major deviations from the original OECD 308 Test Guidelines protocol and the Appellants have no certainty on whether the results obtained will be regarded as satisfactory by [the Agency] and the registration will be regarded as compliant after the update.’*
 - *Moreover, ‘[t]he test requires a level of sensitivity unjustifiably ten times higher than the OECD 308 Test Guidelines without adequate reasoning and justification.’*
151. As regards the vitellogenin determination in the fish feeding bioaccumulation test the Appellants argue that:
- *The requirement to use at least 16 additional fish ‘is based on a publication of an in vitro study of questionable reliability and the concern derived from this publication is not adequately justified’.*
 - *Moreover, ‘the Contested Decision fails to indicate clearly that, in the case of a negative outcome, i.e. if no increase in vitellogenin in the treated fish compared to controls is observed, no further studies will be required with regard to that concern.’*
152. The Agency argues that in substance evaluation its margin of discretion applies first to the assessment of the need for further information to address a potential concern and second to the determination of what further studies are appropriate to address the concerns identified.
153. The Agency states that, pursuant to Article 13(3), it is not limited in its choice of test methods to those which are laid down in the Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1). According to the Agency, pursuant to the first sentence of Article 13(3), the Agency can recognise other international test methods as appropriate.
154. The Agency argues further that, in accordance with the second sentence of Article 13(3), information may also be generated in accordance with other test methods provided that the conditions set out in Annex XI are met. In the context of substance evaluation requests may include modifications to standard test methods, where such modifications are necessary to investigate the concern under examination. In relation to the Contested Decision the modifications to the OECD protocols have been unanimously agreed by the MSC.
155. The Agency argues that adaptations to the test guidelines and methods in the Contested Decision are motivated by the need to adapt these methods to allow for investigation of the concerns identified. The Agency argues that the modifications were explained in the Contested Decision to a sufficient level of detail to allow the Appellants to conduct the relevant tests.

Findings of the Board of Appeal

156. The Board of Appeal has previously held that under substance evaluation it may be appropriate to request information using modified test methods, for example, to examine parameters which are not normally considered in standard test methods. This helps ensure that information generated pursuant to a substance evaluation decision meets real information needs (see the decision in *Akzo Nobel Industrial Chemicals and Others*, cited at paragraph 87 above, paragraph 88).
157. With these considerations in mind the Board of Appeal will examine the Appellants' arguments regarding the test protocols set out in the Contested Decision.

(i) Vitellogenin determination

158. As the Contested Decision must be annulled insofar as it requires the Appellants to provide information on vitellogenin determination (see paragraph 105 above) it is not necessary for the Board of Appeal to examine the Appellants' claims related to the specific testing required in that regard.

(ii) Soil simulation testing (OECD TG 307)

159. As stated in paragraph 81 above, the Board of Appeal accepts that there are potential grounds for concern that need to be clarified by the soil simulation testing requested in the Contested Decision. The Board of Appeal also observes that the results of soil simulation testing may provide information that clarifies the concern regarding the degradation of the Substance and any consequent transformation products. This information would contribute to the assessment of the PBT/vPvB properties of the Substance and consequently improve risk management measures. The Board of Appeal will consider therefore whether the specific testing requested has a realistic possibility of delivering the required information.
160. According to the Contested Decision the Appellants are requested to provide information from soil simulation testing using test method '*aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307*' with a number of modifications based on the Huang study. The Board of Appeal observes that, once it has been established that there are grounds for concern regarding the degradation of the substance in soil, the Appellants do not contest the use of OECD TG 307. Rather the Appellants contest the modifications to it introduced by the Agency in the Contested Decision based on the Huang study, what the Appellants refer to as the '*Huang deviations*'. The Appellants claim that the Huang study is scientifically flawed, and unreliable and that the use of OECD TG 307 with the '*Huang deviations*' is unsuitable for the aim pursued. The Board of Appeal will examine whether these claims are founded.
161. The Board of Appeal observes that the Huang study was carried out on BDE-209 (the main of the BDEs - decabromodiphenyl ethers - present in commercial decaBDE) and not on the Substance. The findings from the Huang study address the accumulation of BDE congeners in plants and the transformation of BDE-209 into other products in the soil-plants system. The main outcome of the Huang study was that accumulation of BDE congeners was observed in the roots and shoots of plants (six species were used in the test, namely ryegrass, alfalfa, pumpkin, summer squash, maize, and radish) and that lower brominated substances were detected in soil and plant samples. The evidence also showed a different proportion of the transformation products in plant tissues than in the soil and a lower rate of dissipation of BDE-209 in non-planted soil, thereby indicating that the metabolism of plants may contribute to debromination of decaBDE. Hence the importance of studying the behaviour of the Substance in the plant-soil system and not only in soil. The results from the requested study are therefore relevant to the grounds of concern which the test is intended to clarify. The

- soil simulation test with the '*Huang deviations*' is therefore appropriate to determine whether the results observed in the Huang study for BDE-209 are also observed with the Substance.
162. The Appellants argue, however, that the Huang Study is scientifically flawed and unreliable, in part because it was not performed following an internationally agreed test method or according to Good Laboratory Practice. The Appellants also argue that the raw data are not available, the supplemental data provided with the publication are limited, the study has not been replicated by another laboratory and the findings are inconsistent with previous work. The Contested Decision recognises the challenges incumbent in undertaking the requested study. With reference to the Huang study the Agency states in the Contested Decision that '*whilst it is conceded that this study was not performed in accordance with any test guideline, full study details are not available and the study has not been replicated exactly by another laboratory [...], these points do not necessarily make the results invalid*'. The Appellants have submitted in the course of the substance evaluation procedure that they '*question the appropriateness of including plants in any investigations [...] as they consider this to be basic research in need of substantial method validation and development*'.
 163. The Board of Appeal notes that the main feature in the Huang study that is not present in OECD TG 307 is the use of plants. The Board of Appeal finds that the Huang study is sufficiently rigorous and, as explained in the literature, has a sufficiently solid scientific basis for its results on decaBDE. As the Board of Appeal has already accepted the structural similarity between decaBDE and the Substance (see paragraph 45 above), using the Huang study as a reference to determine the transformation of the Substance in soil is not without foundation. The Board of Appeal observes that the Appellants do not dispute the transformation of decaBDE in soil and that these transformation products may have PBT/vPvB properties. The Huang study contributes to clarifying the basis for this transformation in providing a possible explanation of the role of plants in that transformation and therefore can be considered to be a valid and relevant source of evidence. The reliability of the Huang study cannot be disputed by its deviation from the criteria established in OECD TG 307. The Board of Appeal finds that the methodology in the Huang study is scientifically justified as it is related to the structure of decaBDE and the operation of the soil-plants system as a whole. The conditions in the Huang study are therefore realistic and representative of the actual conditions in the natural world.
 164. The Appellants state in the present case that there is a lack of data in the Huang study, but they do not explain which data are missing and how this fact could affect the reliability of the study in order to be able to dismiss it as evidence that should be disregarded. The Board of Appeal considers that the Huang study includes a sufficient explanation of the test, the methods followed and its results. The Appellants also argue, in support of their unreliability argument, that the Huang study has not been replicated by another laboratory. However, the Appellants do not substantiate this argument and there is no evidence on whether any laboratory has tried to replicate this study unsuccessfully. It is therefore not possible to conclude that the study cannot be repeated. The Board of Appeal finds that, whilst it recognises the complexities inherent in repeating the Huang study, the Appellants' argument that the Huang study is unreliable must therefore be dismissed as unfounded.
 165. In the Notice of Appeal the Appellants state that '*the Agency has failed to demonstrate that a repeated Huang study on decaBDE would lead to consistent and reliable results*'. However, the Board of Appeal notes that, in order to request a test under the substance evaluation procedure, the Agency is not obliged to replicate the tests used as evidence to establish a ground for concern in order to verify its findings.
 166. Finally the Appellants argue that the findings of the Huang study are inconsistent with previous studies, meaning in essence that the study is scientifically flawed. However,

- the Appellants fail to identify other previous studies with which the Huang study is not consistent and in what ways. The Board of Appeal observes that the Huang study was published in an authoritative scientific journal and does not find any reason to dismiss it as an invalid source of evidence, taking into account that the transformation of decaBDE in soil is not only a finding of the Huang study, but a finding established by other studies and that this is not disputed by the Appellants. The Board of Appeal also observes that, taking into account the action of plants in the fate of decaBDE in soil, the test seems to be a realistic approach to the actual conditions found in nature. Furthermore, the '*Huang deviations*' allow the test to examine not only the transformation and persistence of the substance in soil, but also the role of plants in that transformation and potentially the accumulation of a substance and/or its transformation products in plants. The Board of Appeal finds therefore that the Appellants' argument that the Huang study is scientifically flawed is unfounded.
167. Regarding the relevance of the particular '*Huang deviations*' the Board of Appeal will first examine the issues raised by the Appellants with regard to the duration of the requested study. The Contested Decision requests, according to the Agency as a modification to OECD TG 307, that '*the study shall be run for at least six months*'. The Contested Decision also states that '*the plant treatment shall use the same test duration and growing conditions as the [Huang] study*'. The Appellants argue that plants are used in the Huang study for less than six months and that this requirement is therefore contradictory. The Board of Appeal observes that in the Huang study '*plant shoots aboveground and roots belowground were harvested separately after growth for 60 days*' and that '*pots were kept in a controlled environment growth chamber for 60 days under controlled conditions of illumination, temperature and relative humidity*'.
168. The OECD TG 307 provides that '*the rate and pathway studies should normally not exceed 120 days [...] because thereafter a decrease of the soil microbial activity with time would be expected in an artificial laboratory system isolated from natural replenishment. Where necessary to characterise the decline of the test substance and the formation and decline of major transformation products, studies can be continued for longer periods (e.g. 6 or 12 months) [...]. Longer incubation periods should be justified in the test report and accompanied by biomass measurements during and at the end of these periods*'. The Board of Appeal considers that the duration of plants in the test could be shorter than the duration of the testing on the soil and that therefore there is no contradiction between a 60 days duration for plants in the test and a longer duration for the test on soil. When requesting a six months duration for the test and a shorter duration for the test on plants there is therefore no contradiction in the Contested Decision. Once the plants have been harvested, after at least 60 days, in order to check for the presence of the Substance or its transformation products in their tissues, the test on the soil should be prolonged by four months in order to determine the persistence of the Substance and its transformation products in soil.
169. Regarding the issue of the plants to be used in the test, the Contested Decision requests that the choice of plant species must be based on the Huang study. The Board of Appeal observes that the Appellants know which plant species were used in the Huang study as these are detailed in the study which was submitted with the Notice of Appeal. The Board of Appeal notes that in the Huang study transformation products of BDE-209 were found in the roots and shoots of the plants used in the test. Together with this, the difference in concentration of lower brominated BDEs in plant tissues and the different rate of dissipation of BDE-209 in non-planted soil shows that the metabolism of plants could play a role in the transformation of BDE-209 into transformation products with PBT/vPvB properties. Furthermore, BDE-209 and its transformation products were found in all the plant species tested and there is no indication in the Huang study that the plant species concerned made any difference on the bioaccumulation of the Substance or its transformation. The Board of Appeal

- notes that the Contested Decision does not say that the choice of species should be the same as in the Huang study but that the choice should be based on the Huang study. The Contested Decision states that *'the choice of plant species is left to the registrant, they should justify the selection based on the evidence from the decaBDE study'*. The Appellants argue that four out of six plant species used in the Huang study do not have a life expectancy that is sufficient to cover the six months duration of the test. This could lead to the selection of other species which might change the results and any comparison to the Huang study could be impacted.
170. The Board of Appeal observes, firstly, that the choice of plants is left to the Appellants. Secondly, that during the hearing the Intervener (the eMSCA) clarified that the life of the plants used in the test would not cover the six months requested for the test and that the Appellants should use the same plant species as used in the Huang study in order to get comparable results irrespective of the lifespan of each plant. As noted in paragraph 168 above, the Contested Decision does not require that the lifespan of the plants should be 6 months. The 6 months duration refers to the duration of the study on soil with the plants present for at least 60 days.
 171. In light of the above, the Board of Appeal concludes that the Appellants' claim that the Huang deviations are inappropriate must be rejected as unfounded.
 172. Finally, the Appellants argue that there is an unacceptable legal uncertainty over the test conditions of the soil simulation testing as requested in the Contested Decision because of the modifications of OECD TG 307 to achieve the same conditions as the Huang study. The wording of the Contested Decision, argue the Appellants, is unacceptably ambiguous. Therefore the Appellants *'request that a sufficient degree of appreciation is left in the performance of the test'* and that *'the testing conditions going beyond those of OECD guidelines should not be prescriptive so that the appellants could adapt them as the laboratory work is going on in order to ensure that meaningful results are generated and there is a reasonable certainty that the outcome of the test is compliant with the requirements of the contested decision'*.
 173. The Board of Appeal observes that, following the wording of the Contested Decision, adaptations to be made to OECD TG 307 to follow the conditions of the Huang study include test duration and choice of plant species. Both issues have been addressed in the previous paragraphs.
 174. The Board of Appeal observes also that a further modification to OECD TG 307 to follow the conditions of the Huang study is related to *'growing conditions'* of the plants, which should be also *'based'* on the Huang study. The Appellants are aware of the growing conditions used in the Huang study as these are detailed in the study annexed to the Notice of Appeal. In the Huang study, under the title *'soil properties and preparation'*, the properties and preparation of the soil used in the experiment are explained in detail. Moreover, under the title *'pot experiment'*, the study explains the growing conditions of the plants before harvesting. The Board of Appeal further notes that reference to the soil properties and preparation can be found in OECD TG 307. However, there is no reference to growing conditions as in OECD TG 307 the use of plants is not foreseen. The Board of Appeal further observes that, regarding the growing conditions, the Contested Decision only requires that these conditions be *'based'* on the Huang study.
 175. The Board of Appeal observes also that, even if the requested test should follow only OECD TG 307 without the *'Huang deviation'*, a significant number of issues would remain potentially open as the test guideline does not impose strict conditions for the conduct of the test but leaves a significant degree of discretion to the personnel in charge of the test. With this in mind, the Board of Appeal notes that, for instance, when dealing with the choice of soils, OECD TG 307 states that:

'An OECD Workshop on soil and sediment selection, held at Belgirate, Italy in 1995 [...] agreed, in particular, on the number and types of soils for use in this test. The types of soils tested should be representative of the environmental conditions where use or release will occur. For example, chemicals that may be released in subtropical to tropical climates should be tested with Ferrasols or Nitosols (FAO system). The Workshop also made recommendations relating to collection, handling and storage of soil samples, based on the ISO Guidance [...]. The use of paddy (rice) soils is also considered in this Guideline.'

176. OECD TG 307 further provides:

'23. To determine the transformation pathway, a representative soil can be used; a sandy loam or silty loam or loam or loamy sand [...] with a pH of 5.5-8.0, an organic carbon content of 0.5 - 2.5% and a microbial biomass of at least 1% of total organic carbon is recommended [...].

24. For transformation rate studies at least three additional soils should be used representing a range of relevant soils. Those soils should vary in their organic carbon content, pH, clay content and microbial biomass [...].

25. All soils should be characterised, at least, for texture (% sand, % silt, % clay) [...], pH, cation exchange capacity, organic carbon, bulk density, water retention characteristic and microbial biomass (for aerobic studies only). Additional information on soil properties may be useful in interpreting the results. For determination of the soil characteristics [certain recommended methods] can be used. Microbial biomass should be determined by using the substrate-induced respiration (SIR) method [...] or alternative methods [...].'

177. By contrast, the Huang study describes the soil selection as follows:

'A loamy soil without detectable PBDEs was used in this experiment. Its selected characteristics are as follows: pH (H₂O) 7,32; organic matter 3,11%; cation exchange capacity, 25,0 cmol kg⁻¹; NaHCO₃ extractable P, 4,5 mg kg⁻¹; clay 23%; silt 35% and sand 32%.'

178. This means that the OECD test guideline is in practice less prescriptive on this issue than the Huang study. In fact, regarding soil selection, the Contested Decision does not refer to the Huang study, but rather refers to OECD TG 307, apart from requesting a higher volume of soil in order to permit the growing of plants. The Contested Decision also says that *'the soils should be free from contamination with potential transformation products and not contain stones'* and that *'the influence of soil organic/inorganic carbon content, pH, clay content and microbial biomass/activity shall be assessed by repeating relevant parts of the test with three additional soils (depending on the results of the main study)'*. The Board of Appeal finds therefore that the majority of the discretion in this regard comes from OECD TG 307 itself and not from the *'Huang deviations'*.

179. The Board of Appeal finds that the same can be said for other requests in the Contested Decision, as the concentration of the substance (dosing of the substance), the number of replicates, the shielding of vessels from dust contamination, the number of sampling intervals and the relevance of volatiles/mineralization products all come from OECD TG 307. For instance, OECD TG 307 provides on application rate (dosing of the substance):

'For general chemicals, the application rate should be estimated based on the most relevant route of entry; for example, when the major route of entry in soil is through sewage sludge, the chemical should be dosed into the sludge at a concentration that reflects the expected sludge concentration and the amount of sludge added to the soil should reflect normal sludge loading to agricultural soils. If this concentration is not high enough to identify major transformation products, incubation of separate soil

samples containing higher rates may be helpful, but excessive rates influencing soil microbial functions should be avoided.'

180. The Board of Appeal observes that the application of OECD TG 307 does not lead to a higher degree of precision than the Contested Decision as there is always an important margin of discretion left to the persons in charge of the tests. That margin of discretion is precisely what the Appellants are asking for when they say that that '*the testing conditions going beyond those of OECD guidelines should not be prescriptive so that the appellants could adapt them as the laboratory work is going on in order to ensure that meaningful results are generated and there is a reasonable certainty that the outcome of the test is compliant with the requirements of the contested decision*'. In this particular case, it is not the fact that the testing conditions as explained in the Contested Decision go beyond those of OECD TG 307 that leaves some issues open but that the conditions in OECD TG 307 itself leave a significant margin of discretion.
181. In this regard, the Board of Appeal fully recognises that complex questions may require complex approaches to address them, which is in part inherent in the nature of substance evaluation. However, on the one hand, it is not appropriate that a registrant who may be required to spend a considerable amount of time and money should be subject to considerable uncertainty as to whether the results of the tests conducted consequent to a decision will be useful and/or acceptable to the Agency. On the other hand, the Agency is not in a position to ensure certainty in this regard by including in a decision all the minute details of the testing required, thereby leaving the persons in charge of the testing no margin of discretion. Absolute certainty in decisions on complex testing requirements is both impossible and undesirable.
182. The Board of Appeal observes that in this case the Appellants are asking for a margin of discretion in how to conduct the requested tests and not a rigid statement of all the conditions to be met in the conduct of a test. It is not a legal flaw in a decision of the Agency if a margin of discretion is granted to the companies involved as this is often a necessity in the conduct of complex tests addressing complex issues. An Agency decision does however need to be clear in terms of the objectives pursued by the requested tests and to set-out important parameters for the conduct of those tests. It is then the responsibility of the registrant(s) to exercise any margin of discretion correctly to ensure that the objectives pursued are met. It is the responsibility of the Agency to decide, in a follow-up to a decision, whether the registrant(s) concerned have met the objectives pursued and applied any margin of discretion correctly.
183. In this regard, it must further be recalled that Article 41 of the Charter of Fundamental Rights of the European Union states that every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union. Article 10(3) of the European Code of Good Administrative Behaviour, issued by the European Ombudsman and endorsed by the European Parliament, also provides that the administration '*shall, where necessary, advise the public on how a matter which comes within [its] remit is to be pursued and how to proceed in dealing with the matter*'. Article 22(2) of that Code states that the administration shall '*provide members of the public with the information that they request. [It] shall take care that the information communicated is clear and understandable*'.
184. The Board of Appeal finds that, especially when novel or unusual test methods are required, it is incumbent on the Agency to work closely with the registrants concerned to maximise the probability of useful results arising from the requested testing (see, to that effect and by analogy, Case A-005-2011, *Honeywell Belgium*, Decision of the Board of Appeal of 29 April 2013, paragraph 200). The Board of Appeal observes that the Agency stated at the oral hearing that it was always available to provide contextual information to help remove uncertainties and clarify what is required. The Board of Appeal strongly supports such an approach and observes that this course of

- action is in line with the requirements of the European Code of Good Administrative Behaviour.
185. For the same reasons, it is also desirable that, where feasible and appropriate, the eMSCA concerned should also provide similar support to registrants. The Board of Appeal observes in this regard that in the present case the eMSCA was able, at the oral hearing, to clearly articulate its position on the discretionary issues in the conduct of the requested study. Many of these clarifications could have been usefully included in the Contested Decision. If the eMSCA's considerable insight and valuable expertise could also be made available to the Appellants before and during the conduct of the requested study, this would further contribute to maximising the possibility of useful results being produced to clarify the concern at issue.
 186. In conclusion, the Board of Appeal finds that the Agency could have, as part of its decision-making, placed greater emphasis on clarifying various issues with regard to the conduct of the requested study to help ensure that the study is conducted (from both a practical and a regulatory perspective) in such a way as to maximise the possibility of useful results being produced to clarify the concern posed by the Substance.
 187. Nevertheless, the Board of Appeal finds that, whilst the Contested Decision lacks clarity on certain aspects of the requested test, and in particular the modifications to OECD TG 307, this lack of clarity is not sufficient to justify an annulment of the Contested Decision.
 188. In particular the Board of Appeal has found that, in relation to this request for information, the Agency has demonstrated a concern that needs to be investigated further and clarified (see paragraph 81 above). The Board of Appeal also observes that the Appellants contest the adaptations to OECD TG 307 rather than the requirement to use the test guideline itself. In addition, and without this being a decisive consideration in the present case, the Board of Appeal takes the view that the provision of the requested information should not be delayed further by re-starting the decision-making procedure.
 189. With regard to the identification of the Substance and its transformation products in the requested study, the Appellants also claim that the Contested Decision requires a level of sensitivity unjustifiably higher than that specified in OECD TG 307. The Contested Decision states that *'[t]he focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1% (analytical sensitivity permitting)'*. OECD TG 307 states however, with regard to the sensitivity of the analytical method, that *'the limit of detection (LOD) of the analytical method for the test substance and for the transformation products should be at least 0.01 mg · kg⁻¹ soil (as test substance) or 1% of applied dose whichever is lower. The limit of quantification (LOQ) should also be specified'*. OECD TG 307 also says that *'the amounts of test substance, transformation products, volatile substances (in % only), and nonextractable should be given as % of applied initial amount and, where appropriate, as mg · kg⁻¹ soil (based on soil dry weight) for each sampling interval'* and goes on to say that *'major transformation products should be identified and their concentrations should also be plotted against time to show their rates of formation and decline. A major transformation product is any product representing ≥10% of applied dose at any time during the study'*. Insofar as the results of the test are focused on transformation products the Appellants claim that the applicable limit of detection (hereinafter the 'LOD') should be 10% and not 1% or 0.1%.
 190. The Appellants claim that the limit of detection of 0.1% is not justified and is not technically feasible.

191. Regarding the feasibility of the LOD, the Board of Appeal observes that the Contested Decision only requires the 0.1% LOD for the transformation products if it is technically possible after '*reasonable attempts*'. The Board of Appeal observes that there are no legal grounds to annul an obligation simply because it is predicated upon its technical feasibility. In fact, there are numerous European Regulations and Directives that predicate obligations on their technical feasibility. For example, Articles 4 and 5 of Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC, codified version as corrected, OJ L 229, 29.6.2004, p. 23), provide for the replacement of carcinogens or mutagens at work, or for the reduction of their use, '*in so far as is technically possible*'. The use of terms such as '*reasonable attempts*' and '*analytical sensitivity permitting*' to deal with uncertainty cannot therefore be deemed to be unlawful in itself. If a particular legal requirement, such as in the present case the requirement to quantify transformation products of the Substance '*down to 0.1%*', contains an inherent degree of uncertainty, a conditional obligation can be used to address that uncertainty. If, in the performance of the requested test, the Appellants find that it is technically impossible to reach the 0.1% LOD despite making reasonable efforts, then they should state that this is the case and why. It will then be for the Agency to evaluate the accuracy of that statement in its follow-up, and to act accordingly. The Appellant's arguments relating to the unlawfulness of the requested LOD must therefore be rejected.
192. The Board of Appeal will next consider whether the Contested Decision is lawful in introducing the change in LOD from that set out in OECD TG 307, that is a LOD of 0.1% and not 1% (EBP) or 10% (transformation products).
193. Regarding OECD TG 307, the Board of Appeal considers that the objective of the test is to identify transformation products within the limits of detection and not only major transformation products. Following OECD TG 307, the LOD of the analytical method for the test substance and the transformation products should be at least 0.01 mg · kg⁻¹ soil (as test substance) or 1% of applied dose whichever is lower. The Board of Appeal has previously held that under substance evaluation it may be appropriate to request information using modified test methods because this helps ensure that information generated pursuant to a substance evaluation decision meets real information needs (see the decision in *Akzo Nobel Industrial Chemicals and others*, cited at paragraph 87 above, paragraph 88). In the circumstances of this particular case, it is important to note that OECD TG 307 dates from 2002 and that the LOD that is now realistically and technically obtainable is several times of magnitude lower than it was in 2002. As a general point, the Board of Appeal notes that the LOD in OECD TG 307 is, broadly speaking, at the milli scale, that used in the Huang study was at the micro scale and that measuring at the nano scale is now potentially technically feasible. Furthermore, the Board of Appeal notes that if a LOD of 1% had been applied in the Huang study several of the lower brominated congeners, potentially those that are most likely to have PBT/vPvB properties, would not have been detected.
194. In light of the above, it must be concluded that the requirement to quantify transformation products of the Substance at levels lower than those foreseen in OECD TG 307 is conditional on technical feasibility and the making of '*reasonable attempts*' to quantify transformation products of the Substance '*down to 0.1% (analytical sensitivity permitting)*'. The Board of Appeal also notes that the transformation products identified between a LOD of 0.1% and 1% are potentially the most likely to have PBT/vPvB properties, and that the requested test is designed to clarify a concern that those transformation products may have PBT/vPvB properties. The Board of Appeal finds therefore that Agency, in the Contested Decision, was justified in

deviating from the LOD established in OECD TG 307 and the Appellants' arguments in that regard must be rejected as unfounded.

(iii) Sediment simulation testing protocol (OECD Test Guideline 308)

195. Regarding the sediment simulation testing protocol (OECD TG 308), the Appellants confine themselves to questioning the LOD requested by the Contested Decision. According to the Contested Decision *'the focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1%'*. OECD TG 308 states that *the limit of detection (LOD) of the analytical method for the test substance and for the transformation products should be at least 0.01 mg · kg⁻¹ in water or sediment (as test substance) or 1% of the initial amount applied to a test system whichever is lower'*. However, OECD TG 308 provides that *'[c]oncentration of the test substance and the transformation products at every sampling time in water and sediment should be measured and reported (as a concentration and as percentage of applied). In general, transformation products detected at ≥10% of the applied radioactivity in the total water-sediment system at any sampling time should be identified unless reasonably justified otherwise. Transformation products for which concentrations are continuously increasing during the study should also be considered for identification, even if their concentrations do not exceed the limits given above, as this may indicate persistence. The latter should be considered on a case by case basis, with justifications being provided in the report'*.
196. The Board of Appeal has already found, for the reasons stated in paragraphs 192 to 194 above, that the Agency, in the Contested Decision, was justified in deviating from the LOD established in OECD TG 307. For the same reasons, the Agency was also justified in deviating from the LOD established in OECD TG 308 and the Appellants' arguments in that regard must be rejected.

V. Allegedly inappropriate deadline imposed to provide the requested information

Arguments of the Parties

197. The Appellants claim that the deadline for submitting the information given in the Contested Decision, namely 2 years, 6 months and 6 days, is not appropriate and is therefore unlawful. The Appellants argue that the requested tests alone would take longer to perform than the deadline given and additional time is required to analyse the results and to prepare a dossier update. The Appellants claim inter alia that two of the laboratories they contacted with a view to performing the tests foresee additional workload due to the deviations from the test guidelines required in the Contested Decision. The Appellants estimate that the total time for the requested tests, analysis of results and preparation of a dossier update is 39 months.
198. The Appellants state that the main reason an extension of the deadline foreseen in the Contested Decision is needed is because it takes a number of months to generate the radiolabelled substance. The testing on radiolabelled material can only begin once that material is available.
199. The Appellants also argue that the Agency failed to take into consideration a number of factors when setting the deadline. For example, the test houses contacted have provided an earliest date on which they can commence the studies which does not allow compliance with the deadline set in the Contested Decision. The Appellants add that weather conditions may also be a limiting factor for the soil studies.

200. The Agency states that the Appellants' estimate of the timeframe needed to conduct the tests is highly exaggerated and that the 30 months provided for the generation of that data are sufficient. In particular, the Agency argues that the Appellants have ignored the fact that the tests can be conducted in parallel. The Agency also argues that the quotes from laboratories provided by the Appellants do not confirm that the information cannot be generated within the time-limit set in the Contested Decision as either they involve a considerable delay in commencing the testing or in fact indicate that the Contested Decision can be complied with.

Findings of the Board of Appeal

201. The Board of Appeal does not consider that the estimates provided by the two test houses for performing the tests demonstrate that the information requested cannot be provided by the deadline set in the Contested Decision. The Board of Appeal highlights that certain of the testing requirements could be conducted in parallel. Moreover, the lapse of 10 to 11 months foreseen by the Appellants before testing can commence is exaggerated and, as the Agency explained at the hearing, certain preparatory work is already foreseen in the deadline set.
202. In addition, the Board of Appeal observes that the Appellants' arguments on this issue are inconsistent. For example, the Appellants claim in the Notice of Appeal that 39 months are required to perform the testing and later in their submissions argue that 36 months are required. Similarly the Appellants have at different times argued that 6 months are required for preparing the radiolabelled substance and at another they have claimed that 3 to 4 months are sufficient.
203. The Board of Appeal considers therefore that the Appellants have not established that the deadline in the Contested Decision is incorrect nor why additional time would be required to comply with the Contested Decision. The Appellants' plea regarding the inadequacy of the deadline set in the Contested Decision to provide the requested information is therefore dismissed.
204. In any event, the Board of Appeal observes that the time-limit set in the Contested Decision must be appraised taking into account the Board of Appeal's findings in the present case. For example, the Board of Appeal has decided that the requirement to provide information on vitellogenin induction should be removed from the Contested Decision and that certain amendments should be made to the test protocols prescribed for performing the tests (see paragraphs 105 and 144 above). As a consequence of the present decision of the Board of Appeal and in light of the suspensive effect of appeal proceedings, the Appellants will have the same amount of time as originally set by the Contested Decision to conduct fewer tests.

VI. *Alleged infringement of the principle of legal certainty and the principle of the protection of legitimate expectations*

Arguments of the Parties

205. The Appellants claim that because of the extensive use of undefined and unsubstantiated terms in the context of the legal obligations imposed on the Appellants, the Contested Decision infringes the principle of legal certainty and breaches the Appellants' legitimate expectations.
206. The Appellants argue that the Agency's actions and communications related to substance evaluation must observe the principles of good administration and legitimate expectations, including the requirement of clarity. In particular, the

- Appellants submit that the Agency is required to communicate with them in the Contested Decision in a clear, precise and accurate manner.
207. The Appellants also claim that where a final decision deviates substantially from the previous draft versions, there are grounds to challenge that decision on the basis that the principle of the protection of legitimate expectations and the principle of legal certainty have not been respected.
208. In particular the Appellants submit that there is no indication whatsoever in ECHA Guidance that ECHA can and will adopt decisions under Article 46(1) which: (i) require addressees of a substance evaluation to provide data on competitors' substances not subject to the Contested Decision; (ii) impact on entities which have not participated in the substance evaluation procedure; and (iii) where there is a significant degree of legal uncertainty as to whether the addressees of the decision can, in fact and in law, provide the data required.
209. The Appellants also claim that the Contested Decision imposes obligations that are expressed through undefined and uncertain terms, such as '*Registrant(s)*', '*commercial substance*' and '*registered substance*', thereby placing the Appellants in a situation in which the actions to be undertaken to ensure compliance with their obligations are uncertain. The Appellants add that it is unclear in the Contested Decision what is meant by '*registered substance*' and that the Appellants cannot know from the Contested Decision which forms of the Substance should be tested.
210. The Agency argues that it is unequivocally clear that the Contested Decision is only binding on its addressees and that the wording of the Contested Decision is clear.
211. The Agency also argues that there is consistent case-law providing that the statement of reasons must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter. Where the persons concerned are involved in the process by which a measure comes about, requirement to state reasons may be circumscribed, since those persons acquire information through their involvement. The Agency argues that the threshold for the obligation to state reasons should be set at a level that reflects the fact that the Appellant was involved in the decision making process laid down in Articles 50 and 51.

Findings of the Board of Appeal

212. In view of the Board of Appeal's findings in particular regarding the clarification of the substance to be tested and the use of conditional terms such as '*reasonable attempts*' and '*analytical sensitivity permitting*' in the Contested Decision, the Board of Appeal considers that it is not necessary to specifically address the Appellants' pleas alleging the infringement of the principle of legal certainty and of the Appellants' legitimate expectations.

VII. Alleged breach of the right to be heard

Arguments of the Parties

213. The Appellants submit that, by not taking into account their comments on the revised draft decision, submitted on 7 January 2014, the Agency infringed their right to be heard, and as a result the Contested Decision should be annulled. The Appellants claim that Article 51(5) does not restrict the right of registrants to submit comments on proposals for amendments only. The Appellants further argue that Article 51(5) must be read in light of Article 41(2) of the Charter of Fundamental Rights of the European Union and of the fact that concerned registrants, such as the Appellants, are given the right to comment throughout the substance evaluation procedure.

214. The Appellants also submit that the Agency breached the Appellants' right to be heard by not allowing them to comment on the changes to the Contested Decision introduced during the MSC meeting at which the decision was agreed.
215. The Agency states that the Appellants were given the opportunities to provide observations as foreseen in the REACH Regulation. In addition, one of the Appellants was present at the MSC meeting held on 4 February 2014, where it was invited to articulate its views. This constitutes an additional safeguard not foreseen in the REACH Regulation.
216. The Agency states that whilst the REACH Regulation grants a right to comment on proposals for amendment, it does not grant registrants the right to comment on the updated version of the draft decision that is sent to the MSCAs prior to the MSC meeting, nor on the amendments made at the meeting of the MSC. According to the Agency, such a process could lead to a never-ending circle of commenting rounds, as the eMSCA and the Agency would need in turn to respond to any comments by registrants.
217. The Agency also argues that if the MSC were to consult the Appellants on the final outcome of its deliberations it would not be possible to respect the 60 days deadline of Article 51(6) to unanimously agree on the decision.

Findings of the Board of Appeal

218. The present plea consists of two parts, which it is appropriate to examine separately.
219. By the first part of the present plea, the Appellants claim that, by not taking their comments of 7 January 2014 on the revised draft decision into account in so far as they did not relate to the proposals for amendment, the Agency infringed their right to be heard.
220. The Contested Decision states that:

'By 7 January 2014, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. In addition, the Registrant(s) provided comments on the draft decision. The [MSC] took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrants' comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).'
221. The Board of Appeal observes that the right to comment on amendments to a draft decision which did not relate to proposals for amendment is not foreseen in the REACH Regulation and in particular in Article 51(2) to (8) and Article 52, which set out the procedure for the adoption of decisions under substance evaluation. The situation at dispute in the present proceedings is therefore not covered by the procedural rules set out in the REACH Regulation.
222. In this respect, the Board of Appeal has previously held that Article 51(5) must be understood as giving the Appellants the opportunity to comment on any proposals for amendment to the draft decision and not once more on the draft decision itself. As the Appellants' comments did not relate to the proposals for amendment of the draft decision the Agency was therefore justified in not considering those comments (see, to that effect, the decision in *International Flavors & Fragrances*, cited at paragraph 71 above, paragraph 117).
223. The Board of Appeal also observes however that in accordance with Article 41(2) of the Charter of Fundamental Rights of the European Union the right to good

administration includes *'the right of every person to be heard, before any individual measure which would affect him or her adversely is taken'*.

224. Furthermore, in accordance with settled case-law of the European Union Courts, observance of 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 European Union law which must be guaranteed even in the absence of any rules governing the proceedings in question (see Case C-32/95 P, *Commission v Lisrestal and Others*, EU:C:1996:402, paragraph 21). That principle requires that the addressee of a decision which significantly affects its interests should be given the opportunity to effectively make known its views on the correctness and relevance of the facts, objections and circumstances put forward by the institution (see, for example, Case T-314/01, *Avebe v Commission*, EU:T:2006:266, paragraph 49 and the case-law cited).
225. The Board of Appeal therefore considers that in certain circumstances it is possible that the addressees of a decision should be given the opportunity to comment beyond the opportunities foreseen in Articles 51(2) to (8) and 52.
226. In the present case, however, the Board of Appeal considers that the Appellants have not adequately justified their claim in this regard. The Appellants have not identified in their submissions any facts, objections and circumstances on which the Contested Decision was based and on which they were not given the opportunity to effectively make known their views during the substance evaluation procedure and the decision-making process. The Appellants have not therefore demonstrated that they should have been granted opportunities to comment beyond those specifically foreseen in the REACH Regulation. The first part of this plea is therefore dismissed.
227. By the second part of the present plea, the Appellants claim that the Agency breached their right to be heard by not allowing them to comment on the changes introduced during the MSC meeting at which the Contested Decision was agreed.
228. The Contested Decision states in this regard that *'[a]fter discussion in the [MSC] meeting on 3 to 7 February 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 6 February 2014'*.
229. For the reasons set out in paragraphs 221 to 224 above, the Board of Appeal considers that although the right to comment on amendments to a draft decision made at the MSC is not foreseen in the REACH Regulation, it is possible that the addressees of that decision could, depending on the nature of those amendments, potentially be entitled to make known their views on them.
230. The Board of Appeal finds, however, that the Appellants have not identified in their pleadings any elements capable of giving rise to a right to comment beyond the opportunities already foreseen in the REACH Regulation. The second part of the present plea must therefore also be rejected.
231. The Appellants' plea regarding the breach of the right to be heard is therefore dismissed.

Refund of the appeal fee

232. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

233. As the appeal has been decided in favour of the Appellants in several important respects, and in light of the particular circumstances of the case, the appeal fee shall be refunded.

Effects of the Contested Decision

234. According to Article 91(2), an appeal before the Board of Appeal shall have suspensive effect.

235. The Contested Decision, partially upheld in the present appeal proceedings, required the registrants, now the Appellants, to submit the required information by 29 November 2016, which is 2 years, 6 months and 6 days from the adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in the light of the principle of suspensive effect laid down in Article 91(2), as if it referred to 2 years, 6 months and 6 days from the date of notification of the final decision of the Board of Appeal.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls all elements of the Contested Decision that instruct, or imply, that the Substance to be tested is anything other than a representative sample of the Substance as registered by the addressees of the Contested Decision.**
- 2. Annuls the requirement to provide information on vitellogenin determination.**
- 3. Dismisses the appeal for the remainder.**
- 4. Decides that the information required by the Contested Decision shall be submitted by 19 January 2019.**
- 5. Orders the refund of the appeal fee.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal