EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

09 September 2015

(Substance evaluation - UVCB - Misuse of power - Proportionality - Animal welfare - Legitimate expectations - Equal treatment - Good administration - Duty to state reasons)

Case number	A-004-2014
Language of the case	English
Appellants	Altair Chimica SpA, Italy Caffaro Industrie SpA, Italy Fortischem a.s., Slovakia Ineos Chlorvinyls Limited, United Kingdom Ineos Enterprises France Z.I., France Kaustik Europe B.V., Netherlands Leuna-Tenside GmbH, Germany Prakash Chemicals Europe B.V., Netherlands Química del Cinca, S.L., Spain
Representatives	Herbert Estreicher and Marcus Navin-Jones, Keller and Heckman LLP
Intervener	REACHLaw Oy, Finland
Contested Decision	Decision of 25 February 2014 on the substance evaluation of alkanes, C_{14-17}, chloro (medium-chain chlorinated paraffins) 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-2114273983-36-01/F, SEV-D-2114273973-37-01/F, SEV-D-2114273975-33-01/F, SEV-D-2114273969-26-01/F, SEV-D-2114273977-29-01/F, SEV-D-2114273979-25-01/F, SEV-D-2114273972-39-01/F, SEV-D-2114273980-42-01/F, and SEV-D-2114273978-27-01/F

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Barry Doherty (Legally Qualified Member)

Registrar: Sari Haukka

gives the following

Decision

Summary of the facts

1. On 16 May 2014, the Appellants lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision.

2. The Appellants request the Board of Appeal to:
   - set aside the Contested Decision, which requests the Appellants to submit certain information on medium-chain chlorinated paraffins (hereinafter 'MCCP' or the 'Substance') by 25 February 2017. For some of the requested information the Contested Decision also indicates the test methods to be used for the generation of such information and the specific composition of MCCP to be tested,
   - order the reimbursement of the costs incurred by the Appellants in these appeal proceedings, and
   - refund the appeal fee.

Background to the dispute

3. MCCP is a substance of unknown or variable composition, complex reaction products or biological materials (hereinafter 'UVCB') containing linear chloroalkanes predominantly in the range of C_{14-17} and with chlorination levels generally in the range of 40-70% by weight. The use of MCCP supports manufacturing operations in the aerospace, automotive, construction and mining industries, as well as other industrial operations.

4. On the basis of an opinion of the European Chemicals Agency's Member State Committee (hereinafter 'MSC'), MCCP was included in the community rolling action plan (hereinafter 'CoRAP') for substance evaluation pursuant to Article 44(2) (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise) to be evaluated in 2012. The initial grounds of concern that led to the Substance being placed on CoRAP were the need to check exposure scenarios with regard to environmental exposure to ensure that the risk characterisation ratios are below one for identified uses, and to review the registrants' persistence, bioaccummulation and toxicity (hereinafter 'PBT') assessment for the Substance. The CoRAP was published on the website of European Chemicals Agency (hereinafter the 'Agency') on 29 February 2012. The evaluating Member State Competent Authority appointed to carry out the evaluation was the United Kingdom (hereinafter the 'eMSCA').

5. In September 2012, the eMSCA provided the Appellants with a copy of the draft substance evaluation report. On 15 October 2012, the eMSCA and representatives of the Appellants held a meeting regarding the report. On 4 November 2012, the MCCP REACH Consortium, the platform through which the Appellants spoke with one voice in the substance evaluation procedure, submitted its comments on the report and on 12 November 2012 the eMSCA responded in writing to the comments and revised the draft report accordingly.

6. The eMSCA considered that further information was required to clarify the concerns that had led to MCCP being placed on CoRAP. The eMSCA therefore prepared a draft decision pursuant to Article 46(1) to request further information. The eMSCA submitted the draft decision to the Agency on 27 February 2013.

7. On 4 April 2013, the Agency sent the draft decision to the Appellants and invited them, pursuant to Article 50(1), to provide comments within 30 days. On 3 May 2013, the Appellants provided comments on the draft decision. On 10 May 2013, the Agency notified the eMSCA of the comments received. The eMSCA subsequently revised the draft decision.

8. On 5 September 2013, in accordance with Article 52(1), the eMSCA notified the Competent Authorities of the other Member States and the Agency of its revised draft decision and invited them, pursuant to Articles 52(2) and 51(2), to submit proposals to amend the revised draft decision within 30 days. Subsequently, the Agency submitted proposals for amendment.

9. On 11 October 2013, the Agency notified the Appellants of the proposals for amendment to the revised draft decision and invited them, pursuant to Articles 52(2) and 51(5), to provide comments on the proposals for amendment within 30 days.

10. The eMSCA reviewed the Agency's proposals for amendment and further amended the revised draft decision accordingly.

11. On 21 October 2013, the Agency referred the amended draft decision to the MSC.

12. On 8 November 2013, the Appellants provided comments on the proposed amendments and on the amended draft decision.

13. On 6 December 2013, the MCCP REACH Consortium sent a letter to the MSC outlining its *'concerns with the persistence and bioaccumulation aspects of the MCCP substance evaluation and proposed testing plan to further evaluate these endpoints'*.

14. After discussion in the MSC meeting of 10-13 December 2013, at which a representative of the Appellants was present, a unanimous agreement of the MSC on the amended draft decision was reached.

15. On 25 February 2014, the Agency adopted and notified the Contested Decision to the Appellants. The Contested Decision requests additional information for MCCP including:

    (a) Information on the amounts of carbon chain lengths shorter than C_{14} that are present at or above 0.1 % weight by weight (hereinafter 'w/w') for all of the MCCP product types supplied by the registrants;

(b) Bioaccumulation in fish: Aqueous and Dietary Exposure [OECD test guideline (hereinafter 'OECD TG') 305]. Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 50-52% by weight;
(c) Bioaccumulation in fish: Aqueous and Dietary Exposure (OECD TG 305). Exposure can be either via aqueous or dietary exposure, and the test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 55-60% by weight;
(d) Aerobic and anaerobic transformation in aquatic sediment systems (EU TMC.24/OECD TG 308). The test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 50-52% by weight;
(e) Aerobic and anaerobic transformation in aquatic sediment systems (EU TMC.24/OECD TG 308). The test substance shall be a C_{14} chlorinated n-alkane with a chlorine content of 55-60% by weight;
(f) Aerobic and anaerobic transformation in aquatic sediment systems (EU TM C.24/OECD TG 308). The test substance shall be a C_{15} chlorinated n-alkane with a chlorine content of around 51% by weight;
(g) A PBT assessment for all relevant constituents of the substance and any transformation product found to be formed in a relevant environmental compartment at any time point, at a concentration exceeding or equal to 0.1 % w/w (grouped as appropriate).

Procedure before the Board of Appeal

16. On 16 May 2014, the Appellants lodged the present appeal (see paragraphs 1 and 2 above).

17. On 2 and 3 July 2014 respectively, the Danish REACH Competent Authority and the UK REACH Competent Authority applied to intervene in the proceedings before the Board of Appeal in support of the Agency. By separate decisions of 10 October 2014, the Board of Appeal, having heard the Parties, dismissed both applications to intervene due to the fact that they did not fulfil all the necessary requirements for intervention stipulated in Article 8 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').

18. On 7 July 2014, REACHLaw Oy applied to intervene in the proceedings before the Board of Appeal supporting the remedy sought by the Appellants and their arguments. By decision of 6 October 2014, the Board of Appeal, having heard the Parties, granted REACHLaw Oy's application to intervene.

19. On 1 September 2014, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

20. On 29 September 2014, the Board of Appeal requested the Appellants to submit their observations on the Defence. The Appellants lodged their observations on 28 November 2014.

21. On 14 November 2014, REACHLaw Oy (hereinafter the 'Intervener') informed the Board of Appeal that it did not intend to submit further observations on the Notice of Appeal and the Defence.

22. On 12 December 2014, in accordance with Article 15(2)(c) of the Rules of Procedure, the Board of Appeal invited the Appellants to clarify their pleas in law and arguments. The Appellants were reminded of the procedural requirement that the submissions made by an appellant must be sufficiently clear and precise to enable the Agency to defend itself and the Board of Appeal to rule on the appeal, if appropriate without any other information. The Board of Appeal underlined that it had found it extremely difficult to identify clearly the precise pleas in law raised by the Appellants in their submissions, and what facts were invoked in support of each plea.

23. The Board of Appeal's request included the following:

'The Board of Appeal invites you to provide a clear, precise and exhaustive list of all pleas raised in your Notice of Appeal. In addition, in order to guarantee legal certainty and sound administration of the appeal proceedings, you are requested to indicate, for each of these pleas, the paragraph(s) of the Notice of Appeal and of the subsequent observations on the Defence that contain the arguments raised in support.'

The Board of Appeal highlighted that *'this request is not an opportunity to expand on your arguments or to add new arguments'.*

24. In response to the Board of Appeal's request, the Appellants provided a clarification document on 13 January 2015 with a list of pleas and arguments.

25. On 6 March 2015, the Board of Appeal invited the Agency to provide observations on the Appellants' observations on the Defence in light of the clarifications provided by the Appellants and to respond to certain questions. The Agency submitted its response and observations on 10 April 2015.

26. On 17 April 2015, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 30 April 2015 and 4 May 2015 respectively, the Appellants and the Agency informed the Board of Appeal that they did not request a hearing. On 20 May 2015, the Parties were notified of the Board of Appeal's decision that it was not necessary to hold a hearing in this case.

Reasons

27. At the outset, the Board of Appeal observes that, even after the opportunity given to the Appellants to clarify their pleas in law and arguments (see paragraphs 22 to 24 above), the Board of Appeal still found it difficult in places to identify and follow the Appellants' pleas and corresponding arguments due to shortcomings in the Appellants' submissions in terms of clarity, structure, and substance.

28. In light of the clarifications document provided by the Appellants on 13 January 2015 and the Appellants' other submissions, the Board of Appeal has identified ten pleas. The first (manifest error of assessment), second (misuse of powers), and third (acting outside the scope of discretionary powers) pleas are based on the shared claim that the information requested in the Contested Decision has no realistic prospect of providing scientifically reliable data to clarify whether the Substance has PBT properties. By the fourth plea, the Appellants claim that the Agency breached the principle of proportionality. By the fifth plea, the Appellants claim that the Agency acted in breach of animal welfare requirements. The sixth plea consists of the claim that the Agency breached the principles of legitimate expectations and legal certainty.

The seventh plea is based on the claim that the Agency breached its duty to state reasons. The eighth and ninth pleas are based on the claim that the Agency breached the principles of equal treatment, good administration, and transparency by not addressing the Contested Decision to all MCCP registrants. Finally, by their tenth plea, the Appellants claim that the Agency violated the principles of good administration and due process by refusing to circulate to the MSC a document provided by the Appellants.

29. The Board of Appeal notes that, despite shortcomings observed by the Board of Appeal in the Notice of Appeal, the Agency was able to respond and structured its Defence in a similar manner to the ten pleas identified above. In their observations on the Defence, the Appellants did not object to the manner in which the Agency interpreted their pleas.

The first, second, and third pleas alleging manifest errors of assessment, misuse of powers, and that the Agency acted outside the scope of its discretionary powers

30. The Board of Appeal observes that the first, second, and third pleas are based on the same factual claims. It is therefore appropriate to examine them together.

Arguments of the Parties

31. In support of their first, second, and third pleas, the Appellants claim that the information requested in the Contested Decision has no realistic prospect of providing scientifically reliable data to clarify whether the Substance has PBT or very persistent and very bioaccumulative (hereinafter 'vPvB') properties.

32. In particular, the Appellants claim that the Agency's approach to evaluating the properties of the Substance using a *'constituents-based fractionation testing approach'* is flawed. According to the Appellants, the constituents of the Substance cannot currently be identified and the materials that need to be tested according to the Contested Decision (hereinafter 'test materials') are themselves UVCBs. The Appellants add that if these test materials were to be produced commercially they would require new CAS numbers for substance identification purposes and would be subject to registration as different substances, UVCBs, under the REACH Regulation.

33. In addition, according to the Appellants, whether the test materials specified in the Contested Decision have PBT/vPvB properties will not depend on the carbon chain length and chlorination level alone, as suggested in the Contested Decision. The Appellants submit that, although the underlying factors driving the possible PBT/vPvB properties of the constituents of the Substance are not yet fully understood, one of the primary drivers is very likely to be the distribution of the chlorine atoms along the carbon chain length of particular linear alkanes, relating to the number and distribution of carbon-chlorine bonds. The constituents-based fractionation testing approach followed in the Contested Decision does not take account of this factor in defining the test materials. The Appellants further contend that the Agency and the eMSCA have not established a clear scientific rationale justifying why testing on specified carbon chain length test materials is more appropriate than testing the Substance across the range of chlorination levels. The Appellants claim that the carbon chain length distribution in the Substance is very narrow, limited to $C_{14\text{-}17}$. As a result, if there is any correlation between chain length and PBT/vPvB characteristics it will be weak and not relevant for a chemical with such a narrow chain length distribution.

34. Furthermore, the Appellants claim that the testing requested in the Contested Decision contradicts the Agency's own policy requiring testing on constituents of a substance only if the constituent in question exceeds 0.1% w/w. According to the Appellants, this policy is stipulated in the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, version 1 (hereinafter the 'Agency Guidance'). Moreover, the Appellants claim that this policy was upheld by the General Court in Case T-93/10, *Bilbaína de Alquitranes and Others* v *ECHA* (EU:T:2013:106). The Appellants submit that no single constituent of the Substance will ever be present at levels exceeding or equal to 0.1% w/w. Consequently, even if a single constituent of the Substance is regarded as being a PBT, that constituent will never be contained within the Substance above the 0.1% w/w threshold. As a result, that constituent would not trigger classification of the Substance as a PBT or vPvB.

35. The Appellants further claim that OECD TG 308, identified in the Contested Decision for persistence testing, is fundamentally inappropriate for testing either the Substance or the test materials identified in the Contested Decision. There are too many limitations associated with the use of this test method and in particular for a substance like MCCP. OECD TG 308 combines many different environmental compartments and conditions and the matrix of these combined conditions makes it impossible to draw meaningful conclusions on the behaviour and fate of the Substance.

36. The Appellants add that they recently commissioned OECD TG 301 D studies on a chlorinated n-pentadecane (C_{15}), 51% chlorination by weight, test material as identified in the Contested Decision. This was conducted using a similar set-up to earlier testing on C_{14} chloroalkanes which is summarised in the registration dossier for the Substance. The OECD TG 301 D studies demonstrated over 60% biodegradation, and complete mineralization, by day 60 indicating that the test substance is inherently biodegradable and not persistent. The Appellants believe that the results of these studies make the requested OECD TG 308 with the test material being a C_{15} chlorinated *n*-alkane with a chlorine content of around 51% by weight unnecessary.

37. The Appellants further disagree with the Contested Decision that conducting fish bioconcentration factor (hereinafter 'BCF') tests is the most appropriate means of evaluating the bioaccumulation of the Substance. The Appellants submit that the analysis, commissioned by the Appellants to assess the bioaccumulation of the Substance and the utility of BCF tests, emphasises the importance of biotransformation and elimination rates in assessing bioaccumulation potential. This analysis indicates that additional BCF tests will probably result in similar elimination rates to those seen for constituents of the Substance and therefore will not provide any new insights into the bioaccumulation potential of the Substance. The Appellants submit that the Agency should examine bioaccumulation for the Substance primarily on the basis of its biomagnification factor (hereinafter 'BMF') and tropic magnification factor (hereinafter 'TMF'). The Appellants claim that using BMF and TMF provides a number of inherent benefits such as being more relevant for assessing the bioaccumulation potential of a substance in the environment and a metric which directly measures bioaccumulation. The Appellants add that while the Agency claims that BMF studies have experimental limitations it does not explain what it feels these limitations are or how they pertain to the specific data cited in the bioaccumulation assessments of the Substance. Moreover, the two BCF studies that the Agency is requesting will cost € 200 000 or more taking into account the expense of synthesizing both cold and radiolabelled test materials.

38. The Agency disputes the merits of the Appellants' arguments.

Findings of the Board of Appeal

39. At the outset, the Board of Appeal recalls that the REACH Regulation, as is clear from Article 1 thereof, aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. Importantly, regard being had to Recital 16 of the REACH Regulation, it must be stated that the Community legislature established the first of those three objectives, namely to ensure a high level of protection of human health and the environment, as the main purpose of the REACH Regulation (see Case C−558/07, *S.P.C.M. and Others*, EU:C:2009:430, paragraph 45).

40. As regards substance evaluation, Recital 66 of the REACH Regulation states that *'the Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to human health or the environment, including by reason of their presence on the internal market in high volumes, on the basis of evaluations performed'.* In addition, Recital 68 of the REACH Regulation states that *'evaluation may lead to the conclusion that action should be taken under the restriction or authorisation procedures or that risk management action should be considered in the framework of other appropriate legislation […]'.*

41. In that context, the Board of Appeal acknowledges that, if the Agency is to be able to pursue effectively its role under the REACH Regulation, and in particular in the framework of substance evaluation, account being taken of the technical assessments which it must undertake, the Agency must be recognised as enjoying a broad discretion (see Case T-96/10, *Rütgers Germany and Others* v *ECHA*, EU:T:2013:109, paragraph 134). The exercise of that discretion is not, however, excluded from review by the Board of Appeal.

42. In particular, when an appellant claims that the Agency has made a manifest error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached (see, by analogy, Case T-71/10, *Xeda International and Pace International* v *Commission*, EU:T:2012:18, paragraph 71).

43. When an appellant claims that the Agency misused its powers, the Board of Appeal must examine whether the Agency adopted a measure with the exclusive or main purpose of achieving an end other than that stated or evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case (see Case C-84/94, *United Kingdom* v *Council*, EU:C:1996:431, paragraph 69). The Board of Appeal observes that the acts of the European Union (hereinafter 'EU') institutions and agencies are in principle presumed to be lawful until such time as they are annulled or withdrawn (see, by analogy, Case C-344/98, *Masterfoods and HB*, EU:C:2000:689, paragraph 53). It is therefore for the appellant to adduce objective evidence that the Agency acted unlawfully by misusing its power.

44. When an appellant claims that the Agency acted outside its discretionary powers, the Board of Appeal must examine whether, in adopting the act, the Agency exercised its discretion correctly, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate (see Case

A-005-2011, *Honeywell Belgium N.V.,* Decision of the Board of Appeal of 29 April 2013, paragraph 77, and Case A-001-2012, *Dow Benelux B.V.*, Decision of the Board of Appeal of 19 June 2013, paragraph 114).

45. It is in the light of those considerations that the arguments put forward by the Appellants in support of their first, second, and third pleas must be examined.

46. The Board of Appeal will address the Appellants' arguments in four groups as follows: first, the arguments that concern the constituents-based fractionation testing approach; second, the claims regarding the existence of a 0.1% w/w threshold for analysis of the PBT/vPvB properties of constituents of a substance; third, the arguments relating to OECD TG 308 and the assessment of the persistence of the Substance, and fourth, the claims that relate to the BCF tests and the assessment of the bioaccumulation of the Substance.

(i) Constituents-based fractionation testing approach

47. The Appellants essentially claim that the Agency's decision to evaluate the properties of the Substance using a constituents-based fractionation testing approach is flawed (see paragraphs 32 and 33 above).

48. In the Contested Decision, the Agency acknowledges that *'the [Appellants] believe that a whole product testing approach would be preferable'*. The Agency explains however that testing the whole substance will not generate useful information for direct comparison with the criteria of Annex XIII because a single representative sample of MCCP does not exist due to the range of chlorination and carbon chain length distribution. According to the Agency, a whole substance approach also cannot distinguish different levels of hazard, in terms of the combinations of properties, between relevant constituents.

49. The Board of Appeal observes that, as acknowledged by the MCCP REACH Consortium in the document 'Definition of MCCP' annexed to the Notice of Appeal, the Substance contains many constituents with varying chlorine content and with a range of carbon chain lengths, with the predominant carbon number distribution ranging between, but not limited to, $C_{14\text{-}17}$. The Board of Appeal notes that the registrants of the Substance have decided on the substance identity profile for the Substance as set out in the document 'Definition of MCCP'. The registered substance is MCCP and not 'commercial MCCP' or some other subset of MCCP. Whilst individual registrants of the Substance have to indicate precisely what they manufacture in, or import into, the EU through the provision of registrant specific substance identity information, the substance evaluation in question has to address MCCP as a whole. The Board of Appeal observes that the registrants of MCCP could have submitted registrations for several different substances, in effect subsets of what is covered by the profile of MCCP. The Appellants therefore chose to register MCCP as a single substance, despite the complex composition of MCCP and the fact that, according to the Appellants, the constituents of the Substance cannot currently be identified. The choice of how to define the scope of a joint registration is the responsibility of the registrants concerned and may have implications for the relevant duties and obligations pursuant to the REACH Regulation.

50. The Board of Appeal, recognising that the Substance is a complex UVCB and that there is no single representative test material for all compositions of MCCP, accepts that there are difficulties in selecting appropriate test materials. However, the Board of Appeal finds that the substance evaluation has identified several carbon chain length and chlorine content combinations present in the Substance that potentially meet the

PBT screening criteria and accepts therefore that it is appropriate to generate further information on these constituents to clarify this PBT concern. The Board of Appeal also finds that since these particular combinations may not exist in isolation it is appropriate to follow a constituents-based fractionation testing approach. This approach is to conduct testing on test materials that are broadly representative of these combinations on the basis of likely physico-chemical properties, whilst recognising that the test materials themselves are not commercial products. The Board of Appeal notes that the approach followed by the Agency is not novel for the assessment of this type of substance. The Appellants themselves cite data in their registrations for test materials with specific chain lengths and chlorination levels.

51. The Board of Appeal also accepts that, as stated in the draft substance evaluation report and summarised in the Contested Decision, it is not feasible to determine the PBT properties of each constituent of the Substance based on experimental information. A read-across/modelling approach has therefore been used to estimate the persistence and bioaccumulation properties of the Substance and is explained in detail in the draft substance evaluation report. The constituents of MCCP that potentially meet the persistence criterion are not necessarily the same as those that potentially meet the bioaccumulation criterion and vice versa. In addition, as explained in the draft substance evaluation report and summarised in the Contested Decision, for MCCP products containing 50% chlorine by weight or more, $C_{<14}$ constituents of MCCPs might have a problematic persistence and bioaccumulation profile, especially at chlorination levels of 65% by weight or more. In addition, some of the main constituents of MCCP, and in particular C_{14} constituents with chlorine contents in the range 50-56% by weight and C_{15} constituents with ~51% by weight chlorine content, are potentially PBT. The C_{16} and C_{17} chain lengths do not appear to be of concern. At the same time, the PBT profile for some of the constituents is uncertain because of inherent limitations in the underlying data sets. The Board of Appeal notes that the Contested Decision addresses some of the remaining uncertainty by requesting further testing of the constituents that potentially satisfy both the persistence and bioaccumulation criteria. The Board of Appeal notes that in the substance evaluation of MCCP a combination of the hydrocarbon block method, the defined constituents approach and the fraction profiling assessment were used. The Board of Appeal notes that this approach triggers a significantly lower number of testing requirements for the Substance than would be the case if only the hydrocarbon block method or defined constituents approach had been applied and in this respect is a proportionate approach.

52. The Board of Appeal notes that the evaluation by the eMSCA indicates that constituents with lower chlorine contents are readily biodegradable and do not therefore meet the persistence criteria of Annex XIII. The evaluation demonstrated however that persistence is predicted to increase with increasing chlorine content. Substances with a chlorine content of above 50% by weight are generally not readily biodegradable although they still undergo some degradation in ready biodegradation tests. It is not clear however from the evaluation if this increased persistence means that such substances would meet the persistence criteria in terms of an environmental half-life in sediment or soil.

53. In addition, since the Substance is released into wastewater and is highly absorbing, the substance evaluation concluded that it was appropriate to investigate fate in sediment. Depending on the outcome of these tests, confirmation of the bioaccumulation potential of the C_{14} constituents may also be required as the current PBT profile is based on read-across only and more definitive information could be

necessary. Importantly, the substance evaluation indicated that commercial MCCP products can contain up to around 1% $C_{<14}$ constituents and these are predicted to have BCF values above 2,000 l/kg over a wide chlorine range. Some $C_{<14}$ constituents with higher chlorine contents are known to meet the persistence criterion based on a measured half-life in sediment. According to the substance evaluation, these constituents also appear to meet the toxicity criterion of Annex XIII and so it is important to establish the actual amounts of these constituents in the Substance. The Board of Appeal observes that the Appellants were aware of the need, as identified by the eMSCA, for further information to appropriately characterise the $C_{<14}$ constituents as shown by the document 'Summary of 15 October 2012 Meeting with Environmental Agency on MCCP Substance Evaluation' submitted by the Appellants as an annex to the Notice of Appeal.

54. In light of the above, the Board of Appeal finds that the Appellants' arguments with respect to the choice of testing materials demonstrate a difference of scientific opinion between them and the Agency but do not demonstrate an error on the part of the Agency. The Board of Appeal finds that it is apparent from the draft substance evaluation report, the Contested Decision, and the other written submissions that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance, including importantly the comments submitted by the Appellants during the substance evaluation procedure, when reaching their conclusions as regards the choice of test materials.

55. Furthermore, the Board of Appeal finds that the detailed scientific assessment, reasoning, and conclusions given by the eMSCA and the Agency were well founded, justified and address the arguments put forward by the Appellants. Additionally, the Board of Appeal notes that the eMSCA and the Agency consistently and coherently made known their views on the issues raised by the Appellants over a considerable period of time. In other words, the Board of Appeal finds that the eMSCA and the Agency went to considerable lengths to explain the rationale supporting the conclusions reached in the draft substance evaluation report and the Contested Decision.

56. The Board of Appeal therefore rejects the Appellants' assertion that the Agency's decision to evaluate the properties of the Substance using a constituents-based fractionation testing approach is flawed. The Board of Appeal finds that the Agency did not exceed its margin of appreciation when defining the test materials in the present case and did not misuse its powers. The Appellants have produced no evidence demonstrating that the Agency requested the Appellants to follow a constituent-based fractionation testing approach with the exclusive or main purpose of achieving an end other than that pursued by the REACH Regulation in the context of substance evaluation. Similarly, the Appellants have produced no evidence demonstrating that the Agency's choice of test materials in the Contested Decision was made with the exclusive or main purpose of evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case.

57. The Appellants' arguments relating to the constituents-based fractionation testing approach must therefore be rejected.

(ii) 0.1% w/w threshold for analysis of the PBT/vPvB properties of constituents of a substance

58. The Appellants essentially claim that the testing requested in the Contested Decision contradicts the Agency's policy which allegedly requires testing on constituents of a substance only if the constituent in question exceeds 0.1% w/w (see paragraph 34 above).

59. In the Contested Decision, the draft substance evaluation report, and in other written submissions, the eMSCA and the Agency explain that for complex UVCBs, such as the Substance, it is common that the bulk of the individual constituents are present in a concentration that equals or exceeds 0.1 % w/w. The Agency states that the very low concentrations of individual constituents do not obviate the concerns related to the potential PBT/vPvB properties of the Substance. The Agency also states that the structural similarity of individual constituents within a fraction means that the PBT/vPvB properties of individual constituents can be considered to be additive in considering the properties of the Substance. The similarities of the isomers in terms of structure and intrinsic properties therefore justify identifying the relevant concentration as the sum of all isomers in one fraction, the fraction corresponding to a defined carbon chain length and a specified range of chlorination.

60. In light of the objectives of the REACH Regulation regarding the protection of human health and the environment, the importance of identifying substances with PBT/vPvB properties, and the composition of the Substance, the Board of Appeal agrees with the Agency that, in the case at issue, the additivity of the effects related to the PBT/vPvB properties of similar isomers of the Substance justify considering the sum of isomers within a specified carbon chain length and chlorine content as being a relevant concentration for PBT/vPvB assessment. Moreover, contrary to the Appellants' assertions, the Board of Appeal finds that the Agency Guidance is not in conflict with the above reasoning. In Chapter R.11 of the Agency Guidance it is stated that constituents, additives, and impurities are relevant for PBT/vPvB assessment when they are present in a concentration that equals or exceeds 0.1% w/w. However, the Agency Guidance also clearly mentions that this threshold value of 0.1% w/w could be elevated or reduced for the sake of proportionality of assessment efforts and the level of risk being considered. The approach followed in the present case is therefore not inconsistent with the Agency Guidance.

61. Furthermore, the Board of Appeal takes the view that the Appellants' reference to the judgment in Case T-93/10, *Bilbaína de Alquitranes and Others* v *ECHA* (EU:T:2013:106) does not support the Appellants' argument. Contrary to the Appellants' claim, the General Court did not find that the Agency is bound to request testing on constituents only if the constituent in question exceeds 0.1% w/w. The General Court merely indicated that the approach applied by the Agency in that specific case to determine the PBT/vPvB properties of the substance concerned was legitimate without giving a general rule that would apply in the present case.

62. The Board of Appeal therefore finds that, contrary to the Appellants' assertions, the Agency was not bound by law or previous practice to require testing on constituents of the Substance only if the constituent in question exceeded 0.1% w/w. Annex XIII does not provide specific rules relating to the identification of the PBT/vPvB properties of UVCBs where the exact composition is unknown or variable and which contain different constituents. It is for the Agency, acting within its margin of discretion, to identify the appropriate method for the identification of PBT/vPvB properties on a case-by-case basis, in light of the objectives of the REACH Regulation, and after examining, carefully and impartially, and taking into consideration, all the relevant facts and circumstances of the individual case.

63. The Board of Appeal finds that, in the present case, the Agency examined, carefully and impartially, and took into consideration, all the relevant facts and circumstances, in reaching the conclusions set out in the Contested Decision as regards the choice of test materials. Whilst the Appellants may disagree with the Agency's approach, the Board of Appeal has found that, in the present case, the Agency was not bound to request testing on constituents only if the constituent in question exceeds 0.1% w/w. Furthermore, the Board of Appeal finds that the detailed scientific assessment, reasoning, and conclusions given by the eMSCA and the Agency were well founded, justified and address the arguments put forward by the Appellants. Additionally, the Board of Appeal notes that the eMSCA and the Agency consistently and coherently made known their views on the issues raised by the Appellants over a considerable period of time. In other words, the Board of Appeal finds that the eMSCA and the Agency went to considerable lengths to explain the rationale supporting the conclusions reached in the draft substance evaluation report and the Contested Decision.

64. The Board of Appeal also finds that the Agency exercised correctly its discretion when defining the test materials in the present case and did not misuse its powers. The Appellants have produced no evidence demonstrating that the Agency's choice was made with the exclusive or main purpose of achieving an end other than that pursued by the REACH Regulation in the context of substance evaluation. Similarly, the Appellants have produced no evidence demonstrating that the Agency's choice was made with the exclusive or main purpose of evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case.

65. The Appellants' arguments alleging the existence of a binding 0.1% w/w threshold for analysis of the PBT/vPvB properties of constituents of a substance must therefore be rejected.

(iii) OECD TG 308 and persistence assessment

66. The Appellants essentially claim that the OECD TG 308 is fundamentally inappropriate for testing either the Substance or the test materials identified in the Contested Decision (see paragraph 35 above).

67. In this respect, the Board of Appeal notes that it is apparent from the draft substance evaluation report, the Contested Decision and from the other written submissions that the eMSCA and the Agency examined, carefully and impartially, and took into consideration all relevant information on the Substance, including, importantly, the comments submitted by the Appellants during the substance evaluation procedure, in reaching their conclusions on the appropriate test guideline to be followed for assessing the persistence of the Substance. In the Contested Decision, after summarising the Appellants' comments and concerns regarding OECD TG 308, the Agency explains that it has carefully reviewed those comments and taken *'account of the available enhanced ready tests in the substance evaluation, including carrying out an extensive read-across'*. The Agency further explains that, whilst further enhanced ready biodegradation and Sequential Batch Reactor (hereinafter 'SBR') studies may provide useful supplementary information for the assessment of persistence, they do not allow any conclusion to be drawn about the degradation half-life of a substance in sediment, which is required for comparison with the criteria of Annex XIII. In addition, the Agency notes that OECD TG 308 uses natural sediment and is the standard approach when degradation in sediment is investigated. The Agency further points to the fact that this test method has already been used for short-chain chlorinated

paraffins. Moreover, the Agency explains that even if a substance degrades relatively quickly in the dissolved phase following desorption, a long residence time in sediment is still a relevant consideration since organisms that feed on sediment will potentially be exposed to high concentrations of the substance.

68. In addition, the Board of Appeal observes that the Agency took into account the Appellants' concerns that the complexity of the test materials may make identification and quantification of metabolites difficult and, as a result, noted in the Contested Decision that if it is not possible to identify metabolites using OECD TG 308, then other approaches to profile the persistence properties of the metabolites may be considered.

69. With regards to the limitations of OECD TG 308 identified by the Appellants (see paragraph 35 above), the Board of Appeal finds that none of these limitations can lead to the invalidation of this test method for the purposes of the Contested Decision. Furthermore, OECD TG 308 is OECD-approved, internationally agreed and accepted, widely used for regulatory purposes, and is currently recommended in Chapter R.11 of the Agency Guidance for this purpose.

70. In light of the above, the Board of Appeal finds that the Appellants' arguments with respect to the use of OECD TG 308 for assessing the persistence of the Substance demonstrate a difference of scientific opinion between them and the Agency but do not demonstrate an error on the part of the Agency. The Board of Appeal finds that it is apparent from the draft substance evaluation report, the Contested Decision, and the other written submissions that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance, including importantly the comments submitted by the Appellants during the substance evaluation procedure, when reaching their conclusions as regards the choice of OECD TG 308 for assessing the persistence of the Substance. Furthermore, the Board of Appeal finds that the detailed scientific assessment, reasoning, and conclusions given by the eMSCA and the Agency were well founded, justified, and address the arguments put forward by the Appellants. Additionally, the Board of Appeal notes that the eMSCA and the Agency consistently and coherently made known their views on the issues raised by the Appellants over a considerable period of time. In other words, the Board of Appeal finds that the eMSCA and the Agency went to considerable lengths to explain the rationale supporting the conclusions reached in the draft substance evaluation report and the Contested Decision.

71. In addition, the Board of Appeal finds that the Agency exercised correctly its discretion when requesting the use of OECD TG 308 in the present case and did not misuse its powers. The Appellants have produced no evidence demonstrating that the Agency's choice of the OECD TG 308 was made with the exclusive or main purpose of achieving an end other than that pursued by the REACH Regulation in the context of substance evaluation. Similarly, the Appellants have produced no evidence demonstrating that the Agency's choice was made with the exclusive or main purpose of evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case.

72. For reasons of completeness, as regards the OECD TG 301 D studies commissioned by the Appellants (see paragraph 36 above) which became available after the Contested Decision was adopted, the Board of Appeal observes that it is for the Appellants to assess whether the information requirement as explained in the Contested Decision is

satisfied by the results of the OECD TG 301 D studies or not and, consequently, whether they should proceed with a OECD TG 308 study.

73. The Appellants' arguments relating to OECD TG 308 must therefore be rejected.

(iv) Fish bioconcentration factor (BCF) tests and bioaccumulation assessment

74. The Appellants essentially claim that the BCF tests requested are inappropriate for assessing the bioaccumulation of the Substance (see paragraph 37 above).

75. In this respect, the Board of Appeal notes that it is apparent from the draft substance evaluation report, the Contested Decision and from the other written submissions that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance, including, importantly, the comments submitted by the Appellants during the substance evaluation procedure with respect to the appropriateness and limitations of the BCF tests, when reaching their conclusions on the testing to be performed in order to assess the bioaccumulation of the Substance.

76. In the document 'Comments on Preliminary Bioaccumulation Assessment of […] MCCPs, […], April 30, 2013', the Appellants' comments are addressed by the eMSCA. The eMSCA acknowledges that biomagnification factors (hereinafter 'BMF') or trophic magnification factors (hereinafter 'TMF') provide additional information that is relevant to help assess whether substances are bioaccumulative. However, the eMSCA explains that the key parameter that needs to be identified in the context of the REACH Regulation is still the BCF. The eMSCA adds that, although there is little or no evidence for biomagnification of MCCP from field data:

'the Substance is potentially bioaccummulative or in some cases very bioaccummulative based on BCF within the meaning of the criteria and associated guidance. This is why the focus of the substance evaluation conclusions is on obtaining definitive information to allow a conclusion to be drawn within a reasonable timeframe whilst trying to minimise the amount of testing required'.

77. The Board of Appeal notes moreover that, in the document 'Response to comments from the MCCPs REACH Consortium: Comments in Response to […] MCCPs Substance Evaluation and Draft Decision, 3 May 2013', the eMSCA explains that:

'overall, [the analysis commissioned by the Appellants to assess the bioaccumulation of the Substance and the utility of BCF tests] heightens our suspicions that some constituents of the Substance may meet the criteria for B or vB. Given the uncertainties in the modelling approach, our position remains that testing is needed to confirm (or otherwise) that the B or vB criteria are met for those chain lengths and chlorine contents specified in the draft decision. Should the registrants consider that there are sufficiently reliable BCF data to confirm that the B (and vB) criteria are already met, them clearly the testing would not be necessary on the grounds of animal welfare. However, the consequences would be that the registrants must update their PBT assessment to reflect this conclusion'.

78. The eMSCA further explains that *'we think the consequences of not carrying out the tests will be that MCCPs can be concluded to meet the Annex XIII criteria for B and vB based on the BCF predictions by [the review commissioned by the Appellants]'*.

79. Furthermore, in the Contested Decision, the Agency explains why it disagrees with the Appellants' comments with respect to the BCF tests as well as why BMF and TMF tests have not been chosen instead for the bioaccumulation assessment of the Substance.

80. The Board of Appeal finds that the eMSCA and the Agency examined, carefully and impartially, the Appellants' argument with respect to field biomagnification studies and sufficiently explained why, in the present case, the BCF test would still need to be performed. The Agency explained that field biomagnification studies generally have significant experimental limitations, and lack of biomagnification in one food chain does not automatically mean that it can be excluded for all others. Several factors could be important, such as the metabolic potential of the species examined, and whether the food chain is dominated by benthic or pelagic organisms. Moreover, a significant level of accumulation arising from bioconcentration processes is a legitimate concern since it may lead to effects at one level of a food chain that could have consequences for predators. The Agency further explained that although a weight of evidence approach should be used when comparing the available data with the criteria of Annex XIII, the only numerical criteria relate to the BCF. The Agency Guidance explains that *'because food chain transfer and secondary poisoning are basic concerns in relation to PBT and vPvB substances, an indication of biomagnification potential can on its own right be considered to conclude that a substance meets the B or vB criteria but absence of such a biomagnification potential cannot be used to conclude that these criteria are not fulfilled'*. In addition, the contribution of metabolites to bioaccumulation observed in the existing studies is unclear as there are limited data on this aspect. Finally, although lack of biomagnification potential is clearly an important consideration, the Contested Decision explains that the lack of biomagnification is not sufficient to outweigh the fact that a substance may meet the bioaccumulation criteria based on BCF alone.

81. With regard to the Appellants' argument relating to the cost of the BCF tests, the Board of Appeal observes that the protection of the environment constitutes one of the primary objectives of the REACH Regulation and takes precedence over economic considerations. The Board of Appeal notes that the importance of the objectives pursued may justify substantial negative economic consequences for certain operators (see Case T-269/11, *Xeda International SA* v *Commission*, EU:T:2014:1069, paragraph 138). In addition, the Board of Appeal observes that the allegedly high cost of a test in this case does not itself demonstrate, as claimed by the Appellants, that the Agency made an error, exceeded its margin of discretion, or misused its powers. The Appellants' argument as regards the cost of the BCF tests is therefore rejected.

82. In light of the above, the Board of Appeal finds that the Appellants' arguments with respect to the use of BCF tests for assessing the bioaccumulation of the Substance demonstrate a difference of scientific opinion between them and the Agency but do not demonstrate an error on the part of the Agency. The Board of Appeal finds that it is apparent from the draft substance evaluation report, the Contested Decision and the other written submissions that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance, including importantly the comments submitted by the Appellants during the substance evaluation procedure, when reaching their conclusions as regards the choice of BCF tests for assessing the bioaccumulation of the Substance. Furthermore, the Board of Appeal finds that the detailed scientific assessment, reasoning, and conclusions given by the eMSCA and the Agency were well founded, justified and address the arguments put forward by the Appellants. Additionally, the Board of Appeal notes that the eMSCA

and the Agency consistently and coherently made known their views on the issues raised by the Appellants over a considerable period of time. In other words, the Board of Appeal finds that the eMSCA and the Agency went to considerable lengths to explain the rationale supporting the conclusions reached in the draft substance evaluation report and the Contested Decision.

83. In addition, the Board of Appeal finds that the Agency did not exceed its margin of appreciation when requesting the BCF tests in the present case and did not misuse its powers. The Appellants have produced no evidence demonstrating that the Agency's choice of the BCF tests was made with the exclusive or main purpose of achieving an end other than that pursued by the REACH Regulation in the context of substance evaluation. Similarly, the Appellants have produced no evidence demonstrating that the Agency's choice was made with the exclusive or main purpose of evading a procedure specifically prescribed by the REACH Regulation for dealing with the circumstances of the case.

84. The Appellants' arguments relating to the BCF tests must therefore be rejected.

Concluding observations of the Board of Appeal with regard to the first, second, and third pleas

85. Having regard to all of the foregoing considerations, the first, second, and third pleas relied on by the Appellants in support of their appeal must be rejected.

The fourth plea alleging breach of the principle of proportionality

Arguments of the Parties

86. By their fourth plea, the Appellants claim that the Agency breached the principle of proportionality. They claim that the test materials and the testing requested in the Contested Decision are not appropriate or necessary to evaluate whether the Substance has PBT or vPvB properties and that less onerous alternatives to the tests requested exist. According to the Appellants, the Agency has already accepted during the substance evaluation of 1,1-(ethane-1,2-diyl)bis[pentabromobenzene] (hereinafter 'EBP') that testing on theoretical constituents rather than on a commercial product cannot be regarded as lawful and proportionate. In addition, the Appellants claim that the information requested in the Contested Decision is not appropriate or necessary given the high financial costs of generating the requested information.

87. Furthermore, the Appellants claim that the Agency's decision to request OECD TG 308 studies without waiting for the completion of the OECD TG 301 D studies runs counter to the requirement for a stepwise approach and breaches the principle of proportionality. The Appellants add that, in response to their comments dated 4 November 2012 on the draft substance evaluation report on MCCP, the eMSCA acknowledged that there is on-going research on the biodegradation of MCCP and that *'unfortunately it looks as though the timing of this research is such that it will not be possible to take into account of the results during the current SEv process. The evaluating authority only has twelve months from publication of the CoRAP to send its completed report to ECHA […]'.* The Appellants claim that, firstly, the legal procedural requirements cannot override the requirements regarding a stepwise approach to testing. Secondly, the Appellants claim that the twelve months from publication of the CoRAP deadline referred to by the eMSCA applies from the time that the Appellants submit the requested information.

88. The Agency disputes the merits of the Appellants' arguments. With respect to the argument that the Agency should have awaited the outcome of the ongoing studies before taking a decision, the Agency submits that the legislation aims to ensure that substance evaluations are completed within a reasonable time and this is why, according to Article 46(1), the substance evaluation should not last longer than twelve months and the decision-making process is subject to strict timelines. The Agency claims that these strict timelines are set to ensure that a concern regarding a substance can be rapidly clarified which serves the REACH Regulation's primary objectives of a high level of protection of human health and the environment. Furthermore, as explained in the Contested Decision, an OECD TG 308 study enables a half-life in sediment to be derived which is needed for comparison with the Annex XIII criteria in order to assess the persistence of the Substance. Whilst data from an enhanced ready biodegradation study may provide additional information for the assessment of persistence, it would not allow any conclusion to be drawn about degradation half-life in sediment.

Findings of the Board of Appeal

89. At the outset, the Board of Appeal recalls that the principle of proportionality requires that measures do not exceed the limits of what is appropriate and necessary in order to achieve the objectives legitimately pursued by the measure in question. When there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see Case C−15/10, *Etimine*, EU:C:2011:504, paragraph 124 and Case A-005-2011, *Honeywell Belgium N.V.,* Decision of the Board of Appeal of 29 April 2013, paragraphs 115 to 117).

90. As regards the objectives pursued by the Contested Decision, it has already been held (see paragraph 39 above) that the primary objective of the REACH Regulation is to ensure a high level of protection of human health and the environment. To this effect, the Contested Decision requests information in order to assess in particular the Substance's persistence, bioaccumulation and toxicity.

91. In the first place, the Board of Appeal recalls that the Appellants' claim that the information requested in the Contested Decision is not appropriate to clarify whether the Substance has PBT or vPvB properties has been already rejected in the context of the first, second, and third pleas (see paragraphs 39 to 85 above). The Board of Appeal has already determined that the Agency took into consideration all the relevant facts and circumstances relating to the Substance when defining the test materials to be used and the tests to be performed in order to clarify the identified concerns for the purpose of the substance evaluation of MCCP.

92. As explained in paragraph 51 above, the Board of Appeal finds that it is not feasible to determine the PBT/vPvB properties of each constituent of the Substance based on experimental information. The Board of Appeal finds that a read-across/modelling approach, as explained in the draft substance evaluation report, is a proportionate and appropriate method to estimate the persistence and bioaccumulation properties of the Substance. The constituents of the Substance that potentially meet the persistence criterion are not necessarily the same as those that potentially meet the bioaccumulation criteria and vice versa. In addition, as explained in the draft substance evaluation report and summarised in the Contested Decision, for MCCP products containing 50% chlorine by weight or more, $C_{<14}$ constituents of MCCP might have a problematic persistence and bioaccumulation profile, especially at chlorination

levels of 65% by weight or more. Furthermore, some of the main constituents of MCCP, and in particular C_{14} constituents with chlorine contents in the range 50-56% by weight and C_{15} constituents with ~51% by weight chlorine content, are potentially PBT. At the same time, the persistence and bioaccumulation profile for some of the constituents is uncertain because of inherent limitations in the underlying data sets. On this basis, the Board of Appeal finds that the approach in the Contested Decision, to address some of the remaining uncertainty in the assessment of the Substance by requiring further biodegradation testing of the constituents that potentially meet both the persistence and bioaccumulation criteria, is proportionate as it focuses on those constituents of greatest concern. The Board of Appeal recalls that in the substance evaluation of MCCP a combination of the hydrocarbon block method, the defined constituents approach and the fraction profiling assessment were used. The Board of Appeal finds that this approach triggers a significantly lower number of testing requirements for the Substance than would be the case if only the hydrocarbon block method or defined constituents approach were applied and in this respect this approach is a proportionate approach.

93. In addition, in the case at issue, as indicated in paragraph 60 above, the Board of Appeal finds that the additivity of the effects related to the PBT/vPvB properties of similar isomers of the Substance justify considering the sum of isomers within a specified carbon chain length and chlorine content as being a relevant concentration for the PBT/vPvB assessment. The Board of Appeal has already determined that the approach followed in the present case is in line with the Agency Guidance (see paragraph 60 above). The Board of Appeal therefore finds that the requested information is both necessary and appropriate. Furthermore, the Appellants have not demonstrated that there is a less onerous approach to address the concerns identified. In light of the above, the Board of Appeal finds that the Agency's approach in this regard is proportionate and reflects both the complexity of the issue and the level of concern being addressed.

94. In their observations on the Defence, the Appellants claimed that the Agency has already accepted in the substance evaluation of another substance, namely EBP, that testing on theoretical constituents rather than on a commercial product cannot be regarded as lawful and proportionate. This is apparently a reference to the Agency's Decision on the substance evaluation of EBP, which is available on the Agency's website. The Board of Appeal takes the view that the reference to the substance evaluation of EBP is not capable of supporting the Appellants' argument. The Board of Appeal observes that it cannot be argued that the approach which the Agency adopted in the context of the substance evaluation of another substance is automatically applicable to the present case, especially given the complexity of MCCP and the need for the Agency to make a thorough assessment of possible testing needs on a case-by-case basis. In any event, without going into the merits of the Agency's Decision in the substance evaluation of EBP, the Board of Appeal observes that, contrary to the Appellants' assertions, the Decision on the substance evaluation of EBP does not state that testing on the basis of a constituents-based fractionation testing approach is not legally permissible and proportionate. The Appellants' argument in this respect is therefore rejected.

95. As regards the OECD TG 308 studies, the Board of Appeal has already observed that the Agency explained the appropriateness and necessity of those studies, took into account the Appellants' concerns, and noted in the Contested Decision that if it is not possible to identify metabolites in a OECD TG 308 study then other approaches to profile the PBT properties of the metabolites may be considered (see paragraphs 66 to

71 above). The Board of Appeal therefore finds that the requested information is both necessary and appropriate. Furthermore, the Appellants have not demonstrated that there is a less onerous approach to address the concerns identified. In light of the above, the Board of Appeal finds that the Agency's approach in this regard is proportionate and reflects both the complexity of the issue and the level of concern being addressed.

96. With regard to the Appellants' argument relating to the cost of the BCF tests, the Board of Appeal recalls, first, that the protection of the environment constitutes one of the primary objectives of the REACH Regulation, as stipulated in Article 1 thereof and, second, that the protection of the environment takes precedence over economic considerations. The Board of Appeal notes that the importance of the objectives pursued may justify substantial negative economic consequences for certain operators (see Case T-269/11, *Xeda International SA* v *Commission*, EU:T:2014:1069, paragraph 138). The Board of Appeal finds that the Appellants have failed to demonstrate that the cost of the BCF tests is disproportionate to the aims pursued by the Contested Decision. The Appellants' claim is therefore dismissed.

97. In addition, the Board of Appeal finds that the Agency did not breach the principle of proportionality by not waiting for the completion of the OECD TG 301 D studies. In this respect, the Board of Appeal recalls that under the substance evaluation procedure, according to Articles 45 and 46, the competent authority of a Member State shall evaluate the allocated substance. If the *'competent authority considers that further information is required […] it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission'*. A draft decision *'shall be prepared within 12 months of the publication of the CoRAP on the Agency's website for substances to be evaluated that year'*. Contrary to the Appellants' assertions therefore the REACH Regulation itself imposed a clear obligation on the eMSCA to prepare the draft decision on the substance evaluation of MCCP within twelve months of the publication of the CoRAP on the Agency's website. Given that the publication of the CoRAP in which the Substance was included was published on 29 February 2012, the eMSCA was obliged by law to prepare a draft decision at the latest by 28 February 2013.

98. The Board of Appeal observes that imposing an automatic obligation on the Agency to suspend its proceedings each time a new study is conducted or planned, whose timing and relevance are uncertain, could run counter to the primary objectives of the REACH Regulation as it could lead to substance evaluation procedures being significantly delayed (see, by analogy, Case A-004-2012, Lanxess Deutschland GmbH, Decision of the Board of Appeal of 10 October 2013, paragraphs 54 to 61 and Case T-334/07, *Denka International* v *Commission*, EU:T:2009:453, paragraph 181).

99. In the present case, while the eMSCA acknowledged that there is on-going research on the biodegradation of MCCP, it also noted that the timing of this research is such that it would not be possible to take into account the results thereof during the current substance evaluation procedure (see paragraph 87 above). The Board of Appeal observes that the timeline for the conclusion of the OECD TG 301 D studies was uncertain at the time the eMSCA was conducting the substance evaluation of MCCP. Moreover, the Appellants had no control or influence over when the results of the OECD TG 301 D studies would become available or indeed what these results would be. In their comments of 4 November 2012 on the draft substance evaluation report on MCCP, the Appellants noted that *'there is ongoing research still being conducted […] on the biodegradation of MCCP constituents […]. Hopefully this additional research*

will be available by early 2012 and can be considered prior to the initiation of any additional testing'. It is clear from the above that the Appellants did not know when the results of the OECD TG 301 D studies would become available. Importantly, it follows from the written submissions of the Parties that the final report on the OECD TG 301 D studies was only, in fact, completed on 30 April 2014. This is over two months after the Contested Decision was notified to the Appellants and over one year after 28 February 2013, the last day on which, according to Article 45, the eMSCA could prepare a draft decision on the substance evaluation of MCCP. Moreover, the final report on the OECD TG 301 D studies was only finally available two years later than the estimate of early 2012 provided by the Appellants. Whilst not decisive in this regard the Board of Appeal observes that the eMSCA noted that *'when considering alternatives to the OECD 308 test it is important to understand that the information that is now required is a half-life for biodegradation in the environment (preferably sediment)'* and expressed doubts as to *'whether [the OECD 301 D studies] will deliver such half-life information for the components of interest'*. In light of the above, the Board of Appeal concludes that the Contested Decision did not violate the principle of proportionality by not waiting for the results of the OECD TG 301 D studies.

100. In conclusion, the Board of Appeal finds that the testing requested and the test materials chosen are appropriate and necessary for the objective pursued by the Contested Decision and the disadvantages caused are not disproportionate to the aims pursued. Furthermore, the Appellants have not demonstrated that there are less onerous options to satisfy the objective pursued by the Contested Decision. Having regard to all of the foregoing considerations, it must be held that none of the arguments put forward by the Appellants in support of the fourth plea are capable of establishing that the Agency breached the principle of proportionality.

The fifth plea alleging that the Agency acted in breach of animal welfare requirements

Arguments of the Parties

101. By their fifth plea, the Appellants firstly claim that the Contested Decision is in breach of animal welfare requirements and violates in particular Article 13 of the Treaty on the functioning of the European Union (hereinafter 'TFEU'), Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33; hereinafter 'Directive 2010/63'), and Article 25 of the REACH Regulation. According to the Appellants, the Contested Decision is needlessly wasteful of animal life as the information requested therein will not provide scientifically reliable data to clarify whether the Substance has PBT or vPvB properties.

102. The Appellants claim secondly that the Agency's decision not to apply a stepwise approach to testing in the case at issue violates animal welfare requirements. In this respect, the Appellants claim that the Agency was legally required to wait for the outcome of the ongoing OECD TG 301 D studies before requiring an OECD TG 308 study for the assessment of the Substance's persistence. The Appellants also claim that, as regards the assessment of bioaccumulation, any additional bioaccumulation studies should have only been directed towards those constituents of the Substance that are believed to meet the persistence and toxicity criteria in order to minimize testing on vertebrate animals.

103. The Agency disputes the merits of the Appellants' arguments. The Agency claims that this plea can only concern the Agency's requests for information on bioaccumulation as these are the only vertebrate tests required by the Contested Decision. For the assessment of persistence no vertebrate tests have been requested. The Agency submits that, in any event, a careful consideration has been made as to what experimental studies are needed to clarify the concern identified using vertebrate or non-vertebrate testing.

104. With respect to the argument that the Agency should have awaited the outcome of the OECD TG 301 D studies before adopting the Contested Decision, the Agency submits that an OECD TG 301 D study is performed to measure persistence and therefore aims to address a similar concern to OECD TG 308. However, according to the Agency, the OECD TG 308 tests imposed by the Agency are non-vertebrate tests. The Agency therefore does not see how waiting for the results of the OECD TG 301 D studies would render vertebrate animal testing unnecessary.

105. With regards to the stepwise approach, the Agency notes that the Contested Decision sets a three year deadline for providing the required information. The Agency also argues that the Contested Decision explicitly refers to the possibility of tiered testing, explaining that further sediment or bioaccumulation testing may be omitted if persistence or bioaccumulative properties can be established at an earlier stage. The Agency therefore claims that this plea is unfounded and should be dismissed.

Findings of the Board of Appeal

106. At the outset, it should be recalled that Article 13 of the TFEU provides that:

'in formulating and implementing the Union's agriculture, fisheries, transport, internal market […] policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions […].'

107. In addition, Article 25(1) of the REACH Regulation provides that *'in order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort […]'*.

108. The protection of animal welfare is therefore an important consideration in the framework of EU legislation and the REACH Regulation in particular. The Board of Appeal notes that, under the REACH Regulation, the Agency has a legal obligation to consider animal welfare in its decision-making. Where the Agency requires additional testing pursuant to a substance evaluation, it must ensure that vertebrate animals are used only as a last resort and its actions should demonstrably not run counter to the principles of Directive 2010/63 (see, by analogy, Case A-005-2011, *Honeywell Belgium N.V.,* Decision of the Board of Appeal of 29 April 2013, paragraphs 90, 94, 108 and 110).

109. It is in the light of those considerations that the arguments put forward by the Appellants must be examined.

110. In the first place, the Board of Appeal recalls that the Appellants' claim that the information requested in the Contested Decision will not provide scientifically reliable data has been already rejected in the context of the first, second, and third pleas (see paragraphs 39 to 85 above). The Board of Appeal has also already determined that

the information requests are proportionate to the objectives pursued by the Contested Decision (see paragraphs 89 to 100 above). The Appellants' first claim is therefore rejected.

111. With regard to the Appellants' second claim, the Board of Appeal observes that the Appellants' assertion that the Agency did not apply a stepwise approach falls into two parts. First, that the Agency was legally required to wait for the outcome of the ongoing OECD TG 301 D studies before requiring an OECD TG 308 study to be conducted for the assessment of the Substance's persistence, and, second, that the Agency did not apply a stepwise approach with regard to the requested bioaccumulation studies.

112. As regards the first part of this claim, the Board of Appeal observes that the OECD TG 308 studies, which were requested in the Contested Decision for the purposes of assessing the persistence of the Substance, do not involve testing on vertebrate animals. The Appellants' claim that the Agency should have waited for the results of the OECD 301 D studies in order to avoid unnecessary animal testing must therefore be rejected. In any event, the Board of Appeal has already found that, in the circumstances of this case, the Agency did not have any obligation to wait for the results of the OECD TG 301 D studies (see paragraphs 97 to 99 above).

113. As regards the second part of this claim, the Board of Appeal considers that the Appellants effectively make two separate arguments. Firstly, they claim that, under Article 25(1), the Agency is under an obligation to ensure that testing on vertebrate animals is undertaken only as a last resort. Secondly, they claim that where the Agency has decided that testing on vertebrate animals is the only option to meet the information requirements identified, the number of animals used in those tests should be kept to a minimum. These two arguments will be addressed in turn.

114. The Board of Appeal recalls that, in the context of the first, second, and third pleas (see paragraphs 75 to 82 above), it found that the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance when reaching its conclusions that the BCF tests should be performed in order to assess the bioaccumulation of the Substance. The Board of Appeal has also already determined that the bioaccumulation information requests in the present case are proportionate to the objective pursued by the Contested Decision (see paragraph 96 above). Importantly, the Board of Appeal found that both during the decision-making process and in the Contested Decision the eMSCA and the Agency explained why they considered that the vertebrate tests in question were the only option to elucidate the identified concern as well as why other alternatives, and in particular the BMF and TMF tests, could not provide the information needed for the bioaccumulation assessment of the Substance. The Board of Appeal finds therefore that the information requested for the purposes of assessing the bioaccumulation of the Substance does not violate the requirement in Article 25(1) that testing on vertebrate animals must be undertaken only as a last resort.

115. The Board of Appeal will now turn to the second part of the Appellants' claim, namely that the Agency breached its obligation to ensure that the number of animals used in the BCF tests is kept to a minimum.

116. In this respect, the Board of Appeal notes that the REACH Regulation reflects the 3Rs principle, that is the reduction, refinement, and replacement of testing on vertebrate animals as set out in Directive 2010/63 (see Case A-005-2011, *Honeywell Belgium*

N.V., Decision of the Board of Appeal of 29 April 2013, paragraph 104). The Board of Appeal also observes that the Agency's 'REACH Practical Guide 10: how to avoid unnecessary testing on animals', published on 02 June 2010, states that *'[f]urthermore, when new animal testing is necessary, where possible, scientifically sound approaches to the implementation of the 3Rs […] which are already stipulated under the REACH Regulation should be used'*.

117. In view of the above, the Board of Appeal considers that, when requiring tests pursuant to the substance evaluation process, the Agency should consider how the fewest number of animals possible can be used to satisfy the objective pursued.

118. As regards the testing requested to assess the bioaccumulation of the Substance, the Board of Appeal recalls, first, that the Substance contains many hundreds of constituents and that it is neither feasible nor justifiable to determine separately the bioaccumulation properties of every constituent based on experimental information. Second, the Board of Appeal notes that in order to determine the bioaccumulation status of the Substance the Agency requested testing on two different C_{14} chlorinated n-alkane samples with chlorine contents of 50-52% and 55-60% by weight. The Board of Appeal has already found that the above constituent-based fractionation testing approach is appropriate and proportionate to the objective pursued by the Agency (see paragraph 92 above). The Board of Appeal observes that the Agency's request for bioaccumulation tests to be performed only on two test materials rather than on all constituents of the Substance demonstrates that the Agency took care in identifying the testing requirements while ensuring that no unnecessary testing on vertebrate animals will be performed in satisfying the objective pursued. In addition, the Board of Appeal notes that the Contested Decision sets a timeline of three years for the Appellants to provide the information requested therein. The Board of Appeal considers that this timeline allows for a stepwise approach to be followed. Furthermore, the Board of Appeal finds that the Contested Decision explicitly refers to the possibility of tiered testing in explaining that further sediment or bioaccumulation testing may be omitted if the persistence or bioaccumulative properties of the Substance can be established already at an earlier stage in the testing programme. The Appellants' argument that the Agency did not follow a stepwise approach with respect to the bioaccumulation testing requested in the Contested Decision must therefore be rejected.

119. Having regard to all of the foregoing considerations, the Board of Appeal finds that none of the arguments put forward by the Appellants in support of the fifth plea are capable of establishing that the Agency breached animal welfare requirements and Article 25(1). In these circumstances, the fifth plea relied on by the Appellants in support of their appeal must be rejected.

The sixth plea alleging breach of the principles of legal certainty and legitimate expectations

Arguments of the Parties

120. By their sixth plea, the Appellants allege that the Agency breached the Appellants' legitimate expectation that requests for further data under Article 46(1) aim to verify the suspected concern, clarify whether the Substance constitutes a risk to human health or the environment, and are based upon sound and consistent judgment. The Appellants further claim that the Contested Decision breaches the legitimate

expectation created by the Agency Guidance that testing requested pursuant to Article 46(1) will be on the registered substance and not theoretical constituents.

121. The Agency disputes the merits of the Appellants' arguments.

Findings of the Board of Appeal

122. The Board of Appeal observes that the arguments and assertions raised by the Appellants in support of the claim that the Agency violated their legitimate expectations have already been replied to, and rejected, in the context of the first, second, third, and fourth pleas. The Board of Appeal has already determined that the Agency took into consideration all the relevant facts and circumstances relating to the Substance when defining the test materials and the test guidelines to be used for the purpose of the substance evaluation of MCCP. In addition, the Board of Appeal has found that the choice of both the test materials and the testing guidelines was proportionate to the aims pursued by the Contested Decision.

123. As regards the Appellants' assertion that, by not requesting testing on the Substance itself, the Agency departed from the Agency Guidance which requires testing to be conducted on the registered substance, the Board of Appeal recalls that in line with the REACH Regulation and the Agency Guidance, the Agency enjoys a margin of discretion as to the choice of test materials that it is appropriate to use to assess the properties of the registered substance in question. This is particularly the case where the substance is a complex UVCB. In the present case, the Board of Appeal has already concluded that the test materials chosen are appropriate to assess the properties of the Substance and proportionate to this aim, and reflect both the complexity of the issue and the level of concern being addressed. The Board of Appeal further observes that there cannot be legitimate expectations in the absence of precise, unconditional and consistent assurances (see Case T-209/01, *Honeywell* v *Commission*, EU:T:2005:455, paragraph 100) and the Appellants have not invoked any such assurances.

124. Having regard to all of the foregoing considerations, the Board of Appeal finds that none of the arguments put forward by the Appellants in support of the sixth plea is capable of establishing that the Agency breached the principles of legal certainty and legitimate expectations. In these circumstances, the sixth plea relied on by the Appellants in support of their appeal must be rejected.

The seventh plea alleging a breach of the duty to state reasons

Arguments of the Parties

125. By their seventh plea, the Appellants allege that the Agency did not provide reasons with respect to the test materials and the testing methods chosen, as no such valid reason exists. The Appellants add that, to the extent that reasons are given, these are incorrect and lack scientific rigour.

126. The Agency disputes the merits of the Appellants' arguments.

Findings of the Board of Appeal

127. 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 power 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).

128. The Board of Appeal 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 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, and Case A-006-2012, *Momentive Specialty Chemicals B.V.*, Decision of the Board of Appeal of 13 February 2014, paragraph 113). The Board of Appeal finds that the Appellants have not shown that the Agency breached the duty to state reasons as they merely argue that the reasons provided are incorrect.

129. As regards the claim that the reasons given are incorrect, the Board of Appeal has already found that the eMSCA and the Agency examined, carefully and impartially, and took into consideration, all relevant information on the Substance, including importantly the comments submitted by the Appellants during the substance evaluation procedure, when reaching their conclusions. Moreover, after examining the reasons given by the Agency in the Contested Decision, the Board of Appeal did not find any illegality or error in the choice of the test materials, the testing requested, and the test guidelines identified in the Contested Decision.

130. While it is not decisive in this regard, it is important to bear in mind that the adequacy of 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 C-417/11 P, *Council* v *Bamba*, EU:C:2012:718, paragraph 54). 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 Case A-006-2012, *Momentive Specialty Chemicals B.V.*, Decision of the Board of Appeal of 13 February 2014, paragraph 105).

131. The Board of Appeal observes that, in the case at issue, the Appellants were closely involved in the administrative process 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. The Board of Appeal finds that the reasoning of the Contested Decision is appropriate to the act at issue, and discloses in a clear manner the reasoning followed by the Agency for each information request.

132. Having regard to all of the foregoing considerations, the Board of Appeal finds that none of the arguments put forward by the Appellants in support of the seventh plea is capable of establishing that the Agency breached its duty to state reasons. In these circumstances, the seventh plea relied on by the Appellants in support of their appeal must be rejected.

The eighth and ninth pleas alleging that the Agency breached the principle of equal treatment and the principles of good administration and transparency

Arguments of the Parties

133. The Board of Appeal observes that the eighth and ninth pleas both concern the addressees of the Contested Decision. It is therefore appropriate to examine them together.

134. By their eighth plea, the Appellants criticise the Agency for not addressing the Contested Decision to all registrants of the Substance. The Appellants claim that two registrants of MCCP, which were not addressees of the Contested Decision, are in the same position as the Appellants in that they registered the Substance before the Contested Decision was adopted. The Appellants submit that there has been a difference in the treatment by the Agency of the Appellants as compared to the two other registrants of MCCP, which cannot be objectively justified.

135. The Agency disputes the merits of the Appellants' arguments. The Agency notes that it addressed the Contested Decision to all registrants of MCCP with active registrations on 4 April 2013, the date when the initial draft decision on the substance evaluation of MCCP was sent to the registrants of the Substance for comments pursuant to Article 50(1). The Agency submits that all addressees of the Contested Decision must be able to exercise their procedural rights and be provided with an opportunity to comment on draft substance evaluation decisions. The Agency adds that, as the number of registrants for substances is dynamic and dependent on business decisions, there is a necessity for a cut-off point to identify addressees for substance evaluation decisions. According to the Agency, the decision-making procedure would be jeopardised if the consultation process had to be restarted whenever new registrants entered the market. With regard to the two registrants of MCCP who are not addressees of the Contested Decision, the Agency notes that both of them submitted their registrations after the Agency had sent the draft substance evaluation decision to the MCCP registrants for comments on 4 April 2013. One of the other registrants submitted its registration dossier on 26 April 2013 and the other on 12 December 2013.

136. By their ninth plea, the Appellants criticise the Agency for not clearly identifying the addressees of the Contested Decision and for not communicating to the addressees of the Contested Decision that not all MCCP registrants listed on the Agency's dissemination portal at the time the Contested Decision was adopted were addressees of the Contested Decision. The Appellants allege that it was not possible for them to identify the other addressees of the Contested Decision.

137. The Agency disputes the merits of the Appellants' arguments.

Findings of the Board of Appeal

138. As a preliminary remark, the Board of Appeal notes that the principle of equal treatment is a general principle of EU law, enshrined in Articles 20 and 21 of the

Charter of Fundamental Rights of the European Union (OJ C 83, 30.3.2010, p. 389). The principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (see Case C-127/07, *Arcelor Atlantique and Lorraine and Others*, EU:C:2008:728, paragraph 23). Breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all the elements which characterise them. The elements which characterise different situations, and hence their comparability, must in particular be determined and assessed in the light of the subject-matter and purpose of the act which makes the distinction in question. The principles and objectives of the field to which the act relates must also be taken into account (Case C-127/07, *Arcelor Atlantique and Lorraine and Others*, EU:C:2008:728, paragraphs 25 and 26).

139. As noted in paragraph 97 above, according to Article 46, a draft substance evaluation decision is to be prepared within twelve months of the publication of the CoRAP on the Agency's website for substances to be evaluated that year. The legislator gave the eMSCA a specific timeframe of twelve months for the preparation of the draft decision. According to Article 50(1), '*[t]he Agency shall notify any draft decision…to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt'*. The Board of Appeal notes that if a registrant had not registered the substance at the time the draft substance evaluation decision was notified then it would not receive that draft decision to comment on.

140. After the concerned registrants who have received the draft decision have made their comments on that draft, if any, Article 52 requires that the draft decision is circulated, together with any comments by the registrant(s) or downstream user(s), to the Agency and to the competent authorities of the other Member States (hereinafter 'MSCAs'). The provisions of Article 51(2) to (8) apply *mutatis mutandis* to the adoption of the final substance evaluation decision. In particular, the Agency and MSCAs may submit proposals for amendment which will be then shared with the concerned registrants for their comments. The Board of Appeal observes that, for reasons of equal treatment and observance of the rights of defence, these registrants must necessarily be the same as those who commented on the draft substance evaluation decision pursuant to Article 50(1).

141. The Board of Appeal observes that the interpretation suggested by the Appellants, whereby registrants who submitted registration dossiers after the draft decision was notified should also be addressees of the substance evaluation decision, would lead to discrimination against these new registrants. These new registrants would not have had the same opportunity to exercise their rights of defence and to participate on an equal footing in the substance evaluation procedure. In addition, the Board of Appeal notes that the interpretation suggested by the Appellants could lead to an endless loop whereby the whole substance evaluation procedure would restart each time a new dossier is submitted during the period between the preparation of the draft decision and the adoption of the final decision. The Board of Appeal considers that none of the above situations could have been the intention of the legislator as they would raise concerns regarding equality, due process, legal certainty and jeopardise the achievement of the primary objectives of the REACH Regulation.

142. The Board of Appeal notes that, in the present case, the draft decision following the substance evaluation of MCCP was notified to active registrants on 4 April 2013. The two registrants of MCCP who were not included as addressees of the Contested

Decision did not have active registrations at the time the draft decision was notified to MCCP registrants for their comments. As a result, these two new registrants did not have the opportunity to participate in the substance evaluation procedure and submit comments on the draft substance evaluation decision for MCCP. In contrast, the Appellants and the Intervener, who eventually became the addressees of the Contested Decision, had active registrations at that time and exercised their rights under the REACH Regulation in the substance evaluation procedure leading up to the adoption of the Contested Decision. The situation of the two companies who were late registrants of MCCP was not therefore comparable to that of the Appellants. The Board of Appeal finds therefore that, in addressing the Contested Decision only to the registrants with active registrations at the time the draft decision was notified, the Agency did not breach the principle of equal treatment.

143. As regards the Appellants' ninth plea alleging that the Agency violated the principles of good administration and transparency by not clearly identifying the addressees of the Contested Decision, the Board of Appeal notes at the outset that the Appellants introduced this claim for the first time in the Appellants' clarification document of 13 January 2015. Nowhere in their Notice of Appeal do the Appellants raise such a claim. Before examining the merits of this claim, the Board of Appeal will therefore need to consider whether this claim is admissible.

144. In this respect, the Board of Appeal notes that, according to Article 12(2) of the Rules of Procedure, new pleas may not be introduced in the course of the proceedings unless they are based on matters of law and fact which come to light in the course of proceedings.

145. The Board of Appeal observes that in their clarification document of 13 January 2015 the Appellants identify as one of their pleas the violation of the principle of good administration and the violation of the requirement for transparency as a result of the Contested Decision not clearly identifying its addressees. However, the Appellants do not provide any reason to explain why they did not introduce this plea in the Notice of Appeal. The Board of Appeal also recalls that it gave a clear instruction that the clarifications request was not an opportunity for the Appellants to expand on their pleas and arguments (see paragraph 23 above). The Board of Appeal also notes that the Appellants do not show or claim that this plea is based on matters of law and fact which came to light in the course of the appeal proceedings.

146. The Appellants' ninth plea is therefore inadmissible. For reasons of completeness, the Board of Appeal notes that this plea is also unfounded as the Appellants' assertion that it was not possible for them to identify the addressees of the Contested Decision cannot be accepted. The Board of Appeal observes that the Appellants spoke with one voice when providing comments on the draft substance evaluation report. The comments were put forward by the 'MCCP REACH Consortium' as evidenced by the written submissions. At that time, according to the written submissions, only the Appellants and the Intervener had active registrations for MCCP. All these registrants cooperated between themselves in order to provide common comments.

147. Moreover, as demonstrated by the evidence accompanying the written submissions, the first draft decision, which was sent to the Appellants on 4 April 2013 for their comments, has the same addressees as the Contested Decision. These addressees are identified by their registration numbers which are identical in the first draft decision to those in the Contested Decision. The Board of Appeal therefore notes that the addressees did not change between the draft decision and the Contested Decision. At

the time the draft decision was sent to the Appellants for their comments the addressees were identified by their registration numbers. Contrary to their claim, the Appellants managed to identify the other addressees as evidenced by the fact that they provided a single set of comments on the draft decision as the 'MCCP REACH Consortium'. Moreover, there is no evidence that the Appellants raised any concerns with the Agency or the eMSCA that they were unable to identify the other registrants of MCCP that were concerned by the draft decision.

148. After the draft decision was sent to the Appellants for their comments, two other undertakings submitted new registrations for MCCP. However, the fact that these two registrants are not addressees of the Contested Decision is obvious as no new registration numbers were added in the section of addressees to the Contested Decision in comparison to that section in the draft decision. In conclusion, the Board of Appeal cannot accept the claim that the Appellants were unable to identify the addressees of the decision.

149. The Appellants may have preferred if the Contested Decision had also been addressed to the two undertakings that registered MCCP after the draft decision was sent for comments on 4 April 2013. However, this is not sufficient to demonstrate any illegality on the part of the Agency.

150. Whilst not decisive in this regard, the Board of Appeal also notes that, from an examination of the submissions in the case, the Appellants cooperated with at least one of the new registrants in the later stages of the substance evaluation procedure. In a letter dated 8 November 2013 sent by the MCCP REACH Consortium in response to the revised draft decision, one of the two new registrants of MCCP appears, for the first time, amongst the members of the REACH MCCP Consortium. However, the fact that the Appellants voluntarily included the new registrant in their deliberations does not constitute evidence of any inability to identify the addressees of the Contested Decision.

151. For reasons of completeness, and as regards the Appellants' argument with respect to the relevance of the dissemination portal, the Board of Appeal notes that the dissemination portal is intended to provide information on chemicals and does not bind the Agency as to the choice of addressees for its decisions. Furthermore, the Agency provided explicit advice to the Appellants in the cover letter to the 4 April 2013 draft decision and invited them to use the REACH-IT Co-Registrants Page in order to unambiguously identify all other addressees of the draft decision, who remained the same in the Contested Decision.

152. In light of the above, the Board of Appeal concludes that the Appellants were in a position to identify the addressees of the Contested Decision. Their claim is therefore dismissed.

153. Having regard to all of the foregoing considerations, the Board of Appeal finds that none of the arguments put forward by the Appellants in support of the eighth and ninth pleas is capable of establishing that the Agency breached the principle of equal treatment by not addressing the Contested Decision to all MCCP registrants and the principles of good administration and transparency by not clearly identifying the addressees of the Contested Decision. In these circumstances, the eighth and ninth pleas relied on by the Appellants in support of their appeal must be rejected.

The tenth plea alleging a violation of the principles of good administration and due process

Arguments of the Parties

154. By their tenth plea, the Appellants claim that the Agency violated the principles of good administration and due process by refusing to circulate to the MSC a document provided by the Appellants which outlined the Appellants' *'concerns with the persistence and bioaccumulation aspects of the MCCP substance evaluation and proposed testing plan to further evaluate these endpoints'*.

155. The Agency disputes the merits of the Appellants' arguments.

Findings of the Board of Appeal

156. At the outset, the Board of Appeal observes that according to Article 41 of the Charter of Fundamental Rights, which concerns the right to good administration, '*every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union. This right includes the right of every person to be heard, before any individual measure which would affect him or her adversely is taken […]*'.

157. The Appellants claim that the Agency violated the principle of good administration and due process by refusing to circulate to the MSC a document provided by them prior to the MSC meeting of 10-13 December 2013 at which the Contested Decision was agreed. The Agency does not dispute the fact that the document was not circulated to the MSC before the MSC meeting.

158. The Board of Appeal observes however that the Appellants were given the opportunity to be heard during the substance evaluation procedure on several occasions. In particular, in accordance with Articles 46(1) and 50, the Agency notified the draft substance evaluation decision to the Appellants and gave them the opportunity to provide comments thereon. In accordance with Article 52, the Appellants' comments on the draft decision were made available to the Agency and to the MSCAs. In accordance with Articles 52(2) and 51(5), the Agency communicated its proposal for amendment to the revised draft decision to the Appellants, invited them to comment within the legally prescribed timeframe, and referred their comments to the MSC for their consideration.

159. The Board of Appeal observes that, according to the evidence accompanying the written submissions, in addition to the opportunities to be heard expressly stated in the REACH Regulation, the Appellants were given the opportunity to make their positions known to the eMSCA and the Agency on other occasions during the substance evaluation of MCCP. In particular, the Appellants had the opportunity to meet with the eMSCA regarding the draft substance evaluation report, submitted comments on it in writing (see paragraph 5 above), and participated in the MSC meeting of 10-13 December 2013 (see paragraph 14 above).

160. The Board of Appeal observes that the document sent by the Appellants to the Agency prior to the MSC, which is the subject of this plea, was unsolicited and essentially repeated the comments already made by the Appellants during the substance evaluation procedure and decision-making process. The Board of Appeal further notes that the Agency had no legal obligation to forward this document to the MSC.

161. Moreover, the participation of registrants in MSC meetings is not prescribed by the REACH Regulation. It is at the discretion of the MSC to decide whether such participation is appropriate (see Case A-006-2012, *Momentive Specialty Chemicals B.V.*, Decision of the Board of Appeal of 13 February 2014, paragraph 127). The Board of Appeal notes that, in the present case, the Appellants were given the opportunity to participate in the MSC and to provide comments orally during the discussion on the amended draft decision.

162. In light of all the above, the Board of Appeal finds that the Appellants were given sufficient opportunities to be heard and to present their position before the Contested Decision was adopted.

163. In conclusion, the Board of Appeal finds that the Appellants failed to provide any evidence that the Agency breached the principles of good administration and due process by not circulating to the MSC a document produced by the Appellants for the purposes of the MSC meeting and the Appellants' plea should therefore be dismissed.

164. For reasons of completeness, the Board of Appeal observes that, in a footnote to their Notice of Appeal, the Appellants link the alleged violation of the principle of good administration also to the fact that the eMSCA delegated its substance evaluation work with respect to the Substance to another body. The Board of Appeal recalls that, according to Article 45(1), *'in carrying out an evaluation of a substance, the competent authority may appoint another body to act on their behalf'*. Therefore, the Board of Appeal finds that the Appellants' claim is rejected as unfounded.

165. Consequently, the Appellants' tenth plea is rejected and the appeal must therefore be dismissed in its entirety.

Other issues under examination

Refund of the appeal fee

166. 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 decision is rectified in accordance with Article 93(1) of the REACH Regulation or the appeal is decided in favour of an appellant.

167. As the Board of Appeal has decided the appeal in favour of the Agency in the present case the appeal fee shall not be refunded.

Claim for reimbursement of appeal costs

168. In their Notice of Appeal, the Appellants request the Board of Appeal to order the Agency to pay the Appellants' costs arising from the appeal proceedings.

169. The Board of Appeal observes that there is no legal basis in the Rules of Procedure for the reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to taking of evidence in appeal proceedings.

170. Consequently, and as in the present case no costs arose in relation to taking of evidence, the Board of Appeal rejects the Appellants' request for reimbursement of costs that it incurred in the appeal proceedings.

Effects of the Contested Decision

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

172. The Contested Decision, upheld in the present appeal proceedings, required the registrants, now the Appellants and the Intervener, to submit the required information by 25 February 2017, which is 3 years from the date 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 3 years from the date of the final decision of the Board of Appeal.

173. Consequently, the information required by the Contested Decision shall be submitted within 3 years from the date of notification of the Board of Appeal's Decision in present case.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information required by the Agency's Decision of 25 February 2014 on the substance evaluation of MCCP, notified to the Appellants through the annotation numbers SEV-D-2114273983-36-01/F, SEV-D-2114273973-37-01/F, SEV-D-2114273975-33-01/F, SEV-D-2114273969-26-01/F, SEV-D-2114273977-29-01/F, SEV-D-2114273979-25-01/F, SEV-D-2114273972-39-01/F, SEV-D-2114273980-42-01/F, and SEV-D-2114273978-27-01/F, shall be submitted by 9 September 2018.**
3. **Decides that the appeal fee shall not be refunded.**
4. **Rejects the claim for the reimbursement of costs incurred by the Appellants in the appeal proceedings.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal