EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

7 December 2016

(*Substance evaluation – Addressees of a decision – Concerned registrants – Relevant conditions for testing*)

Case number	A-013-2014
Language of the case	English
Appellant	BASF SE, Germany
Intervener	The French REACH Competent Authority
Contested Decision	Decision of 11 September 2014 on the substance evaluation of octocrilene 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 Appellant through the annotation number SEV-D-2114287467-34-01/F

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

I. Summary of the facts

1. On 10 December 2014, the Appellant lodged the present appeal at the Registry of the Board of Appeal requesting the Board of Appeal to annul the Contested Decision in its entirety in particular because of a violation of essential procedural requirements and breaches of the principles of legal certainty and equal treatment.

2. In the alternative, should the Board of Appeal dismiss the request to annul the Contested Decision in its entirety, the Appellant requests the Board of Appeal to annul or amend the Contested Decision insofar as it requires the Appellant to submit information related to bioaccumulation test(s) and to conduct an Androgenised Female Stickleback Screen study (hereinafter the 'AFSS study').

3. The Appellant also requests the refund of the appeal fee.

II. Background to the dispute

4. On the basis of an opinion of the Member State Committee (hereinafter the 'MSC'), and due to initial grounds for concern relating to '*Environment/Suspected persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB); Exposure/Wide dispersive use, high aggregated tonnage*', octocrilene (CAS No 6197-30-4, EC No 228-250-8; hereinafter the 'Substance') was included in the Community rolling action plan (hereinafter the 'CoRAP') for substance evaluation in 2012 pursuant to Article 44(2) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The CoRAP was published on the website of the European Chemicals Agency (hereinafter the 'Agency') on 29 February 2012. The Competent Authority of France (hereinafter the 'eMSCA') was appointed to carry out the evaluation.

5. During the evaluation of the Substance the eMSCA identified additional concerns related to human health (thyroid toxicity and toxicity to reproduction) and the environment (endocrine disruption and exposure of the aquatic compartment).

6. Following the evaluation of the Substance the eMSCA concluded that further information was required to assess the concerns identified in paragraphs 4 and 5 above. The eMSCA prepared a draft decision pursuant to Article 46(1) to be addressed to three registrants of the Substance (hereinafter the 'three addressees of the Contested Decision'). The draft decision was submitted to the Agency on 28 February 2013.

7. On 28 March 2013, a fourth registration was submitted for the Substance (hereinafter the 'fourth registration' or 'fourth registrant').

8. On 4 April 2013, the Agency sent the draft decision to the three addressees of the Contested Decision, including the Appellant, and invited them, pursuant to Article 50(1), to provide comments within 30 days of receipt.

9. On 22 April 2013, a fifth registration was submitted for the Substance (hereinafter the 'fifth registration' or 'fifth registrant').

10. On 29 April 2013, the fourth registration passed the technical completeness check and received a registration number pursuant to Article 20(3).

11. On 2 May 2013, the fifth registration passed the technical completeness check and received a registration number pursuant to Article 20(3).

12. The three addressees of the Contested Decision provided comments to the Agency on the draft decision by the deadline of 6 May 2013.

13. On 10 May 2013, the Agency notified the eMSCA of the comments received from the three addressees of the Contested Decision. The eMSCA revised the draft decision in light of the comments received (hereinafter the 'revised draft decision').

14. On 13 August 2013, the eMSCA informed the Appellant that it was aware of other registration dossiers for the Substance but that, in line with the Agency's practice, those new registrants would not be included in the on-going decision-making procedure.

15. On 18 December 2013, in accordance with Article 52(1), the eMSCA notified the Competent Authorities of the other Member States (hereinafter the 'MSCAs') and the Agency of its revised draft decision and invited them, pursuant to Articles 52(2) and 51(2), to submit proposals for amendment (hereinafter 'PfAs') within 30 days.

16. PfAs were subsequently received from five MSCAs and the Agency.

17. On 7 February 2014, the Agency notified the three addressees of the Contested Decision of the PfAs and invited them, pursuant to Articles 52(2) and 51(5), to provide comments on them within 30 days.

18. The eMSCA reviewed the PfAs and amended the revised draft decision (hereinafter the 'amended draft decision').

19. On 16 December 2013, the Agency referred the amended draft decision to the MSC.

20. By 10 March 2014, the three addressees of the Contested Decision provided comments on the PfAs.

21. Following discussions in the MSC meeting of 8 to 10 April 2014, a unanimous agreement of the MSC on the decision, as modified at the meeting, was reached on 10 April 2014.

22. The Contested Decision was adopted by the Agency on 11 September 2014 requesting the three addressees of the Contested Decision to submit by 18 September 2016 the following information:

    (i) *In vivo* mechanistic study in rat;
    (ii) Extended One Generation Reproduction Toxicity Study in rats, oral route, with the developmental neurotoxicity (DNT) cohort and an extended pre-mating period of 10 weeks (OECD Test Guideline (hereinafter 'TG') 443);
    (iii) Water solubility (EU Test Method (hereinafter 'TM') A.6 with an adequate analytical method able to quantify low levels of the Substance and a validated limit of quantification);
    (iv) Adsorption - Desorption Using a Batch Equilibrium Method (OECD TG 106);
    (v) Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308);
    (vi) *Daphnia magna* Reproduction Test (OECD TG 211);
    (vii) Bioaccumulation: recalculation of the BCF (bioconcentration factor) value from data on the bioaccumulation test already provided, or a new test to be conducted according to OECD TG 305 in Zebra fish (dietary route of exposure);
    (viii) Earthworm Reproduction Test (OECD TG 222);
    (ix) AFSS study (variant of OECD TG 230);
    (x) Information on the direct emission scenario to the aquatic environment in the risk assessment;
    (xi) Additional information on the environmental exposure assessment; and
    (xii) Estimation of the PEC_{soil} (predicted environmental concentration in soil) via sludge.

23. The Contested Decision sets out the addressees thereof as follows:

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

Registrant(s) meeting the following criteria are not addressees of this decision: i) Registrant(s) who registered the [Substance] exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the [Substance] in accordance with Article 50(3) […] before the decision is adopted by [the Agency]'.

24. The Annex to the Contested Decision lists three registration numbers corresponding to the addressees of the Contested Decision.

III. Procedure before the Board of Appeal

25. On 10 December 2014, the Appellant lodged the present appeal.

26. On 16 February 2015, the French REACH Competent Authority applied for leave to intervene in the proceedings before the Board of Appeal in support of the Agency, on the grounds that it had acted as the eMSCA in the present case. By its Decision of 2 October 2015, the Board of Appeal, having heard the Parties, granted the application. Despite being invited to do so by the Board of Appeal, the Intervener did not provide observations on the procedural documents submitted by the Parties in the case.

27. On 26 March 2015, the Agency submitted its Defence claiming that the appeal is in part inadmissible and in part unfounded or, alternatively, that the appeal should be dismissed as unfounded in its entirety.

28. Following consultation with the Parties, the proceedings were stayed between 1 June and 1 September 2015.

29. On 16 September 2015, since the position of legally qualified member of the Board of Appeal was vacant and in order to achieve the full composition of the Board of Appeal, the Chairman, pursuant to the first subparagraph of Article 3(2) of 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), designated an alternate member, Rafael López Parada, to act in the present case as the legally qualified member of the Board of Appeal.

30. On 29 October 2015, the Appellant submitted its observations on the Defence.

31. On 6 January 2016, Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 3, 6.1.2016, p. 41) was published in the *Official Journal of the European Union*.

32. On 4 February 2016, the Agency submitted its observations on the Appellant's observations on the Defence.

33. The written procedure was closed on 12 February 2016. In view of the Appellant's request for a hearing to be held, and pursuant to Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 14 April 2016. At the hearing, the Parties and the Intervener made oral presentations and responded to questions from the Board of Appeal.

IV. Reasons

34. In support of its appeal the Appellant raises several pleas which will be divided into two groups for examination by the Board of Appeal. The first group of pleas relates to whom the Contested Decision is, and should have been, addressed and the second group of pleas relates to two of the information requirements in the Contested Decision. The Board of Appeal will firstly address the issues related to the addressees of the Contested Decision.

V. The Appellant's pleas related to the addressees of the Contested Decision

Arguments of the Parties

35. The Appellant claims that, although the draft of the Contested Decision was addressed to three registrants of the Substance, there were in fact five registrants of the Substance, all of which were members of the joint submission.

36. The Appellant claims that the Agency's wilful omission of existing registrants from the list of addressees of the draft decision violates Articles 50(1) and 51(5) as well as the principles of equal treatment and legal certainty.

37. The Appellant claims that the fourth and fifth registrants of the Substance, who are not addressees of the draft decision, are also '*concerned registrants*' within the meaning of Articles 50 and 53. The Appellant argues that other legal entities registering the Substance at a later point in time will also become '*concerned registrants*' by reason of their obligation to register the Substance.

38. With regard specifically to the fourth registration the Appellant argues that, as according to Article 20(3) the initial submission date of a registration becomes the registration date if the technical completeness check is passed, the Agency should have considered the fourth registration as 'existing' for the purpose of establishing the list of addressees of the draft decision.

39. The Appellant considers that it would be a sensible approach for the decision-making procedure to be put on hold every time a new registration is submitted during that process. The Appellant states that additional information from other registrants may serve to invalidate concerns identified during the substance evaluation process as well as negating the need for further animal tests.

40. The Appellant argues that '*by wilfully excluding existing and known registrants from the proceedings*' the Agency denied the possibility of valuable stakeholder input and deprived these registrants the right to be heard foreseen in Articles 50(1) and 51(5). The Appellant argues further that the new registrants have a legitimate interest in being involved in the decision-making procedure as they will also be affected by the follow-up procedure foreseen in Article 48.

41. The Appellant argues further that the Agency's decision to exclude certain existing registrants from the proceedings is arbitrary and violates the principle of legal certainty according to which '*[…] the law must be certain, in that it is clear and precise, and its legal implications foreseeable, especially when applied to financial obligations*'. The Appellant argues that where existing registrants are not addressees of the final decision, this omission implies that they are not legally required to submit the requested information, in turn relieving them of the legal obligation to contribute to the costs incurred by the registrant conducting any required studies pursuant to that decision.

42. The Appellant claims that in a communication of 13 August 2013 the '*eMSCA insinuates that other existing registrants are not concerned by the draft decision and that responsibility rests with the lead registrant and its dossier*'. The Appellant claims that this breaches several provisions of the REACH Regulation and the right to equal treatment and legal certainty. The Appellant argues that the role of the lead registrant bears no special significance nor does it imply any additional responsibilities for the purpose of a decision taken following a substance evaluation.

43. The Appellant argues that, contrary to the Agency's assertions, this situation cannot be resolved by contractual means in the Substance Information Exchange Forum ('SIEF'). The Appellant claims that the question of what information a registrant is required to submit is not a contractual one, but a question that has to be answered by the legal provisions of the REACH Regulation as well as the Agency as the relevant regulatory authority. It is not a registrant's place to give a binding ruling on what information other

co-registrants have to submit and, if appropriate, pay a share of the cost for in accordance with Article 53.

44. The Appellant states further that Article 4(2) of Commission Implementing Regulation (EU) 2016/9 provides that '*[t]he cost-sharing model shall include for all registrants of a particular substance provisions for sharing any costs resulting from a potential substance evaluation decision'.* The Appellant argues that, without an explicit binding statement in this regard, there is no way for the lead registrant to force other registrants to share the costs arising from testing pursuant to a substance evaluation decision, especially since Article 4(1) of Commission Implementing Regulation (EU) 2016/9 states that each registrant is only required to share the costs of information it is obliged to submit to the Agency. According to the Appellant, given that Commission Implementing Regulation (EU) 2016/9 requires provisions to be made for sharing any costs resulting from a potential substance evaluation decision, registrants need legally binding guidance as to who is actually required, by way of a final decision or otherwise, to submit the information in question and therefore to share the related costs.

45. The Appellant claims that the financial burden of generating information in response to an Agency substance evaluation decision has to be borne by all registrants of the Substance, regardless of the date of registration.

46. The Agency states that it is clear that '*concerned registrants*' within the meaning of Article 50(1) are those registrants that are addressees of the decision in question.

47. The Agency claims that there is no express legal basis allowing it to address substance evaluation decisions to registrants which only registered at a time after the decision-making procedure had started or after a substance evaluation decision has been taken. According to the Agency, consulting new registrants at a later stage or (partially) repeating the decision-making procedure would result in repetitive administrative action, possibly with an indefinite end, and result in a potentially significant delay in the generation of hazard data that is necessary to ensure the safe use of a substance.

48. The Agency states that in order to establish the registrants of a substance at the time of sending a draft substance evaluation decision, the Agency identifies all '*active registrations*' on the date of sending that decision. The Agency states that, in the present case, at the time the draft decision was sent to registrants for their comments pursuant to Article 50(1) (i.e. 4 April 2013) there were three '*active registrations*'.

49. The Agency argues that for the fourth registration the technical completeness check was passed on 29 April 2013 which was after the date the Agency had communicated the draft decision to the existing three registrants. The Agency adds that during the technical completeness check the status of a registration dossier is uncertain pending the Agency's decision. There is no active registration at this stage as it is uncertain whether the submitted registration dossier will pass the completeness check or not.

50. The Agency states that on 22 April 2013 a fifth registration for the Substance was submitted. The registrant received a registration number on 2 May 2013 with the registration date of 22 April 2013. The fifth registration was also therefore made after the date when the draft decision was sent for comments.

51. The Agency states that all registrants of a substance with an active registration should jointly meet the information requests in a decision. The Agency argues that contractual arrangements can be put in place for all registrants of a substance with an active registration, irrespective of the time of registration, to be obliged to share costs for information generated to be in compliance with a substance evaluation decision.

52. The Agency claims that Commission Implementing Regulation (EU) 2016/9 provides a legislative requirement for manufacturers and importers to arrange data and cost sharing amongst themselves for information generated following a substance evaluation decision. The Agency states that Commission Implementing Regulation (EU) 2016/9 explicitly refers in Article 4(2) to registrants of substances '*including the possibility of*

future registrants joining the data-sharing agreement at a later stage'. According to the Agency, it will constitute a breach of the Regulation if this provision is not followed and national authorities are empowered to enforce this provision.

Findings of the Board of Appeal

A. The Agency's objection to the admissibility of the claim regarding the addressees of the Contested Decision

53. The Agency argues that the Appellant claims that the Contested Decision should have been addressed also to other registrants of the Substance. The Agency argues that in this respect the appeal system foreseen in the REACH Regulation does not include legal remedies concerning an alleged failure to act towards third parties by the Agency and the Appellant's claim is therefore inadmissible.

54. The Board of Appeal finds however that the Appellant does not claim that the Agency failed to act by not including the fourth and fifth registrants as addressees of the Contested Decision. In its appeal the Appellant in fact claims that the Agency breached Articles 50(1) and 51(5) by not taking into account the registrations of those later registrants. The Appellant also claims that the Agency breached the principle of equal treatment and legal certainty by addressing the Contested Decision to the three addressees and not also to the fourth and fifth registrants.

55. Furthermore, pursuant to Articles 91(1) and 51(8), the Board of Appeal has jurisdiction over decisions taken pursuant to Article 51.

56. In the light of the foregoing considerations, the Agency's objection of inadmissibility is unfounded. The Appellant's claim is therefore admissible and will be examined by the Board of Appeal.

B. Appellant's plea that the Agency breached the right to be heard of other registrants of the Substance

57. The Appellant argues that by excluding existing and known registrants from the decision-making procedure leading to the adoption of the Contested Decision the Agency denied those registrants the right to be heard.

58. The Board of Appeal finds however that the right to be heard is an individual right and that only those who are affected by a potential breach thereof can bring an action alleging its violation. The Appellant therefore does not have an interest in bringing an action which alleged the violation of the right to be heard in relation to other registrants.

59. The Appellant's claim related to the breach of the right to be heard of the fourth and fifth registrants must therefore be dismissed as inadmissible.

C. Alleged breach of Articles 50(1) and 51(5), as well as the principle of equal treatment

60. Pursuant to Article 50(1):

'*The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly*'.

61. Article 51(5) provides:

'*The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account*'.

62. In light of the above, and in order to address the Appellant's pleas related to a potential breach of Articles 50(1) and 51(5), as well as the principle of equal treatment, the Board of Appeal will consider whether the fourth and fifth registrants should be considered to be '*concerned registrants*' within the meaning of Articles 50(1) and 51(5). In this respect, the Board of Appeal notes that there is no explicit definition of this term in the REACH Regulation.

1. Situation of the fifth registrant

63. The Board of Appeal will firstly examine whether the fifth registrant should have been treated as a '*concerned registrant*' within the meaning of Article 50(1) and as such included as an addressee of the Contested Decision.

64. As a preliminary remark, the Board of Appeal notes that the principle of equal treatment is a general principle of European Union 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, *Société Arcelor Atlantique and Lorraine and Others*, EU:C:2008:728, paragraph 23). A 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, *Société Arcelor Atlantique and Lorraine and Others*, EU:C:2008:728, paragraphs 25 and 26).

65. Pursuant to Article 46(1), the eMSCA was required to prepare the draft decision within twelve months of the publication of the CoRAP on the Agency's website for substances to be evaluated that year. Pursuant 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 submitted its registration dossier for a substance at the time the draft substance evaluation decision was notified then it would not receive that draft decision to comment on.

66. After the concerned registrants or downstream users who have received the draft decision have made their comments on that draft, if any, Article 52(1) requires that the draft decision is circulated by the eMSCA concerned, together with any comments on it, to the Agency and to the 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 PfAs which will then be shared with the concerned registrants or downstream users 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 were given the opportunity to comment on the draft substance evaluation decision pursuant to Article 50(1).

67. The Board of Appeal observes that the interpretation suggested by the Appellant, whereby registrants who submitted registration dossiers after the draft decision was notified to certain registrants should also be addressees of the substance evaluation decision, would lead to discrimination against these new registrants unless those new

registrants were also invited to provide comments on the draft decision and any PfAs and benefit from their rights under the decision-making procedure.

68. The Board of Appeal observes that the Agency's reason for not including the fifth registrant is that the decision-making procedure would have to be re-started in order to ensure that the fifth registrant is not deprived of the right to be heard foreseen in Article 50(1). In this respect the Agency's cut-off point for registrations to be taken into account in the decision-making procedure avoids the possibility of the decision-making procedure being extended unreasonably, or even indefinitely.

69. In addition, the Board of Appeal notes that the interpretation suggested by the Appellant (see paragraph 39 above) could lead to an endless loop whereby the whole substance evaluation procedure would restart each time a new registration dossier is submitted during the period between the point the draft decision is shared for the first time with concerned registrants and the adoption of the final decision. The Board of Appeal considers that this could not have been the intention of the legislator as this would raise concerns regarding equality, due process, legal certainty and jeopardise the achievement of the primary objectives of the REACH Regulation, namely the protection of human health and the environment.

70. The Board of Appeal notes that, in the present case, the draft decision following the substance evaluation of the Substance was notified to certain registrants for their comments, as explained in paragraph 8 above, on 4 April 2013. The fifth registrant of the Substance was not included as an addressee of the Contested Decision as it had not submitted a registration for the Substance by that time. The draft decision was notified to the three addressees of the Contested Decision for their comments because they had submitted registrations at the time the draft decision was circulated for comments and consequently they were identifiable by the Agency at that moment. The Agency was able to identify these registrants and address the draft decision to them and consequently they were able to exercise their right to be heard in accordance with the provisions of the REACH Regulation on substance evaluation. The situation of the fifth registrant was not therefore comparable to that of the Appellant.

71. The Board of Appeal finds therefore that, in not addressing the Contested Decision to the fifth Registrant, the Agency did not breach the principle of equal treatment or Articles 50(1) and 51(5). The Appellant's claim that the fifth registrant should have been included as an addressee of the Contested Decision is therefore dismissed as unfounded.

72. The Board of Appeal will next consider whether the fourth registrant should have been included as an addressee of the Contested Decision on the grounds that its registration was submitted before the draft decision was sent to the three addressees of the Contested Decision for comments, despite the fact that it had not passed the technical completeness check at that moment in time.

2. Situation of the Fourth Registrant

73. The Appellant argues that the Agency acted unlawfully in not involving the fourth registrant in the decision-making procedure as registrations that have been submitted but have yet to pass the technical completeness check should also be considered for this purpose.

74. The Board of Appeal observes that, unlike the fifth registration, the fourth registration was known to the Agency prior to the sending of the draft decision to the three addressees of the Contested Decision. The draft decision could therefore have been sent to the fourth registrant without the need for the decision-making procedure to be interrupted, and potentially re-started.

75. The Board of Appeal also observes that pursuant to Article 20(3) '*[o]nce the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date*'. In the present case, once the technical completeness check had been completed, the registration date

of the fourth registration became the same as the submission date (i.e. 28 March 2013) which is before the date on which the draft decision was sent to the three addressees of the Contested Decision (i.e. 4 April 2013).

76. The situation of the fourth registrant is therefore different from that of the fifth registrant which was examined by the Board of Appeal in paragraphs 63 to 72 above. The fourth registration was submitted prior to the date the draft decision was sent to the addressees thereof for their comments, in other words before the cut-off point developed by the Agency for identifying '*concerned registrants*'. The Board of Appeal is therefore required to decide whether, despite the fact that the fourth registration had not passed the technical completeness check within the meaning of Article 20(2) and (3), the fourth registrant should be considered to be a '*concerned registrant*' within the meaning of Article 50(1).

77. In accordance with Article 41(2) of the Charter of Fundamental Rights of the European Union the right to good administration includes the right of every person to be heard, before any individual measure which would affect him or her adversely is taken.

78. In addition, Article 16 of the European Code of Good Administrative Behaviour issued by the Office of the European Ombudsman states that:

'1. In cases where the rights or interests of individuals are involved, the official shall ensure that, at every stage in the decision making procedure, the rights of defence are respected.

2. Every member of the public shall have the right, in cases where a decision affecting his rights or interests has to be taken, to submit written comments and, when needed, to present oral observations before the decision is taken.'

79. The Board of Appeal considers that during the period a registration is subject to the technical completeness check provided for in Article 20(2) the company submitting the dossier should be considered as a '*concerned registrant*'. This is supported by the wording of the third subparagraph of Article 20(2) which refers to 'registrant' even when the registration has been found to be incomplete and a registration number has not been attributed to that registration. The third subparagraph of Article 20(2) provides that '*if a registration is incomplete, the Agency shall inform the registrant…*' and '*the registrant shall complete his registration…*'.

80. The Board of Appeal observes that if the registrant subsequently fails the technical completeness check that registrant can be removed from the decision-making procedure and consultation process. The Board of Appeal observes that this scenario would in fact be similar to the situation of a manufacturer or importer which ceases activities related to a substance as foreseen in Article 50(2) and (3).

81. As the fourth registration was submitted on 28 March 2013, that is before the draft decision was sent to the '*concerned registrants*', the Agency had sufficient information to identify it as a 'registrant' whose interests were directly affected by the results of the evaluation of the Substance.

82. In view of the above, the Board of Appeal considers that, pursuant to Article 50(1), the fourth registrant should have been considered to be a '*concerned registrant*' when the draft decision was sent to the three addressees of the Contested Decision on 4 April 2013. The draft decision should therefore have been addressed also to the fourth registrant.

83. Despite this finding, the Board of Appeal considers that, in this particular case, the procedural irregularity identified above is not sufficient to lead to the annulment of the Contested Decision (see by analogy for example Case T-242/02, *The Sunrider Corp. v OHIM*, EU:T:2005:284, paragraph 66).

84. The Board of Appeal observes that on 13 August 2013 the eMSCA informed the Appellant, the lead registrant for the Substance, that '*[w]e noticed that new registration dossiers are available […] Please note that if new relevant data would have been available from those new registrants, the lead registrant (you) should have made a dossier update with our agreement within 60 days from the [draft decision] notification to you, in order to allow us to take into account those data in the [substance evaluation report] and the [draft decision]. This was not the case ….*' The eMSCA also observed in its communication of 13 August 2013 that the new registration dossiers submitted after the decision-making procedure had started were very similar in content to those of the lead registrant and as a result no changes to the draft decision were expected as a consequence. This situation was also explored during the oral hearing and this conclusion was confirmed by the Agency and not disputed by the Appellant.

85. The Board of Appeal observes therefore that if there was relevant information in the registration dossiers of the fourth, and indeed the fifth, registrant which could have had an impact on the substance evaluation process and Contested Decision the Appellant was in the position to react and provide additional input to the substance evaluation process. The Appellant however did not do this.

86. Furthermore, the Appellant did not introduce any new evidence or arguments during the present proceedings which would suggest that the Contested Decision would have been different had the information contained in the fourth registration been taken into consideration in the decision-making procedure.

87. In view of the above, the plea alleging breaches of Articles 50(1) and 51(5) as well as the principle of equal treatment must be dismissed.

3. Alleged breach of the principle of legal certainty with regards to the sharing of costs by future registrants

88. The Appellant argues that the Contested Decision breaches the principle of legal certainty since, if the Contested Decision is not addressed to the fourth and fifth registrants, it is not clear whether the fourth and fifth registrants are required to submit the information requested in the Contested Decision. Furthermore, the Appellant claims that it is uncertain whether those registrants are required to share the costs incurred through the generation of that information.

89. The Agency maintains that, even though the fourth and fifth registrants were not addressees of the Contested Decision, Commission Implementing Regulation (EU) 2016/9 contains explicit provisions on the sharing of information and costs resulting from a substance evaluation decision.

90. The Board of Appeal considers that after a substance evaluation decision has been adopted all the members of the joint submission for that substance are potentially concerned by its outcomes. In particular, when new tests on vertebrate animals are required, this may be relevant information for the registration dossiers of present and future registrants. As a result, costs should be shared by all co-registrants (present and future) in a fair, non-discriminatory and transparent way.

91. The REACH Regulation, and in particular Article 47 thereof, envisages that the substance evaluation process is substance-based and takes into account all the information available on a particular substance. If the Agency requests a test in a substance evaluation decision the registrant who performs the test and the other co-registrants for the same substance are potentially obliged to share the cost of that study.

92. This interpretation is consistent with the second subparagraph of Article 4(2) of Commission Implementing Regulation (EU) 2016/9 which provides that '*[t]he cost-sharing model shall include for all registrants of a particular substance provisions for sharing any costs resulting from a potential substance evaluation decision*'.

93. The Board of Appeal observes that this is also applicable to existing agreements between co-registrants pursuant to Article 2(2) and (3) of Commission Implementing Regulation (EU) 2016/9.

94. The Board of Appeal adds that an interpretation to the contrary would lead to the situation by which a potential registrant of a substance included on the CoRAP, in order to avoid costs arising from a substance evaluation decision, might wait until the substance evaluation decision is adopted before submitting its own registration dossier for the substance in question. This would potentially deprive the joint submission and the eMSCA of relevant and useful information which might render tests on animals as unnecessary and/or clarify potential concerns. In addition, the cost burden should not, in effect, become dependent on when a substance evaluation is conducted. The Board of Appeal finds that, in light of the objectives of the REACH Regulation, this cannot have been the intention of the legislator. The costs of testing pursuant to a substance evaluation decision must therefore be shared by all existing and future registrants of the substance in a fair, non-discriminatory and transparent way.

95. In light of the above, the Board of Appeal finds that the Contested Decision does not create legal uncertainty as regards the sharing of costs of the information requested. The Appellant's plea that the Contested Decision generates legal uncertainty regarding the sharing of costs of the information required by that decision is therefore dismissed.

VI. The Appellant's plea concerning the requested information on bioaccumulation

Arguments of the Parties

96. The Appellant claims that it has already submitted a bioconcentration factor value (hereinafter 'BCF value') for the bioaccumulation test. The Appellant submits that a recalculation of the BCF value, as requested in the Contested Decision, using the original data from filtered water would not reflect real exposure conditions and that any assessment based on such a recalculation would therefore infringe Article 47 and Annex XIII.

97. The Appellant further argues that '*requesting a recalculation based on filtered water in order to assess the bioaccumulation of [the Substance] in fish would be in violation of several provisions of the OECD Guideline concerning OECD TG 305*'. The Appellant argues in particular that, according to paragraph 60 of OECD TG 305, since the Substance is highly hydrophobic, the use of filtration must be avoided.

98. The Appellant also claims that the request for recalculation of the BCF value using data from the previously submitted bioaccumulation test is disproportionate as it imposes burdens on the Appellant without a sufficient likelihood that the request will provide scientifically meaningful results. The Appellant argues that, since a recalculated BCF value based on filtered water does not reflect relevant conditions, such a recalculation would serve no regulatory purpose. Furthermore, the specific information requirement is manifestly unsuitable for the purpose of assessing the bioaccumulative properties of the Substance in fish. The Appellant claims that as a recalculation of the BCF value using the original data from filtered water would not reflect real exposure conditions, the information requested has no realistic possibility of leading to improved risk management measures.

99. The Appellant also argues that the study on dolphins (Gago-Ferrero et al., 2013. *First determination of UV filters in Marine Mammals. Octrocrilene levels in Franciscana Dolphins*. Environ. Sci. Technol. 47:5619-5625; hereinafter the 'study on dolphins') cited by the Agency in the Contested Decision to justify the request for information is not relevant for an assessment of bioaccumulation in fish. The Appellant claims that in using the results of the dolphin study to support its decision the Agency committed a manifest error of assessment.

100. The Agency argues that '*due to the specific circumstances in which the existing test was carried out […] using the unfiltered water concentrations to calculate BCF will under-estimate the BCF does not reflect the concentration of the test Substance which was truly dissolved and bioavailable to the fish*'. According to the Agency, '*using the filtered water concentrations will give a more realistic BCF, as this will better reflect the dissolved concentration of the test substance which the fish were exposed to*'.

101. The Agency claims that data from the study on dolphins referred to in the Contested Decision serves only as supporting information to the finding that the bioaccumulation concern needs further investigation. The Agency states that the study on dolphins is not used to demonstrate the bioaccumulation potential of the Substance in fish. The Agency considers that the aim of the bioaccumulation part of a PBT assessment is to assess the potential for bioaccumulation in all wildlife and not just fish. The Agency argues that as a result, '*…although the relevance of the dolphin data as such may be unclear, it should be still considered by the Appellant in [its] PBT assessment in a weight of evidence approach*'.

Findings of the Board of Appeal

102. The Board of Appeal will first examine the Appellant's claims that the request for a recalculation of the BCF value breaches Article 47, Annex XIII and the principle of proportionality, and is '*in violation of several provisions of the OECD Guideline concerning OECD TG 305'*. The Board of Appeal will then examine the Appellant's claim that the Agency committed an error of assessment by relying on the results of the study on dolphins to justify the request for information on bioaccumulation in fish.

103. According to the Contested Decision, the Appellant is required to provide the following information:

'*Bioaccumulation: recalculation of the BCF value from data of the already provided bioaccumulation test, or test to be conducted according to OECD guideline 305 in Zebra fish (dietary exposure)*'.

104. According to point 12.3 of Annex II, '*Requirements for the Compilation of Safety Data Sheets*':

'*Bioaccumulative potential is the potential of the substance or certain substances in a mixture to accumulate in biota and, eventually, to pass through the food chain. Test results relevant to assess the bioaccumulative potential shall be given. This shall include reference to the octanol-water partition coefficient (K_{ow}) and bioconcentration factor (BCF), if available.*

This information shall be given where available and appropriate, for each individual substance in the mixture which is required to be listed in Section 3 of the safety data sheet'.

105. Points 1.1.2 and 1.2.2 of Annex XIII, '*Criteria for the Identification of Persistent, Bioaccumulative and Toxic Substances, and very Persistent, and very Bioaccumulative Substances*', provide:

'*1.1.2. Bioaccumulation*

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

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

106. As can be seen from the provisions of the REACH Regulation cited in paragraphs 104 and 105 above, information on the BCF value is required in the context of an assessment of the bioaccumulation potential of a substance.

107. The justification for requesting the information on bioaccumulation in fish is set out in the Contested Decision as follows:

'*In the literature, concentrations of [the Substance] are reported in fishes in a range from 40 to 2 400 ng.g^{-1} lipids with an average of 630 ng.g^{-1} lipids (Gago-Ferrero et al. […], 2012; Buser et al. […], 2006). These results, taken together with the high lipophilicity of [the Substance], indicate its bioaccumulation potential. Bioamplification could also be expected. From the provided key bioconcentration study on Zebra fish, the proposed calculated BCF value is considered underestimated and accordingly invalid. The measurements of [the Substance] in unfiltered water samples are indeed used to calculate the BCF value while measurements in filtered water samples are reported much lower in the report (raw data not provided). A relevant BCF should have been calculated based on filtered water samples in order to take into account the potential ad/absorption of [the Substance]'.*

108. During the present proceedings the Agency clarified the reasons for requesting the information as follows:

'*The measurements of [the Substance] in unfiltered water samples from the fish BCF study are much higher than the measurements in filtered water samples. [The Agency] considers that this difference is due to adsorption of the test substance to organic matter so that it is not bioavailable to the fish. Thus, the BCF was requested to be re-calculated based on the filtered water concentrations to better reflect the concentration of test substance that was bioavailable to the fish.*'

109. The Board of Appeal observes that the Appellant has not disputed the existence of a potential concern regarding bioaccumulation and therefore the need to provide further information. However, the Appellant argues that it has already submitted a correct calculation of the BCF value, based on results from non-filtered water, and that therefore there is no need for a recalculation or for it to submit any new data. According to the Appellant, a recalculated BCF value based on results from filtered water does not reflect relevant conditions and therefore this recalculation would violate Article 47 and Annex XIII and the principle of proportionality. The Board of Appeal notes that the Contested Decision states that the Appellant '*…agreed to recalculate the BCF values based on filtered samples (instead of the former values calculated on non-filtered samples) but stressed that this does not reflect the real exposure conditions*'.

A. Alleged breach of Annex XIII

110. According to the fourth introductory paragraph to Annex XIII '*[t]he information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*'.

111. The Appellant argues in essence that the recalculated BCF value would not be relevant for an assessment of the bioaccumulation of the Substance since in real life water is not filtered and a recalculation of the BCF value based on the concentration of the Substance in filtered water would not reflect the behaviour of the Substance under '*real life conditions*'. The Appellant therefore claims that basing an assessment of bioaccumulation on this recalculated BCF value would violate the provisions of Annex XIII. The issue for the Board of Appeal to decide therefore is what meant by '*data obtained under relevant conditions'* in the present case.

112. The Board of Appeal observes that Annex XIII refers to '*relevant conditions*' and not '*real life conditions*'. The calculation of the BCF value is aimed at assessing the potential of the Substance to accumulate in biota, not the real accumulation in the specific conditions of a particular case. The Board of Appeal further notes that substance

evaluation is focused on a substance holistically and not on a substance as registered by a specific registrant. There is also nothing in Annex XIII to suggest that testing conditions for bioaccumulation must be limited to the most frequent patterns of distribution of a substance in the environment.

113. In light of the above, the Board of Appeal finds that '*relevant conditions*' within the meaning of Annex XIII means those conditions that allow for an objective assessment of the PBT/vPvB properties of a substance and not the PBT/vPvB properties of a substance in particular environmental conditions.

114. The Board of Appeal further observes that the known physico-chemical properties of a substance must be taken into account when assessing the '*relevant conditions*' which apply. In the present case, the Board of Appeal observes that the Substance is of very low solubility, potentially persistent, lipophilic and, most importantly, highly adsorbing to organic matter. The BCF value must therefore be calculated under conditions such that the bioavailability of the Substance to fish can be estimated correctly and therefore the fraction of the Substance adsorbed to organic matter, which is not bioavailable, must be excluded from the calculation.

115. The Board of Appeal notes that whilst OECD TG 305 states that organic matter should not be removed (filtered) when taking samples to measure a substance's concentration in water, this is because OECD TG 305 is based on the premise '*that organic matter should be kept as low as possible'* and the '*content of organic* [matter] *should be* [strictly] *monitored'* in all the previous stages before the taking of samples for analysis.

116. The Board of Appeal observes that if the Appellant had provided evidence showing that the estimated bioavailability of the Substance reflected '*relevant conditions*' for the assessment of PBT/vPvB properties a recalculation of the BCF value would not be necessary. However, the Contested Decision correctly finds that the BCF value calculated by the Appellant does not reflect '*relevant conditions*' and as a consequence imposes conditions on the recalculation of the BCF value to reflect '*relevant conditions*'. The Board of Appeal therefore considers that recalculation of the BCF value with the concentration of the Substance in filtered water is justified.

117. The Board of Appeal observes that the Appellant is given a choice of recalculating the BCF value or conducting a new test according to OECD TG 305. If the Appellant rejects the adaptation of the method requested by the Agency (recalculation of the BCF value with the concentration of the Substance in filtered water), then it is allowed to carry out a new test following the provisions of OECD TG 305.

118. The Appellant's plea that the Agency breached Annex XIII must therefore be dismissed.

B. Alleged breach of Article 47

119. The Appellant argues that the Contested Decision also infringes Article 47(1) which provides that '*[an] evaluation of a substance shall be based on all relevant information submitted on that particular substance […]*'. Specifically, the Appellant argues that a recalculation of the BCF value using the original data from filtered water would not reflect real exposure conditions and that therefore the data obtained from this request would not be '*relevant information*'.

120. The Board of Appeal notes that the meaning of '*relevant information*' in Article 47(1) is different from that of '*relevant conditions*' in Annex XIII. '*Relevant information*' in Article 47(1) means that all information that could be useful in the evaluation of a substance should be taken into account in that evaluation. If a substance evaluation is only of particular potential properties or risks then it is quite likely that not all information on the substance would be relevant to the particular properties or risks being assessed. In other words, some information on the substance may not be relevant for that particular evaluation. In the present case, all the data obtained from both the filtered and non-filtered water is relevant to this evaluation.

121. Furthermore, for the reasons explained above (see paragraphs 110 to 118), obtaining information based on filtered water must, in any case, be considered '*relevant information*', within the meaning of Article 47, for the assessment of the bioaccumulative properties of the Substance. The Appellant's claim that the Agency breached Article 47 must therefore be dismissed.

C. Alleged violation of OECD TG 305

122. As regards the Appellant's plea that the Contested Decision is '*in violation of several provisions of the OECD Guideline concerning OECD TG 305*', the Board of Appeal firstly observes that OECD TG 305 is not a legally binding piece of legislation that could be 'breached' by the Agency. The Board of Appeal has also previously held that under substance evaluation it may be appropriate to request information using modified test methods, for example, to examine parameters which are not normally considered in standard test methods. This helps to ensure that information generated pursuant to a substance evaluation decision meets real information needs (see Case A-009-2014, *Albemarle Europe Sprl and Others*, Decision of the Board of Appeal of 12 July 2016, paragraph 156). Under substance evaluation the Agency may therefore, under certain circumstances, deviate from test methods or guidelines where appropriate and if duly justified.

123. As set out paragraphs 110 to 121 above, the Agency was justified in requesting that the BCF value be recalculated using data on filtered water. As a result, even if the Agency's request did not follow the precise requirements of OECD TG 305 this does not in itself mean that the Agency committed an error that would entail the annulment of this part of the Contested Decision.

124. Furthermore, the Appellant has been given the choice not to recalculate the BCF value and to repeat the test adhering to OECD TG 305. The Appellant's claim that the request for the recalculation of the BCF value should be annulled on the grounds that it is '*in violation of several provisions of the OECD Guideline concerning OECD TG 305*' must therefore be dismissed.

125. In light of the above, the Appellant's claim related to the requirement to recalculate the BCF value using the original data from filtered water and to provide the raw data must be dismissed in its entirety.

D. Breach of the principle of proportionality

126. The Appellant also argues that the Contested Decision is disproportionate because the requested information is unlikely to produce scientifically meaningful results and is unsuitable for assessing the bioaccumulation of the Substance in fish. The Appellant claims further that, since a recalculation of the BCF value using the original data from filtered water would not reflect real exposure conditions, the information requested has no realistic possibility of leading to improved risk management measures.

127. The Board of Appeal notes that the principle of proportionality requires that European Union 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; see also Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 72).

128. For the reasons explained above (see paragraphs 110 to 125) when examining the relevance of the requested information and its compliance with Annex XIII and Article 47, the Board of Appeal accepts the necessity and suitability of the request to recalculate

the BCF value using filtered water in order to clarify whether the Substance is bioaccumulative.

129. The Board of Appeal also observes that if the Substance is shown to be PBT or vPvB following the assessment of the information required by the Contested Decision the Substance may be considered to be a substance of very high concern and therefore potentially subject to authorisation and/or restrictions. As a result, the Board of Appeal considers that the Contested Decision has a realistic possibility of leading to improved risk management measures.

130. Furthermore, as stated above in paragraph 112 above, under substance evaluation the particular potential properties of, and risks posed by, a substance are considered holistically and not only the potential properties of, and risks posed by, a substance in certain registrant specific environmental conditions. In the present case, if the recalculation of the BCF value in filtered water shows the Substance to be bioaccumulative, risk management measures may be relevant for all or certain uses of the Substance.

131. The Board of Appeal will therefore examine whether the measure imposed was the least onerous. In this respect, the Board of Appeal observes that the Contested Decision provides the Appellant with the option of either recalculating the BCF value with filtered water or carrying out a dietary bioaccumulation test in fish (OECD TG 305). In this respect, the Board of Appeal notes that the Contested Decision already makes provision for the least onerous measure, namely not repeating the test if the relevant information for the recalculation could be provided by the Appellant. Furthermore, the Appellant has not provided an alternative, other than simply not performing the recalculation.

132. The Board of Appeal finds that the Appellant's claim that the request to provide the requested information on bioaccumulation breaches the principle of proportionality must therefore be dismissed.

E. Alleged error of assessment in using information on dolphins to justify the concern

133. The Appellant claims that in using the results of the study on dolphins to support its decision the Agency committed a manifest error of assessment.

134. The section of the Contested Decision entitled '*Summary of the Registrants' comments and response to comments*' contains the following paragraph:

'*The eMSCA highlights that recent results of a scientific study (Gago-Ferrero et al.[…], 2013) indicate for the first time that [the Substance] accumulates in liver of dolphins at high concentration levels (up to 782 ng.g*$^{-1}$ *lipid weight) similar to those of anthropogenic organic persistent pollutants. eMSCA invites the Registrant(s) to consider this new study in the hazard assessment of the substance.*'

135. The Appellant argues that this statement indicates that the Agency used the study on dolphins as a basis for its decision to request additional information on bioaccumulation in fish. According to the Appellant, this study is not relevant to bioaccumulation in fish and as a result the Agency committed a manifest error of assessment regarding the data upon which the request is based.

136. In deciding whether there is an error in 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, Case A-004-2014, *Altair Chimica SpA and Others*, Decision of the Board of Appeal of 9 September 2015, paragraph 42, as well as by analogy, Case T-71/10, *Xeda International and Pace International v Commission*, EU:T:2012:18, paragraph 71).

137. The Board of Appeal observes that the request for information was initially justified by the concerns identified from other literature (see paragraph 107 above).

138. The Board of Appeal also notes that the reference to the study on dolphins was inserted following the Appellant's comments on the draft decision in which the Appellant argued that the recalculation based on filtered samples did not reflect real exposure conditions.

139. In the Defence the Agency indicates that the study on dolphins was indeed one of the grounds for identifying the potential concern that the requested information is intended to clarify:

'*…[T]here is a specific concern for [the Substance] and its bioaccumulation potential. In particular, and as presented in the Contested Decision, there are several sources of scientific literature which indicate the occurrence of [the Substance] in fish or in liver tissue for dolphins. These results, together with the high lipophilicity of [the Substance], indicate its bioaccumulation potential and form the need for further information in that respect*'.

140. The Contested Decision does not however state that the study on dolphins is used to assess the bioaccumulation potential of the Substance. Rather it is one of several pieces of evidence that indicate the potential concern that needs to be clarified. This is also confirmed by the Agency which stated in the Defence that '*[…] it is not claimed by [the Agency] that data on dolphins is used for demonstrating bioaccumulation potential of the Substance in fish*'. The Agency argues that, contrary to the Appellant's assumption, the study on dolphins serves only as supporting information to indicate the concern which needs further investigation. The Board of Appeal observes that Point 3.2.2(b) of Annex XIII is aimed at assessing bioaccumulation generally and is not restricted to fish. This provision also states that other information on bioaccumulation potential can be used. The Board of Appeal finds, therefore, that the study on dolphins is '*relevant information*' within the meaning of Article 47 and should therefore form part of the information on which the evaluation of the Substance is based.

141. The Board of Appeal considers therefore that the study on dolphins must be seen as just one of several indicators of a potential concern used by the Agency. The Agency has identified other evidence to justify the request for information to clarify the bioaccumulation potential of the Substance (see paragraph 107 above) which has not been contested by the Appellant. Consequently, even if the Board of Appeal were to find that the study on dolphins was not relevant to the justification of the potential concern on bioaccumulation, there were other grounds on which the request was based which have not been contested. As a result, the Appellant's claim that the Agency committed a manifest error of assessment must be dismissed.

142. In view of the above, the Appellant's plea related to the request to provide information on bioaccumulation must be dismissed.

VII. Appellant's plea concerning the request for information using the AFSS study

Arguments of the Parties

143. The Appellant claims that the requirement to provide information using the AFSS study breaches the principle of proportionality as it will not generate useful information for the assessment of the endocrine disrupting properties of the Substance.

144. The Appellant argues that '*the AFSS will neither provide the unique indication of anti-androgenicity nor sufficient information on all flagged potential endocrine mechanism of action*'. According to the Appellant, the Agency has therefore not demonstrated that performing the AFSS study has a realistic possibility of leading to improved risk management measures.

145. The Appellant claims that the AFSS study would be of questionable scientific value. According to the Appellant the AFSS study has not been endorsed by the OECD as a test guideline, but only as a guidance document, for the following reasons:

- the AFSS study focuses only on one mechanism of endocrine action and therefore is not suitable for a general screen on endocrine disrupting chemicals. As a result, the AFSS study '*has to be used in addition to OECD TG 229 or TG 230, which, for [the Substance], do not exist*';
- '*the AFSS needs an additional treatment with dihydrotestosterone that provokes inconsistencies with current developments and practice*'; and
- sticklebacks are not available from commercial suppliers or the Appellant's own breeding stocks and therefore have to be collected from the field which creates problems related to geographical variation in genetics and contamination.

146. The Appellant argues further that, since the requested test is unsuitable to generate reliable information relevant for the assessment of the Substance, the Contested Decision violates Article 25.

147. According to the Agency, there are *in vitro* studies available for the Substance which address the anti-androgenic, androgenic, and estrogenic potentials of the Substance. These studies demonstrate very low estrogenic and androgenic potential but indicate a potential concern with regard to anti-androgenic effects. According to the Agency, the anti-androgenic activity is the only mechanism raising a concern regarding the potential of the Substance to induce *in vivo* effects on the endocrine system. The Agency argues therefore that there is a concern that needs to be investigated further and that the test chosen is suitable to clarify that concern.

148. The Agency states that, due to the specific need to clarify the anti-androgenic mechanism, no general screen on endocrine disrupting properties was considered necessary.

149. The Agency claims that the requested study can be performed in accordance with an internationally recognised test method which was considered appropriate by the authorities involved in the decision-making procedure. The Agency adds that, in accordance with Article 13(3), the Agency may recognise an internationally agreed test method as being appropriate.

150. The Agency argues that no problems in using sticklebacks from the field have been identified and that any potential weaknesses with this test have been already accounted for during its validation.

Findings of the Board of Appeal

151. According to the Contested Decision '*… a potential estrogen agonist/antagonist and potential androgen antagonist effect of [the Substance] are raised and more information is considered needed to clarify this concern*'.

152. In order to clarify the identified concern the Contested Decision requires the Appellant to carry out an AFSS study on the three-spined stickleback (*Gasterosteus aculeatus*) (OECD TG 230 modified, Series on Testing and Assessment n^{o} 148) using the Substance.

153. The Board of Appeal observes at the outset that the Appellant has not disputed in the present proceedings that there is a ground for concern regarding the anti-androgenic potential of the Substance. The Appellant is rather contesting the suitability of the requested test to clarify that concern.

154. The Board of Appeal notes that according to the Contested Decision, the AFSS study '*is the only one specifically targeted on the anti-androgenic actio*n…'. The Board of Appeal also observes that the requirement to conduct an OECD TG 229 test was included in the draft decision but was later removed following the Appellant's comments, and the PfAs by certain MSCAs, '*… because it has low statistical power to detect anti-androgens.*'

155. The Board of Appeal observes that, as confirmed by the Appellant in its Notice of Appeal, the AFSS study is an *in vivo* assay which focuses on one mechanism of endocrine action.

This is made clear in the introduction to the OECD guidance document on the AFSS study:

'*This [AFSS study] describes a 21-day in vivo assay for identifying endocrine active chemicals with (anti)androgenic activity in fish using female sticklebacks (Gasterosteus aculeatus). The concept of this assay is derived from work on the three-spined stickleback, since the presence of the specific biomarker (i.e. spiggin) for androgens is present only in this species. Although current OECD Test Guidelines 229 and to some extent 230 can detect androgen antagonism in addition to other endocrine disrupting actions, the activity detected is not always clearly specific to androgen antagonism….*'

156. The OECD guidance document on the AFSS study explains further that:

'*The AFSS protocol is in principle similar to the new OECD TG 230 (21-day Fish Assay: A short-term screening for oestrogenic and androgenic activity and aromatase inhibition), with two major differences: 1) only female fish are used, and 2) all groups except controls (water, solvent and test substance at the highest concentration used) receive 5* µg*/L dihydro-testosterone (DHT), in addition to the test substance compound. DHT is used in order to induce a fully controlled moderate level of the androgen regulated protein spiggin in the female stickleback kidney, to allow the detection of (anti)androgens. Following a chemical exposure period of 21 days, the AFSS detects androgen receptor agonists and antagonists*.'

157. The Board of Appeal finds that the OECD guidance document therefore highlights that the AFSS study is looking specifically for androgen antagonism, the concern specifically identified in the Contested Decision, and that whilst this effect may be detected by OECD TG 229 or OECD TG 230 the activity detected is not always clearly specific to androgen antagonism. The Board of Appeal also finds that there is nothing in the relevant OECD test guidelines or other documents to indicate that OECD TG 229 and/or OECD TG 230 are considered as a necessary prerequisite or precondition for conducting an AFSS study. If OECD TG 229 and OECD 230 are not conducted, there may be a lack of information on other endocrine disrupting actions but this will not affect the validity of the results of an AFSS study on androgen antagonism.

158. The Board of Appeal finds therefore that the AFSS study is an appropriate test to obtain information on the anti-androgenic potential of the Substance, the concern identified in the Contested Decision as requiring further investigation. As a result, the AFSS study has a realistic possibility of clarifying the potential concern identified and if the results of the test are positive appropriate risk management measures could be put in place accordingly, including potentially authorisation and/or restrictions.

159. The Board of Appeal also observes that, pursuant to Article 13(3), '*[w]here tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate […]*'.

160. Consequently, pursuant to Article 13(3), the Agency may recognise an international test method as being appropriate. In this regard the Board of Appeal observes that no agreed OECD TG specifically targeted at anti-androgenic potential has been identified during the present proceedings. Furthermore, Article 13(3) does not limit the scope of test methods to those that have been adopted by OECD as test guidelines. The Board of Appeal also observes that the Appellant has not proposed a more appropriate test method for investigating the identified concern.

161. The Board of Appeal observes further that the AFSS study requested in the Contested Decision follows the test approach supported by the OECD conceptual framework for the testing of endocrine disruption (Guidance document on standardized test guidelines for evaluating chemicals for endocrine disruption, Series on Testing and Assessment, No. 150, OECD, Paris 2012; hereinafter the 'OECD conceptual framework'). This test method

has also been endorsed by the Working Group of the National Coordinators of the Test Guidelines Programme of the OECD. In addition, the AFSS study, OECD 229 and OECD 230 are all at level 3 of the OECD conceptual framework.

162. The Board of Appeal therefore concludes that the AFSS study is a recognised international test method recognised by the Agency pursuant to Article 13(3) and as such the Appellant's arguments in this regard must be dismissed as unfounded.

163. In the interests of completeness, the Board of Appeal observes that many of the arguments raised in these appeal proceedings regarding the use of dihydrotestosterone and potential problems related to the use of sticklebacks collected from the field have been examined in the OECD Peer Review Report of the Validation of the 21-day Androgenised Female Stickleback Screening Assay (24 August 2011; hereinafter the 'Peer Review'), which is published on the OECD website. The Board of Appeal observes that the Peer Review was part of the process for the adoption of the AFSS study and the result of that process, including consideration of these arguments, was the adoption of the AFSS study as part of the OECD conceptual framework. It is not the role of the Board of Appeal to re-evaluate the views expressed in a peer review or the process leading to the adoption of a test method. The AFSS study is part of the OECD conceptual framework and as such is considered by the Board of Appeal to be internationally agreed.

164. The Appellant's plea related to the proportionality of the request to perform the AFSS study must therefore be dismissed as unfounded.

165. The Appellant also argues that since an AFSS study is unsuitable to generate the information required, the Contested Decision breaches Article 25(1) which provides that '*[i]n order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests*.' However, the Board of Appeal has already dismissed the Appellant's arguments related to the suitability of the AFSS study to investigate concerns related to the anti-androgenic potential of the Substance. Furthermore, the Board of Appeal observes that the Appellant has not identified any suitable alternative to the requested study. The Appellant's arguments related to the infringement of Article 25(1) must also therefore be dismissed as unfounded.

166. In view of the above, the Appellant's appeal must be dismissed in its entirety.

VIII. Refund of the appeal fee

167. 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.

168. As the appeal has been dismissed, the appeal fee shall not be refunded.

IX. Effects of the Contested Decision

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

170. The Contested Decision, upheld in the present appeal proceedings, required the registrant, now the Appellant, to submit information by 18 September 2016, which is 24 months plus one week from the adoption of the Contested Decision on 11 September 2014. 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 24 months plus one week from the date of notification of the Board of Appeal's decision of 19 December 2016 rectifying the Board of Appeal's final decision of 7 December 2016 in the present case.[1]

171. Consequently, the information required by the Contested Decision shall be submitted to the Agency within 24 months plus one week from the date of notification of the Board of Appeal's decision of 19 December 2016 rectifying the Board of Appeal's final decision of 7 December 2016 in the present case.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information requested in the Contested Decision shall be submitted to the Agency by 26 December 2018.**
3. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal

[1] Paragraphs 170 and 171, and Point 2 of the Order of this Decision have been corrected in accordance with the Board of Appeal's rectification decision of 19 December 2016 which was adopted pursuant to Article 26 of the Rules of Procedure.