EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

8 September 2017

(Substance evaluation – PBT assessment – Persistence – Proportionality – Relevant conditions for persistence testing – Equal treatment)

Case number	A-026-2015
Language of the case	English
Appellants	Envigo Consulting Limited, United Kingdom DJChem Chemicals Poland Spółka Akcyjna, Poland
Representatives	Ruxandra Cana, Craig Simpson and Eléonore Mullier Steptoe & Johnson LLP, Belgium
Intervener	The German Member State Competent Authority Represented by: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Germany
Contested Decision	Decision of 1 October 2015 on the substance evaluation of 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives, adopted by the European Chemicals Agency pursuant to Article 46 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 BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. This appeal is directed against a substance evaluation decision adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 46 of the REACH Regulation (all references to Titles, Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

2. The Appellants are registrants of the substance 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivatives (CAS No 68953-84-4, EC No 273-227-8; hereinafter the 'Substance' or 'BENPAT'). The Substance is used predominantly in the production of tyres as an antioxidant in rubber mixtures. It is registered in quantities above 1000 tonnes *per annum*.

3. The Substance was included in the Community rolling action plan ('CoRAP') for substance evaluation in 2013 due to initial grounds for concern relating to its persistent, bioaccumulative and toxic (hereinafter 'PBT') properties and its wide dispersive use, including use by consumers.

4. The German Member State Competent Authority (hereinafter the 'eMSCA') was appointed to carry out the evaluation.

5. The eMSCA prepared a draft decision pursuant to Article 46(1) requesting further information on the Substance. This draft decision was notified to the registrants of the Substance in accordance with Article 50(1) on 28 August 2014.

6. The registrants duly commented on the draft decision by 6 October 2014. The eMSCA considered those comments and notified a revised version of the draft decision to the other Member State Competent Authorities and to the Agency on 5 March 2015. Three Competent Authorities and the Agency submitted proposals for amendment pursuant to Article 51(2) in conjunction with Article 52(2).

7. The eMSCA reviewed the proposals for amendment and further amended the draft decision accordingly. The amended draft decision was referred to the Member State Committee (hereinafter the 'MSC') on 20 April 2015.

8. On 8 May 2015, the registrants of the Substance provided comments on the proposals for amendment. These were considered at the MSC meeting, together with the amended draft decision, on 8 to 11 June 2015.

9. The MSC reached unanimous agreement on a modified version of the amended draft decision in its meeting of 8 to 11 June 2015. The Contested Decision was subsequently adopted by the Agency on 1 October 2015.

10. The Contested Decision requires the Appellants to submit, *inter alia*, further information on the persistence of the Substance by 8 April 2018. Section II of the Contested Decision, entitled '*Information required*', is worded as follows:

    '*Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:*

    […]

    [-] Simulation testing on ultimate degradation in surface water (test method: Aerobic mineralisation in surface water - simulation biodegradation test, EU C.25/ OECD 309) as specified in section III. 4 using constituent R-8981 as representative for BENPAT [hereinafter the "OECD TG 309 study"].

    [-] In case the [OECD TG 309 study] does not allow to conclude that [the Substance] is persistent (P) or very persistent (vP) according to Annex XIII, 1.1.1. / 1.2.1. of the REACH Regulation additional sediment simulation testing (test method:

Aerobic and anaerobic transformation in aquatic sediment system, EU C.24/OECD 308 as specified in section III. 3) using constituent R-8982 as representative for BENPAT [hereinafter the "OECD TG 308 study"].'

11. As regards the OECD TG 309 study, Section III of the Contested Decision, entitled '*Statement of reasons*', provides:

'*It is important that metabolites are identified to show that degradation in the test system was observed. To this end the following conditions shall be fulfilled:*

- *Metabolites representing crucial steps in transformation pathways (key metabolites) shall be identified by use of QSAR. Standard solutions shall ensure that detection and quantification of these key metabolites is possible. […].*
- *Sufficient measurements shall be done to enhance kinetic modelling. […]*
- *The test substance shall be radiolabelled due to the low water solubility for an appropriate verification of the degradation. […]*
- *The test shall be done as pelagic test without addition of sediment. Test evaluation shall be comprehensive and orientate itself at the proceedings usual for pesticides.*

[…]

For the registered substance detection and identification of metabolites shall be provided. This is also based on indications in available data.'

12. In addition, Section III of the Contested Decision contains the following statement:

'*BENPAT is suspected to be of very high concern due to its PBT (persistent, bioaccumulative, toxic) properties. Evidence shows that BENPAT is bioaccumulative and [toxic]. As the [bioaccumulation] and the [toxicity] criteria [in Annex XIII] are fulfilled the [persistence] criterion has to be assessed*.'

Procedure before the Board of Appeal

13. On 23 December 2015, the Appellants lodged the present appeal at the Registry of the Board of Appeal.
14. On 8 March 2016, the Agency submitted its Defence.
15. On 13 April 2016, the eMSCA was granted leave to intervene in this case in support of the Agency.
16. On 2 June 2016, the Appellants submitted their observations on the Defence.
17. On 8 July 2016, the Agency submitted its observations on the Appellants' observations on the Defence.
18. On 20 June 2016, the eMSCA submitted its statement in intervention.
19. On 31 October 2016, the Appellants and the Agency submitted their observations on the statement in intervention.
20. On 3 February 2017, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. As the Appellants requested a hearing to be held, and pursuant to Article 13 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), as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4), the Parties were summoned to a hearing which took place on 27 April 2017. At the hearing, the Parties and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

21. The Appellants request the Board of Appeal to:
    - annul the Contested Decision insofar as it requires the OECD TG 309 study and the OECD TG 308 study;
    - annul the Contested Decision insofar as it concludes that the Substance is bioaccumulative in accordance with Annex XIII;
    - order the refund of the appeal fee; and
    - take '*such other or further measures as justice may require*'.
22. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

23. The Appellants raise three pleas in law against the Contested Decision which the Board of Appeal will examine in Sections I, II and III below.

I. The first plea in law, alleging that the requests for the OECD TG 309 and OECD TG 308 studies are disproportionate

24. By their first plea in law the Appellants claim that the requirement in the Contested Decision to perform the OECD TG 309 and OECD TG 308 studies is disproportionate.
25. This plea consists of four parts. The Appellants claim, first, that further persistence testing on the Substance is unnecessary; second, that the OECD TG 309 study is not appropriate to achieve the objective pursued; third, that the OECD TG 308 study is not appropriate to achieve the objective pursued; and fourth, that an OECD TG 307 study is a more appropriate, and less onerous, option than either the OECD TG 309 or the OECD TG 308 studies.
26. Each of the four parts of the first plea will be examined in turn.

A - The first part of the first plea, alleging that further persistence testing is unnecessary

Arguments of the Parties

27. By the first part of their first plea, the Appellants claim that it is not necessary to conduct further persistence testing on the Substance. According to the Appellants, the Agency's finding that the Substance could be persistent is vitiated by several errors.
28. The Appellants rely, in particular, on an enhanced persistence screening study included in their registration dossiers and filed in evidence with the Notice of Appeal (M. Daniel and others, *Assessment of the biodegradation rate of [^{14}C]R898 in a modified carbon dioxide evolution test (OECD 301B)*, Brixham Environmental Laboratory, June 2012; hereinafter the 'OECD TG 301/302 study').
29. The Appellants argue that the OECD TG 301/302 study shows that, within 28 days, 19 to 27% of the Substance is mineralised.
30. According to the Appellants, the OECD TG 301/302 study also shows that 31 to 38% of the Substance is metabolised by microorganisms or otherwise broken down into other substances.

31. Consequently, according to the Appellants, the results of the OECD TG 301/302 study show that between 50 and 65% of the Substance fully degrades within 28 days. It logically follows that more than half of the Substance fully degrades within 40 days. Therefore, although the speed of degradation measured in the OECD TG 301/302 study is not sufficiently high to reach the '*pass level*' required for a finding of non-persistence in the screening study, the Appellants argue that it shows that the Substance does not exceed the half-life for persistence in any of the environmental compartments listed in Section 1.1.1. of Annex XIII. According to the Appellants, these results demonstrate that the Substance is not persistent within the meaning of Annex XIII. The Agency therefore committed an error in considering that the results of the OECD TG 301/302 study were insufficient to address the persistence of the Substance.

32. The Appellants add that their approach is supported by the Agency's Guidance on information requirements and chemical safety assessment (version 2.0, 2014; hereinafter the 'Guidance on registration'). They claim that Chapter R11 of this Guidance shows that it is possible to derive a half-life of a substance from screening tests.

33. The Appellants also challenge the conclusion in the Contested Decision that further persistence testing is necessary because '*it is not known whether the metabolites formed in the available [OECD TG 301/302 study] would pose a problem regarding persistence*'.

34. The Appellants argue that the Agency failed to take into account information that addressed the persistence of the metabolites of the Substance. They claim that, although they were not able to identify the metabolites formed in the OECD TG 301/302 study directly, they have identified these metabolites through a pathway prediction model developed by the University of Minnesota in the United States of America (hereinafter the 'Minnesota Pathway Model'). According to the Appellants, the polarity of the metabolites of the Substance, which can be determined on the basis of their predicted identity, indicates that those metabolites are likely to be less persistent than the Substance itself.

35. The Appellants also challenge the Contested Decision insofar as it requires that, when performing the OECD TG 309 study, '*metabolites representing crucial steps in transformation pathways (key metabolites) shall be identified by use of [quantitative structure-activity relationship models]*'. The Appellants submit that these results are already available to the Agency from the application of the Minnesota Pathway Model.

36. The Appellants further challenge the Contested Decision insofar as it states that the '*incorporation [of the Substance] into biomass*' has not been established. According to the Appellants, the OECD TG 301/302 study investigated this '*incorporation*' and the Agency erred by rejecting the results of the OECD TG 301/302 study on the grounds that '*some doubts remain whether real incorporation or simple adsorption was measured because the procedure for evidence of incorporation into biomass is not a standard procedure*'.

37. The Agency states that the Appellants' registration dossiers included several persistence screening studies, one of which was the OECD TG 301/302 study. According to the Agency, such screening studies only show that a substance is not persistent if the '*pass level*' required for a finding of non-persistence is reached. Due to the nature and set-up of screening studies, the required '*pass level*' is higher than the half-life criteria set out in Section 1.1.1. of Annex XIII.

38. The Agency argues that the Substance did not reach the '*pass level*' for a finding of non-persistence in any of the submitted screening studies, including the OECD TG 301/302 study. The available information therefore shows that the Substance is potentially persistent. The results of the OECD TG 301/302 study do not call into question this conclusion.

Findings of the Board of Appeal

39. By the first part of the first plea, the Appellants claim, in essence, that further persistence testing is disproportionate because it is not necessary.

40. The principle of proportionality requires that acts of EU law must not exceed what is appropriate and necessary to attain the objective pursued. When there is a choice between several appropriate measures, the least onerous measure must be used (judgment of 15 September 2016, *Morningstar* v *Commission*, T-76/14, EU:T:2016:481, paragraph 84 and the case-law cited).

41. In order to demonstrate the necessity of a request for information in the context of substance evaluation, the Agency must be able to demonstrate that there is a potential risk to human health or the environment, that this risk needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures (Case A-015-2015, *Evonik Degussa and Others*, Decision of the Board of Appeal of 30 June 2017, paragraph 78 and the previous decisions cited therein).

42. As regards the existence of a potential risk to human health or the environment, it should be recalled that the identification of a potential risk is based on a combination of hazard and exposure information. Where there is high potential exposure to a substance the evidence of a potential hazard may be correspondingly less (to this effect, *Evonik Degussa*, cited in the previous paragraph, paragraphs 79 and 82 and the previous decisions cited therein).

43. In order to establish a potential risk to the environment on grounds of persistence, the Agency must be able to show, first, that there is a potential for exposure to the Substance in any or all of the environmental compartments listed in Section 1.1.1. of Annex XIII (water, sediment, and soil). It must also be able to show, second, that the Substance poses a potential persistence hazard in the environment in that its half-life may exceed the relevant threshold.

44. With regard to potential environmental exposure, the Board of Appeal observes that the Substance has been registered in considerable quantities (above 1000 tonnes *per annum*) and that it is used in the manufacture of tyres, particularly as an antioxidant in rubber mixtures.

45. It is not disputed that the Substance can be contained in the rubber particles that '*rub off*' from tyres during use and that it can subsequently '*leach*' into the environment.

46. The Appellants used a model to predict the distribution of the Substance in the environment (hereinafter the 'Level III fugacity model'). According to this model, once the Substance has '*leached*' from rubber particles, its three main constituents are expected to be found in the water (3.98-7.71%), sediment (22.1-34.4%) and soil (59.6-70.2%) compartments.

47. The Board of Appeal therefore finds that there is a potential for exposure to the Substance in all of the environmental compartments listed in Section 1.1.1. of Annex XIII.

48. With regard to the existence of a potential environmental hazard, the Board of Appeal observes that the Appellants' registration dossiers contain several persistence screening studies (ready or inherent biodegradability studies, and enhanced biodegradability studies).

49. The Substance did not reach the '*pass level*' for a finding of non-persistence in any of these screening studies, including the OECD TG 301/302 study. According to the Contested Decision:

'*Screening tests on ready biodegradability show only marginal degradation of BENPAT and enhanced screening tests on degradation show that BENPAT does not reach the pass level. Thus the screening tests provided by the Registrant(s) do not allow to conclude that the substance is not persistent but indicate persistence of BENPAT according to Section [1.1.1.] of Annex XIII […]. In the enhanced screening tests BENPAT did not reach the pass level*.'

50. The Board of Appeal notes that the purpose of screening studies is not to identify whether a substance has a particular intrinsic property but to identify those substances which are unlikely to have a particular property. The objective being to avoid unnecessary testing. In this case, the results of the screening studies included in the Appellants' registration dossiers did not exclude that the Substance may be persistent. From this, in the absence of any further information, it can be logically concluded that the Substance might be persistent in the environment.

51. The Appellants allege, however, that the Agency committed several errors in the assessment of one of the enhanced screening studies at issue, namely the OECD TG 301/302 study, and other associated information. Each allegation will be examined in turn.

1. The allegation that the Agency failed to take into account information on the persistence of the metabolites of the Substance

52. The Appellants claim that, in arriving at its conclusion that the Substance poses a potential environmental hazard, the Agency failed to take into account information on the persistence of the metabolites of the Substance.

53. This information consists, in essence, of the finding that the metabolites of the Substance are less persistent than the Substance itself. This finding, which was included in the Appellants' registration dossiers, was derived from the application of the Minnesota Pathway Model (see paragraph 34 above).

54. In particular, the Appellants stated in their comments on the draft decision:

'*In order to understand the biodegradation pathways relevant for the Substance and the likelihood the Substance's metabolites will be incorporated in the biomass, the [Minnesota Pathway Model] was used to predict possible metabolites of the Substance […]. Two amino acids, aspartic acid and glycine were identified as plausible products. These could, in turn, be incorporated into the cell protein fraction. […] The registrant tried to calculate the number of metabolites, but due to the large number of potential degradation products (> 38), this was not feasible. As such, [the eMSCA] recommended, during the January 2013 live meeting, that the registrant assess the persistence of the degradation products on the basis of polarity, since polarity can be a measure for the potency of persistence. This assessment has been conducted and it was concluded that the degradation products are more polar than the parent compound. Thus, there is sufficient evidence that (1) primary degradation takes place (2) potential degradation products in water have been identified (3) potential degradation products are not persistent.*'

55. At the outset, the Board of Appeal notes that, according to the fifth introductory paragraph to Annex XIII, the assessment of whether a substance is PBT or vPvB '*shall also take account of the PBT/vPvB properties of […] relevant transformation and/or degradation products*'. It follows that information on the persistence of the metabolites of the Substance must be taken into account by the Agency when assessing the persistence of the Substance itself.

56. The Contested Decision states in this regard that '*[i]t is important that metabolites are*

identified [by means of experimental data] to show that degradation in the test system [of the OECD TG 301/302 study] was observed'. At the hearing, the Agency explained that it considers the identification of the metabolites by means of experimental data to be a necessary condition for drawing any conclusions concerning their persistence.

57. The Board of Appeal observes that the Appellants' findings concerning the persistence of the metabolites of the Substance derive from a deductive chain. The Appellants reasoned that the identity of the metabolites can be predicted, their polarity deduced from their identity, and their persistence from their polarity.

58. However, as clarified by the Appellants (see paragraph 34 above), the metabolites formed in the OECD TG 301/302 study could not be identified directly, nor are there any other experimental data allowing their identification. It follows that the Appellants' findings on the persistence of the metabolites of the Substance are not supported by any experimental data concerning the identity of those metabolites.

59. In these circumstances, the Agency was justified in holding that the deductive chain on which the Appellants relied – namely that the polarity of the metabolites can be deduced from their identity, and their persistence from their polarity – cannot, unless justified by further data on the identity of those metabolites, dispel the concern that the metabolites may be persistent.

60. The allegation that the Agency failed to take into account information on the persistence of the metabolites of the Substance must consequently be rejected.

2. The allegation that the Agency committed an error in assessing the results of the OECD TG 301/302 study

61. The Appellants claim, in essence, that the Agency's finding that the Substance is potentially persistent is tainted by an error in the assessment of the results of the OECD TG 301/302 study.

62. At the outset, it is necessary to reject the Appellants' argument that, according to the Agency's Guidance on registration, persistence screening studies can be used to derive the half-life of a substance for the purposes of PBT assessment.

63. It is apparent from Titles II and VI that registration and substance evaluation are two separate, although interlinked, processes. A registration is intended *inter alia* to provide hazard information, whilst the purpose of substance evaluation is to assess all the relevant information available on a substance, including from registrations, and to determine whether there is a potential risk that needs to be clarified as well as the means to clarify such a potential risk. The purpose of the two processes, whilst closely linked, is therefore clearly different.

64. In particular, whilst the weight-of-evidence assessment method may be similar under registration (Annex XI) and substance evaluation (Annex XIII), it is apparent that the conclusions reached by a registrant under Annex XI are not binding on the Agency when it reaches its own conclusions under Annex XIII. Whilst a registrant may consider that a weight-of-evidence assessment shows, for registration purposes, that a substance is not persistent, the Agency is entitled, pursuant to a substance evaluation, to come to the conclusion that the same substance is potentially persistent.

65. It follows that it is irrelevant whether the Guidance on registration allows registrants to derive half-lives of substances from screening studies. The issue is rather whether the Agency, in finding that the Substance is potentially persistent, has committed an error.

66. The Appellants claim, in this regard, that the Agency committed an error in its assessment of the results of the OECD TG 301/302 study as regards calculating the half-life of the Substance. They argue that, although OECD TG 301 and 302 studies are

generally designed to measure ready or inherent degradation, the Appellants extended the OECD TG 301/302 study to include an examination of the formation of metabolites. They claim that in so doing they established that the half-life of the Substance is less than the half-life for persistence in any of the environmental compartments listed in Section 1.1.1. of Annex XIII (see paragraphs 29 to 31 above).

67. This line of argument must be rejected for the following reasons.

68. First, there is an inherent difference between the set-up of ready or inherent biodegradation screening studies such as the OECD TG 301/302 study and of simulation studies such as OECD TG 309 and 308 studies.

69. The testing conditions of ready or inherent biodegradation screening studies are designed to maximise the degradation of a substance in a short period of time, for instance by means of a higher temperature, by the use of inocula and by ensuring that the tested substance is, in essence, the only carbon source available to micro-organisms.

70. The testing conditions of simulation studies, by contrast, are designed to derive a half-life for a tested substance in a certain environmental compartment. In the aquatic compartment, for instance, this is done by approximating the environmental conditions of pelagic waters by means of a lower temperature and the use of water derived from natural sources, that is with no inoculum and potentially containing organic matter as an additional carbon source.

71. Degradation in screening tests may take place, as a result of the test conditions, at a considerably higher rate than in simulation tests. As a consequence, a half-life derived on the basis of the OECD TG 301/302 study, which is a screening study, cannot be considered to be comparable to the results that will be derived from a simulation study, for example the requested OECD TG 309 study.

72. Second, the Appellants have in any event failed to establish that the half-life of the metabolites is shorter than the half-life of the Substance because they have not proven the identity of the metabolites (see paragraphs 57 to 59 above). As a consequence, although information on the persistence of the metabolites of the Substance must be taken into account when assessing the persistence of the Substance (see paragraph 55 above), the Appellants cannot rely on their assumption concerning the persistence of the metabolites in order to establish a half-life of the Substance.

73. The Appellants' argument that the Agency made an error in concluding that the OCED TG 301/3012 study does not address the persistence concern of the Substance must therefore be rejected.

3. The allegation that the Agency's assessment of the results of the OECD TG 301/302 study is vitiated by an error as regards the incorporation of the Substance into the biomass

74. The Appellants claim that further persistence testing is unnecessary because the results of the OECD TG 301/302 study demonstrate that part of the Substance is incorporated into the biomass and breaks down into metabolites which are further transformed. According to the Appellants, the fact that the testing approach used to determine whether the Substance was incorporated into the biomass is '*non-standard*' does not allow the results of the OECD TG 301/302 study to be dismissed.

75. The Board of Appeal observes that the substance evaluation report prepared by the eMSCA states in this regard:

'*The available studies show no biodegradation of BENPAT in standard test systems for ready biodegradability. Furthermore, the analysis of possible biodegradation pathways*

shows that BENPAT biodegrades slowly, if at all. The Enhanced Ready Biodegradability Tests show low biodegradation of BENPAT. The registrants state that one of the studies [i.e. the OECD TG 301/302 study] shows incorporation of the substance into biomass. However, it is not clear whether BENPAT was really incorporated into biomass under the conditions of the study. The observed effect might also be caused by adsorption of the substance into the biomass. […] As simulation studies are missing, precise environmental half-life data cannot be derived.'

76. Similarly, the Contested Decision states:

'*In the enhanced screening tests BENPAT did not reach the pass level. Metabolites were found but not identified. Nevertheless, an enhanced CO2 evolution test [i.e. the OECD TG 301/302 study], which was one of the enhanced screening tests mentioned, could indicate incorporation, i.e. degradation and use for growth, of BENPAT into biomass. However some doubts remain whether real incorporation or simple adsorption was measured because the procedure for evidence of incorporation into biomass is not a standard procedure. The supposed incorporation is a further indication of why an in-depth persistence assessment of BENPAT is necessary to elucidate whether the substance is persistent or not*.'

77. The Board of Appeal notes in this regard that the assessment by the Agency of the results of any information in a weight-of-evidence assessment under Annex XIII must take place on a case-by-case basis and in light of all the circumstances of the specific case.

78. Contrary to the Appellants' argument, it is apparent from the sections of the substance evaluation report and of the Contested Decision cited in paragraphs 75 and 76 above that the Agency's reason for holding that the OECD TG 301/302 study did not sufficiently investigate the incorporation of the Substance into the biomass was not simply that the method was '*non-standard*'. The Agency held that, because there is no standard analytical methodology in this regard, and in light of the tendency of the Substance to bind to solid matter, it is uncertain whether the Substance had been incorporated into the biomass or had instead been adsorbed. It follows that the Agency's assessment was not based on a generic rejection of '*non-standard*' test methods.

79. The Appellants also claim that the Contested Decision is inconsistent in that, on the one hand, it dismisses the results of the OECD TG 301/302 study for being '*non-standard*' whilst, on the other hand, it requires the Appellants to interpret the results of the requested OECD TG 309 study in a '*non-standard*' fashion.

80. However, the Board of Appeal observes that the evaluation of the results of the OECD TG 301/302 study performed by the Appellants and the evaluation of the results of the required OECD TG 309 study are separate and distinct exercises.

81. As assessments must take place on a case-by-case basis (see paragraph 77 above), there is no contradiction insofar as the Contested Decision deems the results of the evaluation of one study by a '*non-standard*' method to be inconclusive and requests the evaluation of the results of a different study by means of a different, equally '*non-standard*', method.

82. The Board of Appeal finds, therefore, that the Agency did not commit an error in the assessment of the results of the OECD TG 301/302 study as regards the incorporation of the Substance into the biomass.

4. Conclusion on the first part of the first plea

83. The Board of Appeal recalls that the screening studies included in the Appellants' registration dossiers did not demonstrate that the Substance would not be persistent in the environment (see paragraph 50 above). It is therefore possible that the Substance

may be persistent. Moreover, no error on the part of the Agency has been detected in this regard (see Sections 1 to 3 above). Consequently, the Board of Appeal finds that the Agency has established that the Substance poses a potential environmental hazard.

84. The Board of Appeal further recalls that there is a potential for environmental exposure to the Substance in the water, soil and sediment compartments (see paragraph 47 above).

85. The Board of Appeal finds therefore that the Contested Decision demonstrates that the Substance poses a potential risk to the environment.

86. This potential risk needs to be clarified, through the clarification of the persistence concern, because of the serious threat to the environment caused by persistent chemicals.

87. The Board of Appeal further notes that substances which are PBT or vPvB may be identified as substances of very high concern (hereinafter 'SVHC'). Further persistence testing, assessed together with the existing data, could show that the Substance is persistent within the meaning of Annex XIII. This may lead to its identification as a SVHC in accordance with Article 57, and subsequently to restriction or authorisation requirements in accordance with Titles VII and VIII. Further persistence testing therefore has a realistic possibility of leading to improved risk management measures.

88. It follows that the first part of the first plea must be rejected entirely.

B - The second part of the first plea, alleging that the OECD TG 309 study is not appropriate to achieve the objective pursued

Arguments of the Parties

89. By the second part of their first plea the Appellants argue that the OECD TG 309 study is not appropriate to achieve the objective pursued, that is to clarify whether the Substance is persistent in the environment.

90. First, according to the Appellants the Substance binds to the glass walls of the testing apparatus and this will render the test results impossible to interpret. In order to overcome this technical difficulty, a number of adaptations would have to be made to the test protocol for the OECD TG 309 study, as was done for the OECD TG 301/302 study. According to the Appellants, these adaptations have already been rejected by the Contested Decision as '*non-standard*'. The required testing is therefore not appropriate to investigate the degradation of the Substance.

91. Second, the Appellants argue that the required OECD TG 309 study will not address the alleged persistence of the Substance because the testing conditions prescribed by the Contested Decision are not '*environmentally relevant*'. According to the Appellants, due to its low solubility and its high tendency to bind to solid matter, the Substance is unlikely to distribute to the water phase in the natural environment. Soil, and not water, is therefore the '*main compartment of concern*'.

92. In support of this argument, the Appellants rely on:

- previous studies performed on the Substance, showing in particular its tendency to bind to solid matter and to form non-extractable residues (hereinafter 'NERs');
- an expert opinion submitted with the Notice of Appeal, stating that the Substance covalently binds to soil and sediment to form NERs that are predominantly not bioavailable and that an OECD TG 307 study (aerobic and anaerobic transformation in soil) is consequently more appropriate to investigate the persistence of the Substance than an OECD TG 309 study;

- the Level III fugacity model which shows that the Substance will mainly be found in soil and sediment;
- the exposure scenarios used in the Appellants' registration dossiers, and an OECD publication entitled '*Emission scenario document on additives in the rubber industry*' (OECD Series on Emission Scenario Documents No 6, ENV/JM/MONO (2004)11, 24 June 2004), showing that the Substance '*leaches*' slowly from tyre particles and, once in the aquatic environment, quickly binds to soil and sediment.

93. The Appellants add that the formation of NERs is also a form of degradation of the Substance that will take place once the Substance is in the natural environment. However, the requested OECD TG 309 study only investigates mineralisation and the formation of metabolites. As a consequence, according to the Appellants, this study is not appropriate to determine whether the Substance is persistent or not.

94. Third, the Appellants claim that the OECD TG 309 study is not appropriate to investigate the formation of metabolites of the Substance because of the low solubility of the Substance. In light of the requirements in the test guideline for OECD TG 309 studies it would be impossible to derive a half-life for the Substance and, additionally, identify the metabolites formed in the same test. The Appellants also state that there is no analytical method available to identify the minute quantities of metabolites that would be formed in the test.

95. The Agency argues that the OECD TG 309 study is appropriate to achieve its objective because it will identify the half-life of the Substance in pelagic water. This value can then be compared against the criterion in Section 1.1.1.(b) of Annex XIII and a conclusion reached on whether the Substance is persistent.

96. As regards the requirement to identify the metabolites formed in the OECD TG 309 test, the Agency conceded at the hearing that such identification '*is difficult*', but that the Appellants should '*do their best*' on the basis of the techniques specified in the Contested Decision. The Agency added that it could not say whether it is possible to identify the metabolites in the OECD TG 309 study or not. Determining whether the metabolites can be identified at such low concentrations would require a detailed assessment on the part of the laboratory performing the test. However, the Appellants should '*find the means to try to convince [the Agency and the eMSCA] that the metabolites are not problematic*'. According to the Agency and the eMSCA, if the Appellants can demonstrate that there is no analytical method that is sensitive enough, they will not have to identify the metabolites formed in the test.

Findings of the Board of Appeal

97. The Appellants put forward three lines of argument in support of the second part of the first plea. The Board of Appeal will examine each of these in turn.

1. The allegation that the testing regime prescribed for the OECD TG 309 study is not appropriate to investigate the half-life of the Substance

98. The Appellants claim that the testing regime required by the Contested Decision for the OECD TG 309 study is not appropriate to investigate the half-life of the Substance because the latter, being very adsorptive, will bind to the glass walls of the testing apparatus.

99. This argument is predicated on the fact that, according to the Appellants, the Agency has already rejected the possibility of making adaptations to the test method, in order

to overcome the tendency of the Substance to bind to the glass walls of the testing apparatus, as was done for the OECD TG 301/302 study.

100. The Board of Appeal recalls, however, that every assessment performed by the Agency must take place on a case-by-case basis and in light of all the circumstances of the specific case (see paragraph 77 above).

101. The Contested Decision found that the results of the OECD TG 301/302 study concerning the incorporation of the Substance into the biomass are inconclusive because the analytical method used to that end was '*not a standard procedure*' and it was not certain whether the study measured degradation or adsorption. However, this does not mean that the Agency has rejected all results obtained through non-standardised methods in general or any adaptations to the OECD TG 309 test protocol in particular.

102. In particular, the Contested Decision neither examined nor rejected any adaptations made with a view to overcoming the tendency of the Substance to bind to the glass walls of the testing apparatus. The '*non-standard*' procedure referred to in the Contested Decision is only the method of measuring the incorporation of the Substance into the biomass (see the section of the Contested Decision cited in paragraph 76 above).

103. The Board of Appeal therefore finds that, as the Agency has not rejected the possibility of making adaptations to the requested OECD TG 309 study in order to overcome the tendency of the Substance to bind to the glass walls of the testing apparatus, the Appellants' argument must be rejected.

2. The allegation that the testing conditions prescribed for the OECD TG 309 study are not environmentally relevant

104. The Appellants argue that the OECD TG 309 study is not appropriate to address the alleged persistence of the Substance because the testing conditions prescribed are not '*environmentally relevant*' or '*naturally-occurring*'; soil, rather than pelagic water, is the '*main compartment of concern*'.

105. In order to decide on this claim, the Board of Appeal must examine whether, in a situation such as the one at issue in the present case in which a potential risk has been identified for all the environmental compartments listed in Section 1.1.1. of Annex XIII, the Agency may request further persistence testing for any compartment or whether it must choose the one that approximates most closely the actual pattern of distribution of a substance in the environment.

106. At the outset, the Board of Appeal recalls that the fourth introductory paragraph to Annex XIII provides: '*The information used for the purposes of assessment of the PBT/vPvB properties [of a substance] shall be based on data obtained under relevant conditions'*.

107. In accordance with Section 1.1.1. of Annex XIII, '*[a] substance fulfils the persistence criterion (P) in any of the following situations:*

(a) the degradation half-life in marine water is higher than 60 days;

(b) the degradation half-life in fresh or estuarine water is higher than 40 days;

(c) the degradation half-life in marine sediment is higher than 180 days;

(d) the degradation half-life in fresh or estuarine water sediment is higher than 120 days;

(e) *the degradation half-life in soil is higher than 120 days*.'

108. It is apparent from the use of the word '*any*' in Section 1.1.1. of Annex XIII that a substance can be found to be persistent in the environment if its half-life in any one of the five listed environmental compartments exceeds the relevant threshold.

109. Bearing in mind that the purpose of persistence testing pursuant to substance evaluation is to clarify an intrinsic property of a substance, and not the persistence of a substance in particular environmental conditions, it follows that '*relevant conditions*' within the meaning of Annex XIII means those conditions that allow for an objective assessment of the persistence of a substance, specifically against the half-life criteria set out in Section 1.1.1. of Annex XIII (see, to this effect, Case A-013-2014, *BASF*, Decision of the Board of Appeal of 7 December 2016, paragraph 113).

110. The Board of Appeal further notes that the persistence criteria set out in Annex XIII concern the intrinsic hazardous properties of a substance and not the risk that a particular use or uses may pose in practice. Actual exposure information, although a relevant element for the assessment of the risk posed by a substance, is not part of the assessment of whether a substance is persistent in accordance with Annex XIII.

111. The Board of Appeal observes that if the actual environmental exposure patterns at a point in time and for a particular use were relevant to the assessment of the persistence of a substance the logical conclusion would be that for other uses with different environmental exposure conditions persistence testing would potentially be required in other compartments. This would potentially require new persistence tests to be conducted to reflect different uses. Consequently, the situation might arise whereby a substance is considered to be persistent in one compartment but not in another. This is clearly not consistent with the wording of Annex XIII, '*[a] substance fulfils the persistence criterion (P) in any of the following situations*', and there is nothing in the REACH Regulation requiring further or different persistence testing depending on the use. The Board of Appeal finds therefore that it would not be appropriate, pursuant to substance evaluation, to limit the assessment of inherent properties to particular and current uses of a substance.

112. It follows from the reasons set out above that, once the Agency has established that a substance poses a potential risk to the environment in several compartments, under substance evaluation it may require testing in any of those compartments. It is not obliged to choose, from several compartments, the one that mirrors most closely the distribution patterns of a substance in the environment from one particular use or user.

113. In order to ensure the achievement of a high level of protection of the environment, which is one of the main objectives of the REACH Regulation (see, to this effect, judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 45), the Agency should choose the compartment in which it considers that a substance is most likely to be found to exceed the half-life threshold for persistence, and/or in which the assessment will not be complicated by, for example, the formation of large amounts of NERs. This is a scientific assessment that must be performed by the Agency, or evaluating Member State Competent Authority, on a case-by-case basis.

114. As the Agency explained at the hearing, the objective of the OECD TG 309 study requested in this case is not to determine the persistence of the Substance under '*environmentally relevant*' or '*naturally-occurring*' conditions. Its objective is rather to determine whether the Substance exceeds the relevant half-life threshold in any one of the environmental compartments listed in Section 1.1.1. of Annex XIII, in this case in pelagic water.

115. It is common ground between the parties that the derivation of a half-life for the Substance in the OECD TG 309 study is feasible as the preferred concentration in such a study is below 10 µg/l, which is lower than the solubility of the Substance (45 µg/l).

116. It follows that it is irrelevant whether, as the Appellants argue at length (see paragraphs 91 to 93 above), testing in soil or in sediment would approximate the environmental fate of the Substance more closely than testing in water, since these arguments amount to claiming that the required OECD TG 309 test does not reflect '*naturally-occurring*' conditions.

117. The allegation that the OECD TG 309 study is not appropriate to address the alleged persistence of the Substance because it is not '*environmentally relevant*' must consequently be rejected.

3. The allegation that the OECD TG 309 study is not appropriate to achieve its objective with regard to the identification of metabolites

118. The Appellants argue that the OECD TG 309 study is not suitable to obtain information on the identity of the metabolites of the Substance because of its low solubility.

119. The Board of Appeal recalls at the outset that the Contested Decision requires the OECD TG 309 study in order to determine the half-life of the Substance in pelagic water (see paragraph 114 above). In addition, the Contested Decision requires the Appellants to identify the metabolites formed from the Substance in that same study.

120. The Board of Appeal further notes that information on the identity, and consequently the persistence, of the metabolites formed from the Substance constitutes, in principle, relevant information that must be taken into account when assessing the persistence of the Substance itself (see paragraphs 55 to 59 above).

121. The test guideline for OECD TG 309 studies states:

'*Because of analytical limitations, it is frequently impossible to measure the concentration of test substance with the required accuracy, if the test substance is applied at a concentration ≤ 100 µg/L […]. Higher concentrations of test substance (>100 µg/L and sometimes >1 mg/L) may be used for the identification and quantification of major transformation products or if a specific analysis method with a low detection limit is not available. If high concentrations of test substance are tested, it may not be possible to use the results to estimate the first order degradation constant and half-life, as the degradation will probably not follow first order kinetics*.'

122. The Board of Appeal finds that as the solubility of the Substance is at most 45 µg/l and the required concentration for the identification of major transformation products is greater than 100 µg/l, and sometimes greater than 1 mg/l, it is not realistic to expect the OECD TG 309 study to be suitable to identify the metabolites of the Substance that will be formed in the study. Furthermore, the Board of Appeal notes that neither the Agency nor the Appellants have been able to identify a suitable '*specific analysis method with a low detection limit*' for the identification of the '*major transformation products*' likely to be produced during the conduct of an OECD TG 309 study with the Substance.

123. The Agency and the eMSCA argue, in effect, that the Appellants should try to identify the metabolites formed in the study, although it is not known if they can succeed (see paragraph 96 above). The Board of Appeal observes that these arguments do not demonstrate that the required OECD TG 309 study is appropriate to identify the metabolites of the Substance. The Agency's arguments seek to shift onto the Appellants the onus for designing and evaluating the OECD TG 309 study in such a way as to allow the identification of the metabolites. The Board of Appeal observes that the Appellants have made considerable efforts to investigate how the '*major transformation products'* might be identified (see paragraph 34 above) and quantified but neither they nor the Agency and eMSCA have arrived at a solution.

124. The Board of Appeal finds therefore that the Agency has failed to establish that the required OECD TG 309 study is appropriate to achieve its objective insofar as it obliges the Appellants to identify the metabolites of the Substance in the conduct of that study. The Appellants' allegation that the OECD TG 309 study is not appropriate to achieve its objective with regard to the identification of metabolites must consequently be upheld.

125. The Board of Appeal notes however that according to the test guideline for OECD TG 309 studies '*transformation products detected at ≥ 10% of the applied concentration at any sampling time should be identified unless reasonably justified otherwise. […] The need for quantification and identification of transformation products should be considered on a case by case basis, with justifications being provided in the report*.' The Appellants therefore must continue to make all reasonable efforts to identify and quantify the major transformation products during the conduct of the OECD TG 309 study and record these efforts in the study report accordingly.

4. Conclusion on the second part of the first plea

126. In light of the above, the second part of the first plea must be upheld and the Contested Decision annulled as regards the requirement to identify the metabolites of the Substance formed in the OECD TG 309 study.

127. The second part of the first plea must be rejected as regards the allegation that the OECD TG 309 study is not appropriate to determine the half-life of the Substance.

C - The third part of the first plea, alleging that the OECD TG 308 study is not appropriate to achieve the objective pursued

Arguments of the Parties

128. The Contested Decision requires an OECD TG 308 study (aerobic and anaerobic transformation in aquatic sediment system) to be performed if the results of the OECD TG 309 study are inconclusive.

129. By the third part of their first plea in law, the Appellants argue that an OECD TG 308 study will not identify degradation by compartment (i.e. in pelagic water and in sediment), and therefore will not produce degradation half-lives of the Substance that can be assessed against the criteria in Annex XIII. This is because, given the properties of the Substance, especially its tendency to partition from the water phase and to form NERs in the solid phase, the complex test system of an OECD TG 308 study, which includes both water and sediment, will not lead to results that can be clearly interpreted.

130. In this regard, the Appellants rely on the results of a Long-Range Research Initiative by the European Chemical Industry Council on the test guideline for OECD TG 308 studies (ECO18-Eawag: *Improved strategy to assess chemical persistence at the water-sediment interface*; hereinafter the 'CEFIC LRI project'). According to the Appellants, the CEFIC LRI project confirms that the results acquired through OECD TG 308 studies are so variable that, in the circumstances of the present case, they cannot be used as the basis for any conclusions on the persistence of the Substance.

131. The Agency argues that the degradation potential of the Substance needs to be clarified for all compartments (water, sediment, and soil) although a finding of persistence in one compartment will, in principle, suffice to identify the Substance as persistent. In the Agency's view, an OECD TG 308 study will determine the half-life of the Substance in sediment and is therefore appropriate to achieve its objective, namely to determine the persistence of the Substance in the environment.

132. In addition, as concerns the requirement to identify the NERs formed in an OECD TG 308 study, the Agency argues that this is complex but feasible.

Findings of the Board of Appeal

133. The Contested Decision requires the Appellants to perform an OECD TG 308 study (aerobic and anaerobic transformation test in an aquatic sediment system), but only if the results of the OECD TG 309 study '*[do] not allow to conclude that BENPAT is persistent (P) or very persistent (vP) according to Annex XIII*'.

134. The Contested Decision states:

'*[S]ediment is also a compartment of concern: BENPAT is highly adsorptive and therefore it will adsorb rapidly and to a high degree in sediment. A high degree of non-extractable residues (NER) is expected to be generated in the [OECD TG 308 test] and separation of degradation from dissipation processes will probably be difficult. To enhance interpretability of data [the] following conditions shall be fulfilled:*

- *Metabolites representing crucial steps in transformation pathways (key metabolites) shall be identified by the use of QSAR. Standard analytical solutions shall ensure that detection and quantification of these key metabolites is possible.*

  […]

- *Test evaluation shall be comprehensive and orientate itself at the proceedings usual for pesticides. The following aspects are of special interest for test evaluation: Rate and course of kinetics of parent and metabolites in the water phase shall be compared with the respective results of the OECD 309 and considered in interpretation. Special consideration shall be given to:*

  1. *the kinetics in the water phase of both test systems and the differences found.*
  2. *the kinetics in the water phase compared to the course of NER formation in the sediment phase of the OECD 308,*
  3. *the time at which metabolites emerge and their succession in the respective test system and*
  4. *a comparison of the time at which metabolites emerge and their succession in both test systems.*

  All of these aspects are needed for the interpretation of the processes observed.

- *The main constituent R-898 shall be tested instead of BENPAT. R-898 is the most methylated and least water soluble constituent of BENPAT and represents the worst case.*

To assess persistence of BENPAT it is necessary to differentiate between mere elimination and degradation processes […]. To this end detection and identification of metabolites are fundamental requirements.'

135. The Appellants argue, in essence, that an OECD TG 308 study is not appropriate to investigate its persistence due to the properties of the Substance.

136. The Board of Appeal observes in this regard that the Substance presents particular difficulties as regards performing an OECD TG 308 study. Not only is the Substance expected to partition from the water phase into the solid phase of the test system, but in the solid phase it is also expected to form NERs. As both Parties confirmed at the hearing, it is currently uncertain whether it will be possible to identify and quantify the NERs formed by the Substance in an OECD TG 308 study. In essence, it is not certain whether the study will measure the adsorption or degradation of the Substance.

137. The Board of Appeal notes that the CEFIC LRI project report raised a number of questions as to the suitability of the OECD 308 test guideline for assessing the persistence of substances such as the Substance in this case. The Board of Appeal further notes that the eMSCA stated in the course of these proceedings that '*[c]urrently there is no finalized [sic] approach to integrate NERs in the environmental assessment of substances, since it is work in progress*'.

138. The Board of Appeal finds therefore, from the evidence and arguments presented in this case, that there is at present no scientific consensus as to how the results of an OECD TG 308 study should be evaluated as regards the identity and properties of NERs.

139. Moreover, as is evidenced by the section of the Contested Decision cited in paragraph 134 above, an additional reason for the OECD TG 308 study is that its results on metabolites, assessed together with the results of the OECD TG 309 study, should allow the Agency to determine whether the metabolites of the Substance are persistent. However, as the requirement to identify the metabolites of the Substance formed in the OECD TG 309 study will be annulled (see paragraph 126 above), it is currently unknown to what extent the metabolites will be identified during the conduct of the OECD TG 309 study.

140. In light of the above, the Board of Appeal finds that the Agency has failed to establish that the OECD TG 308 study is appropriate to achieve its objective.

141. For the sake of completeness, the Board of Appeal notes that the Agency may be able to establish at a future point in time that an OECD TG 308 study is appropriate to investigate the persistence of the Substance, including an examination of the identity and properties of its metabolites. However, the Agency's justification for an OECD TG 308 study would need to take into account any other relevant and newly available information such as, for example, the results of the OECD TG 309 study.

142. For these reasons, the third part of the first plea, alleging that the OECD TG 308 study is not appropriate to achieve the objective pursued, must be upheld and the Contested Decision annulled insofar as it requests the OECD TG 308 study.

D - The fourth part of the first plea, alleging that the OECD TG 309 and OECD TG 308 studies are neither the most appropriate nor the least onerous option

Arguments of the Parties

143. The Appellants argue that an OECD TG 307 study (aerobic and anaerobic transformation in soil) would be a '*more appropriate*' and less onerous way to clarify the persistence of the Substance than either the OECD TG 309 or the OECD TG 308 study.

144. In particular, an OECD TG 307 study would be less onerous than an OECD TG 309 or 308 study because it would require fewer samples to be taken during the course of the study. The financial cost would therefore be lower.

145. The Agency, supported by the eMSCA, argues that an OECD TG 307 study would not be appropriate to investigate the persistence of the Substance. The results of such a study would be extremely difficult to interpret because the Substance would form a high quantity of NERs in soil and it is not currently possible to determine with certainty whether these NERs are bioavailable or not.

146. The Agency adds that if an OECD TG 307 study produced a negative or inconclusive result further simulation testing would still be needed for the water and sediment compartments. An OECD TG 307 study therefore is not less onerous than either an OECD TG 309 or an OECD TG 308 study.

Findings of the Board of Appeal

147. There is no need to examine the Appellants' arguments insofar as they relate to the OECD TG 308 study as the relevant part of the Contested Decision will in any event be annulled (see paragraph 142 above).

148. As regards the OECD TG 309 study, the Appellants claim that an OECD TG 307 study would be a '*more appropriate*' and less onerous option to investigate the persistence of the Substance.

149. The Board of Appeal recalls that when there is a choice between several appropriate measures, the principle of proportionality requires the least onerous measure to be used (*see* paragraph 40 above).

150. However, the Board of Appeal also recalls that the Substance binds readily to solid matter to form NERs. There is currently no viable method to identify these NERs and it is therefore currently impossible to determine whether they are persistent in soil or not with any degree of confidence (see paragraphs 136 to 138 above).

151. In light of the above, the Board of Appeal finds that an OECD TG 307 study would not be appropriate to achieve the objective pursued by the OECD TG 309 study, namely to determine whether the Substance exceeds the relevant half-life threshold in any one of the environmental compartments listed in Section 1.1.1. of Annex XIII (see paragraph 114 above).

152. Consequently, as it is not appropriate to achieve the same objective, an OECD TG 307 study cannot constitute a less onerous option than the required OECD TG 309 study.

153. The fourth part of the first plea in law must therefore be rejected.

E - Conclusion on the first plea in law

154. It follows from all of the above that the first plea in law, alleging that the requirement in the Contested Decision to perform the OECD TG 309 and OECD TG 308 studies is disproportionate, must be upheld as regards the obligation to identify the metabolites of the Substance formed in the OECD TG 309 study and with regard to the entirety of the OECD TG 308 study.

155. The first plea in law must by contrast be rejected regarding the requirement to conduct the OECD TG 309 study to identify the half-life of the Substance in pelagic water.

II. The second plea in law, alleging a breach of the principle of equal treatment or '*non-discrimination*'

Arguments of the Parties

156. The Appellants argue that the Contested Decision breaches the principle of equal treatment or '*non-discrimination*' by treating the Substance differently from two comparable substances, namely N-(1,4-dimethylpentyl)-N'-phenylbenzene-1,4-diamine (CAS No 3081-01-4, EC No 221-374-3; hereinafter '7PPD') and N,N'-bis-1,4-dimethylpentyl)-p-phenylenediamine (CAS No 3081-14-9, EC No 221-375-9; hereinafter '77PD'). For these two substances, the Agency adopted substance evaluation decisions requiring OECD TG 307 studies to be performed to address the concern that they may be persistent.

157. The Agency argues that 7PPD and 77PD hydrolyse rapidly in water, whereas the Substance does not. As the properties of 7PPD and 77PD are different from the Substance in this important respect, there can be no breach of the principle of equal treatment or '*non-discrimination*'.

Findings of the Board of Appeal

158. According to settled case-law, 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 (judgment of 14 September 2010, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission*, C-550/07 P, EU:C:2010:512, paragraph 55).

159. The Board of Appeal finds that, even if the three substances were to be considered comparable, the difference in the rates of hydrolysis between 7PPD and 77PD, on the one hand, and the Substance, on the other, objectively justifies any difference in treatment. 7PPD and 77PD are expected to hydrolyse rapidly once in water whilst the Substance is not expected to do so. This difference in rates of hydrolysis is potentially an important factor in the determination of the persistence of the three substances in question and the tests chosen for that purpose.

160. The Board of Appeal therefore finds that the Agency was objectively justified in treating 7PPD and 77PD differently from the Substance in the assessment of persistence in the respective substance evaluation decisions.

161. The second plea must therefore be rejected.

III. The third plea in law, alleging that the finding that the Substance is bioaccumulative is vitiated by an error of assessment

Arguments of the Parties

162. By their third plea in law, the Appellants challenge the Contested Decision insofar as it states that '*[e]vidence shows that BENPAT is bioaccumulative and [toxic]. As the [bioaccumulation] and [toxicity] criteria are fulfilled the [persistence] criterion has to be addressed*.'

163. The Appellants argue that the Agency committed an error of assessment in concluding that the Substance is bioaccumulative in accordance with Annex XIII. In particular the Appellants argue that the available information does not support this conclusion. Based on the available evidence, the Agency could have '*request[ed] the generation of an additional dietary bioaccumulation study*' to clarify the point.

164. The Appellants also argue that the conclusion that the Substance '*is bioaccumulative*' is vitiated by an error in that the Agency was premature in reaching, as part of the substance evaluation, a definite conclusion.

165. The Agency argues that the statement at issue simply '*support[s] its conclusion that there is a potential risk that the Substance is a [sic] PBT*'. For the purposes of adopting the Contested Decision, the Agency was not required to give '*a full ledged [sic] justification why the substance meets the [bioaccumulation] criterion. A full justification would be needed when for example [the Agency] decides under Article 59 of the REACH Regulation to identify the Substance as a substance of very high concern meeting the PBT criteria set out in Annex XIII*.'

Findings of the Board of Appeal

166. It must be noted at the outset that the Contested Decision does not require any information on bioaccumulation. The statement that the Substance '*is bioaccumulative*', which the Appellants challenge by their third plea in law, is part of the statement of reasons in the Contested Decision, in particular of the subsection entitled '*Environment: Further information on persistence*'.

167. The Board of Appeal notes that the Appellants have not been heard on this point because this statement was inserted in the amended draft decision in consequence of the Appellants' comments on the draft decision, and no proposals for amendment were submitted in this regard.

168. The Board of Appeal further finds that the Agency was not required to reach a firm conclusion on the bioaccumulative properties of the Substance in order to request further information on persistence. It is in any event common ground between the Parties that there is information showing that the Substance might be bioaccumulative although, according to the Appellant, this information is insufficient to support a definite conclusion.

169. The statement that the Substance '*is bioaccumulative*' consequently should not have been included in the Contested Decision. It should therefore be removed from the Contested Decision without it being necessary to examine whether the information on which that conclusion was based is sufficient to support it.

170. However, the Board of Appeal observes that, insofar as certain grounds in themselves provide a sufficient basis for a decision, any errors in other grounds have no effect on its operative part (see, to this effect, judgment of 29 March 2012, *Spain* v *Commission*, T-398/07, EU:T:2012:173, paragraph 95).

171. It follows that there is no need to annul the contested requests for persistence testing on the basis of the third plea in law as that plea is ineffective as regards the assessment of the persistence of the Substance.

Refund of the appeal fee

172. 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; hereinafter the 'Fee Regulation'), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

173. That provision is silent, however, as regards the refund of the appeal fee in cases such as this in which the contested information requirements are annulled in part and the case is not remitted to the competent body of the Agency for re-evaluation with regard to the annulled requests for information in accordance with Article 93(3). Article 10(4) of the Fee Regulation makes no provision for the refund of part of the appeal fee, and the choice before the Board of Appeal is therefore either a full refund or no refund.

174. In the circumstances of the present case, the Board of Appeal considers that the appeal must deemed to have been decided in favour of the Appellant within the meaning of Article 10(4) of the Fee Regulation, since the greater and most burdensome part of the contested information requirements has been annulled. The appeal fee shall therefore be refunded.

Effects of the Contested Decision

175. According to Article 91(2), an appeal has suspensive effect.

176. The Contested Decision, which is only partially annulled in the present appeal proceedings, required the registrants, now the Appellants, to submit the required information by 8 April 2018, which is two years, six months and seven days from the adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in the light of the principle of suspensive effect laid down in Article 91(2).

177. The Board of Appeal observes however that the original deadline covered, potentially, the performance of two tests, the OECD TG 309 study and the OECD TG 308 study, in sequence. It cannot however be assumed by the Board of Appeal that the two tests would take the same time and the deadline can therefore be halved. The Board of Appeal notes that the preparation, test development and reporting time, bearing in mind some of the complexities discussed in the decision above, would be heavily weighted to the first test. The Parties have however not submitted any detailed information addressing the time that each test would take.

178. In light of the above, the Board of Appeal decides that 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 two years, six months and seven days from the date of notification of the final decision of the Board of Appeal.

179. Consequently, the OECD TG 309 study, without the requirement to identify the metabolites of the Substance, shall be submitted within two years, six months and seven days from the date of notification of this Decision of the Board of Appeal. In light of the objective of the REACH Regulation regarding the protection of the environment the Appellants are however invited to provide the information at issue as soon as possible.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it requires the identification of the metabolites of the Substance formed in the OECD TG 309 study.**
2. **Annuls the Contested Decision insofar as it requires the OECD TG 308 study.**
3. **Decides that the statement on bioaccumulation in the 'Statement of Reasons' should be removed from the Contested Decision.**
4. **Dismisses the appeal for the remainder.**
5. **Decides that the remaining information derived from the OECD TG 309 study required by the Contested Decision shall be provided by 15 March 2020.**
6. **Decides that the appeal fee shall be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal