ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

15 January 2019

(Substance evaluation – PBT assessment – Grounds for concern – Bioaccumulation – Proportionality – Error of assessment – Annex XIII)

Case number	A-004-2017
Language of the case	English
Appellant	3v Sigma S.p.A., Italy
Intervener	The German Member State Competent Authority Represented by: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Germany
Contested Decision	Decision of 20 December 2016 on the substance evaluation of bis(2-ethylhexyl) 4,4'-{6-[4-tert-butylcarbamoyl) anilino]-1,3,5-triazine-2,4-diyldiimino}dibenzoate adopted by the European Chemicals Agency (the 'Agency') under 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; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. The Appellant is a registrant of the substance bis(2-ethylhexyl) 4,4'-{6-[4-tert-butylcarbamoyl)anilino]-1,3,5-triazine-2,4-diyldiimino}dibenzoate (CAS No 154702-15-5, EC No 421-450-8; 'UVASORB HEB').

2. UVASORB HEB is used as a UV-filter in personal care products and is registered by the Appellant at the 100 to 1000 tonnes per year tonnage band. In addition to the Appellant, UVASORB HEB has been registered by three other registrants.

3. UVASORB HEB was included in the Community rolling action plan ('CoRAP') for substance evaluation in 2015 due to initial grounds for concern relating to its potential persistent, bioaccumulative and toxic ('PBT') or very persistent and very bioaccumulative ('vPvB') properties.

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

5. The eMSCA prepared a draft decision under Article 46(1) of the REACH Regulation requesting further information on UVASORB HEB (all references to Titles, Articles, and Annexes concern the REACH Regulation unless stated otherwise). The draft decision contained a request to provide information on an OECD TG 309 study and '*further information on uses and environmental emissions*'.

6. On 26 April 2016, the draft decision was notified to the Appellant who commented on it by 2 June 2016 in accordance with Article 50(1).

7. On 21 July 2016, the eMSCA notified the draft decision to the competent authorities of the other Member States and the Agency for their comments. Two competent authorities and the Agency submitted proposals for amendment to the draft decision in accordance with Articles 51(2) and 52(2).

8. One of the proposals for amendment suggested requesting an OECD TG 308 study instead of the OECD TG 309 study. Another proposal suggested offering the registrants an option of performing an OECD TG 301 study or an OECD TG 306 study using radiolabelled test compounds prior to, or instead of, an OECD TG 309 study.

9. On 23 September 2016, the Appellant commented on the proposals for amendment in accordance with Articles 51(5) and 52(2). In its comments, the Appellant stated that the proposal to replace the OECD TG 309 study with an OECD TG 308 study was '*entirely logical'*. The Appellant opposed the proposal to perform an OECD TG 301 or OECD TG 306 study prior to, or instead of, an OECD TG 309 study.

10. Following the proposals for amendment and the Appellant's comments, the eMSCA '*agreed to replace*' the request for an OECD TG 309 study with a request for an OECD TG 308 study and amended the draft decision accordingly. The amended draft decision was referred to the Member State Committee ('MSC').

11. On 10 October 2016, the MSC reached unanimous agreement on the Contested Decision.

12. On 20 December 2016, the Agency adopted the Contested Decision.

13. The Contested Decision requires the Appellant to submit the following information by 27 September 2018:

    '1.1. Sediment simulation testing (Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD 308) using the registered substance (UVASORB HEB) at 20°C according to the specification of the test conditions listed in Appendix 1 Section 1.1.3. [to the Contested Decision] [the 'OECD TG 308 study'].

1.2. Further information on uses and environmental emissions, as specified further in Appendix 1 [to the Contested Decision].'

14. Section 1.1.3. of Appendix 1 to the Contested Decision specifies the test conditions for the OECD TG 308 study:

'*The requested simulation study on degradation of UVASORB HEB in sediment should enable i) the determination of degradation pathways of UVASORB HEB in sediment with regard to the formation of metabolites and ii) the identification of formed metabolites of UVASORB HEB. The OECD 308 simulation test should be performed using ^{14}C-radiolabelled UVASORB HEB. The radiolabel should be located in most stable part of the molecule, thus the 1,3,5-triazine ring. Radiolabelling of the most stable part of the molecule is necessary for identification of transformation products relevant for PBT assessment (at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not possible).*

[…]

According to the test on ready biodegradation, UVASORB HEB degrades slowly. To maximize the probability for the formation and identification of metabolites of UVASORB HEB in the requested OECD 308 test, a temperature of 20°C has been selected.'

Procedure before the Board of Appeal

15. On 20 March 2017, the Appellant filed this appeal.
16. On 22 May 2017, the Agency submitted its Defence.
17. On 20 July 2017, the Appellant submitted its observations on the Defence.
18. On 15 September 2017, the Agency submitted its observations on the Appellant's observations on the Defence.
19. On 3 October 2017, the eMSCA was granted leave to intervene in this case in support of the Agency.
20. On 16 November 2017, the eMSCA filed its statement in intervention.
21. On 28 November and 4 December 2017 respectively, the Agency and the Appellant filed their observations on the statement in intervention.
22. On 8 March 2018, the Appellant and the Agency replied to written questions from the Board of Appeal.
23. On 22 May 2018, an oral hearing was held at the Appellant's request. At the oral hearing, the Parties and the eMSCA made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

24. The Appellant requests the Board of Appeal to:

    1. annul the Contested Decision in its entirety,

    2. order the refund of the appeal fee, and

    3. order the Agency to pay the costs of the proceedings.

25. The Agency, supported by the eMSCA, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

26. In the present proceedings, the Parties use the terms '*degradation products*', '*transformation products*', and '*metabolites*'. Although these may have different meanings depending on the context in which they are used, the Board of Appeal will use the term '*transformation and/or degradation products*' (as used in Annex XIII) to cover all these terms for the purposes of this decision.

27. In the Contested Decision, the Agency refers to the '*parent compound*', meaning UVASORB HEB before it is transformed or degraded. The Board of Appeal will refer in this decision to the 'parent Substance' or 'parent Substance UVASORB HEB' when it is referring to UVASORB HEB before it is transformed or degraded.

28. In the Contested Decision, the Agency requests the Appellant to perform an OECD TG 308 study primarily in order to identify the transformation and/or degradation products of UVASORB HEB. According to the Agency, such a study is needed because there are indications that UVASORB HEB may pose a risk to the environment due to the potential PBT/vPvB properties of its predicted transformation and/or degradation products. The Agency argues that identifying the transformation and/or degradation products of UVASORB HEB by performing the requested study is the first step towards clarifying whether the transformation and/or degradation products of UVASORB HEB have PBT/vPvB properties and therefore whether UVASORB HEB itself should be identified, under Annex XIII, as PBT or vPvB.

29. In addition to the OECD TG 308 study, the Contested Decision requires the Appellant to provide further information on uses and environmental emissions of UVASORB HEB.

30. The Appellant contests both information requests. According to the Appellant, and as agreed by the Agency, it is already known that the parent Substance UVASORB HEB does not have PBT or vPvB properties. The Appellant argues that the formation of transformation and/or degradation products is unlikely in realistic environmental conditions. Therefore, according to the Appellant, UVASORB HEB cannot be identified as PBT or vPvB due to the potential PBT/vPvB properties of its transformation and/or degradation products. Moreover, the Appellant claims that even if UVASORB HEB would transform or degrade in the environment, none of the predicted transformation and/or degradation products are bioaccumulative and therefore they cannot be PBT or vPvB. As a result, according to the Appellant, UVASORB HEB cannot be identified as having PBT or vPvB properties according to the criteria in Annex XIII.

31. The Appellant raises four pleas which apply to the two information requests in the Contested Decision (see paragraph 13 above). The Appellant claims that, by adopting the Contested Decision, the Agency:

    1. breached the principle of proportionality,

    2. committed a manifest error of assessment,

    3. breached the REACH Regulation, and

    4. acted *ultra vires* (exceeded its powers).

32. The Board of Appeal will examine these pleas, first, in relation to the request for an OECD TG 308 study (Section 1), and, second, in relation to the request to submit further information on uses and environmental emissions (Section 2).

1. Pleas related to the request for the OECD TG 308 study

33. The Board of Appeal will examine, first, the Appellant's plea that the request for the OECD TG 308 study is disproportionate (Section 1.1.); second, the plea that the Agency's request was vitiated by a manifest error of assessment (Section 1.2.); and, third, the pleas that the Agency breached the REACH Regulation and acted *ultra vires* in requesting the study (Section 1.3.).

1.1. The first plea: the request for the OECD TG 308 study is disproportionate

34. The principle of proportionality requires that measures adopted by the European Union institutions do not exceed the limits of what is appropriate and necessary in order to attain 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 (judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 124).

35. In support of its first plea the Appellant specifically claims that the requested OECD TG 308 study is disproportionate because it is not necessary and not appropriate to achieve the objective pursued.

1.1.1. The claim that the OECD TG 308 study is not necessary

Arguments of the Appellant

36. The Appellant raises three arguments in support of its claim.

37. First, the Appellant argues that the parent Substance is not PBT or vPvB. According to the Appellant, it is undisputed that the parent Substance UVASORB HEB is not bioaccumulative or toxic. Further testing to clarify the PBT/vPvB properties of the parent Substance is therefore not needed.

38. Second, the Appellant argues that the formation of transformation and/or degradation products is unlikely in realistic environmental conditions. Although quantitative structure-activity relationship ('QSAR') models predict that UVASORB HEB may form transformation and/or degradation products, the OECD TG 301B screening study contained in the Appellant's registration dossier demonstrates that the formation of transformation and/or degradation products is '*unlikely […] in the real world*'. Therefore, transformation and/or degradation products do not pose a potential risk to the environment.

39. Third, the Appellant argues that none of the predicted transformation and/or degradation products are bioaccumulative. According to the Appellant, even if transformation and/or degradation products are formed, as predicted by the QSAR model EAWAG-BBD used in the Appellant's PBT assessment to assess the degradation pathways of UVASORB HEB, none of '*the potential degradation products*' can fulfil the PBT/vPvB criteria. According to the Appellant, both the parent Substance and its transformation and/or degradation products may be persistent (P). In the course of the appeal proceedings the Appellant also agreed that some of the predicted transformation and/or degradation products may be toxic (T). However, the Appellant argues that the predicted transformation and/or degradation products cannot fulfil the PBT/vPvB criteria because none of them can be considered to be bioaccumulative (B) for the following reasons:

a) The Agency based its conclusion on the bioaccumulation potential of the transformation and/or degradation products on unreliable screening information. The octanol-water coefficient ('log K_{ow}') values calculated using QSAR models are an unreliable indicator of bioaccumulation potential for ionisable substances such as the transformation and/or degradation products of UVASORB HEB.

b) Other, more reliable, experimental data indicate that the predicted transformation and/or degradation products are not bioaccumulative. The measured log K_{ow} values for the predicted transformation and/or degradation products are likely to be lower than the calculated log K_{ow} values. This can be concluded from the fact that the measured log K_{ow} value for UVASORB HEB available in G. Constantini, *Filtro UVF: Determinazione di alcune caratteristiche chimico-fisiche*, 1995 (the 'Constantini study') is significantly lower than the QSAR calculated log K_{ow} values for UVASORB HEB.

c) The additional screening information used by the eMSCA to show bioaccumulation potential, the membrane-water partition coefficient ('log K_{lipw}'), is not reliable. The log K_{lipw} values are an unreliable indicator of bioaccumulation potential of the transformation and/or degradation products of UVASORB HEB.

d) According to other reliable screening information in the Appellant's PBT assessment, the bioconcentration factor ('BCF') values, the predicted transformation and/or degradation products of UVASORB HEB are not bioaccumulative. Instead of using log K_{ow} values or log K_{lipw} values, the bioaccumulation potential of the transformation and/or degradation products should have been assessed using BCF values. BCF values are a criterion for bioaccumulation in Annex XIII. The BCF values of the predicted transformation and/or degradation products calculated using the QSAR models T.E.S.T., VEGA and EPISUITE/BCFBAF are significantly below 2000, which is the threshold for bioaccumulation in Annex XIII. This demonstrates that none of the predicted transformation and/or degradation products should be considered to be bioaccumulative.

40. On the basis of the arguments in paragraph 39 above, the Appellant concludes that none of the predicted transformation and/or degradation products of UVASORB HEB are bioaccumulative. As a result none of the predicted transformation and/or degradation products can be PBT or vPvB. Therefore, UVASORB HEB cannot be considered to be PBT or vPvB based on the properties of its transformation and/or degradation products. As the parent Substance is not PBT or vPvB itself, no further studies are needed to clarify the PBT/vPvB properties of UVASORB HEB. As a result, the OECD TG 308 study is unnecessary.

Arguments of the Agency and the eMSCA

41. The Agency, supported by the eMSCA, disputes the Appellant's arguments as follows.

42. First, the Agency agrees that the parent Substance UVASORB HEB, before its transformation and/or degradation, is not bioaccumulative or toxic. However, according to Annex XIII '*the identification of PBT/vPvB substances should also take account of the PBT/vPvB properties of relevant transformation and/or degradation products*'.

43. Second, the available screening information (from the EAWAG-BBD QSAR model) indicates that UVASORB HEB may biologically degrade and form transformation and/or degradation products. Based on the predictions from several QSAR models (COSMOmic 1504, EPISUITE, VEGA, T.E.S.T. and CHEMSPIDER), some of the predicted

transformation and/or degradation products may be PBT or vPvB as defined in Annex XIII.

44. The Agency argues that, based on the available information on degradation and the structure of UVASORB HEB, it is likely that UVASORB HEB is transformed and degraded in the environment to a certain degree. As UVASORB HEB is a large molecule, the degradation pathways are potentially complex and may lead in turn to complex transformation and/or degradation products. There is a range of transformation and/or degradation products of UVASORB HEB that may be formed and some of these may have PBT/vPvB properties.

45. Third, the Agency and the eMSCA contest the Appellant's four arguments against the bioaccumulation potential of the predicted transformation and/or degradation products (see paragraph 39 above):

    a) The QSAR models used to calculate the log K_{ow} values tend to underestimate the bioaccumulation potential of ionised substances, i.e. calculated log K_{ow} values are likely to be lower than the measured values. Moreover, even allowing for the tendency for calculated log K_{ow} values to be underestimated, many of the log K_{ow} values for ionised transformation and/or degradation products of UVASORB HEB, calculated using QSAR models EPISUITE/KOWWIN and VEGA, exceed 4.5 which is the threshold value for bioaccumulation potential according to Annex XIII. The calculated log K_{ow} values therefore indicate that some of the predicted transformation and/or degradation products of UVASORB HEB may be bioaccumulative.

    b) The measured log K_{ow} value of UVASORB HEB available in the Constantini study and used by the Appellant to argue that the transformation and/or degradation products of UVASORB HEB cannot be bioaccumulative is not reliable because that study was not performed according to a relevant test guideline.

    c) During the substance evaluation, the eMSCA calculated log K_{lipw} values for the transformation and/or degradation products. The Contested Decision states that '*alternative parameters are needed instead of log K_{ow} to assess the bioaccumulation potential of the ionized fraction of the metabolites*'. However, at the oral hearing the eMSCA explained that this statement is a drafting mistake. Whilst the log K_{lipw} values are further evidence of the bioaccumulation potential, the calculated log K_{ow} values are sufficient on their own to demonstrate that some of the predicted transformation and/or degradation products of UVASORB HEB may be bioaccumulative.

    d) The BCF values calculated by the Appellant using QSAR models (T.E.S.T., VEGA and EPISUITE/BCFBAF) cannot be used to conclude that the transformation and/or degradation products of UVASORB HEB are not bioaccumulative. First, log K_{ow} values are the primary bioaccumulation screening criteria under Annex XIII. Second, there are shortcomings in all of the three QSAR models used by the Appellant to calculate BCF values. The T.E.S.T. study report does not address whether the transformation and/or degradation products of UVASORB HEB are in the applicability domain of the model. The predicted transformation and/or degradation products are outside the applicability domain of the VEGA and the EPISUITE/BCFBAF models. The calculated BCF values are therefore not reliable.

46. The Agency concludes that further experimental data are needed in order to clarify whether the predicted transformation and/or degradation products of UVASORB HEB are PBT or vPvB.

47. The aim of the requested OECD TG 308 study, as part of a stepwise approach, is to identify the transformation and/or degradation products which are formed when

UVASORB HEB transforms or degrades in the environment. Subsequently, further information may need to be generated on the transformation and/or degradation products in order to assess whether UVASORB HEB meets the criteria set out in Annex XIII for identification as PBT or vPvB.

48. The next steps of the substance evaluation of UVASORB HEB depend on the results of the OECD TG 308 study. If the study indicates that UVASORB HEB does not form transformation and/or degradation products, further studies will not be needed. By contrast, it may be necessary to request further testing if transformation and/or degradation products are formed.

Findings of the Board of Appeal

49. In order to demonstrate the necessity of a request for information in the context of substance evaluation, the Agency must be able to establish 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 (see Case A-015-2015, *Evonik Degussa and Others*, Decision of the Board of Appeal of 30 June 2017, paragraph 78).

50. Therefore, in order to determine whether the OECD TG 308 study is necessary it has to be examined:

1. whether the Agency has established that the potential environmental exposure to UVASORB HEB and the potential PBT or vPvB properties of its transformation and/or degradation products demonstrate that there is a potential risk;
2. if so, whether that potential risk needs to be clarified; and
3. whether the information resulting from the requested OECD TG 308 study has a realistic possibility of leading to improved risk management measures.

1.1.1.1. Potential risk

51. The identification of a potential risk is based on a combination of hazard and exposure information (*Evonik Degussa and Others*, cited in the paragraph 49 above, paragraph 79).

1.1.1.1.1. Potential hazard

52. The Appellant has raised three arguments against the Agency's conclusion that UVASORB HEB may pose a hazard due to the potential PBT/vPvB properties of its predicted transformation and/or degradation products. The Board of Appeal will examine each of the arguments in turn.

Whether the parent Substance is PBT or vPvB

53. The first argument of the Appellant is that the parent Substance UVASORB HEB is not PBT or vPvB and therefore an OECD TG 308 study is not necessary (see paragraph 37 above).

54. Under 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 constituents of a substance and relevant transformation and/or degradation products*'. Therefore, although it is undisputed that the parent Substance UVASORB HEB is not

PBT or vPvB, it is necessary to examine the properties of its transformation and/or degradation products if there are indications that these products are potentially PBT or vPvB and are therefore '*relevant transformation and/or degradation products*' for the PBT assessment. The Appellant's first argument must therefore be rejected.

Whether transformation and/or degradation products may be formed

55. The second argument of the Appellant is that the formation of transformation and/or degradation products is unlikely in '*realistic*' environmental conditions (see paragraph 38 above).

56. One of the purposes of substance evaluation is to clarify uncertainty. In this case, the objective of the contested information request is to clarify the uncertainty over whether, and which, transformation and/or degradation products are likely to be formed.

57. Under the fourth introductory paragraph to Annex XIII, the PBT assessment of substances must be based on data obtained under '*relevant conditions*'. '*Realistic conditions*' can vary widely across the European Union, depending on where and when a substance is being used and the use(s) in question. '*Relevant conditions*' means conditions that allow for an objective assessment of the properties of a substance instead of particular environmental or '*realistic*' conditions (see Case A-013-2014, *BASF*, Decision of the Board of Appeal of 7 December 2016, paragraph 113).

58. Moreover, the QSAR predictions provided by the Appellant as part of its PBT assessment indicate that UVASORB HEB may form transformation and/or degradation products in the environment.

59. As a result, the Agency has established that transformation and/or degradation products of UVASORB HEB may be formed in the environment. The Appellant's argument that the formation of transformation and/or degradation products is unlikely in '*realistic*' environmental conditions must consequently be rejected.

Whether the predicted transformation and/or degradation products may be bioaccumulative

60. The third argument of the Appellant concerns the bioaccumulation potential of the transformation and/or degradation products of UVASORB HEB. The Appellant argues that, based on reliable QSAR data, none of the predicted transformation and/or degradation products of UVASORB HEB are bioaccumulative and therefore none of the predicted transformation and/or degradation products can be PBT or vPvB, which makes the requested testing unnecessary (see paragraph 39 above).

61. The Board of Appeal will examine, first, the provisions of the REACH Regulation concerning the screening of potential bioaccumulative properties and, second, the arguments of the Parties as regards the reliability of the bioaccumulation screening information on the basis of those provisions.

a) Bioaccumulation criteria in the REACH Regulation

62. Annex II lays down the '*Requirements for the compilation of Safety Data Sheets*'. Under Section 12(3) of Annex II, bioaccumulation potential means the '*potential of a substance […] to accumulate in biota and, eventually to pass through the food chain'*.

63. Annex XIII lays down the criteria for the identification of PBT/vPvB substances. Under Section 1.1.2. of Annex XIII, a substance fulfils the bioaccumulation criterion when the

experimentally derived bioconcentration factor (BCF) for aquatic species is higher than 2000. In the present case no experimentally derived BCF values are available. It is therefore necessary to consider the screening criteria established in Annex XIII to see if the transformation and/or degradation products are, based on the data that are available, potentially bioaccumulative.

64. Section 3 of Annex XIII establishes the criteria to be used for screening persistence, bioaccumulation and toxicity. The screening of the bioaccumulation potential can be done either by using results from the application of QSAR models or experimental data.

65. Section 3.1.2.(a) of Annex XIII indicates that the primary indicator for the screening of bioaccumulation potential is the log K_{ow} value determined either experimentally under Section 7.8 of Annex VII or calculated using QSAR models under Section 1.3 of Annex XI. The threshold value for bioaccumulation potential is given as the log K_{ow} value being higher than 4.5 in the Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014, p. 54). Section 3.1.2.(b) of Annex XIII states that *'other information'* may be used to assess the bioaccumulation potential if the '*suitability and reliability'* of that other information *'can be reasonably demonstrated'*.

b) Reliability of the QSAR calculated BCF values

66. The Appellant argues that the QSAR calculated BCF values are reliable and demonstrate that none of the predicted transformation and/or degradation products are bioaccumulative.

67. QSAR calculated BCF values are not explicitly included as an indicator of bioaccumulation potential in Section 3.1.2.(a) of Annex XIII. However, they may qualify as *'other information*' referred to in Section 3.1.2.(b) if their '*suitability and reliability*' can be demonstrated.

68. The calculated BCF values, using QSAR models EPISUITE/BCFBAF, T.E.S.T. and VEGA, vary between 0.16 and 1258.9 and are therefore all below the threshold for bioaccumulation (see paragraph 63 above). However, these values cannot be used to conclude that the transformation and/or degradation products of UVASORB HEB are not bioaccumulative. The Appellant's PBT assessment report itself states that those values cannot be assumed to be reliable. The reliability of the results from the T.E.S.T. and the EPISUITE/BCFBAF models is '*not given*'. In the case of the VEGA model, the values are not reliable because most of the transformation and/or degradation products are, or may be, outside the applicability domain of the model. This means that the predicted transformation and/or degradation products are not substances for which these QSAR models are considered to give reliable results.

c) Reliability of the QSAR calculated log K_{ow} values

69. Both parties agree that most of the transformation and/or degradation products of UVASORB HEB are ionised in the environment. The Appellant argues that the QSAR calculated log K_{ow} values included in the PBT assessment are not reliable for such ionisable substances (see paragraph 39 above) and therefore cannot be used to indicate bioaccumulation potential. However, under Section 3.1.2.(a) of Annex XIII, log K_{ow} values are the primary screening information for bioaccumulation potential. There is nothing in Annex XIII to indicate that log K_{ow} values should not be applied as indicators of bioaccumulation potential for ionisable substances, as argued by the Appellant. The log K_{ow} values of the predicted transformation and/or degradation products, as calculated using QSAR models EPISUITE/KOWWIN and VEGA, vary

between -1.37 and 14.43. For six different transformation and/or degradation products the calculated log K_{ow} values exceed the threshold of 4.5 used by the Agency to indicate that a substance may be bioaccumulative (see paragraph 65 above).

70. Moreover, the Appellant has not rebutted the arguments of the Agency that the log K_{ow} value of 4.12 for UVASORB HEB reported in the Constantini study is not reliable because that study was not performed according to a relevant test guideline (see paragraph 45(b) above). The results in the Constantini study cannot therefore disprove the reliability of the calculated log K_{ow} values for the transformation and/or degradation products of UVASORB HEB.

Conclusion on the potential hazard

71. The Appellant has not established the '*suitability and reliability*' of the QSAR calculated BCF values as screening information for the bioaccumulation potential of the transformation and/or degradation products of UVASORB HEB, as required by Section 3.1.2.(b) of Annex XIII (see paragraph 66 to 68 above). The Appellant has also not established that the QSAR calculated log K_{ow} values used by the Agency are an unreliable indicator of the bioaccumulation potential of the predicted transformation and/or degradation products (see paragraph 69 to 70 above).

72. The '*Reasons'* Section of the Contested Decision refers to log K_{lipw} values as an indicator of the bioaccumulation potential for the ionised transformation and/or degradation products of UVASORB HEB. However, as the calculated log K_{ow} values in themselves show that the transformation and/or degradation products may be bioaccumulative, there is no need to examine the relevance of log K_{lipw} values in indicating bioaccumulation potential in the present case.

73. The Appellant's argument that none of the predicted transformation and/or degradation products are bioaccumulative is therefore rejected. Moreover, the Appellant agrees that the transformation and/or degradation products may be persistent and toxic (see paragraph 39). Therefore the Agency has established that UVASORB HEB may pose a concern as it may form transformation and/or degradation products that may be PBT/vPvB.

1.1.1.1.2. Potential environmental exposure

74. UVASORB HEB is registered by the Appellant in the tonnage band of 100 to 1000 tonnes per year. UVASORB HEB has also been registered by three other registrants. UVASORB HEB is mainly used as a an ingredient in sunscreens. It can therefore be released into the environment as emissions from manufacturing plants, from municipal wastewater and directly into swimming waters through its use in sunscreens.

75. There is therefore a clear potential for environmental exposure to UVASORB HEB.

1.1.1.1.3. Conclusion on the potential risk

76. On the basis of the screening information available in the Appellant's PBT assessment report, the Agency has demonstrated that UVASORB HEB may pose a concern due to the PBT or vPvB properties of its predicted transformation and/or degradation products (see paragraphs 71 to 73 above). The potential for environmental exposure is clear (see paragraphs 74 to 75 above). Therefore UVASORB HEB poses a potential risk to the environment.

1.1.1.2. Need to clarify the potential risk

77. Substances which are identified as PBT or vPvB are considered to be substances of very high concern under Article 57 of the REACH Regulation and are potentially subject to additional risk management measures, such as authorisation under Title VII, restrictions under Title VIII, and/or harmonised classification and labelling under Article 37 of the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1; the 'CLP Regulation'). The potential concern that UVASORB HEB meets the criteria to be identified as PBT or vPvB under Annex XIII therefore needs to be clarified.

1.1.1.3. Possibility of improving risk management measures

78. The identification and quantification of the transformation and/or degradation products may be followed by further testing to clarify whether UVASORB HEB should be identified as PBT or vPvB. If it is, then new risk management measures may be required.

79. New risk management measures, such as improved risk management measures at manufacturing sites, better waste management, and revised instructions on safe use may be identified in the chemical safety assessment and safety data sheets, if appropriate under Article 14(6). As an eventual consequence of the OECD TG 308 study and any appropriate further testing new improved risk management measures consequent to restrictions, authorisation and/or harmonised classification and labelling may also be required (see paragraph 77 above).

1.1.1.4. Conclusion on the claim that the OECD TG 308 study is not necessary

80. The Agency has established that UVASORB HEB poses a potential risk to the environment that needs to be clarified. Whether UVASORB HEB should be identified as PBT/vPvB needs to be clarified. Identification of the transformation and/or degradation products of UVASORB HEB in an OECD TG 308 study, and further testing if appropriate, may lead to improved risk management measures. The OECD TG 308 study is therefore necessary to provide the experimental data required to clarify the transformation and/or degradation products formed in aquatic sediment.

81. The Appellant's claim that the OECD TG 308 study is not necessary is rejected.

1.1.2. The claim that the OECD TG 308 study is not appropriate to achieve the objective pursued

Arguments of the Appellant

82. The second claim of the Appellant concerning the breach of the principle of proportionality is that the request for an OECD TG 308 study is not appropriate to achieve the objective pursued because the study is required to be performed at an unrealistic temperature, namely 20 °C.

83. Performing the study at 20 °C will lead to erroneous results as greater percentages of transformation and/or degradation products will be formed in the test than would be the case under real life conditions.

84. The Agency's failure to take into account realistic environmental conditions makes the test purely theoretical and of no practical application.

Arguments of the Agency and the eMSCA

85. According to OECD test guideline 308, 20 °C is an appropriate temperature to perform the study and the degradation pathways of UVASORB HEB are the same at 20 °C as they would be if the test was conducted at 12 °C.

86. The temperature of 20 °C is generally used in the Agency's decisions when the objective of the requested study is the identification of transformation and/or degradation products.

87. Conducting the study at 20 °C leads to faster formation, and higher concentrations, of transformation and/or degradation products than would be the case if it was performed at 12 °C. This increases the likelihood of successfully identifying the transformation and/or degradation products formed within the duration of the study.

Findings of the Board of Appeal

88. A measure is appropriate if it is capable of achieving its objective (see Case A-006-2016, *SI Group UK and Others*, Decision of the Board of Appeal of 6 June 2018, paragraph 100 and the case-law cited). Therefore, in order to demonstrate the appropriateness of an information request in the context of substance evaluation, the Agency must be able to establish that the potential risk posed by the substance can be clarified by the requested information.

89. In the Notice of Appeal, the Appellant claimed that the unrealistic testing temperature required by the Contested Decision was a '*forced way to a degradation*' which could lead to the formation of some transformation and/or degradation products that would not occur under '*realistic conditions*'. At the oral hearing, however, the Appellant agreed that conducting the study at a higher temperature does not change the degradation pathways of a substance. Rather it increases the quantities of the transformation and/or degradation products that would also be formed by testing at a lower temperature.

90. The Board of Appeal finds, first, that the aim of the study is not to mimic real-life environmental conditions but to allow for an objective assessment of the properties of the substance (see paragraph 57 above).

91. Second, the proposed testing temperature is in accordance with OECD test guideline 308. Paragraph 33 of the OECD test guideline 308 states that the study should be performed at a constant temperature in the range of 10 to 30 °C with 20 ± 2 °C being an appropriate temperature.

92. Third, even if the purpose of the study was to mimic real life conditions, which it is not (see paragraph 90 above), 20 °C is not an unrealistic temperature for surface water and sediment in certain parts of the European Union at certain times of year. If a substance bioaccumulates in the environment it is therefore likely to be subject to such temperatures.

93. Fourth, when a simulation study is conducted at 20 °C the percentages of certain transformation and/or degradation products may be higher than they would be if the same study was performed at 12 °C. The faster rate of formation of the transformation and/or degradation products should make the identification of these products, which is the objective of the study, easier. The temperature at which the test is conducted

should be taken into account when assessing the study results and deciding on possible further information requests. The possibility that the percentages of certain transformation and/or degradation products may be higher than they would be if the same study was performed at lower temperature does not mean that conducting the study at 20 °C would be inappropriate.

94. It follows from the above that the temperature specified in the Contested Decision, namely 20 °C, to conduct the OECD TG 308 study is appropriate to identify the transformation and/or degradation products of UVASORB HEB.

95. The Appellant's claim that the OECD TG 308 study is not appropriate to achieve its objective is consequently rejected.

1.1.3. Conclusion on the first plea

96. The Agency has established that the request for an OECD TG 308 study is both necessary (see paragraphs 71 to 81 above) and appropriate (see paragraphs 88 to 95 above).

97. The OECD TG 308 study will not by itself enable a conclusion to be reached on whether the transformation and/or degradation products formed, if any, are PBT or vPvB. However, the study will clarify which, if any, transformation and/or degradation products are formed. This is a legitimate objective of the information request as the Agency has established that transformation and/or degradation products of UVASORB HEB may pose a potential risk to human health or the environment. Depending on the results the OECD TG 308 study, further information may be requested to clarify whether any of the transformation and/or degradation products are PBT or vPvB.

98. The Appellant's plea that the Agency breached the principle of proportionality in requesting the OECD TG 308 study is therefore rejected.

1.2. The second plea: the request for the OECD TG 308 study is vitiated by a manifest error of assessment

Arguments of the Appellant

99. The Appellant argues that the Agency committed an error when assessing the QSAR predictions regarding the bioaccumulation potential of the transformation and/or degradation products of UVASORB HEB.

100. It can be concluded from the measured log K_{ow} value for UVASORB HEB available in the Constantini study, and the calculated BCF values of the predicted transformation and/or degradation products, that none of the transformation and/or degradation products are bioaccumulative (see paragraph 39 above).

101. Therefore, the Agency committed a manifest error of assessment when it found that the predicted transformation and/or degradation products of UVASORB HEB may be PBT or vPvB.

Arguments of the Agency and the eMSCA

102. The Contested Decision explains how all available data and the comments made by the Appellant during the decision-making procedure were addressed and explains why the Appellant's interpretation of the data derived from the QSAR models cannot be accepted.

103. The fact that the Parties have a different scientific opinion does not mean that the Agency committed a manifest error of assessment.

Findings of the Board of Appeal

104. When an appellant claims that the Agency has committed a manifest error of assessment, the Board of Appeal must examine whether the Agency has examined carefully and impartially all the relevant facts of the individual case which support the conclusions reached (see Case A-023-2015, *Akzo Nobel Chemicals and Others*, Decision of the Board of Appeal of 13 December 2017, paragraph 45 and the case law cited).

105. In the present case, when coming to its conclusion that the OECD TG 308 study was necessary, the Agency has examined carefully and impartially all the relevant arguments and facts. In particular, the Agency has examined carefully and impartially all the studies and the QSAR predictions in the PBT assessment provided by the Appellant as well as the reliability of that data (see paragraphs 55 to 70 above).

106. The Appellant's plea that the Agency committed a manifest error of assessment in requesting the OECD TG 308 study is rejected.

1.3. The third and fourth pleas: the request for the OECD TG 308 study breaches the REACH Regulation and is *ultra vires*

107. The pleas that the Agency breached the REACH Regulation and acted *ultra vires* in requesting the OECD TG 308 study will be examined together due to the similarity of the arguments used by the Appellant to support them.

Arguments of the Appellant

108. Paragraph 41 of OECD test guideline 308 states that '*transformation products detected at ≥10 % of the applied radioactivity in the total water-sediment system at any sampling time should be identified unless reasonably justified otherwise*'. According to the Agency's Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.11: PBT/vPvB assessment, version 2.0, November 2014, p. 34), all the transformation and/or degradation products above 0.1 % should be taken into account in the PBT assessment of a substance.

109. The Appellant submits that the Contested Decision requires it to identify all transformation and/or degradation products which exceed a concentration of 0.1 % whilst under Annex XIII only the '*relevant transformation and/or degradation products*' shall be taken into account in the PBT assessment of a substance.

110. The Appellant argues, in essence, that the 0.1 % threshold referred to in the Guidance on Information Requirements and Chemical Safety Assessment (see paragraph 108 above) should be applied only to transformation and/or degradation products which are '*already known to exist*'. The 0.1 % threshold '*is not intended as a requirement to*

start by identifying every possible environmental metabolite that could occur at ≥ 0.1 %'.

Arguments of the Agency and the eMSCA

111. The OECD TG 308 study is requested because no experimental evidence on the formation of transformation and/or degradation products is available. The relevance of the transformation and/or degradation products for the PBT assessment of UVASORB HEB can be determined only once experimental data on the identity of the transformation and/or degradation products formed are available.

112. Based on the QSAR models, UVASORB HEB may form transformation and/or degradation products which are potentially PBT or vPvB (see paragraphs 43 to 45 above). If those transformation and/or degradation products are identified in the requested OECD TG 308 study, they would become '*relevant*' within the meaning of Annex XIII.

113. During the appeal proceedings, the Agency conceded that the reference to the 0.1 % threshold for the identification of the transformation and/or degradation products in the Contested Decision '*is an oversight and can be corrected'*. The threshold for identification should be 10 % as defined in the paragraph 41 of the OECD TG 308 guideline to which the Contested Decision also refers.

Findings of the Board of Appeal

114. It is undisputed that the parent Substance UVASORB HEB in itself does not fulfil the PBT or vPvB criteria set out in Annex XIII. The Board of Appeal will examine whether the Agency breached Article XIII or acted *ultra vires* when it requested the Appellant to perform the OECD TG 308 study as part of the assessment of the PBT/vPvB properties of UVASORB HEB and did not limit the assessment to the '*relevant transformation and/or degradation products*' that are '*already known to exist'*.

115. The QSAR models included in the Appellant's PBT assessment indicate that UVASORB HEB may form transformation and/or degradation products which may be PBT or vPvB (see paragraphs 55 to 70 above). It is therefore consistent with the substance evaluation provisions of the REACH Regulation to request further experimental information which will help to confirm or disprove the QSAR predictions.

116. Once the transformation and/or degradation products of UVASORB HEB have been identified in an experimental study, and if further studies are necessary to determine whether they are PBT or vPvB, an assessment of whether UVASORB HEB should be identified as PBT or vPvB (see paragraphs 47 to 48 above) can be made.

117. As regards the threshold for identification, the Contested Decision states that the transformation and/or degradation products should be identified '*at a concentration of ≥ 0.1 % w/w unless it can be demonstrated that this is technically not possible'* (Contested Decision, p. 9). However, the Contested Decision also states that '*the appropriate threshold for identification of the transformation products is specified in paragraph 41 of the test guideline'* (Contested Decision, p. 12).

118. There is therefore an internal inconsistency in the Contested Decision. However, in the course of these appeal proceedings the Agency explicitly agreed that the 10 % threshold at paragraph 41 of the OECD TG 308 should be followed. Therefore, despite the internal inconsistency of the Contested Decision, there is no dispute about the threshold for identification between the Parties. The 10 % threshold for identification should be applied.

119. The Appellant's pleas that the Agency breached the REACH Regulation and acted *ultra vires* in requesting the OECD TG 308 study are therefore rejected.

1.4. Conclusion on the pleas related to the request for the OECD TG 308 study

120. The Agency did not breach the principle of proportionality (see Section 1.1. above), did not commit a manifest error of assessment (see Section 1.2. above), did not breach the REACH Regulation and did not act *ultra vires* (see Section 1.3. above) when it requested the Appellant to perform an OECD TG 308 study.

121. All the Appellant's pleas related to the request to perform an OECD TG 308 study are therefore rejected. The Appellant's appeal is consequently dismissed with regard to the request for an OECD TG 308 study.

2. Pleas related to the request to submit further information on uses and environmental emissions

Arguments of the Appellant

122. If UVASORB HEB does not meet the PBT or vPvB criteria in Annex XIII there is no justification for the Agency to request information on uses and environmental emissions.

123. The Appellant therefore claims that the Agency breached the principle of proportionality, committed a manifest error of assessment, breached the REACH Regulation and acted *ultra vires* when it requested the Appellant to provide further information on uses and environmental emissions of UVASORB HEB.

Arguments of the Agency and the eMSCA

124. Information on uses and environmental emissions is needed '*for choosing the most appropriate risk management option of UVASORB HEB*' in case it is classified as PBT or vPvB.

125. If UVASORB HEB is not identified as a PBT or vPvB, information on uses and environmental emissions would be used to perform a risk assessment and to obtain information for further investigations.

126. The Contested Decision justifies the request for information on uses and environmental emissions by the fact that the registration dossier does not contain an exposure assessment.

127. At the oral hearing, the eMSCA noted that UVASORB HEB may pose a risk if some of the transformation and/or degradation products are toxic or persistent even if none of them are identified as PBT or vPvB. The annual environmental exposure to UVASORB HEB is considerable and therefore potential toxicity or persistence alone are sufficient reasons for requesting further information on uses and environmental emissions.

Findings of the Board of Appeal

128. Under Article 14(4), registrants must include exposure assessments in the chemical safety report if the substance falls into certain hazard classes under the CLP Regulation or is identified as PBT or vPvB.

129. UVASORB HEB is not classified as hazardous under the CLP Regulation, and it is not yet known whether it should be identified as PBT or vPvB in accordance with the criteria in Annex XIII.

130. The Contested Decision does not, in its Appendix 1 or elsewhere, define the information that the Appellant should provide in order to meet this information request.

131. Furthermore, it is not yet known whether UVASORB HEB forms any transformation and/or degradation products which are PBT or vPvB.

132. The Agency has not precisely itemised the information that it needs in order for the Appellant to comply with the information request. The Agency has not, at this point in time, established that UVASORB HEB or its transformation and/or degradation products should be identified as PBT or vPvB according to Annex XIII. As a result, the Agency has failed to demonstrate the necessity for, and the appropriateness of, the requested information. The request for information on uses and environmental emissions therefore breaches the principle of proportionality (see paragraph 34 above).

133. As the request to provide information on uses and environmental emissions has been found to breach the principle of proportionality it is annulled. It is not therefore necessary to examine the Appellant's other pleas in this regard.

3. Conclusion on the appeal

134. For the reasons set out in Section 1 above, the appeal is dismissed to the extent it concerns the request for an OECD TG 308 study. The OECD TG 308 must be performed at a temperature of 20 °C as defined in the Contested Decision.

135. The 10 % threshold for identification of transformation and/or degradation products defined in paragraph 41 of OECD TG 308 should be followed.

136. For the reasons set out in Section 2 above, the Contested Decision is annulled as regards the request for information on uses and environmental emissions.

Claim for reimbursement of costs

137. The Appellant requests the Board of Appeal to order the Agency to pay the costs of these proceedings.

138. Under Article 17a 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, the 'Rules of Procedure', as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4), the parties to an appeal bear their own costs.

139. The application for the reimbursement of costs is therefore rejected.

Refund of the appeal fee

140. Under Article 10(4) of the Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency under the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee is refunded if the appeal is decided in favour of an appellant.

141. As the appeal has been partially decided in favour of the Appellant, the appeal fee is refunded.

Effects of the Contested Decision

142. Under Article 91(2), an appeal has suspensive effect.

143. The Contested Decision required the Appellant to provide the information requested by 27 September 2018, which is one year, nine months and seven days from the date of its notification.

144. The Appellant must therefore provide information on the OECD TG 308 study by 22 October 2020.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision to the extent it requests further information on uses and environmental emissions.**
2. **Dismisses the appeal for the remainder.**
3. **Decides that the information on the OECD TG 308 study must be submitted to the Agency by 22 October 2020.**
4. **Decides that the appeal fee is refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal