EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

14 February 2023

(Dossier evaluation – Compliance check – Column 2 of Section 9.2. of Annex VIII – PBT/vPvB assessment – Annex XIII – Duty to state reasons)

Case number	A-012-2021
Language of the case	English
Appellant	Covestro S.L., Spain
Representatives	Jean-Philippe Montfort and Thomas Delille Mayer Brown Europe-Brussels LLP, Belgium
Contested Decision	Decision of 26 August 2021 on a compliance check of the registration for the substance reaction mass of 2,6-Bis[(dimethylamino)methyl]-4-(1-{3-[(dimethylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)phenol and 4-(1-{3,5-Bis[(dimenthylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)-2,6-bis[(dimethylamino)methyl]phenol, adopted by the European Chemicals Agency under Article 41 of the REACH Regulation The Contested Decision was notified to the Appellant under annotation number CCH-D-2114566726-36-01/F

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Nikolaos Georgiadis (Technically Qualified Member), and Marijke Schurmans (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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1. Background to the dispute

1. The appeal concerns a compliance check of the registration for the substance reaction mass of:

   2,6-Bis[(dimethylamino)methyl]-4-(1-{3-[(dimethylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)phenol and 4-(1-{3,5-Bis[(dimenthylamino)methyl]-4-hydroxyphenyl}-1-methylethyl)-2,6-bis[(dimethylamino)methyl]phenol (the **Substance**).[1]

2. On 14 May 2018, the Appellant registered the Substance at the 10 to 100 tonnes per year tonnage band. As a result, under Article 12(1)(c) of the REACH Regulation[2], the technical dossier for the Substance referred to in Article 10(a) must include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the Appellant and as a minimum the information specified in Annexes VII and VIII.

3. On 9 October 2020, the Agency initiated a compliance check on the Appellant's registration dossier for the Substance in accordance with Article 41.

4. On 23 March 2021, in accordance with Articles 41(3) and 50(1), the Agency notified to the Appellant a draft decision with the opportunity to provide comments on it by 29 April 2021. The Appellant did not provide any comments on the draft decision.

5. On 1 July 2021, the Agency notified the draft decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1).

6. On 26 August 2021, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(3).

7. The Contested Decision requires the Appellant to submit information on:

   - Short-term repeated dose toxicity (28 days; Section 8.6.1. of Annex VIII) to be combined with the screening for reproductive/developmental toxicity below (**Information Requirement 1**),
   - Screening for reproductive/development toxicity (Section 8.7.1. of Annex VIII; test method: EU B.64/OECD test guideline (**TG**) 422) by oral route, in rats (**Information Requirement 2**),
   - Simulation testing on ultimate degradation in surface water (triggered by Section 9.2. of Annex VIII; test method EU.C.25/OECD TG 309) (**Information Requirement 3**),
   - Soil simulation testing (triggered by Section 9.2. of Annex VIII; test method: EU C.23./OECD TG 307) (**Information Requirement 4**),
   - Sediment simulation testing (triggered by Section 9.2. of Annex VIII; test method: EU C.24/OECD TG 308) (**Information Requirement 5**),
   - Identification of degradation products (triggered by Section 9.2. of Annex VIII; test method: using an appropriate test method) (**Information Requirement 6**), and
   - Bioaccumulation in aquatic species (triggered by Sections 0.6.1. and 4. of Annex I and Section 2.1. of Annex XIII; test method: OECD TG 305, aqueous exposure) (**Information Requirement 7**).

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[1] EC number 947-794-3.

[2] 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). All references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise.

8. According to the Contested Decision, the Appellant is required to submit to the Agency an update of the registration dossier containing the information required by 3 December 2024.

2. Procedure before the Board of Appeal

9. On 25 November 2021, the Appellant filed this appeal.

10. On 26 January 2022, the Agency filed its Defence.

11. On 9 March 2022, the Appellant filed its observations on the Defence.

12. On 13 April 2022, the Agency filed its observations on the Appellant's observations on the Defence.

13. On 5 October 2022, a hearing was held as the Board of Appeal considered it to be necessary in accordance with Article 13(1) of the Rules of Procedure[3]. The hearing was held at the Agency's premises. At the hearing, the Parties made oral submissions and responded to the questions from the Board of Appeal.

3. Form of order sought

14. The Appellant requests the Board of Appeal to annul Information Requirements 3 to 7 and to order the refund of the appeal fee.

15. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

4. Assessment of the case

16. The Appellant raises two pleas alleging that the Agency:

- misinterpreted and breached Articles 10, 12(1) and 41, as well Annexes VIII and XIII, and incorrectly exercised its discretion under Article 41 (**first plea**), and
- breached the duty to state reasons (**second plea**).

4.1. First plea: The Agency misinterpreted and breached Articles 10, 12(1) and 41, as well as Annexes VIII and XIII, and incorrectly exercised its discretion under Article 41

17. The Appellant's arguments under the first plea will be examined, first, in relation to Information Requirements 3, 4 and 5, second, in relation to Information Requirement 6, and third, in relation to Information Requirement 7.

4.1.1. Requests for information on the three degradation simulation studies (Information Requirements 3, 4, and 5)

Arguments of the Parties

18. The Appellant argues that, in requesting information on the three degradation simulation studies (Information Requirements 3, 4, and 5), the Agency misinterpreted and breached Articles 10, 12(1) and 41, as well Annexes VIII and XIII.

19. The Appellant argues that it provided all the standard information requirements on degradation required under Column 1 of Annexes VII and VIII and therefore there is no data gap in its registration dossier under Section 9.2. of Annexes VII and VIII.

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[3] 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).

20. The Appellant argues that it considered the results of the chemical safety assessment (**CSA**) for the purposes of Column 2 of Section 9.2. of Annex VIII and decided that they do not indicate the need to investigate further the degradation of the Substance. According to the Appellant, this is because there is negligible release of the Substance into the environment and the risk characterisation ratios (**RCRs**) are negligible (< 0.01) for all environmental compartments which demonstrates the absence of risk posed by the Substance.

21. The Appellant argues that the Agency failed to assess the considerations given by the Appellant and did not itself give due consideration to the results of the CSA. The Appellant argues that the consideration carried out by a registrant under Column 2 of Section 9.2. of Annex VIII is not limited to the assessment of the persistent, bioaccumulative and toxic (**PBT**) or very persistent and very bioaccumulative (**vPvB**) properties of a substance but refers to the results of the CSA as a whole. The Appellant argues that the Agency therefore failed to take into consideration all facts and circumstances of the case and incorrectly exercised its discretion.

22. The Appellant argues that the obligation '*to consider*' under Column 2 of Section 9.2. of Annex VIII is less stringent than the obligation '*to propose*' which appears in Column 2 of Section 9.2. of Annex IX.

23. The Appellant argues that the Agency committed an error in deciding that the Substance is a potential PBT or vPvB substance based on the available information. Specifically, the Appellant argues that, based on the available screening studies, the Substance is very persistent but is not bioaccumulative.

24. The Appellant argues that the Agency could not validly base the request for the three degradation simulation studies on Section 2.1. of Annex XIII. This is because Annexes VII to X constitute the main normative framework for registration information requirements. Annexes I and XIII must be read as being complementary to the provisions of Annexes VII to X. However, according to the Appellant, Annexes VII to X must be given priority in case any conflict of wording arises between their provisions and the complimentary rules of Annex I or XIII.

25. The Appellant argues that, if the three degradation simulation studies were conducted, the results thereof would not impact the results of the CSA; the results of the CSA would still be that the releases of the Substance into the environment are negligible and that it poses no risk to the environment. According to the Appellant, the requested information would not provide any relevant information which would significantly influence the calculated RCRs in the risk assessment.

26. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

(a) Annex XIII is not the legal basis for requesting Information Requirements 3, 4, and 5

27. According to the Contested Decision, the three degradation simulation studies (Information Requirements 3, 4, and 5) are requested on the basis of Column 2 of Section 9.2. of Annex VIII[4].

[4] See, for example, Section A (page 1) of the Contested Decision.

28. Under Column 2 of Section 9.2. of Annex VIII, '*further degradation testing shall be considered if the [CSA] according to Annex I indicates the need to investigate further the degradation of the substance […]*'.

29. In the present case, according to points 3, 4, and 5 of Appendix A to the Contested Decision, there is a need to investigate further the degradation of the Substance because, based on the available screening studies, the Substance is a potential PBT or vPvB.

30. Annex XIII sets out the applicable criteria for determining, first, whether a substance is a potential PBT or vPvB substance based on screening studies[5], and second, whether it can be concluded that that substance is a PBT or vPvB substance based on assessment studies[6].

31. Contrary to the Appellant's argument, Annex XIII is not the legal basis for requesting those information requirements in the Contested Decision. The criteria set out in Annex XIII are used by the Agency as grounds for demonstrating that there is a need to investigate further the degradation of the Substance within the meaning of Column 2 of Section 9.2. of Annex VIII. Consequently, as stated in the Contested Decision, the legal basis for requiring the Appellant to submit information on the three degradation simulation studies (Information Requirements 3, 4, and 5) is Column 2 of Section 9.2. of Annex VIII.

(b) The Agency did not commit an error by failing to take into account the available information on exposure and risk

(i) The Appellant provided the standard information on degradation required under Column 1 of Annex VII and VIII

32. It is undisputed in the present proceedings that the Appellant fulfilled the information requirements on degradation required in Column 1 of Section 9.2.1.1. of Annex VII and Column 1 of Section 9.2.2.1. of Annex VIII.

33. However, the Appellant disagrees with the Agency's decision that further degradation testing is required under Column 2 of Section 9.2. of Annex VIII to further investigate the degradation of the Substance.

(ii) Under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is not obliged, subject to certain exceptions, to take into account information on exposure and risk related to a substance

34. The Appellant argues that, in the present case, no additional information on degradation is required under Column 2 of Section 9.2. of Annex VIII because the CSA, as documented in the chemical safety report (**CSR**), for the Substance indicates that:

- There is negligible release of the Substance into the environment; and
- There is no risk posed by the Substance since the RCRs are negligible (< 0.01) for all environmental compartments.

[5] Section 3.1. of Annex XIII.

[6] Section 3.2. of Annex XIII.

35. In principle, the REACH Regulation requires registrants to submit information on the intrinsic properties of a substance in accordance with Annexes VII to X even if, based on its current uses, the substance can be shown to pose no risk due to limited, or no, exposure[7] to that substance.

36. The levels and patterns of exposure to a substance may vary over time depending, for example, on the uses of that substance, whilst the intrinsic properties of a substance, once they are identified, notably as they result from the information requirements set out in Annexes VII to X, remain the same[8].

37. In addition, where a substance has several registrants, uses and exposure may vary from one registrant to another whilst the intrinsic properties of that substance are the same for all. Under Articles 10 and 11, registrants may submit to the Agency information on uses and exposure separately from other registrants of the same substance, whilst they are in principle required to submit jointly information on the intrinsic properties of that substance, subject to the limited exceptions set out in Article 11(3).

38. Consequently, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is obliged to verify whether a registration dossier includes information on the intrinsic properties of a substance and not to assess the risks posed by that substance[9]. The Agency is not obliged to take into account exposure and risk, unless exceptions are provided for in the REACH Regulation.

(iii) Column 2 of Section 9.2. of Annex VIII is not an exception to the general principle that, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is not obliged to take into account information on exposure and risk

39. The REACH Regulation provides for exceptions to the general principle that, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is not obliged to take into account information on exposure and risk related to a substance. Those exceptions include the general adaption under Section 3 of Annex XI ('*substance-tailored exposure-driven testing*') and certain specific adaptations under Column 2 of Annexes VII to X where exposure may be relevant to trigger additional requirements[10], or to waive testing required under Column 1 of Annexes VII to X[11]. In those exceptions, the relevance of exposure and/or risk is clearly set out.

40. However, for the following reasons, Column 2 of Section 9.2. of Annex VIII is not an exception to the principle that, under a compliance check verifying compliance with the information requirements in Annexes VII to X, the Agency is not obliged to take into account information on exposure and risk related to a substance.

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[7] Decision of the Board of Appeal of 11 December 2018, *Climax Molybdenum*, A-006-2017, paragraphs 131 to 136.

[8] Decision of the Board of Appeal of 11 December 2018, *Climax Molybdenum*, A-006-2017, paragraph 133.

[9] Decision of the Board of Appeal of 24 March 2020, *Emerald Kalama Chemical and Others*, A-006-2018, paragraph 69. See also, for example, decision of the Board of Appeal of 28 June 2016, *BASF*, Case A-015-2014, paragraph 58; decision of the Board of Appeal of 18 August 2020, *Symrise*, A-009-2018, paragraph 21; and decision of the Board of Appeal of 11 December 2018, *Climax Molybdenum*, Case A-006-2017, paragraphs 131 to 136.

[10] See, for example, Column 2 of Section 8.7.3. of Annex IX which refers to '*significant exposure of consumers or professionals, taking into account, inter alia, consumer exposure from articles'*.

[11] See, for example, Column 2 of Section 9.3.2. of Annex IX '*The [bioaccumulation] study need not be conducted if […] direct and indirect exposure of the aquatic compartment is unlikely*'. See also Column 2 of Section 9.2.1.3. and 9.2.1.4. of Annex IX.

41. First, the reference to '*…the [CSA] according to Annex I...*' in Column 2 of Section 9.2. of Annex VIII does not mean that all aspects of the CSA – which is documented in the CSR – must be assessed before deciding whether additional information on degradation is required.

42. The reference to the CSA in Column 2 of Section 9.2. of Annex VIII means that the registrant, or the Agency, must investigate the parts of the CSA that are relevant to determine whether there is a need to investigate further the intrinsic properties of the substance with regards to its degradation. Contrary to the Appellant's arguments, the Agency was not obliged to assess the parts of the CSA on exposure and risk related to the Substance before deciding whether additional information on degradation was required under Column 2 of Section 9.2. of Annex VIII. That provision refers to the CSA, with a view to assessing the need to investigate the degradation of the substance, which is one of the intrinsic properties of the substance.

43. Second, under Article 14(3)(d) and (4), the PBT and vPvB assessment is a mandatory and self-standing step of the CSA. In addition, Section 4 of Annex I stipulates that the objective of the PBT and vPvB assessment is '*[…] to determine if the substance fulfils the criteria given in Annex XIII […]*'.

44. Furthermore, according to Article 14(3) and (4), it is only after a substance is assessed to be a PBT or vPvB substance, or to fulfil the criteria for any of the hazard classes or categories mentioned in Article 14(4)(a) to (d), that the CSA must include an assessment of exposure and risk characterisation. Consequently, unless the substance in question fulfils the criteria for any of the hazard classes or categories mentioned in Article 14(4)(a) to (d), it would not be necessary to assess potential exposure and risk before assessing the PBT or vPvB properties.

45. Third, a conclusion on whether a substance is a PBT or vPvB substance is required irrespective of the exposure based on its current uses. This is supported by Section 4.0.1. of Annex I which provides that '*the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XIII. Therefore, a separate PBT and vPvB assessment is required*'.

(iv) The Agency did not fail to assess the Appellant's consideration that further information is not needed

46. For the following reasons, the Appellant's argument that the Agency failed to assess the consideration given by the Appellant to the results of the CSA as a whole must be dismissed.

47. First, as stated above, the Agency is not under the obligation to assess exposure and risk for the purposes of requesting additional information on degradation under Column 2 of Section 9.2. of Annex VIII[12]. For the same reason, the Agency was not required to provide reasoning in the Contested Decision as to why the requested information on degradation was necessary despite the Appellant's conclusion on exposure and risk included in its CSR.

48. Second, and in any event, the Appellant's registration dossier does not contain a specific justification setting out why further degradation testing is not required under Column 2 of Section 9.2. of Annex VIII. Under that provision, a registrant must consider whether further degradation testing is needed to investigate further the degradation of the substance in question. If the registrant concludes, based on its consideration of the CSA, that such further degradation testing is not required,

[12] See paragraphs 34 to 45 above.

it must clearly set out in its registration dossier the reasons for that conclusion. This is essential to allow the Agency to assess the validity of the registrant's decision not to perform further degradation testing under Column 2 of Section 9.2. of Annex VIII[13].

49. Section 8.1.2. of the CSR for the Substance entitled '*Summary and overall conclusions on PBT or vPvB properties*' does not state that no additional information is needed under Column 2 of Section 9.2. of Annex VIII based on exposure and risk related to the Substance. In this part of the CSR, the Appellant rather states that its conclusion that the Substance is not a PBT or vPvB substance is based on the following elements. First, the Appellant concludes that the Substance is persistent (**P**) and very persistent (**vP**) because no degradation or biodegradation was observed in the ready biodegradability or the inherent biodegradability studies, or in the hydrolysis study at pH 4, 7 and 9. Second, the Appellant concludes that the Substance is not bioaccumulative (**B**) or very bioaccumulative (**vB**), based on an octanol-water partition coefficient (**Log Kow**) of 3.2. to 4.0. Third, the Appellant concludes that there is no toxicity observed in the environment or humans.

(v) Conclusion

50. In view of paragraphs 32 to 49, the Appellant's argument that the Agency committed an error by failing to take into account the exposure and risk related to the Substance must be rejected.

(c) The Agency did not commit an error in concluding that the available information indicates the need to investigate further the degradation of the Substance under Column 2 of Section 9.2. of Annex VIII

(i) A finding that a substance is a potential PBT or vPvB substance based on degradation screening studies justifies the need to investigate further the degradation of that substance

51. According to the Contested Decision, the need to investigate further the degradation of the Substance under Column 2 of Section 9.2. of Annex VIII is based on the Agency's decision that the results of the screening studies included in the Appellant's registration dossier for the Substance showed that the Substance has potentially PBT or vPvB properties.

52. For the following reasons, a decision, based on the available information, that a substance is a potential PBT or vPvB justifies a request for additional information on degradation under Column 2 of Section 9.2. of Annex VIII.

53. First, Section 2.1. of Annex XIII states that, if the results from degradation screening tests or other information indicate that a substance may have PBT or vPvB properties, the registrant must generate relevant additional information, as set out in Section 3.2. of Annex XIII ('*assessment information*'), to conclude whether the substance in question is, or is not, a PBT or vPvB substance within the meaning of Section 1 of Annex XIII.

54. Second, such an interpretation of Column 2 of Section 9.2. of Annex VIII does not mean that that provision would be merely a repetition of Column 1 of Section 9.2. of Annex IX or that the Agency failed to respect the different levels of obligations applicable to registrants at the Annex VIII and Annex IX level.

[13] See, by analogy, decision of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraphs 83 and 94.

55. The trigger to request the three degradation simulation studies under Column 2 of Section 9.2. of Annex VIII is not the same as the requirement to provide that information under Annex IX.

56. Under Column 1 of Section 9.2. of Annex IX, the degradation simulation studies requested in the Contested Decision are standard information requirements. Therefore, in contrast to the requirement in Column 2 of Section 9.2. of Annex VIII, the requirement to submit that information at the Annex IX level is not dependent on a demonstration that there is a need for that information, for example because the substance is a potential PBT or vPvB substance. The information on degradation under Column 1 of Section 9.2. of Annex IX must be submitted unless the registrant submits an acceptable specific adaptation under Column 2 of the corresponding provision or an acceptable general adaptation under Annex XI[14].

57. Third, the Appellant's argument that the obligation '*to consider*' in Column 2 of Section 9.2. of Annex VIII is less stringent than the obligation '*to propose*' which appears, for example, in Column 2 of Section 9.2. of Annex IX must be rejected. Under both requirements there is an obligation for registrants to examine the available information, and if the requirements of the provision in question are met, there is an obligation to provide the information required by that provision. The use of the verb '*consider*' in the version of Column 2 of Section 9.2. of Annex VIII that was applicable at the time of the adoption of the Contested Decision, i.e. on 26 August 2021, cannot be interpreted as authorising a registrant not to take any action and not provide the necessary information if the CSA indicates the need to investigate further the degradation of the substance at issue.

(ii) The Agency did not commit an error in deciding that the Substance is a potential PBT or vPvB

58. The Appellant argues that the Agency committed an error in deciding that the Substance is a potential PBT or vPvB substance.

- *Admissibility of the Appellant's plea that the Agency failed to demonstrate that the Substance is potentially B or vB*

59. The Agency argues that, in the observations on the Defence, the Appellant raises a new plea alleging that the Agency failed to demonstrate why the information used by the Agency to indicate the potential B or vB properties of the Substance overrules the screening information set out in Section 3.1.2.(a) of Annex XIII relied on by the Appellant.

60. The Agency argues that this plea is inadmissible under Article 12(2) of the Rules of Procedure since it was introduced only in the observations on the Defence.

61. Under Article 12(2) of the Rules of Procedure, no new plea in law may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that it is based on new matters of law or of fact that come to light in the course of the proceedings.

62. In the Notice of Appeal, the Appellant focuses on arguments related to exposure and risk to support its claim that no additional information on degradation is required under Column 2 of Section 9.2. of Annex VIII. In the Notice of Appeal, the Appellant does not specifically raise any plea based on the results of the degradation screening studies available in its dossier.

[14] Decision of the Board of Appeal of 27 September 2022, *Albemarle Europe SPRL, Belgium,* A-005-2021, paragraphs 48, 49 and 89.

63. However, in the Notice of Appeal, the Appellant states explicitly that it does not accept the Agency's decision regarding the potential PBT or vPvB properties of the Substance.

64. In the Defence, the Agency argues that the Appellant does not contest the Agency's position in the Contested Decision that the Substance may have PBT or vPvB properties based on the screening studies available in the registration dossier.

65. It is in response to the Agency's arguments that the Appellant, in its observations on the Defence, states that it is in fact contesting the decision that the Substance may have B or vB properties based on the available screening studies. The Appellant then provides further arguments to support its claim. Those new arguments, introduced after the first exchange of written pleadings, were based on new matters that come to light in the course of the proceedings, within the meaning of Article 12(2) of the Rules of Procedure.

66. In view of paragraphs 59 to 65 above, the Agency's argument that the Appellant's plea is inadmissible under Article 12(2) of the Rules of Procedure must be rejected.

- *Examination of the Appellant's plea that the Agency committed an error in deciding that the Substance is a potential PBT or vPvB substance*

67. In the Contested Decision, the Agency sets out why it considers that, based on the available information in the Appellant's registration dossier for the Substance, the Substance is both potentially P or vP and potentially B or vB. The potential toxicity of the Substance is not at issue in the present case.

Potential P or vP properties of the Substance

68. The Appellant's registration dossier contained the following screening information on the potential P or vP properties of the Substance.

69. Under Column 1 of Section 9.2.1.1. of Annex VII, the Appellant's registration dossier contains the results of an OECD TG 301F study on ready biodegradability[15] and an OECD TG 302C study on inherent biodegradability[16]. The Appellant argues that no biodegradation was observed in those studies and the Substance is considered to be not readily biodegradable and not inherently biodegradable.

70. Under Column 1 of Section 9.2.2.1. of Annex VIII, the Appellant's registration dossier contains the results of an OECD TG 111 study on hydrolysis as a function of pH[17]. The Appellant argues that, based on the results of that study, the Substance can be considered to be hydrolytically stable.

71. The Appellant argues that, based on those screening studies, the Substance meets the vP criterion and no additional information is needed to confirm that conclusion.

72. According to the Contested Decision, the Substance is potentially P or vP as the Substance is not readily biodegradable – based on the results of the Neuhahn (2016) study – or inherently biodegradable – based on the results of the Spoo-Kloppel (2017) study. As a result, according to the Contested Decision, further information is needed to conclude that the Substance meets the P or vP criteria set out in Annex XIII.

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[15] Neuhahn (2016).

[16] Spoo-Kloppel (2017).

[17] Neuland (2017).

73. For the following reasons, the Agency did not commit an error in deciding that additional information is required to conclude whether the Substance has P or vP properties.

74. First, the Agency asserted at the hearing that it may be possible to conclude whether a substance fulfils the P criterion[18] based on screening studies. However, the Agency also specified, without being contradicted by the Appellant on this point, that it is not possible to conclude whether a substance fulfils the vP criterion[19] based only on those screening studies.

75. Second, the method for performing a PBT and vPvB assessment is set out in Annex XIII. The first step of that assessment is the performance of the PBT/vPvB screening studies. According to Section 2.1. of Annex XIII, where the screening studies indicate that a substance may have PBT or vPvB properties, the registrant must generate relevant additional information from the assessment studies set out in Section 3.2. of Annex XIII. This allows for a degradation half-life to be derived and therefore a conclusion on the P or vP properties of the Substance to be reached.

76. Therefore, a registrant's conclusion that a Substance is vP, based solely on screening studies, does not constitute a PBT and vPvB assessment as set out in Annex XIII.

Potential B properties of the Substance

77. According to Section 2.1. of Annex XIII[20], in order to request assessment studies to confirm the PBT or vPvB properties of a substance, the available information must indicate that that substance has both potential P or vP properties and potential B or vB properties. In the present case, it is therefore also necessary to examine the Appellant's claim that the Agency committed an error in deciding that the Substance is potentially B or vB.

78. According to Section 3.1.2. of Annex XIII, the following information must be considered for screening the B and vB properties of a substance:

'*(a) Octanol-water partitioning coefficient experimentally determined in accordance with Section 7.8 of Annex VII or estimated by (Q)SAR models in accordance with Section 1.3 of Annex XI;*

(b) Other information provided that its suitability and reliability can be reasonably demonstrated'.

79. In the CSR for the Substance, the Appellant relied on the information specified in Section 3.1.2.(a) of Annex XIII to conclude that the Substance is not potentially B or vB.

80. Specifically, according to the CSR, the Log Kow range for the Substance at 25°C at pH 7 is 3.2 to 4.0 '*by the HPLC-method according to OECD 117*'. The CSR specifies further that the Log Kow value used for the CSA is 4 at 25°C.

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[18] See Section 1.1.1. of Annex XIII.

[19] See Section 1.2.1. of Annex XIII.

[20] Section 2.1. of Annex XIII provides: '*no additional information needs to be generated for the assessment of PBT/vPvB properties if there is no indication of P or B properties following the result from the screening test or other information*'.

81. According to ECHA's Guidance R.11[21], for organic substances with a Log Kow value below 4.5 it is assumed that the B criterion – that is to say a bioconcentration factor (**BCF**) value of 2 000 – is not exceeded.

82. In the present case, the Agency does not dispute the Appellant's conclusion that the Log Kow for the Substance is less than 4.5. It is also not disputed that on the basis of the Log Kow for the Substance determined in accordance with Section 7.8. of Annex VII, it is normally assumed that the B criterion of Section 1.1.2. or the vB criterion of Section 1.2.2. of Annex XIII would not be met.

83. However, according to the Contested Decision[22], because of the specific properties of the Substance, the low Log Kow value – in other words the information specified in Section 3.1.2.(a) of Annex XIII – is insufficient to conclude on the B or vB properties of the Substance. Specifically, the Contested Decision states:

'*…for some groups of substances (e.g. organometals, ionisable substances, surfactants) other partitioning mechanisms may drive bioaccumulation (e.g. binding to protein/cell membranes) and high potential for bioaccumulation cannot be excluded solely based on its potential to partition to lipid*'.

84. Similar wording is also found in ECHA's Guidance on information requirements and chemical safety assessment[23].

85. In the Contested Decision, the Agency, in effect, decides that '*other information*' within the meaning of Section 3.1.2.(b) of Annex XIII demonstrates that the Substance is potentially B or vB. According to the Contested Decision:

'*For the Substance, uptake may be driven by other mechanisms than lipid partitioning due to ionisation and surface active properties (surface tension 53 mN/m) and therefore high potential for bioaccumulation cannot be excluded based on available information*' (emphasis added).

86. For the following reasons, the Agency did not commit an error in deciding that the Substance may have B or vB properties based on the Substance's ionisation and surface-active properties.

87. First, an indication of the B and vB properties of a substance can be based on the information referred to in either point (a) or point (b) of Section 3.1.2. of Annex XIII. The fact that in the present case the information referred to in point (a) of Section 3.1.2. of Annex XIII indicates that the substance does not have B or vB properties does not prevent the Agency from relying on the information referred to in point (b) of that same section of Annex XIII.

88. Second, according to the CSR for the Substance, a surface tension of 53 mN/m at 20°C was determined for the Substance according to OECD TG 115 using a plate tensiometer. The CSR states that the value used for the CSA is 53 mN/m at 20°C and 1 000 mg/L.

89. In accordance with OECD Guidance Document 23, a substance has surface active properties if the surface tension is below 60 mN/m.[24]

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[21] Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), page 82. According to the Guidance, '*For the PBT and vPvB assessment a screening threshold value has been established, which is log Kow greater than 4.5. The assumption behind this is that the uptake of an organic substance in aquatic organisms is driven by its hydrophobicity. For organic substances with a log Kow value below 4.5 it is assumed that the B criterion, i.e. a BCF value of 2000 (based on wet weight of the organism, which refers to fish in most cases), is not exceeded*'.

[22] Page 5 of the Contested Decision.

[23] Chapter R.11 (version 3.0, June 2017).

[24] OECD Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals, 8 February 2019, page 19.

90. Third, it can be inferred from information in the CSR that the Substance is ionisable – present in ionised forms at environmentally relevant pHs from 4 to 9.

91. Fourth, the information on surface-active and ionisation properties relied on by the Agency in the Contested Decision is found in the Appellant's CSR for the Substance. As the validity of that information is not contested, it must be considered to be '*reliable*' within the meaning of Section 3.1.2.(b) of Annex XIII.

92. Fifth, the Appellant did not present arguments to suggest that the information on surface tension and ionisation properties is not '*suitable*' within the meaning of Section 3.1.2.(b) of Annex XIII for determining the potential B or vB properties of the Substance.

(d) Conclusion on the Appellant's first plea in relation to Information Requirements 3 to 5

93. In view of paragraphs 27 to 92 above, the Agency did not err in requesting Information Requirements 3, 4, and 5 under Column 2 of Section 9.2. of Annex VIII. Therefore, the Appellant's first plea regarding Information Requirements 3, 4, and 5 must be rejected.

4.1.2. The request for information on the identification of degradation products (Information Requirement 6)

Arguments of the Parties

94. The Appellant argues that, in requesting information on the identification of degradation products (Information Requirement 6), the Agency misinterpreted and breached Articles 10, 12(1), and 41, as well as Annexes VIII and XIII.

95. The Appellant argues that the results of the CSA indicate that there is no need to investigate further the degradation of the Substance and, as a consequence, there is also no need to provide information on the identification of degradation products.

96. The Appellant argues that information on the identification of degradation products is not foreseen in Annex VIII.

97. The Appellant argues that, whilst Column 2 of Section 9.2. of Annex IX explicitly refers to '*the need to investigate further the degradation of the substance and its degradation products*', Column 2 of Section 9.2. of Annex VIII refers only to '*the need to investigate further the degradation of the substance*'. According to the Appellant, this means that the identification of the degradation products cannot be required at Annex VIII level.

98. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

99. For the following reasons, the Appellant has not demonstrated that the Agency committed an error in requiring the Appellant to submit information on the identification of degradation products (Information Requirement 6).

100. First, the Appellant's argument that the results of the CSA indicate that there is no need to investigate further the degradation of the Substance has already been rejected[25]. Without committing an error, the Agency demonstrated in the Contested Decision that there is a need to further investigate degradation within the meaning of Column 2 of Section 9.2. of Annex VIII as the results of the available screening studies show that the Substance is a potential PBT or vPvB substance.

101. Second, the Appellant's argument that the identification of degradation products is not foreseen in Annex VIII is based on an incorrect interpretation of Column 2 of Section 9.2. of Annex VIII.

102. Column 2 of Section 9.2. of Annex VIII refers to the need to investigate further the degradation of a substance, which includes the process of degradation and the identification of the degradation products of that substance.

103. Third, degradation testing includes the identification of degradation products. In this respect, the degradation simulation studies requested in the Contested Decision all allow for the identification of degradation or transformation products[26].

104. For example, paragraph 41 of OECD TG 308 on sediment simulation testing 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. Transformation products for which concentrations are continuously increasing during the study should also be considered for identification, even if their concentrations do not exceed the limits given above [i.e., ≥ 10 %], as this may indicate persistence. The latter should be considered on a case by case basis, with justifications being provided in the report*' (emphasis added).

105. Fourth, contrary to the Appellant's argument[27], the difference in wording between Column 2 of Section 9.2. of Annexes VIII and IX does not mean that information on the identification of degradation products cannot be requested at the Annex VIII level.

106. Column 2 of Section 9.2. of Annex VIII allows for further information on the degradation of a substance to be obtained, and therefore may include information on the identification of degradation products. Column 2 of Section 9.2. of Annex IX allows for further information on degradation to be obtained, not only on the substance, but also on the degradation products of that substance.[28] The specific requirement to provide information on the degradation of a substance's degradation products does not arise in the Annexes prior to Column 2 of Section 9.2. of Annex IX.[29]

Conclusion on the Appellant's first plea regarding Information Requirement 6

107. In view of paragraphs 99 to 106 above, the Appellant's first plea regarding Information Requirement 6 must be rejected.

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[25] See paragraphs 27 to 93 above.

[26] Decision of the Board of Appeal of 27 September 2022, *Albemarle Europe*, A-005-2021, paragraphs 91 and 92.

[27] See paragraph 97 above.

[28] Decision of the Board of Appeal of 27 September 2022, *Albemarle Europe*, A-005-2021, paragraph 53.

[29] Decision of the Board of Appeal of 27 September 2022, *Albemarle Europe*, A-005-2021, paragraph 60.

4.1.3. The request for information on a bioaccumulation study (Information Requirement 7)

Arguments of the Parties

108. The Appellant argues that the Agency cannot request bioaccumulation studies on the sole basis of Section 2.1. of Annex XIII under the compliance check procedure.

109. The Appellant argues that the only standard information requirement in Column 1 of Section 9.3. of Annex VIII is '*adsorption/desorption screening*' and that Column 2 of that provision does not contain a trigger for a bioaccumulation study at the Annex VIII level.

110. The Agency argues that, in the absence of an explicit triggering provision in Column 2 of Section 9.3. of Annex VIII, it was, in any event, the legislator's intention that further bioaccumulation data may be triggered at the Annex VIII level.

111. The Agency argues that the amendments to the REACH Regulation under Commission Regulation (EU) 2022/477[30] allow for bioaccumulation testing to be requested under Column 2 of Section 9.3. of Annex VIII.

112. The Agency argues that, according to its guidance, the information necessary for the PBT or vPvB assessment must be generated regardless of the tonnage band.

Findings of the Board of Appeal

113. For the following reasons, based on the version of the REACH Regulation applicable at the time the Contested Decision was adopted, i.e. on 26 August 2021, the Agency was not competent to request information on bioaccumulation in aquatic species (test method: OECD TG 305; Information Requirement 7) under the compliance check procedure from registrants at the Annex VIII level, such as the Appellant.

114. First, at the time the Contested Decision was adopted, Column 1 of Section 9.3. of Annex VIII did not include the bioaccumulation study requested in the Contested Decision as a standard information requirement. Furthermore, Column 2 of Section 9.3. of Annex VIII did not contain a triggering provision for additional information on bioaccumulation equivalent to Column 2 of Section 9.2. of Annex VIII in relation to degradation.

115. Such a triggering provision has been added to Column 2 of Section 9.3. of Annex VIII to the REACH Regulation by Regulation (EU) 2022/477. However, that amendment to the REACH Regulation became applicable on 14 October 2022 and, therefore, is not relevant to the present case.

116. Second, according to Article 41(3), following a compliance check of registrations the Agency may require '*registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements*' (emphasis added).

117. The '*information requirements*' referred to in Article 41(3), with which the Agency may require a registrant to comply, are set out in Annexes VI to X, and in Annex XI as regards the general rules for adaptation of those information requirements. This is consistent with the wording of the introduction to Annex VI which states that '*Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46*'. This is

[30] Commission Regulation (EU) 2022/477 amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 98, 25.3.2022, p. 38).

also confirmed by the titles of Annexes VII to X. For example, Annex VIII is entitled '*Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more'* (emphasis added)'.

118. According to the Contested Decision, the legal basis for requesting the information on a bioaccumulation study (Information Requirement 7) is Sections 0.6.1. and 4. of Annex I and Section 2.1. of Annex XIII[31].

119. Annexes I and XIII – the legal bases relied on by the Agency in the Contested Decision to require Information Requirement 7 – do not set out information requirements within the meaning of Article 41(3). Consequently, under the compliance check process, the Agency cannot require registrants to submit information to comply with those Annexes.

120. In view of paragraphs 113 to 119 above, the Appellant's argument that the Agency is not empowered to request information on a bioaccumulation study from registrants at the Annex VIII level must be upheld, and the Contested Decision must be annulled to the extent that it requests Information Requirement 7.

4.2. Second plea: Breach of the duty to state reasons

Arguments of the Parties

121. The Appellant argues that the Agency breached its duty to state reasons as the Contested Decision contains no assessment of the consideration given by the Appellant to the results of its CSA as a whole. The Appellant argues that the Contested Decision also does not identify or demonstrate any failure on the part of the Appellant in its assessment of the results of the CSA.

122. The Agency disputes the arguments of the Appellant.

Findings of the Board of Appeal

123. Under Article 130, the Agency must state reasons for all decisions it takes under the REACH Regulation. The duty to state reasons is an essential procedural requirement which is enshrined in the second paragraph of Article 296 of the Treaty on the Functioning of the European Union (**TFEU**) and is included in Article 41(2)(c) of the Charter of Fundamental Rights of the European Union as part of the right to good administration[32].

124. A statement of reasons must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution, body or agency which adopted the measure in question, in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the Board of Appeal and the European Union judicature to exercise their powers of review[33]. Whether a statement of reasons is adequate or not depends on all the circumstances of a case, in particular, the content of the measure in question, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations[34].

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[31] See, for example, Section A of the Contested Decision, page 2.

[32] Decision of the Board of Appeal of 29 June 2021, *SNF,* A-001-2020, paragraph 134.

[33] See by analogy judgment of 21 December 2016, *Club Hotel Loutraki and Others* v *Commission*, C 131/15 P, EU:C:2016:989, paragraph 46.

[34] See judgment of 10 March 2016, *HeidelbergCement* v *Commission*, C-247/14 P, EU:C:2016:149, paragraph 16.

125. Since Information Requirement 7 has been annulled, it is necessary to examine the Appellant's second plea in relation to Information Requirements 3 to 6 only.

126. For the following reasons, the Appellant's argument that the Agency did not provide reasons for rejecting its consideration of the CSA and the need for further information on degradation must be rejected.

127. First, as stated above[35], the Appellant's registration dossier does not contain a specific justification setting out why further degradation testing is not needed under Column 2 of Section 9.2. of Annex VIII. In addition, the Appellant did not provide any comments on the draft decision[36] that would indicate the reasons why it opposes the position of the Agency that further degradation testing is needed.

128. Second, the Agency is not obliged to assess itself exposure and risk information for the purposes of deciding whether additional information on degradation is required under Column 2 of Section 9.2. of Annex VIII[37].

129. The Agency was therefore not obliged to include reasoning in the Contested Decision rebutting the Appellant's consideration that further degradation testing was not required under Column 2 of Section 9.2. of Annex VIII based on exposure and risk related to the Substance.

130. Third, the Contested Decision contains reasoning[38] as to why the Agency considered that further degradation testing was required to conclude on the P or vP and B or vB properties of the Substance. In particular, the Contested Decision sets out why the Agency considers that the Substance is potentially P or vP and B or vB. The justification provided is sufficient to allow the Appellant to ascertain the reasons for the Contested Decision and to enable the Board of Appeal to exercise its power of review.

131. Furthermore, the Appellant rather contests the Agency's conclusion that further information on degradation is required as the Substance is a potential PBT or vPvB substance based on the available screening information. In this respect, the duty to state reasons in decisions is an essential procedural requirement which must be distinguished from the question of whether the reasoning is well founded, which is concerned with the substantive legality of the measure at issue. The reasoning of a decision consists of a formal statement of the grounds on which that decision is based. If those grounds are vitiated by errors, those errors will vitiate the substantive legality of the decision, but not the statement of reasons in it, which may be adequate even though it sets out reasons which are incorrect[39].

132. In view of paragraphs 123 to 131 above, the Appellant's second plea must be rejected.

4.3. Result

133. In view of paragraphs 113 to 120 above, the requirement to provide information on a bioaccumulation study (Information Requirement 7) is annulled and the case remitted to the Agency for further action on that point.

134. For the reasons given in paragraphs 27 to 107 and 123 to 132 above, the Appellant's appeal in relation to Information Requirements 3 to 6 is dismissed.

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35 See paragraph 48 above.

36 See paragraph 4 above.

37 See paragraphs 34 to 45 above.

38 See, in particular, Section 3 of Appendix A to the Contested Decision.

39 Decision of the Board of Appeal of 30 June 2017, *Evonik Degussa and Others*, A-015-2015, paragraph 262.

5. Effects of the Contested Decision

135. The contested part of the Contested Decision required the Appellant to submit information on Information Requirements 3 to 7 by 3 December 2024, which is 3 years, 3 months, and 7 days from the date of that decision.

136. Under Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision must therefore be calculated starting from the date of notification of the present decision of the Board of Appeal to the parties.

137. Since Information Requirement 7 has been annulled, the Appellant must consequently provide Information Requirements 3 to 6 requested in the Contested Decision by 21 May 2026.

6. Refund of the appeal fee

138. Under Article 10(4) of the Fee Regulation[40], the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the Contested Decision has been partially annulled, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it requires information on bioaccumulation in aquatic species (Information Requirement 7).**
2. **Dismisses the remainder of the appeal.**
3. **Remits the case to the Agency in so far as it concerns the information on bioaccumulation in aquatic species (Information Requirement 7).**
4. **Decides that the information on simulation testing on ultimate degradation in surface water, soil simulation testing, sediment simulation testing and the identification of degradation products (Information Requirements 3 to 6) required by Contested Decision must be provided by 21 May 2026.**
5. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal

[40] Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6).