EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

27 September 2022

(Dossier evaluation – Compliance check – Section 9.2. of Annex IX to the REACH Regulation – Identification of degradation products)

Case number	A-005-2021
Language of the case	English
Appellant	Albemarle Europe SPRL, Belgium
Representatives	Ruxandra Cana, Eléonore Mullier, and Lukasz Gorywoda Steptoe & Johnson LLP, Belgium
Contested Decision	Decision of 13 January 2021 on a compliance check of the registration for the substance N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide), 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-2114539007-53-01/F

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

1. Background to the dispute

1. This appeal concerns a compliance check of the registration for the substance N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide) (the **Substance**).[1]

2. The Appellant's registration dossier contained adaptations to omit the simulation testing required under Section 9.2.1. of Annex IX to the REACH Regulation.[2] Those adaptations were based mainly on the Appellant's conclusion that the Substance is poorly soluble in water and in organic solvents. In relation to the requirement to provide information on the identification of degradation products under Section 9.2.3. of Annex IX, the Appellant sought to rely on adaptations under Section 2 of Annex XI and Column 2 of Section 9.2. of Annex IX.

3. On 21 March 2017, a substance evaluation process for the Substance was started. On 1 June 2018, a draft substance evaluation decision was notified to the Appellant. That draft substance evaluation decision requested the Appellant to provide information on a simulation study in sediment in accordance with OECD[3] test guideline (**TG**) 308, to be conducted at temperatures of 20°C and 12°C, with the aim of investigating both the persistence and the biodegradation of the Substance and identifying its degradation products.

4. On 19 August 2019, in parallel to the substance evaluation process, the Agency initiated a compliance check of the Appellant's registration dossier in accordance with Article 41.

5. On 14 February 2020, the Agency notified to the Appellant a draft compliance check decision in accordance with Article 50(1). The draft decision required the Appellant and other registrants of the Substance to update their registration dossiers, within 18 months, with the following information on the Substance, depending on the tonnage at which they registered the Substance:

   - water solubility (Section 7.7. of Annex VII; test method: EU A.6./OECD TG 105), and
   - identification of degradation products (Section 9.2.3. of Annex IX) using an appropriate test method.

6. On 23 March 2020, the Appellant submitted comments on the draft compliance check decision in accordance with Article 50(1). In its comments, the Appellant agreed to conduct the water solubility study but contested the need to submit information on the identification of degradation products. The Appellant argued that:

   - there are difficulties in performing the test, including the synthesis of radiolabelled Substance,
   - information on the identification of degradation products should not be required in isolation, but only in connection with a biodegradation/simulation test, and
   - the deadline set in the draft compliance check decision to submit the requested information is too short.

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1 EC No 251-118-6; CAS No 32588-76-4.

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.

3 The Organisation for Economic Co-operation and Development.

7. On 31 March 2020, the Agency informed the Appellant that the substance evaluation process[4] had been suspended pending the outcome of the compliance check process.

8. The Agency amended the reasoning in the draft compliance check decision and the deadline to provide the requested information to take into account the Appellant's comments on that draft. However, the requests for information set out in the draft compliance check decision were not amended.

9. On 29 October 2020, the Agency notified the amended draft compliance check decision and the Appellant's comments to the competent authorities of the Member States in accordance with Article 51(1).

10. On 13 January 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).

11. The Contested Decision requires the Appellant under Article 41 to submit, by 20 April 2023, information on:

    - water solubility (Section 7.7. of Annex VII; test method: EU A.6./OECD TG 105), and
    - identification of degradation products (Section 9.2.3. of Annex IX), using an appropriate test method. The Contested Decision recommends the use of OECD TG 308 and that the test should be conducted at 20°C. The Contested Decision states further that, if the Appellant considers that there are technical difficulties in performing an OECD TG 308 test, it may also use another appropriate and suitable test method, such as an enhanced screening level degradation test, or modelling tools subject to a scientifically valid justification for the chosen method.

    The requested information must be generated using the Substance.

12. The Contested Decision rejects the Appellant's adaptation under Section 2 of Annex XI, based on an alleged technical impossibility to conduct the study on identification of degradation products. The Contested Decision also rejects the Appellant's adaptation under Column 2 of Section 9.2. of Annex IX.

2. Procedure before the Board of Appeal

13. On 12 April 2021, the Appellant filed this appeal.

14. On 14 June 2021, the Agency submitted its Defence.

15. On 4 October 2021, the Appellant submitted its observations on the Defence.

16. On 11 November 2021, the Agency submitted its observations on the Appellant's observations on the Defence.

17. On 31 January 2022, the Appellant and the Agency submitted their replies to questions from the Board of Appeal.

18. On 11 May 2022, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure[5]. At the hearing, the Appellant and the Agency made oral submissions and responded to questions from the Board of Appeal.

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[4] See paragraph 3 above.

[5] 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).

Form of order sought

19. The Appellant requests the Board of Appeal to:

- annul the Contested Decision insofar as it requires the Appellant to submit information on the identification of degradation products under Section 9.2.3. of Annex IX,
- order the refund of the appeal fee, and
- take such other or further measures as justice may require.

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

3. Assessment of the case

21. The Appellant raises the following pleas in law, alleging that the Agency:

- acted *ultra vires,* committed an error of assessment, failed to take relevant information into account, and infringed the principle of proportionality in requiring the Appellant to submit information on the identification of degradation products (**first plea**),
- misinterpreted Section 9.2.3. of Annex IX by requesting information on the identification of degradation products separately from a simulation test under Section 9.2.1. of Annex IX (**second plea**),
- infringed the principle of legal certainty by not specifying the applicable test method for the requested information (**third plea**), and
- infringed the principle of proportionality and failed to take all relevant information into account by requiring the Appellant to provide the requested information by 20 April 2023 (**fourth plea**).

3.1. First plea: Action *ultra vires,* error of assessment, failure to take relevant information into account, and infringement of the principle of proportionality

Arguments of the Parties

22. The Appellant argues that the Agency acted *ultra vires,* erred in its assessment, and failed to take relevant information into account in requesting the Appellant to submit information on the identification of degradation products under Section 9.2.3. of Annex IX. In addition, the Appellant mentions that the Agency infringed the principle of proportionality.

23. The Appellant argues that none of the information in the chemical safety assessment (**CSA**) for the Substance indicates the need to investigate further the degradation of the Substance and its degradation products. The Appellant argues that, therefore, the conditions of Column 2 of Section 9.2. of Annex IX were not met in the present case and the requirement to provide the information under Column 1 of Section 9.2. of Annex IX as a whole was not triggered. Regarding the CSA, the Appellant argues that its registration dossier for the Substance contained a clear adaptation related to the persistence and insolubility of the Substance, as well as the limited ability of bacteria to biotransform the Substance.

24. The Appellant argues that, in the Contested Decision, the Agency reversed the burden of proof set out in Column 2 of Section 9.2. to Annex IX. This is because the Contested Decision rejects the Appellant's adaptation on the ground that the CSA does not demonstrate that there is no need to provide information on degradation products for the assessment of whether the Substance is persistent, bioaccumulative and toxic (**PBT**) or very persistent and very bioaccumulative (**vPvB**).

25. The Appellant also argues that the Agency failed to take all relevant information into account in requesting information on the identification of degradation products, including the conclusion of the 2008 PBT Expert Working Group[6], which is similar to the Appellant's conclusion that the Substance is persistent.

26. The Agency disputes the arguments of the Appellant. The Agency argues that, based on the decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, the interpretation of Column 2 of Section 9.2. of Annex IX supported by the Appellant and the one used by the Agency in the Contested Decision are both incorrect. The Agency argues that by using the word '*further*', Column 2 of Section 9.2. of Annex IX does not apply to the information requirements under Column 1 of that provision but rather refers to degradation testing that is in addition to those standard information requirements.

27. The Agency argues that, although the reasons for rejecting the Appellant's adaptation are incorrect, the conclusion in the Contested Decision is not, and the Appellant's adaptation under Column 2 of Section 9.2. of Annex IX must still be rejected. Therefore, the Agency's error of interpretation should not lead to the annulment of the Contested Decision.

Findings of the Board of Appeal

28. In its registration dossier for the Substance, the Appellant sought to omit the requirement to provide information on the identification of degradation products under Column 1 of Section 9.3.2. of Annex IX by way of adaptations under Column 2 of Section 9.2. of Annex IX and Section 2 of Annex XI.

29. The Appellant's adaptation under Section 2 of Annex XI was rejected in the Contested Decision. Under the first plea, the Appellant does not challenge the rejection of that adaptation.

30. The Appellant's adaptation under Column 2 of Section 9.2. of Annex IX was rejected in the Contested Decision for the following reasons:

'*In the absence of supporting evidence that transformation/degradation products are not formed to any significant extent, your [CSA] does not demonstrate that there is no need to provide information on the degradation products for the PBT/vPvB assessment and risk assessment*.'

31. The Appellant's first plea can be separated into three parts:

- the Agency acted *ultra vires*,
- the Agency committed an error of assessment and failed to take relevant information into account, and
- the Agency infringed the principle of proportionality.

32. These three parts of the first plea will be examined in turn.

3.1.1. The first part of the first plea, alleging that the Agency acted *ultra vires,* is unfounded

33. In order to decide whether the Agency acted *ultra vires* in requesting information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX it is necessary to examine the interpretation of that provision, read together with Column 2 of Section 9.2. of Annex IX.

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[6] EU PBT Expert Working Group for New and Existing Substances – Subgroup on Identification of PBT and vPvB Substances, *Results of the Evaluation of the PBT/vPvB Properties of N,N'-ethylenebis(3,4,5, 6-tetrabromophthalimide)*, 28 March 2008.

(a) *Wording*

34. Column 2 of Section 9.2. of Annex IX provides:

'*Further biotic degradation testing shall be proposed by the registrant if the [CSA] according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the [CSA] and may include simulation testing in appropriate media (e.g. water, sediment or soil).*'

35. In the present case, three separate interpretations of Column 2 of Section 9.2. of Annex IX were presented by the Parties.

36. First, in the Contested Decision, the Agency interpreted Column 2 of Section 9.2. of Annex IX as being a possible '*waiver*' for the obligation to submit the information listed in Column 1 of Section 9.2. of Annex IX – including the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. According to this interpretation, a registrant may omit that information if its CSA for the substance indicates that there is no need to investigate further the degradation of that substance and its degradation products. According to the Contested Decision, those conditions were not met in the present case.

37. Second, the Appellant argues that Column 2 of Section 9.2. of Annex IX constitutes a '*trigger*' for the obligation to submit the information listed in Column 1 of Section 9.2. of Annex IX – including information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. According to this interpretation, a registrant is required to submit that information if its CSA for the substance indicates the need to investigate further the degradation of that substance and its degradation products. According to the Appellant, this '*trigger*' was not set off in the present case.

38. Third, during the present proceedings, the Agency argues that Column 2 of Section 9.2. of Annex IX should be interpreted as meaning that registrants are required to submit information on biotic degradation testing if their CSA indicates the need to investigate further the degradation of the substance and its degradation products. Such testing is additional to that listed in Column 1 of Section 9.2. of Annex IX, as part of the Column 1 standard information requirements on degradation.

39. Column 2 of Section 9.2. of Annex IX provides for '*further biotic degradation testing*'. From the meaning of the word '*further*',[7] and having regard to the wording used in several other language versions,[8] it is clear that the word '*further*' refers to more testing. This is not contested by the Parties. However, the Parties disagree as to what testing the additional testing in Column 2 is further.

40. Based solely on the wording of Column 2 of Section 9.2. of Annex IX, all three of the interpretations of that provision presented by the Parties[9] would be possible.

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[7] According to the Lexico English dictionary '*further*' means '*additional to what already exists or has already taken place, been done, or been accounted for'; 'help the progress or development of (something); promote'*. Consulted in July 2022 on https://www.lexico.com/definition/further.

[8] In the Dutch version of Column 2 of Section 9.2. of Annex IX: '*Nader onderzoek naar de afbraak wordt door de registrant voorgesteld […]*' (emphasis added). In the French version of Column 2 of Section 9.2. of Annex IX: ' *Des essais de dégradation biotique supplémentaires sont proposés par le déclarant […]*' (emphasis added). In the German version of Column 2 of Section 9.2. of Annex IX: '*Weitere Prüfungen der biologischen Abbaubarkeit sind vom Registranten vorzuschlagen […]*' (emphasis added).

[9] See paragraphs 36 to 38 above.

41. Therefore, to determine which of these three interpretations of Column 2 of Section 9.2. of Annex IX is correct, it is necessary to also examine the context in which that provision occurs and the objectives pursued by the rules of which it is part.[10]

(b) Context

42. The information requirements set out in Annexes VII to X are cumulative and must therefore be read as a whole.[11]

43. According to the second paragraph of the introduction to Annex IX, Column 1 of Annex IX establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more. Accordingly, the information required in Column 1 of Annex IX is additional to that required in Annexes VII and VIII.

44. The interpretation of Column 2 of Section 9.2. of Annex IX must be assessed in relation to the provisions on degradation in Annexes VII, VIII and IX.

- *Column 1 of Section 9.2. of Annexes VII, VIII and IX*

45. According to the first paragraph of Annex VI, for the lowest tonnage level, the standard requirements are in Annex VII. Every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added.

46. Under Annex VII, Column 1 of Section 9.2.1.1. requires a registrant to provide the following information on biotic degradation, or an acceptable adaptation under either Column 2 of Section 9.2.1.1. or Annex XI: ready biodegradability.

47. Under Annex VIII, Column 1 of Section 9.2.2.1. requires a registrant to provide the following information on abiotic degradation, or an acceptable adaptation under either Column 2 of Section 9.2.2.1. or Annex XI: hydrolysis as a function of pH.

48. Under Annex IX, Column 1 of Section 9.2. requires a registrant to provide the following information on biotic degradation or an acceptable adaptation under either Column 2 of the corresponding provision of Annex IX or Annex XI:

Column 1 Standard information required	
9.2.	Degradation
9.2.1.	Biotic
9.2.1.2.	Simulation testing on ultimate degradation in surface water
9.2.1.3.	Soil simulation testing (for substances with a high potential for adsorption to soil)
9.2.1.4.	Sediment simulation testing (for substances with a high potential for adsorption to sediment)
9.2.3.	Identification of degradation products

[10] Judgment of 19 September 2019, *Gesamtverband Autoteile-Handel*, C-527/18, EU:C:2019:762, paragraph 30; decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 149.

[11] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 156.

49. These provisions on degradation in Section 9.2. of Column 1 of Annexes VII, VIII and IX are standard information requirements. It is the sole responsibility of a registrant to generate, gather and submit to the Agency information that complies with all the applicable standard information requirements.[12] A registrant is entitled to adapt the standard information requirements set out in these Annexes, either under the specific adaptation rules in Column 2 of those Annexes or under the general adaptation rules in Annex XI.

- *Column 2 of Section 9.2. of Annexes VIII and IX and the link with Column 1*

50. Under Annex VIII, Column 2 of Section 9.2. provides:

'*Further degradation testing shall be considered if the [CSA] according to Annex I indicates the need to investigate further the degradation of the substance […]*'.

51. Under Annex IX, Column 2 of Section 9.2. provides:

'*Further biotic degradation testing shall be proposed by the registrant if the [CSA] according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the [CSA] and may include simulation testing in appropriate media (e.g. water, sediment or soil)*'.

52. In certain cases, the standard information on degradation under Column 1 of Annexes VII, VIII and IX may be insufficient to allow for conclusions to be reached on the degradation of a substance. Consequently, it may be necessary, in certain circumstances, to require additional information on degradation.

53. Column 2 of Section 9.2. of Annex VIII allows for further information on the degradation of a substance to be obtained. 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.

54. In comparison with the requirements under Column 1 of Sections 9.2. of Annexes VII to IX, Column 2 of Annexes VIII and IX go beyond the standard information requirements. Such further testing is required if the CSA indicates the need to investigate further.

55. For substances registered in quantities of 10 tonnes or more per year, a CSA according to Article 14 must be carried out. The CSA includes an assessment of a human health, environmental and physico-chemical hazard, and PBT and vPvB assessments. If the substance fulfils the criteria for any of the hazard classes listed in Article 14(4), the CSA also includes an exposure assessment and risk characterisation. This means that the content of a CSA depends on whether the existing information indicates a need for further information to be included in the CSA. In other words, the content of the CSA, and therefore the potential need for further testing under Column 2, is substance-specific.

56. It must also be highlighted that information on whether a substance is readily biodegradable should normally be part of the CSA unless the registrant is able to adapt the requirement in Column 1 of Section 9.2.1.1. of Annex VII to provide information on ready biodegradability.

57. Column 2 of Section 9.2. of Annex IX allows to go beyond the standard information requirements set out in Column 1 of Section 9.2. of Annex IX. In particular, as regards the identification of degradation products, Column 2 of Section 9.2. of Annex IX allows, where necessary, more information on the identification of

[12] Decision of the Board of Appeal of 29 June 2021, *SNF*, A-001-2020, paragraph 47.

degradation products to be obtained in relation to the degradation testing performed under that provision.

58. It is also feasible for registrants to provide information on degradation which is additional to that already required under Annexes VII and VIII and Column 1 of Section 9.2. of Annex IX. That additional information may include, for example, information on degradation to be obtained in media not foreseen in Column 1 of Section 9.2. of Annex IX. This may include, for example, simulation testing of biodegradation of a substance on its way through the sewer system and sewage treatment plant to the mixing zone in surface water (OECD TG 314) or biodegradation testing in marine water (OECD TG 306).

59. Furthermore, Column 2 of Section 9.2. of Annex IX specifies that '*[t]he choice of the appropriate test(s) […] may include simulation testing in appropriate media (e.g. water, sediment or soil)*'. In comparison with the simulation tests mentioned under Column 1 of Sections 9.2.1. of Annex IX, the examples provided for between brackets cover the same media as those mentioned in Column 2. The use of the words '*may*' and '*e.g. [for example]*' indicates a non-exhaustive list of testing measures that can be used. Therefore, Column 2 of Section 9.2. of Annex IX can go broader in scope or more detailed in scope than Column 1 of Section 9.2. of Annex IX.

60. 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. Consequently, if – following the Appellant's interpretation[13] – a registrant would be able to waive the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX on the basis of a CSA as mentioned in Column 2 of Section 9.2. of Annex IX, it would not be possible to determine whether additional information is needed on those identified degradation products for the purposes of Column 2 of Section 9.2. of Annex IX. Even if standard information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX would have been adapted, a CSA could still indicate a need to investigate further and identify other degradation products.

61. Column 2 of Section 9.2.3. of Annex IX contains a specific rule for adaptation. Under that adaptation, a registrant does not need to provide information on the identification of degradation products if the substance is readily biodegradable. If the requirement to provide information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX were conditional on an examination of the CSA, this would mean that obtaining that information would be subject to two separate Column 2 adaptation possibilities, namely for reasons of being readily biodegradable and based on the CSA. Column 2 of Section 9.2.3. of Annex IX foresees only one adaptation possibility.

- *Conclusion on the context*

62. The context supports the interpretation that Column 2 of Section 9.2. of Annex IX is neither a '*trigger*' – as the Appellant argues – nor a '*waiver*' – as the Agency decided in the Contested Decision – for the requirement to submit information under Column 1 of Section 9.2. of Annex IX. The information requirements under Column 1 of Section 9.2. of Annex IX – which include Section 9.2.3., as well as Sections 9.2.1.2., 9.2.1.3. and 9.2.1.4., of Annex IX – are standard information requirements which oblige registrants to provide, and allow the Agency to require, information on the degradation of the substance at issue.

[13] See paragraph 37 above.

63. Therefore, the obligation for registrants at the Annex IX level to fulfil the information requirements under Column 1 of Section 9.2. of Annex IX does not depend upon an assessment, under Column 2 of Section 9.2. of Annex IX, of whether the CSA indicates a need for that information. An assessment of the CSA is necessary only for the purposes of deciding whether a registrant is required to submit information on biotic degradation testing, which is further or additional – in other words beyond the standard media or more detailed within the standard media – to the standard information requirements under Column 1 of Section 9.2. of Annex IX.

(c) Objectives

64. Section 9.2.3. of Annex IX is part of Annexes VII to X. Annexes VII to X require manufacturers and importers of substances to generate and submit to the Agency information on the intrinsic properties of the substances they manufacture or import.[14]

65. This, in turn, contributes to achieving a high level of protection of human health and the environment which is the main objective of the registration and dossier evaluation provisions in the REACH Regulation.[15]

66. Following the third interpretation of Column 2 of Section 9.2. of Annex IX, set out in paragraph 38 above, registrants of substances at the Annex IX and X levels are required to generate and submit, at least, the standard information set out in Column 1 of Section 9.2.3. of Annex IX and may be required to generate and submit further information where the CSA indicates that this is necessary. That interpretation allows, for example, for the further investigation of a degradation product. Such an outcome is consistent with the objectives of Annexes VII to X.

(d) Conclusion on the first part of the first plea, alleging that the Agency acted ultra vires

67. Based on its wording, context and objectives, Column 2 of Section 9.2. of Annex IX must be interpreted as meaning that a registrant at the Annex IX level proposes biotic degradation testing which is further to that already required under Column 1 of Section 9.2. of Annex IX '*if the CSA for the substance indicates the need to investigate further the degradation of the substance and its degradation products*'.

68. Therefore, the Agency did not act *ultra vires* in requesting in the Contested Decision standard information on the identification of degradation products on the basis of Column 1 of Section 9.2.3. of Annex IX.

(e) No breach of the right to be heard

69. For the following reasons, the conclusion set out in paragraph 68 above is not affected by the Appellant's argument that its right to be heard was infringed by the fact that, during the present proceedings, the Agency changed the reasoning justifying the request for information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX.

70. First, although the Agency's reasons in the Contested Decision for requesting the information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX were incorrect, the Agency was entitled to examine whether the Appellant's registration dossier has a data-gap under Column 1 of

[14] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 171.

[15] See, to this effect, judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 45. See also decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 172.

Section 9.2.3. of Annex IX. Therefore, irrespective of the reasoning contained in the Contested Decision, the Agency did not act *ultra vires*.

71. Second, it is not necessary to examine whether the Agency made an error in its assessment of the criteria for requesting further information based on Column 2 of Section 9.2. of Annex IX as that provision is not relevant for the purpose of requesting the standard information in Column 1 of Section 9.2.3. of Annex IX.

72. Third, the Appellant has not demonstrated that the outcome of the compliance check procedure might have been different had the interpretation of Column 2 of Section 9.2. of Annex IX presented by the Agency during the present proceedings been relied on in the Contested Decision. For example, the Appellant has not argued that, had it known the correct interpretation of Column 2 of Section 9.2. of Annex IX, it would have submitted additional adaptations based on Column 2 of Section 9.2.3. of Annex IX or Annex XI.

73. Furthermore, during the hearing, the Appellant sought to rely on the judgment in T-424/13, *Jinan Meide Casting* v *Council*[16] to support its argument that its right to be heard had been breached. However, contrary to the Appellant's argument, that judgment does not demonstrate that in the present case, the outcome of the case might have been different.

3.1.2. The second part of the first plea, alleging that the Agency committed an error of assessment and failed to take all relevant information into account, is ineffective

74. The Appellant argues that the Agency made an error of assessment in rejecting its adaptation under Column 2 of Section 9.2. of Annex IX. The Appellant also argues that the Agency failed to take all relevant information into account, including the conclusion of the Appellant and the 2008 PBT Expert Working Group that the Substance is persistent.

75. However, the information requirement in Column 1 of Section 9.2.3. of Annex IX is a standard information requirement.[17] The Agency was not required to examine the conditions set out in Column 2 of Section 9.2. of Annex IX.

76. Consequently, even if the Appellant's arguments alleging that the Agency committed an error of assessment and failed to take relevant information into account in its examination of the conditions set out in Column 2 of Section 9.2. of Annex IX were well-founded, those arguments could not lead to the annulment of the Contested Decision.

77. Since the arguments alleging that the Agency committed an error of assessment and failed to take relevant information into account are incapable of bringing about the annulment of the Contested Decision which the Appellant seeks, the second part of the first plea must be rejected as ineffective.

3.1.3. The third part of the first plea, alleging an infringement of the principle of proportionality, is unsubstantiated

78. In the Notice of Appeal, the Appellant mentions that the Agency infringed the principle of proportionality in requesting information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. However, the Appellant does not raise any arguments to support this.

79. The third part of the first plea is therefore unsubstantiated and must be rejected.

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[16] Judgment of 13 June 2016, *Jinan Meide Casting* v *Council,* T-424/13, EU:T:2016:378.
[17] See paragraphs 34 to 67 above.

3.1.4. Conclusion on the first plea

80. In view of paragraphs 33 to 79 above, the Appellant's first plea must be rejected.

3.2. Second plea: Misinterpretation of Section 9.2.3. of Annex IX by requesting information on the identification of degradation products separately from simulation testing under Section 9.2.1. of Annex IX

Arguments of the Parties

81. The Appellant argues that the Agency misinterpreted and misapplied Section 9.2.3. of Annex IX by requesting information on the identification of degradation products on its own without requesting the simulation tests in Section 9.2.1. of Annex IX.

82. The Appellant argues that, when requesting information on the identification of degradation products under Section 9.2.3. of Annex IX, the Agency must also specify which of the simulation tests set out in Section 9.2.1. of Annex IX must be conducted to form the degradation products to be identified.

83. The Agency disputes the arguments of the Appellant. The Agency argues that the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX is a stand-alone information requirement. According to the Agency, this is shown by the fact that the identification of degradation products is found in a section of Annex IX – namely Column 1 of Section 9.2.3. – that is clearly separated from the section dealing with simulation testing – namely Column 1 of Section 9.2.1.

84. The Agency argues that, for the purposes of identifying degradation products under Section 9.2.3. of Annex IX, the Agency is neither bound nor limited to requesting the simulation studies referred to in Column 1 of Section 9.2.1. of Annex IX and can request any study, or studies, it considers appropriate for the purposes of identifying degradation products under Column 1 of Section 9.2.3. of Annex IX.

Findings of the Board of Appeal

85. The Contested Decision requires the Appellant to provide information on the identification of degradation products under Section 9.2.3. of Annex IX. The Contested Decision does not prescribe a specific test through which the Appellant must provide this information. The Contested Decision recommends that the Appellant performs a sediment simulation study according to OECD TG 308.[18]

86. During the present proceedings, the Parties agreed that, before degradation products can be identified, it is necessary to perform degradation testing to allow for the formation of those degradation products. The Parties do not agree that Column 1 of Section 9.2.3. of Annex IX includes testing on its own, as claimed by the Agency, or that it depends on the testing required under Column 1 of Section 9.2.1. of Annex IX, as claimed by the Appellant.

87. It is therefore necessary to determine whether Column 1 of Section 9.2.3. of Annex IX is independent of, or rather dependent on, the other provisions on degradation in Annexes VII to IX.

88. Column 1 of Section 9.2.3. of Annex IX does not specify the method to be used to form a substance's degradation products. However, for the following reasons, the information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX, as a standard information requirement, must be considered as being dependent on the biotic and abiotic degradation testing required under Annexes VII to IX.

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[18] See paragraph 11 above.

89. First, to fulfil the standard information requirements related to degradation, registrants at the Annex IX level must submit either the simulation studies for each specific environmental compartment required for the substance at issue under Column 1 of Section 9.2.1. of Annex IX or acceptable adaptations.[19] Those registrants must also submit the degradation studies required under Column 1 of Section 9.2.1.1. of Annex VII and Column 1 of Section 9.2.2.1. of Annex VIII or acceptable adaptations.

90. The information requirements set out in Annexes VII to IX are cumulative and must be read as a whole.[20] If Column 1 of Section 9.2.3. of Annex IX were interpreted as being independent from the information requirements on degradation in Annex VII, Annex VIII and IX, the cumulative nature of the Annexes would not be ensured.

91. Second, the simulation studies in Column 1 of Section 9.2.1. of Annex IX and the degradation study under Section 9.2.2.1. of Annex VIII all allow for the identification of degradation or transformation products.

92. For example, paragraph 41 of OECD TG 308, which can be performed to fulfil the information requirement regarding sediment simulation testing in Column 1 of Section 9.2.1.4. of Annex IX, 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).

93. Similarly, OECD TG 111, which can be performed to fulfil the information requirement regarding hydrolysis as a function of pH under Column 1 of Section 9.2.2.1. of Annex VIII, states '*analytical methods for quantification of the test substance and, if it is relevant, for identification and quantification of hydrolysis products in aqueous solutions should be available'* (emphasis added).

94. Third, based on the numbering of Annex IX, Section 9.2.3. of Annex IX is separate from the information requirements in Column 1 of Section 9.2. of Annex IX. Therefore, unlike the degradation testing under Section 9.2.1. of Annex IX, Section 9.2.3. of Annex IX is not limited to biotic degradation. Consequently, Section 9.2.3. of Annex IX allows for the identification of the degradation products formed in the biotic degradation tests under Column 1 of Section 9.2.1. of Annex IX, as well as in the abiotic degradation study in Column 1 of Section 9.2.2.1. of Annex VIII.

95. Fourth, the principle of legal certainty is a general principle of European Union law. It requires, amongst other things, that European Union legislation must be applied in a way that is foreseeable by those subject to it[21]. The Agency's argument that it can request the information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX through any study, or studies, it considers appropriate would fail to ensure foreseeability in the application of the standard information requirements related to degradation under Column 1 of Sections 9.2. of Annex IX and under Column 1 of Section 9.2.2.1. of Annex VIII and under Column 1 of Section 9.2.1.1. of Annex VII.

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[19] See Section 3.1.1. above.

[20] See paragraph 42 above.

[21] See judgments of 15 September 2005, *Ireland* v *Commission*, C-199/03, EU:C:2005:548, paragraph 69, and of 11 May 2017, *Deza* v *ECHA*, T-115/15, EU:T:2017:329, paragraph 135; see also Case A-006-2016, *SI Group UK and Others*, Decision of the Board of Appeal of 6 June 2018, paragraph 100.

96. According to Article 12(1) and the introduction to Annexes VII to IX, Column 1 of Annexes VII to X sets out the standard information that registrants are required to include in their registration dossiers, subject to the application of the adaptations under Column 2 and Annex XI. If the Agency were correct in its argument that, under Column 1 of Section 9.2.3. of Annex IX, registrants may be required to provide information on the identification of degradation products through any test, it would not be possible for registrants to know with certainty at the time they register their substances how to fulfil the requirements of that provision.

97. The simulation studies set out in Column 1 of Section 9.2.1. of Annex IX and the degradation study under Section 9.2.2.1. of Annex VIII allow for the identification of degradation products. Legal certainty for registrants is therefore ensured if Column 1 of Section 9.2.3. of Annex IX is interpreted as meaning that registrants are required to identify degradation products through the applicable studies under Column 1 of Section 9.2.1. of Annex IX and the degradation study under Section 9.2.2.1. of Annex VIII. Such an interpretation allows registrants to know without ambiguity what their rights and obligations are and to take steps accordingly.

98. Fifth, with regard to biotic degradation, if the Agency were able to require any test, or tests, for the purposes of Column 1 of Section 9.2.3. of Annex IX, registrants required to conduct studies not contained in Column 1 of Sections 9.2.1.2., 9.2.1.3. and 9.2.1.4. of Annex IX would be deprived of the possibility to rely on the adaptations in Column 2 of Section 9.2.1. of Annex IX.

99. In view of paragraphs 85 to 98 above, Column 1 of Section 9.2.3. of Annex IX cannot be read in isolation from the standard information requirements on degradation set out in Column 1 of Section 9.2.1 of Annex IX and in Column 1 of Section 9.2.2.1 of Annex VIII. Consequently, the Agency cannot require a registrant to provide information on the identification of degradation products without taking into account the standard information requirements set out in Column 1 of Section 9.2.1. of Annex IX and in Column 1 of Section 9.2.2.1. of Annex VIII, through which the degradation products to be identified may be formed. Therefore, in the Contested Decision, the Agency was not permitted to request information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX through any study, or studies, it considered appropriate.

100. In conclusion, to comply with Column 1 of Section 9.2.3. of Annex IX, a registrant must provide either (i) information on the identification of the degradation products resulting from the standard information requirements on degradation set out in Column 1 of Section 9.2.1. of Annex IX and in Column 1 of Section 9.2.2.1. of Annex VIII, or (ii) an acceptable specific adaptation under Column 2 of the corresponding provisions or an acceptable general adaptation under Annex XI.

101. In the present case, the Appellant did not provide in its registration dossier information on the simulation studies required in Column 1 of Sections 9.2.1. of Annex IX, or the study on hydrolysis required in Column 1 of Section 9.2.2.1. of Annex VIII. Instead, the Appellant relied on the specific adaptations in Column 2 of Annexes VIII and IX to omit each of those information requirements.[22]

102. The information requirement under Section 9.2.3. of Annex IX is dependent on the information requirements on abiotic and biotic degradation under Annexes VIII and IX.[23] Consequently, the Agency is required to examine the validity of the adaptations referred to in the previous paragraph before deciding whether it can request the Appellant to provide information on those standard information requirements and, therefore, information on the identification of degradation products formed in those studies under Column 1 of Section 9.2.3. of Annex IX.

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[22] See paragraph 2 above.

[23] See paragraphs 88 to 99 above.

103. Under the specific adaptations in Column 2 of Section 9.2.1. of Annex IX, the Appellant provided similar adaptations based on the behaviour of the Substance and the limited ability of bacteria to biotransform the Substance as under Column 2 of Section 9.2. of Annex IX (the **CSA adaptation**). As the Agency stated in the present proceedings, the specific adaptations are distinct from the CSA adaptation. In the Contested Decision, the Agency examined the CSA adaptation but it did not assess the specific adaptations submitted by the Appellant under Column 2 of Section 9.2.1. of Annex IX or Column 1 of Section 9.2.2.1. of Annex VIII.

104. The Contested Decision recommends the use of OECD TG 308 to identify the degradation in sediment. However, as the Agency, in the Contested Decision, does not examine whether the adaptation or adaptations under Section 9.2.1. of Annex IX submitted by the Appellant are acceptable, it is not possible to determine whether there is a data-gap for those endpoints. Only if the adaptations submitted by the Appellant were deemed by the Agency to be inadequate could the Agency require the Appellant to provide, as a standard information requirement, one or more of those studies and information on the identification of the degradation products formed in those studies. Therefore, the scope of the information to be provided under Column 1 of Section 9.2.3. of Annex IX has not been determined.

105. Conversely, if the Appellant's adaptions for Section 9.2.1. of Annex IX and Section 9.2.2.1. of Annex VIII were accepted by the Agency, it would not be possible for the Agency to request information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. However, as stated in paragraph 60 above, under Column 2 of Section 9.2. of Annex IX, a CSA could still indicate a need to investigate further and identify other degradation products.

106. In view of paragraphs 85 to 105 above, the Appellant's second plea that the Agency misinterpreted and misapplied Column 1 of Section 9.2.3. of Annex IX must be accepted.

3.3. Result

107. The Contested Decision is annulled insofar as it requires the Appellant to provide information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX. The case is remitted to the competent body of the Agency for further action.

108. As the appeal has been upheld, it is not necessary to examine the Appellant's remaining pleas.

4. Refund of the appeal fee

109. In accordance with Article 10(4) of the Fees Regulation,[24] the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal has been decided in favour of the appellant, the appeal fee is refunded.

[24] 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).

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it requires information on the identification of degradation products under Column 1 of Section 9.2.3. of Annex IX.**
2. **Remits the case to the competent body of the Agency for further action.**
3. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal