ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

# DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

**6 June 2023**

*(Dossier evaluation – Compliance check – Competence of the Agency – Legal certainty – Error of assessment – Compliance with the relevant test methods – Article 13 of the REACH Regulation – Duty to state reasons – In vitro gene mutation in bacteria – In vitro cytogenicity in mammalian cells – In vitro micronucleus study – Long-term aquatic toxicity testing on fish – Degradation simulation testing in surface water, soil and sediment – Non-extractable residues – Identification of degradation products)*

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| **Case number** | A-001-2022 |
| **Language of the case** | English |
| **Appellant** | Cytec Engineered Materials GmbH, Germany<br>Represented by<br>Ruxandra Cana, Eléonore Mullier, and Zanda Romata<br>Steptoe & Johnson LLP, Belgium |
| **Contested Decision** | Decision of 25 October 2021 on a compliance check of the registration for the substance 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline), adopted by the European Chemicals Agency under Article 41 of the REACH Regulation<br>The Contested Decision was notified to the Appellant under annotation number CCH-D-2114573706-39-01/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 4,4'-(9H-fluoren-9-ylidene)bis(2-chloroaniline) (the **Substance**).[1]

2. The Appellant – Cytec Engineered Materials GmbH – is the lead registrant of the Substance.[2] It registered the Substance at the 1 to 10 tonnes per year tonnage band (Annex VII to the REACH Regulation[3]) as a manufacturer/importer in May 2017. The Appellant subsequently updated the dossier for Cytec Engineered Materials to the 10 to 100 tonnes per year tonnage band (Annex VIII) in June 2018 and to the 100 to 1 000 tonnes per year tonnage band (Annex IX) in July 2020.

3. The Appellant is also the only representative of Cytec Industries Inc.[4] In this respect, the Substance was treated as a notified substance under Article 24 from June 2006 at the below one tonne per year tonnage band and from May 2007 at the 1 to 10 tonnes per year tonnage band. In November 2012, the Appellant – as the only representative of Cytec Industries – claimed the registration for the Substance at the 1 to 10 tonnes per year tonnage band. In June 2014, the Appellant updated the registration for Cytec Industries to the 10 to 100 tonnes per year band (Annex VIII).

4. On 15 April 2020, the Agency initiated a compliance check of the registration dossiers for the Substance in accordance with Article 41.

5. On 11 December 2020, in accordance with Articles 41(3) and 50(1), the Agency notified to the Appellant a draft decision with the opportunity to provide comments by 1 February 2021. The draft decision required the Appellant and other registrants of the Substance to update their registration dossiers, within 30 months, with the following information on the Substance, depending on the tonnage at which they registered the Substance:

   - *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII, test method: EU B.13/14 / OECD TG 471)[5] using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or *S. typhimurium* TA102,
   - *In vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII; OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; OECD TG 487),
   - Long-term toxicity testing on fish (Column 2 of Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX; OECD TG 210),
   - Simulation testing on ultimate degradation in surface water (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.2. of Annex IX; test method: EU C.25 / OECD TG 309) at a temperature of 12°C and non-extractable residues (**NERs**) must be quantified,

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1 EC number 407-560-9.

2 When referring to Cytec Engineered Materials GmbH, the lead registrant of the Substance, this decision will use '**Cytec Engineered Materials**'.

3 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.

4 When referring to Cytec Industries Inc., on behalf of which the Appellant acts as only representative, this decision will use '**Cytec Industries**'.

5 EU for European Union, OECD for Organisation for Economic Co-operation and Development, TG for test guideline.

- Soil simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.3. of Annex IX; test method: EU C.23 / OECD TG 307) at a temperature of 12°C and NERs must be quantified,
- Sediment simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.4. of Annex IX; test method: EU C.24 / OECD TG 308) at a temperature of 12°C and NERs must be quantified,
- Identification of degradation products (Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX; OECD TG 307 and/or 308 and/or 309).

6. On 29 January 2021, the Appellant submitted comments on the draft decision in accordance with Article 50(1). In its comments, the Appellant raised arguments contesting each of the information requirements in the draft decision, as well as the deadline to provide that information.

7. On 8 February 2021, the Appellant informed the Agency that it had become aware of an existing *in vivo* genotoxicity study (micronucleus test) carried out according to EU test method B.12 (equivalent to OECD TG 474) to which the Appellant did not have access previously. The Appellant submitted the results of that study to the Agency and asked it to reconsider the requirement to provide information under Section 8.4.2. of Annex VIII in light of that information.

8. Following the Appellant's comments on the draft decision, the Agency did not amend the list of the requested information requirements but amended the deadline to provide the requested information from 30 months to 36 months.

9. On 2 September 2021, the Agency notified the draft decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1).

10. On 25 October 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 required the Appellant and other registrants of the Substance to update their registration dossiers, by 30 January 2025, with the following information on the Substance, depending on the tonnage at which they registered the Substance:

- *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII, test method: EU B.13/14 / OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or *S. typhimurium* TA102 (**Information Requirement 1**),
- *In vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII; OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; OECD TG 487) (**Information Requirement 2**),
- Long-term toxicity testing on fish (Column 2 of Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX; OECD TG 210) (**Information Requirement 3**),
- Simulation testing on ultimate degradation in surface water (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.2. of Annex IX; test method: EU C.25 / OECD TG 309) at a temperature of 12°C and non-extractable residues (**NERs**) must be quantified (**Information Requirement 4**),
- Soil simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.3. of Annex IX; test method: EU C.23 / OECD TG 307) at a temperature of 12°C and NERs must be quantified (**Information Requirement 5**),

- Sediment simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.4. of Annex IX; test method: EU C.24 / OECD TG 308) at a temperature of 12°C and NERs must be quantified (**Information Requirement 6**),
- Identification of degradation products (Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX; OECD TG 307 and/or 308 and/or 309) (**Information Requirement 7**).

## 2. Procedure before the Board of Appeal

12. On 25 January 2022, the Appellant filed this appeal.

13. On 28 March 2022, the Agency filed its Defence.

14. On 16 May 2022, the Appellant filed its observations on the Defence.

15. On 17 June 2022, the Agency filed its observations on the Appellant's observations on the Defence.

16. On 30 November 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[6]. The hearing was held at the Agency's premises. At the hearing, the Appellant and the Agency made oral submissions and responded to the questions from the Board of Appeal.

## 3. Form of order sought

17. The Appellant requests the Board of Appeal to annul the Contested Decision, order the Agency to refund the appeal fee, and take such other or further measures as justice may require.

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

## 4. Assessment of the case

19. The Appellant raises a number of pleas in relation to each of the information requirements requested in the Contested Decision. Those pleas will be examined in relation to each information requirement.

### 4.1. Information Requirement 1 (*In vitro* gene mutation study in bacteria)

20. In relation to Information Requirement 1, the Appellant claims that the Agency:
    - erred in its assessment,
    - exceeded its competence,
    - breached Articles 13, 25, and 41, as well as Section 8.4.1. of Annex VII,
    - breached the principle of legal certainty, and
    - breached the duty to state reasons.

[6] 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).

### 4.1.1. Pleas related to error of assessment, exceeding competence, and breach of Articles 13(3) and 41 and Section 8.4.1. of Annex VII

*Arguments of the Parties*

21. The Appellant argues that there is no data gap in its registration dossier for Section 8.4.1. of Annex VII (*in vitro* gene mutation study in bacteria). The Appellant argues that it has complied with this information requirement by submitting:

    (i) the results of an OECD TG 471 study, which was carried out in 1988 according to the version of the OECD test guideline applicable at that time, and

    (ii) a gene mutation assay on *Saccharomyces cerevisiae*, carried out according to the version of OECD TG 480 applicable at the time the study was carried out.

22. The Appellant argues that the Agency erred in its assessment and exceeded its competence under the REACH Regulation by assessing the results of the OECD TG 471 study it submitted in its registration dossier against the version of the test guideline applicable at the time the compliance check was conducted, rather than against the version applicable at the time the study was carried out.

23. The Appellant argues that the Board of Appeal has previously held[7] that, in the context of Article 41, compliance with the relevant test method must be assessed against the version of the OECD test guideline applicable at the time the test was carried out.

24. The Appellant argues that, under the OECD mutual acceptance of data (**MAD**) system, where an OECD test guideline is updated and the new version replaces the former version, the results of tests carried out under the former version continue to be accepted after the update of the test guideline.

25. The Appellant argues that the Agency breached Article 13(3) by failing to assess the appropriateness of the information submitted by the Appellant to fulfil Section 8.4.1. of Annex VII.

26. The Appellant argues that, where the Agency considers that the existing data submitted on a substance does not comply with the Test Methods Regulation[8], it should conduct an independent assessment of whether the alternative data, compliant with an alternative test method, can be considered as '*being appropriate*' within the meaning of Article 13(3).

27. The Appellant argues that, had the Agency conducted the assessment required under Article 13(3), it would have concluded that the results of the OECD TG 471 study submitted by the Appellant are appropriate since:

    (i) the study gave negative results in all strains tested in accordance with the OECD test guideline applicable at the time the study was carried out; and

    (ii) the testing on a fifth strain is not necessary because the Substance is neither an oxidizing agent nor does it contain hydrazines.

28. The Appellant argues that the Agency also committed an error of assessment in rejecting the results of an OECD TG 480 study which was submitted by the Appellant in its registration dossier.

29. The Agency disputes the Appellant's arguments.

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[7] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraphs 112 to 114.

[8] Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1).

30. The Agency argues that the Appellant's plea alleging that the Agency breached Article 13(3) of the REACH Regulation was only introduced in the observations on the Defence and therefore is inadmissible under Article 12(2) of the Rules of Procedure.

*Findings of the Board of Appeal*

*(a) Admissibility of the Appellant's plea that the Agency breached Article 13(3)*

31. 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.

32. The Appellant's plea related to Article 13(3) is a new plea as it was raised for the first time in the observations on the Defence.

33. However, for the following reasons, the delay in submitting that plea is justified and the plea is admissible.

34. First, in its Defence, the Agency presented arguments related to Article 13(3) to justify its decision to require the Appellant to submit further information on the Substance. Specifically, the Agency claimed that it had correctly assessed the studies submitted by the Appellant against the test methods laid down in Article 13(3) and the Test Methods Regulation. The Appellant's new plea related to Article 13(3) was submitted in response to those arguments.

35. Second, the Appellant's plea related to Article 13(3) is closely linked with its plea alleging a breach of Section 8.4.1. of Annex VII and Article 41(1), as put forward in the Notice of Appeal, and serve to amplify that plea.

36. The Agency's claim that the Appellant's plea related to Article 13(3) is inadmissible must therefore be rejected.

*(b) Examination of the Appellant's pleas alleging that the Agency breached Articles 13(3) and 41, as well as Section 8.4.1. of Annex VII, committed an error of assessment and exceeded its competence*

*(i) The Appellant did not comply with the first subparagraph of Article 13(3)*

37. Under the first subparagraph of Article 13(3), where tests on substances are required to generate information on the intrinsic properties of substances, those tests must be carried out in accordance with the test methods laid down in the Test Methods Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

38. Section B.13/14 (mutagenicity: reverse mutation test using bacteria) of the Annex to the Test Methods Regulation – which is equivalent to OECD TG 471 – sets out the test method to be followed for the *in vitro* gene mutation study in bacteria required under Section 8.4.1. of Annex VII.

39. Under Article 10(a)(vi) and (vii), a registration must include a technical dossier including study summaries of the information derived from the application of Annexes VII to XI and robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I. Article 12(1) further specifies the minimum physicochemical, toxicological and ecotoxicological information that must be included in the technical dossier referred to in Article 10(a) under points (vi) and (vii), depending on tonnage per year.

40. The information submitted by the registrant must comply with the law that is applicable at the time of the submission of that registration dossier. The applicable law includes the test methods referred to in paragraphs 37 and 38 above.

41. Under Articles 12(2) and 22(1)(c), as soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer must inform the Agency immediately of the additional information it would require under Article 12(1). The updated information must also comply with the law that is applicable at the time of that update.

42. Consequently, to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation that is applicable at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required.

43. In the present case, the OECD TG 471 study carried out with the Substance submitted by the Appellant to comply with the requirement in Section 8.4.1. of Annex VII was carried out in 1988 according to the version of the test guideline adopted by the OECD on 26 May 1983 (**1983 version**).

44. However, at the time Cytec Engineered Materials submitted its registration for the Substance at the 1 to 10 tonnes per year tonnage band (Annex VII level) – i.e. in May 2017 – Section B.13/14 of the Annex to the Test Methods Regulation included the equivalent of the version of OECD TG 471 adopted by the OECD on 21 July 1997 (**1997 version**).[9]

45. In November 2012, Cytec Industries claimed the registration for the Substance at the 1 to 10 tonnes per year tonnage band (Annex VII level). At that time, Section B.13/14 of the Annex to the Test Methods Regulation also included the equivalent of the 1997 version of OECD TG 471.

46. Consequently, the OECD TG 471 study – the results of which were submitted by the Appellant to the Agency – was not carried out according to the version of that test guideline that was applicable at the time the Appellant submitted, or claimed, the registrations for the Substance. That study was not therefore carried out in accordance with the first subparagraph of Article 13(3). This does not exclude the possibility to accept that study as a valid source of information on the intrinsic properties of the Substance under the second subparagraph of Article 13(3).[10]

47. Therefore, the Agency did not commit an error of assessment or exceed its competence in assessing compliance of the information provided by the Appellant with Section 8.4.1. of Annex VII against the 1997 version of OECD TG 471.

48. This conclusion is not affected by the Appellant's argument[11] based on the Board of Appeal's decision in case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*.

49. In that decision, the Board of Appeal confirmed that the Agency has the power to verify, under Article 41, that a study included in a registration dossier was carried out correctly in accordance with the relevant test method.

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[9] The most recent version of the test guideline is dated 26 June 2020. However, the latest amendment only corrects paragraph 24 of the 1997 version in relation to a CAS number.

[10] See paragraphs 56 to 77 below.

[11] See paragraph 23 above.

50. However, contrary to what the Appellant argues[12], the Board of Appeal did not find in its decision in case A-011-2018 that, as a general rule, compliance with the relevant test method must be assessed against the version of the OECD test guideline applicable at the time the test was carried out. In case A-011-2018 the Board of Appeal stated that the studies in question were carried out and submitted by the Appellant in 2010. Their compliance with the relevant test method therefore had to be assessed against the test methods as they were in 2010. In that case, the relevant registration dossier was submitted in 2010.

51. The Appellant's argument[13] that, based on the MAD system, the requested information is not necessary must also be rejected.

52. The MAD system is not binding on the Agency as the European Union has not acceded to the Convention on the OECD, nor adhered to the MAD Decision.[14]

53. Even if the MAD system were binding on the Agency, this could not lead to the annulment of Information Requirement 1.

54. Under the MAD system, where an OECD test guideline is updated, the results of tests carried out under a previous version of that test guideline continue to be accepted after the update.

55. However, in the present case, the Agency did not reject the results of the previously conducted test. The Agency rather requested data which is additional to that already provided by the Appellant. Specifically, to comply with the 1997 version of OECD TG 471, the Agency requested the Appellant to conduct the *in vitro* gene mutation study in bacteria using only a fifth strain (*E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102) which was not required under the earlier version of that test guideline. The Agency did not request the Appellant to repeat the test on the other four strains which had been used in the test included in the Appellant's registration dossier.

*(ii) The Appellant did not comply with the second subparagraph of Article 13(3)*

56. Under the second subparagraph of Article 13(3), '*information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met*'.

57. Consequently, the results of the OECD TG 471 study submitted by the Appellant may be sufficient to fulfil the information requirement in Section 8.4.1. of Annex VII even though that study was not carried out in accordance with the test method laid down in the Test Methods Regulation at the time it was required to comply with that provision. However, in accordance with the second subparagraph of Article 13(3), the conditions set out in Annex XI must be met.

58. According to the introduction to Annex XI, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of that Annex. Section 1 of Annex XI sets out the conditions under which testing does not appear scientifically necessary, for example because adequate data already exists.

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[12] See paragraph 23 above.

[13] See paragraph 24 above.

[14] Decision of the Board of Appeal of 11 December 2018, Case A-006-2017, *Climax Molybdenum*, paragraphs 91 to 99.

59. It must be noted that the Appellant did not include such adaptations related to Section 8.4.1. of Annex VII in its registration dossier for the Substance, although it is the duty of a registrant who submits an adaptation to set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds.[15] Furthermore, the Agency is not required to examine a registration dossier of its own initiative to look for information that may justify an adaptation[16] or to develop or improve adaptations on a registrant's behalf.[17]

60. However, based on the Appellant's arguments during the present proceedings and the information submitted by the Appellant prior to the adoption of the Contested Decision in relation to Information Requirement 1, the adaptations under Sections 1.1.2. and 1.2. of Annex XI may be relevant. In full compliance with the duty to state reasons, it is necessary to respond to those arguments by examining whether the information submitted by the Appellant prior to the adoption of the Contested Decision would comply with those adaptations.[18]

61. In addition, it should be borne in mind that when examining whether information or evidence submitted in support of a notice of appeal that was not available to the Agency during the decision-making procedure leading to the adoption of the contested decision is admissible, it must be ascertained whether such information or evidence supports new facts or is supporting facts already alleged during the decision-making procedure before the Agency.[19]

62. In this respect, in its comments on the draft decision, the Appellant argued that the data provided in its registration dossier – including the results of an OECD TG 480 study – cover effectively the key parameters covered by the latest version of OECD TG 471.

*(ii)(a) Section 1.1.2. of Annex XI*

63. Section 1.1.2. of Annex XI sets out the conditions under which testing is not required based on data on human health and environmental properties from experiments not carried out according to Good Laboratory Practice (**GLP**) or the test methods referred to in Article 13(3). That provision states the following:

'*Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3) if the following conditions are met:*

*(1) adequacy for the purpose of classification and labelling and/or risk assessment;*

*(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);*

*(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and*

*(4) adequate and reliable documentation of the study is provided*'.

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[15] Decision of the Board of Appeal of 31 October 2022, *Croda EU*, A-011-2021, paragraph 79.

[16] See, for example, decisions of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraph 99 and of 1 August 2016, *BASF Pigment*, A-014-2014, paragraphs 47 and 48.

[17] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraphs 37 and 75.

[18] See judgment of 29 March 2023*, Nouryon and Others* v *Commission,* T-868/19, EU:T:2023:168, paragraph 152.

[19] Decision of the Board of Appeal of 11 December 2018, *Climax Molybdenum*, A-006-2017, paragraph 31.

64. In the present case, if the Appellant would have submitted an adaptation under Section 1.1.2. of Annex XI,[20] to comply with that provision, and in particular point 2 thereof, the Appellant would have been required to compare the OECD TG 471 study that it had carried out according to the 1983 version of the test guideline against the version of the test guideline applicable at the time it was required to comply with the information requirement in question – the 1997 version – to verify whether those versions were comparable.

65. According to Section 1.5.1.1. of Section B.13/14 of the Annex to the Test Methods Regulation – which is equivalent of the 1997 version of OECD TG 471:[21]

'*At least five strains of bacteria should be used. These should include four strains of S. typhimurium (TA 1535; TA 1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four S. typhimurium strains have GC base pairs at the primary reversion site and it is known that may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E. coli WP2 strains or S. typhimurium TA102 (19), which have an AT base pair at the primary reversion site*'.

66. The study must therefore be carried out with at least five strains of bacteria, specifically:

(i) four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100), and

(ii) one strain of either *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 (the **fifth strain of bacteria**).

67. In the results of the OECD TG 471 study submitted by the Appellant, the fifth strain of bacteria (*E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102) – which became a requirement in the 1997 version – was not covered.

68. According to the 1997 version of OECD TG 471, *E. coli* WP2 strains or *S. typhimurium* TA102 may detect oxidising mutagens, cross-linking agents and hydrazines. During the present proceedings, the Appellant did not demonstrate that the strains used in the OECD TG 471 study that it included in its registration dossier could provide the same information.

69. Consequently, the results of the OECD TG 471 study submitted by the Appellant could not be considered to be equivalent to data generated under the version of the test guideline applicable at the time it submitted, or claimed, the registrations for the Substance.

*(ii)(b) Section 1.2. of Annex XI*

70. The requirements for a general adaptation under Section 1.2. of Annex XI (weight of evidence) must be read in conjunction with the specific information requirement in Annexes VII to X which the adaptation seeks to fulfil.[22]

71. Section 8.4.1. of Annex VII requires registrants to submit information on *in vitro* gene mutation in bacteria. In order to successfully rely on an adaptation under Section 1.2. of Annex XI to fulfil that information requirement, a registrant must demonstrate that the available information is sufficient for that purpose.

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[20] See paragraphs 59 and 60 above.

[21] See paragraph 13 of the 1997 version of OECD TG 471.

[22] Decision of the Board of Appeal of 21 October 2020, *Solvay Fluor*, A-001-2019, paragraph 140.

72. To fulfil the information requirement under Section 8.4.1. of Annex VII, in addition to the results of the OECD TG 471 study, the Appellant submitted the results of a study carried out according to OECD TG 480 entitled '*Genetic toxicology: Saccharomyces cerevisiae, gene mutation assay*'.[23]

73. According to the Appellant, the results of the OECD TG 480 study serve the purpose of identifying cross-linking mutagens, which is also the purpose of the *E. coli WP2* or *S. typhimurium TA102* strains required in the 1997 version of OECD TG 471. The Appellant argues that therefore, taken together, the data provided in the registration dossier effectively cover the key parameters required by the latest version of the OECD TG 471.

74. According to the Contested Decision, the OECD TG 480 study submitted by the Appellant does not fulfil the requirement for the missing data on the fifth strain required in the 1997 version of OECD TG 471. This is because, according to the Agency, that study was carried out in yeast rather than bacteria and the OECD TG 480 study does not identify cross-linking mutagens. In addition, according to the Contested Decision, the fifth strain required in the 1997 version of OECD TG 471 may detect certain oxidising agents and hydrazines, additionally to cross-linking agents.

75. During the present proceedings, the Appellant did not demonstrate that the Agency erred in finding that, because the OECD TG 480 study was carried out in yeast rather than bacteria, it could not be used to provide information on the fifth strain of bacteria required in the OECD TG 471. The Appellant did not bring forward any element establishing that the results of the OECD TG 480 study it submitted, which was carried out in yeast, can provide the information that is requested under Section 8.4.1 of Annex VII.

76. Consequently, the information submitted by the Appellant, even when taken together, did not enable a conclusion to be reached on the information requirement under Section 8.4.1. of Annex VII.

77. The deficiency related to the absence of testing on a fifth strain of bacteria, and the absence of any element establishing that the testing on yeast could provide the information on a fifth strain of bacteria, would be sufficient on its own to reject any related weight-of-evidence adaptation, had such an adaptation been submitted by the Appellant. Therefore, it is not necessary to examine the Appellant's claim that the Agency committed an error in stating in the Contested Decision that the OECD TG 480 study does not identify oxidising mutagens, cross-linking agents and hydrazines.[24]

*(iii) Conclusion on the Appellant's pleas*

78. For the reasons set out in paragraphs 37 to 77 above, the Appellant's pleas that the Agency committed an error of assessment, exceeded its competence, and breached Articles 13 and 41, as well as Section 8.4.1. of Annex VII in requesting Information Requirement 1 must be rejected.

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[23] OECD TG 480 was deleted from the list of OECD test guidelines on 2 April 2014.

[24] See by analogy decision of the Board of Appeal of 21 October 2020, A-001-2019, *Solvay Fluor*, paragraph 149.

### 4.1.2. Legal certainty

*Arguments of the Parties*

79. The Appellant argues that the Agency's position as regards the applicability of amended test guidelines could lead to a situation where the Agency could require a registrant to update its dossier every time a test guideline is amended. According to the Appellant, this would leave registrants in a situation of legal uncertainty.

80. The Agency disputes the Appellant's arguments.

*Findings of the Board of Appeal*

81. The principle of legal certainty requires that rules of law must be clear and precise, and that their application must be foreseeable by those subject to them.[25]

82. For the following reasons, there was no uncertainty as regards the version of the test guideline the Appellant was required to follow in the present case.

83. As stated above,[26] to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required.

84. Article 13(3) of the REACH Regulation and Article 1 of the Test Methods Regulation state that the test methods to be applied for the purposes of the REACH Regulation are those set out in the Annex to the Test Methods Regulation.

85. In the present case, at the time the Appellant was required to comply with Section 8.4.1. of Annex VII, Section B.13/14 of the Annex to the Test Methods Regulation included the equivalent of the 1997 version of OECD TG 471. Furthermore, the 1997 version of OECD TG 471 was included in Section B.13/14 of the Annex to the Test Methods Regulation in 2008, that is before the Appellant was required to comply with Section 8.4.1. of Annex VII.

86. Consequently, at the time the Appellant was required to comply with Section 8.4.1. of Annex VII, it was clear that the 1997 version of OECD TG 471 – the equivalent of which was included in Section B.13/14 of the Annex to the Test Methods Regulation – was the applicable version of that study.

87. The Appellant's plea that the Agency breached the principle of legal certainty must therefore be rejected.

### 4.1.3. Article 25 of the REACH Regulation

*Arguments of the Parties*

88. The Appellant argues that accepting the Agency's approach to updated test guidelines would contradict Article 25 as there is no reason why the Agency would not apply the same approach to testing on vertebrate animals. According to the Appellant, this would mean that the Agency could require the repetition of vertebrate animal studies on the ground that the testing guidelines were extended to include additional parameters.

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[25] Judgment of 11 September 2019, *Călin*, C-676/17, EU:C:2019:700, paragraph 50; see decision of the Board of Appeal of 23 August 2022, *Celanese Production Germany*, A-004-2021, paragraph 137.

[26] See paragraphs 37 to 42 above.

89. The Agency argues that the Appellant's reference to Article 25 and vertebrate animal testing as a last resort is not relevant in the present case as Information Requirement 1 does not involve vertebrate animal testing.

*Findings of the Board of Appeal*

90. The Appellant raises arguments to demonstrate that the Agency's approach to amended test guidelines may, in general, lead to a breach of the requirement to undertake testing on vertebrate animals only as a last resort under the first sentence of Article 25(1).

91. However, in the present case, the *in vitro* gene mutation study in bacteria requested in the Contested Decision does not involve testing on vertebrate animals. Consequently, the obligation under the first sentence of Article 25(1) to ensure that testing on vertebrate animals is undertaken only as a last resort is not applicable to this information requirement.

92. The Appellant's claim that the Agency breached Article 25, as its approach may lead to a repetition of testing on vertebrate animals, must therefore be rejected.

### 4.1.4. Failure to state reasons

*Arguments of the Parties*

93. The Appellant argues that the Agency failed to state reasons in the Contested Decision because it does not rebut the Appellant's arguments made in its comments on the draft decision that the OECD TG 471 study submitted by the Appellant should have been assessed by reference to a prior version of the OECD TG 471. The Appellant also argues that the Agency did not provide reasons as to why testing on a fifth strain of bacteria should be considered as a key parameter justifying the repetition of this study.

94. The Agency disputes the Appellant's arguments.

*Findings of the Board of Appeal*

95. 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.[27]

96. 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.[28] 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.[29]

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

[28] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraph 124.

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

97. The Contested Decision refers to the 1997 version of OECD TG 471 and explains that the investigation of a fifth strain of bacteria is necessary for the possible detection of oxidising mutagens, hydrazines and cross-linking agents.

98. It is also clear from the Appellant's comments on the draft decision that the Appellant was aware of the necessity to investigate a fifth strain of bacteria. For example, in those comments, the Appellant stated '*…although the currently required fifth strain is not present, taken together, the data provided in the registration dossier does cover effectively the key parameters required by the latest version of the OECD TG 471*'.

99. The Contested Decision therefore contains sufficient reasoning 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.

100. Consequently, the Appellant's argument that the Agency failed to state reasons for requesting Information Requirement 1 must be rejected.

#### 4.1.5. Conclusion on Information Requirement 1

101. Since all the Appellant's pleas in relation to Information Requirement 1 have been rejected, the Appellant's claim that Information Requirement 1 should be annulled must be dismissed.

### 4.2. Information Requirement 2 (*in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study)

102. The Appellant argues that the Agency committed errors in concluding that:

(i) the OECD TG 473 study submitted by the Appellant did not satisfy the information requirement under Column 1 of Section 8.4.2. of Annex VIII; and

(ii) the Appellant's adaptation under the first indent of Column 2 of Section 8.4.2. of Annex VIII was not acceptable.

#### 4.2.1. The Agency's conclusion that the OECD TG 473 study submitted by the Appellant did not satisfy the information requirement in Column 1 of Section 8.4.2. of Annex VIII

103. The Appellant claims that in rejecting the study it submitted to fulfil Column 1 of Section 8.4.2. of Annex VIII the Agency:

- erred in its assessment,
- exceeded its competence,
- breached the principle of legal certainty, and
- breached Articles 13, 25, and 41, as well as Section 8.4.2. of Annex VIII.

***(a) The Agency erred in its assessment, exceeded its competence, breached the principle of legal certainty and breached Articles 13, 25, and 41, as well as Section 8.4.2. of Annex VIII***

*Arguments of the Parties*

104. The Appellant argues that, for the same reasons as those set out in its arguments under Information Requirement 1,[30] the Agency committed an error by assessing the results of the OECD TG 473 study it submitted in its registration dossier against the version of the OECD test guideline applicable at the time the Contested Decision was adopted rather than against the version applicable at the time the study was carried out.

105. The Agency disputes the Appellant's arguments.

*Findings of the Board of Appeal*

*(i) Contested Decision*

106. The standard information required under Column 1 of Section 8.4.2. of Annex VIII is either an *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study.

107. In the present case, according to the Contested Decision, to fulfil the information requirement under Column 1 of Section 8.4.2. of Annex VIII the Appellant's registration dossier included '*a study similar to OECD TG 473 performed with the Substance in cultured peripheral human lymphocytes which gave negative result*'. That study was carried out in 1991 (**1991 study**).

108. The Contested Decision describes the information that is required under Column 1 of Section 8.4.2. of Annex VIII and states that the 1991 study submitted by the Appellant to fulfil this information requirement does not include the following three parameters:

- Information why the maximum tested concentration of 100 µg/mL was the highest achievable concentration with metabolic activation as cytotoxicity was not observed and precipitation was not reported;
- The scoring of at least 300 metaphases per concentration as only 100 cells were analysed; and
- Short-term treatment without metabolic activation as only 3 hours exposure duration with metabolic activation and 24 hours exposure duration without metabolic activation were tested.

109. The Contested Decision adds that '*the lack of a short-term treatment without metabolic activation is the main deviation. In the absence of this information, a thorough evaluation, which would be needed to conclude a negative outcome, is not possible.*'

*(ii) The Appellant did not comply with the first subparagraph of Article 13(3)*

110. Under the first subparagraph of Article 13(3), where tests on substances are required to generate information on the intrinsic properties of substances, those tests must be carried out in accordance with the test methods laid down in the Test Methods Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

[30] See paragraphs 22 to 26 above.

111. Section B.10 (*in vitro* mammalian chromosome aberration test) of the Annex to the Test Methods Regulation – which is equivalent of OECD TG 473 – sets out the test method to be followed for the *in vitro* cytogenicity study in mammalian cells required under Section 8.4.2. of Annex VIII.

112. For the reasons set out above,[31] to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation that is applicable at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required.

113. In the present case, the OECD TG 473 study carried out with the Substance submitted by the Appellant to comply with the requirement in Column 1 of Section 8.4.2. of Annex VIII was carried out in 1991 according to the version of that test guideline adopted by the OECD on 26 May 1983 (**1983 version**).

114. However, at the time Cytec Industries was required to comply with the information requirements set out in Annex VIII,[32] Section B.10 of the Annex to the Test Methods Regulation included the equivalent of the version of OECD TG 473 adopted by the OECD on 21 July 1997 (**1997 version).**

115. Furthermore, at the time Cytec Engineered Materials was required to comply with the information requirements set out in Annex VIII,[33] Section B.10 of the Annex to the Test Methods Regulation included the equivalent of OECD TG 473 adopted by the OECD on 29 July 2016 (**2016 version**).[34]

116. Consequently, the OECD TG 473 study – the results of which were submitted by the Appellant to the Agency – was not carried out according to the version of the test guideline that was applicable at the time the Appellant was required to comply with the information requirements set out in Annex VIII. That study was not therefore carried out in accordance with the first subparagraph of Article 13(3). This does not exclude the possibility to accept that study as a valid source of information on the intrinsic properties of the Substance under the second subparagraph of Article 13(3).[35]

117. Therefore, the Agency did not commit an error of assessment or exceed its competence by not assessing compliance of the information provided by the Appellant with Section 8.4.2. of Annex VIII against the 1983 version of OECD TG 473.

*(iii) The Appellant did not comply with the second subparagraph of Article 13(3)*

118. Under the second subparagraph Article 13(3), '*information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met*'.

119. Consequently, the 1991 study submitted by the Appellant may be sufficient to fulfil the information requirement in Column 1 of Section 8.4.2. of Annex VIII even though it was not carried out in accordance with the test method laid down in the

[31] See paragraphs 37 to 42 above.

[32] See paragraph 3 above.

[33] See paragraph 2 above.

[34] The 2016 version of OECD TG 473 was included in the Test Methods Regulation by Commission Regulation (EU) 2017/735 amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 112, 28.4.2017, p. 1).

[35] See paragraphs 118 to 128 below.

Test Methods Regulation at the time it was required to comply with that provision. However, in accordance with the second subparagraph of Article 13(3), the conditions set out in Annex XI must be met.

120. According to the introduction to Annex XI, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of that Annex. Section 1 of Annex XI sets out the conditions under which testing does not appear scientifically necessary, for example because adequate data already exists.

121. It must be noted that the Appellant did not include such an adaptation in its registration dossier for the Substance related to Section 8.4.2. of Annex VIII, although it is the duty of a registrant who submits an adaptation to set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds.[36] Furthermore, the Agency is not required to examine a registration dossier of its own initiative to look for information that may justify an adaptation[37] or to develop or improve adaptations on a registrant's behalf.[38]

122. However, based on the information and arguments submitted by the Appellant during the present proceedings and prior to the adoption of the Contested Decision in relation to Information Requirement 2, the adaptation under Section 1.1.2. of Annex XI may be relevant. As stated above,[39] in full compliance with the duty to state reasons, it is necessary to respond to those arguments by examining whether the information submitted by the Appellant prior to the adoption of the Contested Decision would comply with that adaptation.[40]

123. In addition, it should be borne in mind that when examining whether information or evidence submitted in support of a notice of appeal that was not available to the Agency during the decision-making procedure leading to the adoption of the contested decision is admissible, it must be ascertained whether such information or evidence supports new facts or is supporting facts already alleged during the decision-making procedure before the Agency.[41]

124. In this respect, in its comments on the draft decision, the Appellant argued that the data provided in its registration dossier cover effectively the key parameters covered by the latest version of OECD TG 473.

125. As stated above,[42] Section 1.1.2. of Annex XI sets out the conditions under which testing is not required based on data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3). According to Section 1.1.2. of Annex XI, '*data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3)'* if certain conditions are met*.* One of those conditions is '*adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3)'.*

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[36] Decision of the Board of Appeal of 31 October 2022, *Croda EU*, A-011-2021, paragraph 79.

[37] See, for example, decisions of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraph 99 and of 1 August 2016, *BASF Pigment*, A-014-2014, paragraphs 47 and 48.

[38] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 75.

[39] See paragraph 60 above.

[40] See judgment of 29 March 2023*, Nouryon and Others* v *Commission,* T-868/19, EU:T:2023:168, paragraph 152.

[41] Decision of the Board of Appeal of 11 December 2018, *Climax Molybdenum*, A-006-2017, paragraph 31.

[42] See paragraph 63 above.

126. In the present case, if the Appellant would have submitted an adaptation under Section 1.1.2. of Annex XI,[43] to comply with that provision, and in particular point 2 thereof, the Appellant would have been required to compare the OECD TG 473 study that it had carried out according to the 1983 version of the test guideline against the versions of the test guideline applicable at the time it was required to comply with the information requirement in question – the 1997 and 2016 versions – to verify whether those versions were comparable. When compared to a study carried out according to the 1997 and 2016 versions of OECD TG 473, the 1991 study carried out by the Appellant according to the 1983 version of that test guideline lacked three parameters.[44]

127. As stated in the Contested Decision, the main shortcoming in the 1991 study submitted by the Appellant to fulfil this information requirement is that it lacked short term treatment without metabolic activation. In the absence of this information, a thorough evaluation, which would be needed to conclude on the absence of *in vitro* cytogenicity, is not possible. In this respect, paragraph 27 of the 1997 and 2016 versions of OECD TG 473 states:

'*For thorough evaluation, which would be needed to conclude a negative outcome, all three of the following experimental conditions should be conducted using a short term treatment with and without metabolic activation and long term treatment without metabolic activation […]*'.

128. Consequently, in the data submitted by the Appellant, there is not '*adequate and reliable coverage*' of a key parameter within the meaning of Section 1.1.2. of Annex XI. As a result, that data could not be considered to be equivalent to data generated under the version of the test guideline applicable at the time the Appellant was required to comply with the information requirements set out in Annex VIII. Consequently, the Appellant did not comply with the second subparagraph of Article 13(3), in conjunction with Section 1.1.2. of Annex XI.

*(iv) Legal certainty*

129. For the reasons set out in Section 4.1.2. above, the Appellant's arguments that the Agency breached the principle of legal certainty must be rejected.

*(v) First sentence of Article 25*

130. For the reasons set out in Section 4.1.3. above, the Appellant's arguments that the Agency breached the first sentence of Article 25 must be rejected.

*(vi) Conclusion on the Appellant's pleas related to Column 1 of Section 8.4.2. of Annex VIII*

131. For the reasons set out in paragraphs 106 to 130 above, the Appellant's pleas that the Agency committed an error of assessment, exceeded its competence, breached the principle of legal certainty and breached Articles 13, 25 and 41, as well as Column 1 of Section 8.4.2. of Annex VII must be rejected.

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[43] See paragraphs 121 and 122 above.

[44] See paragraph 102 above.

### 4.2.2. Rejection of the Appellant's adaptation under Column 2 of Section 8.4.2. of Annex VIII

132. The Appellant claims that in rejecting the study it submitted to fulfil Column 1 of Section 8.4.2. of Annex VIII the Agency:

- erred in its assessment,
- exceeded its competence,
- breached the principle of legal certainty,
- breached the Appellant's right to be heard and rights of defence, and
- breached Articles 13, 25, and 41, as well as Column 2 Section 8.4.2. of Annex VIII.

*Arguments of the Parties*

133. The Appellant argues that it submitted to the Agency the results of an *in vivo* micronucleus study carried out in 1994 (the **1994 study**) according to test method B.12 set out in the Test Methods Regulation, which is equivalent to an OECD TG 474 study.[45] According to the Appellant, based on this information, Information Requirement 2 is not necessary under the first indent of Column 2 of Section 8.4.2. of Annex VIII.

134. The Appellant argues that the 1994 study was carried out in compliance with the version of the test guideline applicable at the time that study was carried out. The Appellant argues that, for the same reasons as those set out in its arguments under Information Requirement 1,[46] the Agency committed an error by assessing the results of the 1994 study against the most recent version of the OECD test guideline rather than against the version applicable when the study was carried out.

135. The Appellant argues that, at the time the 1994 study was carried out, the test guideline required only one dose to be tested and did not refer to bone marrow depression. The Appellant argues further that, in any event and contrary to the findings in the Contested Decision, the robust study summary provided to the Agency shows that the results of the 1994 study do not show any significant effect on bone marrow proliferation at 48 hours.

136. The Appellant argues that the quantitative structure–activity relationship ('**QSAR**') predictions referred to in the Contested Decision were not mentioned in the draft decision. As a result, the Appellant did not have an opportunity to review or comment on the Agency's QSAR model. According to the Appellant, the Agency therefore breached its duty to state reasons and breached the Appellant's right to be heard and its rights of defence.

137. The Agency disputes the Appellant's arguments.

138. The Agency argues that the QSAR predictions were used only as a supportive argument to respond to the Appellant's comments on the draft decision. The Agency argues that, irrespective of the QSAR predictions, the information request would have remained the same. As a result, there was no need to further address the issue in the Contested Decision or consult the Appellant on it.

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[45] See paragraph 7 above.

[46] See paragraphs 21 to 28 above.

139. The Agency also argues that the full study report of the 1994 study (the **full study report**) was not contained in the registration dossier and was submitted only with the observations on the Defence. As a result, according to the Agency, that evidence is inadmissible under Article 12(1) of the Rules of Procedure.

*Findings of the Board of Appeal*

**(a) Admissibility of the full study report**

140. Under Article 12(1) of the Rules of Procedure, '*[n]o further evidence may be introduced after the first exchange of written pleadings unless the Board of Appeal decides that the delay in offering the evidence is duly justified*'.

141. Since the full study report was submitted by the Appellant with the observations on the Defence, that evidence was submitted after the first exchange of written pleadings. In accordance with Article 12(1) of the Rules of Procedure, it is therefore necessary to consider whether the delay in submitting the full study report as evidence is justified.

142. A delay in offering evidence is justified where, for example, it is presented to support arguments offered to rebut arguments raised for the first time in the defence or where the evidence in question was in preparation at the time of the deadline to submit an appeal and it is clear that the evidence in question could not have been prepared before the deadline to submit the appeal.[47]

143. In the present case, the Agency raised in its Defence arguments for the first time related to the significance of the depression of bone marrow observed in the 1994 study. The full study report was submitted by the Appellant to support arguments rebutting the arguments raised by the Agency in its Defence. The delay in submitting that evidence is therefore justified.

144. The Agency's claim that the full study report is inadmissible must therefore be rejected.

**(b) Examination of the Appellant's pleas and arguments**

145. Under the first indent of Column 2 of Section 8.4.2. of Annex VIII, the *in vitro* cytogenicity study or *in vitro* micronucleus study required under Column 1 of that provision does not usually need to be carried out if adequate data from an *in vivo* cytogenicity test is available.

146. During the decision-making process leading to the adoption of the Contested Decision, the Appellant informed the Agency that it had become aware of an existing *in vivo* micronucleus study (the 1994 study) carried out according to EU test method B.12, which is equivalent to OECD TG 474.

*(i) Compliance with the first subparagraph of Article 13(3)*

147. Under the first subparagraph of Article 13(3), where tests on substances are required to generate information on the intrinsic properties of substances, those tests must be carried out in accordance with the test methods laid down in the Test Methods Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

[47] Decision of the Board of Appeal of 22 March 2022, *Campine*, A-003-2020, paragraphs 43 and 44.

148. Section B.12 (mammalian erythrocyte micronucleus test) of the Annex to the Test Methods Regulation – which is equivalent to OECD TG 474 – sets out the test method to be followed for the *in vivo* micronucleus test required under Column 2 of Section 8.4.2. of Annex VIII.

149. For the reasons set out above,[48] to comply with the first subparagraph of Article 13(3), a registrant must respect the version of the relevant test method laid down in the Test Methods Regulation that is applicable at the time it submitted its registration or updated its registration to the tonnage band under which the information requirement in question is required.

150. In the present case, the 1994 study was carried out in 1994 according to the version of OECD TG 474 adopted by the OECD on 26 May 1983 (**1983 version**).

151. However, at the time Cytec Industries was required to comply with the information requirements set out in Annex VIII, Section B.12 of the Annex to the Test Methods Regulation included the equivalent of the version of OECD TG 474 adopted by the OECD on 21 July 1997 (**1997 version**).

152. At the time Cytec Engineered Materials was required to comply with the information requirements set out in Annex VIII, Section B.12 of the Annex to the Test Methods Regulation included the equivalent of the version of OECD TG 474 adopted by the OECD on 29 July 2016 (**2016 version**).[49]

153. Consequently, the 1994 study was not carried out according to the version of that test guideline that was applicable at the time the Appellant was required to comply with the requirements in Annex VIII. The 1994 study was not therefore carried out in accordance with the first subparagraph of Article 13(3). This does not exclude the possibility to accept that study as a valid source of information on the intrinsic properties of the Substance under the second subparagraph of Article 13(3).[50]

*(ii) Compliance with the second subparagraph of Article 13(3)*

154. For the reasons set out above,[51] under the second subparagraph of Article 13(3), the results of the OECD TG 474 study submitted by the Appellant may be sufficient for the purposes of the first indent of Column 2 of Section 8.4.2. of Annex VIII even though that study was not carried out in accordance with the test method laid down in the Test Methods Regulation at the time it was required to comply with that provision. However, in accordance with the second subparagraph of Article 13(3), the conditions set out in Annex XI must be met.

155. Section 1.1.2. of Annex XI sets out the conditions under which testing is not required based on data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3). According to that provision, '*data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 13(3)'* if certain conditions are met. One of those conditions is '*adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3)'* (emphasis added).

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48 See paragraphs 37 to 42 above.

49 The 2016 version of OECD TG 474 was included in the Test Methods Regulation by Commission Regulation (EU) 2017/735 amending, for the purpose of its adaptation to technical progress, the Annex to Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 112, 28.4.2017, p. 1).

50 See paragraphs 154 to 181 below.

51 See paragraphs 56 and 57 above.

156. The Appellant did not include such an adaptation in its dossier. However, having regard to paragraphs 121 to 123 above, based on the arguments and information submitted during the decision-making process and in the present proceedings it is appropriate to examine whether the conditions of Section 1.1.2. of Annex XI are met in the present case.

157. The dose regime in an OECD TG 474 study is a key parameter of that study as it ensures the generation of conclusive data for the purposes of hazard assessment, hazard identification and risk assessment.

158. In the present case, if the Appellant would have submitted an adaptation under Section 1.1.2. of Annex XI,[52] to comply with that provision, and in particular point 2 thereof, the Appellant would have been required to compare the OECD TG 474 study that it had carried out according to the 1983 version of the test guideline against the versions of the test guideline applicable at the time it was required to comply with the information requirement in question – the 1997 and 2016 versions – to verify whether those versions were comparable. The 1983 version of OECD TG 474 – according to which the 1994 study was carried out – and the 1997 and 2016 versions of that test guideline – the versions applicable at the time Cytec Engineered Materials and Cytec Industries were required to comply with the requirements in Annex VIII[53] – contain different wording with respect to the number of dose levels to be used in the study.

159. According to the 1983 version of OECD TG 474:

'*For the initial assessment of genotoxicity, one dose of the test substance may be used, the dose being the maximum tolerated dose or that producing some indication of cytotoxicity, e.g. a change in the ratio of polychromatic to normochromatic erythrocytes. Additional dose levels may be used when these are indicated by scientific reasons. If the test is being used for verification, at least two additional dose levels should be used.*'[54]

160. According to the 1997 and 2016 versions of OECD TG 474, the study must include a minimum of three doses/groups of treated animals.

161. However, the 1997 version of the test guideline provides that a single dose level, at the limit dose, may be sufficient if:

(a) one dose level of at least 2 000 mg/kg body weight (**bw**) using a single treatment, or as two treatments on the same day, produces no observable toxic effects, and

(b) genotoxicity would not be expected based upon data from structurally related substances.[55]

162. The 2016 version of OECD TG 474 also provides that a single dose level, at the limit dose, may be sufficient in the following circumstances:

'*If dose range-finding experiments, or existing data from related animal strains, indicate that a treatment regime of at least the limit dose […] produces no observable toxic effects, (including no depression of bone marrow proliferation or other evidence of target tissue cytotoxicity), and if genotoxicity would not be expected based upon in vitro genotoxicity studies or data from structurally related substances, then a full study using three dose levels may not be considered*

[52] See paragraph 156 above.

[53] See paragraphs 142 and 143 above.

[54] Page 3 of the 1983 version of OECD TG 474.

[55] Paragraphs 22 and 23 of the 1997 version of OECD TG 474.

*necessary, provided it has been demonstrated that the test chemical(s) reach(es) the target tissue (bone marrow). In such cases, a single dose level, at the limit dose, may be sufficient. When administration occurs for 14 days or more, the limit dose is 1000 mg/kg body weight/day. For administration periods of less than 14 days, the limit dose is 2000 mg/kg/body weight/day*' (emphasis added).[56]

163. The 1994 study submitted by the Appellant, carried out under the 1983 version of the test guideline, included only one limit dose of 2 000 mg/kg bw using a single treatment. The Appellant argues that the single dose used in the 1994 study is sufficient to meet the requirements of the 1983 version as well as the 1997 and 2016 versions of OECD TG 474 as no observable toxic effects, including no depression of bone marrow proliferation, were observed in that study. Specifically, the Appellant argues that, contrary to the findings in the Contested Decision, the results of the 1994 study do not show any significant effect on bone marrow proliferation at 48 hours.

164. According to the Contested Decision, the requirements of Column 2 of Section 8.4.2. of Annex VIII are not met as the 1994 study submitted by the Appellant does not cover specifications required by OECD TG 474. More specifically, the 1994 study did not include the appropriate number of doses as only one dose level was used.

165. According to the Contested Decision, one dose was not sufficient to meet the requirements of OECD TG 474 since:

- depression of bone marrow proliferation at 48 hours indicates that toxic effects were observed in the 1994 study,
- the *in vitro* genotoxicity tests are not adequate to conclude that genotoxicity would not be expected, and
- QSAR predictions for mutagenicity endpoints which were carried out by the Agency indicate potential *in vitro* mutagenicity concern.

- *Observable toxic effects*

166. As stated above,[57] a single dose level, at the limit dose, may be sufficient for the purposes of an OECD TG 474 study.

167. If one dose is to be used, it must firstly be shown that the test at one dose level of at least 2 000 mg/kg bw using a single treatment, or as two treatments on the same day, produces no observable toxic effects.

168. It is not disputed between the Parties that depression of bone marrow proliferation may be an indication of toxic effects. However, the Appellant disputes that the observed bone marrow proliferation at 48 hours in the 1994 study is an indication of toxic effects.

169. According to the robust study summary of the 1994 study, the evaluation criteria for that study were set as follows:

'*A positive response is indicated by a substantial, statistically significant (P < 0.01) increase in the incidence of micronucleated polychromatic erythrocytes compared to the incidence for the concurrent vehicle control group for at least one sampling time.*

*Bone marrow cell toxicity is indicated by a substantial, statistically significant (p < 0.01) decrease in the ratio of polychromatic to normochromatic erythrocytes at the 48-hour sampling point*' (emphasis added).

[56] Paragraph 34 of the 2016 version of OECD TG 474.

[57] See paragraphs 161 and 162 above.

170. In the 1994 study, the ratio of polychromatic to normochromatic erythrocytes at 48 hours was 0.896 in the vehicle control and 0.598 in the animals dosed at 2 000 mg/kg bw. The p value[58] calculated for this decrease is 0.012, which is not below the value of 0.01 set as the threshold for statistical significance in the 1994 study. Consequently, whilst this demonstrates a decrease, that decrease was not statistically significant within the criteria set out in the evaluation criteria for the 1994 study.

171. The Agency did not contest the statistical method used by the Appellant to investigate the results of the 1994 study or the p value ($p < 0.01$). The Agency stated that it would also be possible to set a p-value of $< 0.05$ but did not provide any reasons to justify why the Appellant made an error in setting that value at $< 0.01$.

172. The fact that the effects observed in the 1994 study are not statistically significant is confirmed in the full study report which summarises the individual results after 48 hours. Those results do not indicate a statistically significant decrease in the ratio of polychromatic to normochromic erythrocytes, which would be indicative of bone marrow toxicity.

173. The Agency argues that while the effect may not be statistically significant, the results of the 1994 study indicate over 30 % depression of the bone marrow proliferation in the treatment group compared to the vehicle control at 48 hours. According to the Agency, this can be regarded as a sign of toxicity.

174. The Agency did not justify why the calculation of over 30% decrease of the bone marrow proliferation is more reliable than the statistical method used by the Appellant to establish bone marrow toxicity. Furthermore, the Agency did not provide any other arguments to indicate that there were observable toxic effects in the 1994 study. Consequently, the Agency's arguments are not sufficient to refute the finding that the results from the 1994 study do not show any significant effect on bone marrow proliferation at 48 hours.

175. The Agency did not therefore demonstrate that the depression of bone marrow proliferation at 48 hours indicates that toxic effects were observed in the 1994 study.

- *Genotoxicity based upon in vitro genotoxicity studies*

176. According to the Contested Decision, in order for a single dose level, at the limit dose, to be sufficient for the purposes of an OECD TG 474 study it must also be shown that genotoxicity would not be expected based on *in vitro* genotoxicity studies or data from structurally related substances.

177. Contrary to the Agency's conclusion in the Contested Decision, according to the wording of the 1997 and 2016 versions of OECD TG 474, only an indication rather than a definitive conclusion that '*genotoxicity would not be expected based upon in vitro genotoxicity studies …*'[59] is required. Furthermore, based on the available *in vitro* data on the Substance, which all produced negative results, the Agency made an error in concluding that genotoxicity can be expected.

[58] P is the probability value.

[59] Paragraph 34 of the 2016 version of OECD TG 474.

- *QSAR predictions*

178. The conclusion referred to in the previous paragraph that the Agency made an error in concluding that genotoxicity can be expected is not affected by the finding in the Contested Decision that QSAR predictions for mutagenicity endpoints carried out by the Agency indicate a potential *in vitro* mutagenicity concern. Even if the results of the QSAR predictions indicate a potential mutagenicity concern, they cannot outweigh the other tests on the Substance. In the present case, there are four *in vitro* studies showing no mutagenicity. Moreover, the Agency relies on the results of one QSAR prediction, which is not described in any detail in the Contested Decision, to predict potential mutagenicity concerns. In this respect, the Agency confirmed during the present proceedings that the QSAR predictions are used only as a supporting argument for the mutagenicity concern.

- *Conclusion*

179. In view of paragraphs 154 to 178 above, the Agency committed an error of assessment in rejecting the results of the OECD TG 474 study submitted by the Appellant for the reason that it was carried out using only one limit dose of 2 000 mg/kg bw.

180. The Agency did not demonstrate that the 1994 study submitted by the Appellant was not sufficient to comply with the second subparagraph of Article 13(3). It follows that the Agency did not demonstrate that the OECD TG 474 study submitted by the Appellant was not sufficient to meet the requirements of the adaptation set out in Column 2 of Section 8.4.2. of Annex VIII.

181. Information Requirement 2 must therefore be annulled. As a result, it is not necessary to examine the remainder of the Appellant's pleas in relation to Information Requirement 2.

## 4.3. Information Requirement 3 (long-term toxicity testing on fish)

182. In relation to Information Requirement 3, the Appellant alleges that the Agency:

- erred in its assessment and failed to take relevant information into account,
- breached the principles of legal certainty and legitimate expectations, and
- breached Articles 25 and 41, as well as Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX.

*Arguments of the Parties*

183. The Appellant argues that the Agency erred in deciding that information on long-term toxicity testing on fish under Column 2 of Section 9.1.3. of Annex VIII must be provided on the ground that the Substance is poorly soluble.

184. The Appellant argues that it has complied with Column 2 of Section 9.1.3. of Annex VIII as it had considered whether long-term toxicity testing on fish is necessary. The Appellant argues that, based on the available short-term invertebrate and fish studies, it considered invertebrates to be the most sensitive species. The Appellant argues that, having regard to Article 25, a long-term study on invertebrates was therefore considered to be the most appropriate study. According to the Appellant, the Agency failed to take this consideration into account.

185. The Appellant argues that the Agency also erred in requesting information on long-term toxicity testing on fish under Column 1 of Section 9.1.6. of Annex IX.

186. The Appellant argues that the Agency erred in finding that the Appellant could not rely on Column 2 of Section 9.1. of Annex IX to waive the requirement to conduct long-term toxicity testing in fish under Column 1 of Section 9.1.6. of Annex IX.

187. The Appellant argues that the Agency's interpretation of Column 2 of Section 9.1. of Annex IX, which is based on the Board of Appeal's previous interpretation of that provision in for example case A-011-2018,[60] is contrary to the explicit wording of the REACH Regulation. The Appellant adds that the Board of Appeal's interpretation of that provision in another case is subject to an action for annulment before the General Court of the European Union.[61]

188. The Appellant argues that, irrespective of the correct interpretation of Column 2 of Section 9.1. of Annex IX, the Agency erred in its assessment by not taking into account all information, including information on the uses of the Substance.

189. The Appellant argues that the Agency's interpretation of Column 2 of Section 9.1. of Annex IX breaches the principle of legal certainty. According to the Appellant, that interpretation remains unclear and unpredictable, in particular as it goes against the literal and logical reading of that provision.

190. The Appellant argues that the legal uncertainty is confirmed by the amendments to the REACH Annexes.[62] The Appellant argues that registrants must be given time to comply with the revised standard information requirements. According to the Appellant, it is not clear whether the Appellant would be required to update the dossier as a result of the Contested Decision or as a result of the amendments to the Annexes to the REACH Regulation.

191. The Appellant argues that the Agency breached the principle of the protection of legitimate expectations as the Contested Decision departs from the Agency's Guidance R.7b[63] and R.7c[64]. According to the Appellant, these guidance documents give rise to a legitimate expectation that highly insoluble and highly absorptive substances, such as the Substance, would not be subject to the information requirement for long-term aquatic toxicity testing on fish. The Appellant also argues that, due to the Substance's high potential for adsorption to soil and/or sediment, the relevant compartment is soil or sediment rather than water. The Appellant argues that it has already been established based on the available data – for example the long-term Daphnia study – that the Substance meets the toxic ('T') criterion in the context of the PBT assessment and, accordingly, the emissions to the environment must already be minimised. According to the Appellant, new data on the long-term effects on fish will not in any way change the applicable risk management measures.

192. The Agency disputes the Appellant's arguments.

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60 Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018.

61 Case T-655/20, *Symrise* v *ECHA*.

62 Commission Regulation (EU) 2022/477 amending Annexes VI to X to the REACH Regulation (OJ L 98, 25.3.2022, p. 38).

63 Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7b: Endpoint specific guidance (Version 4.0; June 2017) (**Guidance R.7b**).

64 Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7c: Endpoint specific guidance) (Version 3.0; June 2017) (**Guidance R.7c**).

*Findings of the Board of Appeal*

193. In the Contested Decision, Information Requirement 3 – long-term toxicity testing on fish – is requested under Column 2 of Section 9.1.3. of Annex VIII and Column 1 of Section 9.1.6. of Annex IX. The Appellant contests the request to provide that information under both provisions.

### 4.3.1. Request for information on a long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII

194. Under Column 1 of Section 9.1.3. of Annex VIII, the Appellant's registration dossier included two short-term toxicity studies on fish based on OECD TG 203.

195. Under the version of the REACH Regulation applicable at the time the Contested Decision was adopted – i.e. on 25 October 2021 – Column 2 of Section 9.1.3. of Annex VIII provided that *'the long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble, or for nanoforms if they have low dissolution rate in the relevant test media'*.

#### (a) The Substance is poorly water soluble

196. According to the Contested Decision, '*the Substance is poorly water soluble and information on long-term toxicity on fish must be provided*'.

197. The Appellant does not dispute that the Substance is '*poorly water soluble*'. Consequently, the long-term aquatic toxicity study on fish must be carried out under Column 2 of Section 9.1.3. of Annex VIII unless the Appellant provides an adequate justification as to why that study is not necessary or submits an acceptable general adaptation under Annex XI.

#### (b) Aquatic toxicity testing on fish and aquatic toxicity testing on invertebrates are not interchangeable

198. The Appellant argued during the compliance check procedure and the present proceedings that, based on the available short-term invertebrate and fish studies, it considered invertebrates to be the most sensitive species and therefore considered a long-term study on invertebrates to be the most appropriate study.

199. However, aquatic toxicity testing on fish and aquatic toxicity testing on invertebrates[65] are separate information requirements and are not interchangeable. There is no provision in the REACH Regulation allowing for the omission of aquatic toxicity testing on fish based on an available study, or studies, on invertebrates only.

#### (c) The Agency did not commit an error in not considering the uses of the Substance before requesting information under Column 2 of Section 9.1.3. of Annex VIII

200. For the following reasons, and contrary to the Appellant's arguments,[66] the Agency did not commit an error in not considering the uses of the Substance before requesting the information required under Column 2 of Section 9.1.3. of Annex VIII.

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[65] See for example Section 9.1.5. of Annex IX.

[66] See paragraph 188 above.

201. 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[67] to that substance.

202. 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.[68] The Agency is not, in general, obliged to take into account uses, exposure and risk.

203. However, 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 uses, exposure and risk related to a substance. Those exceptions include the general adaptation 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 and uses may be relevant to trigger additional requirements, or to waive testing required under Column 1 of Annexes VII to X. In those exceptions, the relevance of exposure and/or uses of the substance in question is clearly set out.

204. Column 2 of Section 9.1.3. of Annex VIII does not contain 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 uses.

205. Furthermore, as stated in the Contested Decision, the Appellant did not demonstrate that the criteria of Section 3.2(c) of Annex XI are met in the present case.

206. The Appellant also did not seek to rely on any adaptations under Section 1.2. of Annex XI (weight of evidence) in order to waive the requirement to provide information on long-term toxicity to fish at the Annex VIII or Annex IX level. The Agency is not required to develop and improve adaptations on behalf of a registrant[69] or to develop or improve adaptations on a registrant's behalf.[70]

### (d) The Agency did not breach the principles of the protection of legitimate expectations and equal treatment

207. The right to rely on the principle of the protection of legitimate expectations presupposes that precise, unconditional and consistent assurances originating from authorised, reliable sources have been given to the person concerned by the competent authorities of the European Union. In accordance with the Court of Justice's settled case-law, that right applies to any individual in a situation in which a European Union institution, body or agency, by giving that person precise assurances, has led that individual to entertain well-founded expectations. Precise, unconditional and consistent information, in whatever form it is given, constitutes such an assurance.[71]

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[67] See judgment of 29 March 2023*, Nouryon and Others* v *Commission,* T-868/19, EU:T:2023:168, paragraph 83. See also decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraph 35.

[68] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraph 38.

[69] See, for example, decision of the Board of Appeal of 19 October 2016, *Polynt*, A-004-2015, paragraph 123.

[70] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 75.

[71] See judgment of 13 June 2013*, HGA and Others* v *Commission*, joined cases C-630/11 P to C-633/11 P, EU:C:2013:387, paragraph 132; see also decision of the Board of Appeal of 21 October 2020, *Solvay Fluor*, A-001-2019, paragraph 89).

208. The Appellant argues that the Agency's R.7b and R.7c guidance documents gave rise to a legitimate expectation that highly insoluble and highly absorptive substances, such as the Substance, would not be subject to the information requirement for long-term aquatic toxicity testing on fish. The Appellant argues that the Agency breached the principle of legal certainty and the protection of legitimate expectations by deviating from its guidance.

209. For the following reasons, the Appellant has not demonstrated how the Agency's guidance documents led it to entertain well-founded expectations that it would not be required to provide information on long-term aquatic toxicity testing on fish.

210. First, the guidance documents referred to by the Appellant could not lead to an expectation that aquatic toxicity testing could be replaced with soil or sediment toxicity testing.

211. Second, those guidance documents do not suggest that long-term aquatic toxicity testing could be omitted for highly insoluble and highly absorptive substances. The sections of the guidance documents referred to by the Appellant rather allow for modifications to be made to the aquatic toxicity where necessary.

212. The Appellant's plea that the Agency breached the principle of the protection of legitimate expectations must therefore be rejected.

#### (e) Conclusion

213. The Appellant did not provide an adequate justification for not carrying out a long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII despite the fact that the Substance is poorly water soluble.

214. The Appellant's argument that the Agency erred in requesting the long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII must therefore be rejected.

### 4.3.2. Request for information on a long-term aquatic toxicity study on fish under Column 1 of Section 9.1.6. of Annex IX

215. As set out in Section 4.3.1. above, the Agency did not commit an error in requiring the Appellant to provide information on a long-term aquatic toxicity study on fish under Column 2 of Section 9.1.3. of Annex VIII. As a result, under Article 12(1)(c) and (d), registrants of the Substance at both the Annex VIII and Annex IX level are required to provide that information.

216. Where some of the grounds in a decision on their own provide a sufficient legal basis for the decision, any errors in the other grounds of the decision have no effect on its operative part. Moreover, a plea which, even if well-founded, is incapable of bringing about the annulment which the appellant seeks must be rejected as ineffective.[72]

217. Consequently, the Agency did not commit an error in requiring the Appellant to provide information on long-term toxicity testing on fish under Column 2 of Section 9.1.3. of Annex VIII. The Appellant's pleas related to the request for information under Column 1 of Section 9.1.6. of Annex IX must therefore be rejected as ineffective.

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[72] Judgment of 15 January 2015 in T-1/12, *France* v *Commission,* EU:T:2015:17, paragraph 73; see also order of 26 February 2013 in *Castiglioni* v *Commission*, T-591/10, EU:T:2013:94, paragraphs 44 and 45.

### 4.3.3. Conclusion on Information Requirement 3

218. In view of paragraphs 193 to 217 above, the Agency did not commit an error in requesting the Appellant to provide the information on long-term toxicity testing on fish required under Column 2 of Section 9.1.3. of Annex VIII and Column 1 of Section 9.1.6. of Annex IX.

219. The Appellant's pleas in relation to Information Requirement 3 must therefore be rejected.

## 4.4. Information Requirements 4 to 7

220. In relation to Information Requirements 4 to 7, the Appellant claims that the Agency:

- exceeded its competence,
- erred in its assessment and failed to take relevant information into account,
- breached the principle of legal certainty and legitimate expectations, and
- breached Article 41, Column 2 of Section 9.2. of Annexes VIII and Sections 9.2.1.2., 9.2.1.3., 9.2.1.4. and 9.2.3. of Annex IX.

### 4.4.1. The Agency erred in its assessment, failed to take relevant information into account and exceeded its competence in requesting Information Requirements 4 to 7

*Arguments of the Parties*

221. The Appellant argues that the Agency exceeded its competence and committed an error of assessment in basing Information Requirements 4 to 7 on Section 2.1. of Annex XIII.

222. The Appellant argues that Article 41 does not grant the Agency powers relating to Annex XIII. According to the Appellant, Annex XIII cannot act as a trigger or a legal basis for requesting Information Requirements 4 to 7 under Annexes VIII and IX.

223. The Appellant argues that Section 2.1. of Annex XIII obliges registrants to take further steps when screening studies indicate that a substance 'may' have persistent, bioaccumulative and toxic (**PBT**) or very persistent and very bioaccumulative (**vPvB**) properties. The Appellant argues that, in the present case, the Substance is – based on a weight-of-evidence determination – effectively a PBT/vPvB substance and this final definitive assessment was implemented in the registration dossier and applied in the chemical safety assessment (**CSA**) and chemical safety report. According to the Appellant, as the classification of the Substance as PBT/vPvB achieves the same result as the potential test, it is not necessary to conduct further tests.

224. The Appellant argues that the Agency failed to take into account all of the relevant information submitted by the Appellant. According to the Appellant, the Agency did not provide reasons for rejecting the submission made by the Appellant that the Substance is a PBT/vPvB substance.

225. The Appellant argues that the Agency committed an error of interpretation in rejecting its adaptation under Column 2 of Section 9.2.1.2. of Annex IX on the grounds that the Appellant did not demonstrate that the OECD TG 309 study is not technically feasible. According to the Appellant, there is no requirement under that adaptation for a registrant to demonstrate that the OECD TG 309 study cannot be technically carried out.

226. The Appellant considers that the approach taken by the Agency discriminates against registrants that have invested and developed better analytical methods. According to the Appellant, the Agency's approach encourages registrants not to deploy the most capable analytical methods in order to benefit from the waiver in Column 2 of Section 9.2.1.2. of Annex IX. The Appellant argues that this creates legal uncertainty as the possibility to rely on Column 2 of Section 9.2.1.2. of Annex IX will depend on the Agency's assessment of the specific analytical methods in any given case.

227. The Appellant argues that, having regard to the Board of Appeal's decision in case A-026-2015,[73] the Agency erred in requesting simulation tests in the water compartment where that testing would not generate '*data obtained under relevant conditions*' as required by the fourth introductory paragraph of Annex XIII due to the intrinsic properties of the Substance. The Appellant argues that, given the intrinsic properties of the Substance, the relevant compartment of concern is soil or sediment rather than water.

228. The Appellant argues that the Agency breached the principles of legal certainty and the protection of legitimate expectations by not applying its own Guidance R.11.[74]

229. The Agency disputes the Appellant's arguments.

*Findings of the Board of Appeal*

230. According to the Contested Decision,[75] the three degradation simulation studies (Information Requirements 4, 5, and 6) are requested on the basis of Column 2 of Section 9.2. of Annex VIII and Section 9.2.1. of Annex IX. Information on the identification of degradation products (Information Requirement 7) is requested under Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX.

**(a) Requirement under Column 2 of Section 9.2. of Annex VIII**

(i) Annex XIII is not the legal basis for requesting Information Requirements 4 to 7

231. 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 […]*'.

232. The degradation of a substance includes the process of degradation and the identification of the degradation products of that substance.[76]

233. In the present case, according to points 3, 4, 5, and 6 of Appendix B 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 substance.

234. Contrary to the Appellant's arguments, Annex XIII is not the legal basis for requesting Information Requirements 4 to 7 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

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[73] Decision of the Board of Appeal of 8 September 2017, *Envigo Consulting and DJChem Chemicals Poland*, A-026-2015.

[74] Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment (Version 3.0; June 2017) (**Guidance R.11**).

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

[76] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraphs 99 to 106.

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 and the identification of degradation products (Information Requirements 4 to 7) at the Annex VIII level is Column 2 of Section 9.2. of Annex VIII.

(ii) The Agency did not fail to assess the Appellant's submission regarding the need to submit further information

235. For the following reasons, the Appellant's argument that the Agency failed to assess the submission made by the Appellant that the Substance is a PBT and vPvB substance must be rejected.

236. First, 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 that registrant concludes, based on its consideration of the CSA, that such further degradation testing is not required, 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.[77]

237. Second, in any case, the Agency took into account in the Contested Decision the Appellant's argument, made in the comments on the draft decision, that additional information is not required on the grounds that the Substance is a PBT/vPvB substance.[78] Consequently, the Appellant's argument that the Agency did not provide any reasons for rejecting the Appellant's submission that the Substance is a PBT and vPvB substance must be rejected.

(iii) 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

238. 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 showed that the Substance has potentially PBT or vPvB properties.

239. 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.[79]

240. Consequently, 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.[80]

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[77] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraph 48. See also, by analogy, decision of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraphs 84 and 98.

[78] See pages 8 and 9 of the Contested Decision.

[79] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraph 53.

[80] Decision of the Board of Appeal of 14 February 2023, *Covestro*, A-012-2021, paragraphs 52 to 57.

(iv) The Agency did not commit an error in concluding that there is a need for further information on degradation under Column 2 of Section 9.2. of Annex VIII

241. The Parties agree on the B/vB and T properties of the Substance. The divergence between the Parties only concerns the P/vP properties of the Substance. In effect, the Appellant relies on a weight-of-evidence approach within the meaning of the introduction to Section 2.1. of Annex XIII. According to that provision:

*'[f]or the identification of PBT and vPvB substances a weight of evidence determination using expert judgment shall be applied, by comparing all relevant and available information listed in Section 3.2 with the criteria set out in Section 1'*.

242. In this respect, the Appellant relies on screening studies and QSAR results as a reason not to perform the requested studies.

243. However, the Appellant's weight-of-evidence approach in the case at issue does not allow a conclusion to be reached on the P/vP properties of the Substance as it is not possible to derive a degradation half-life for the Substance based on the available information. The determination of a degradation half-life is a prerequisite to determine whether the Substance is P/vP as defined in Sections 1.1.1. and 1.2.1. of Annex XIII.

244. Consequently, as it is not possible, based on the available screening studies and the QSAR results, to conclude on the P/vP properties of the Substance, there is a 'need' for further information within the meaning of Column 2 of Section 9.2. of Annex VIII.

(v) The Agency did not breach the principle of legal certainty and the principle of protection of legitimate expectations

245. According to the Contested Decision:

'*As specified by ECHA Guidance [Section] R.11.4.1.1., no further testing or assessment of persistence of other environmental compartments is normally necessary if a conclusion "P" or "vP" is reached for one compartment […]. As already explained in [the Contested Decision], when determining the sequence of simulation degradation testing you are advised to consider the information provided in Appendix E [to the Contested Decision]*'.

246. For the following reasons, the Appellant's argument that the Agency failed to follow its own Guidance R.11 and in doing so breached the principle of legal certainty and the principle of the protection of legitimate expectations must be rejected.

247. Contrary to the Appellant's arguments, Guidance R.11 does not suggest that degradation simulation testing may be omitted based on screening data on persistency. The part of Guidance R.11 referred to in the Contested Decision is relevant for determining the sequence of degradation simulation testing. Furthermore, no further simulation tests are normally necessary if a conclusion on P/vP is reached for one compartment. In the present case, no conclusion on the P or vP properties of the Substance has been reached.

(vi) Conclusion on the requests for Information Requirements 4 to 7 at the Annex VIII level

248. In view of paragraphs 230 to 247 above, the Agency did not commit an error in requesting Information Requirements 4 to 7 from registrants of the Substance at the Annex VIII level.

### (b) Requests under Section 9.2. of Annex IX

#### (i) Information Requirements 4 to 7 are standard information requirements at the Annex IX level

249. The information requirements under Column 1 of Section 9.2. of Annex IX – which includes Sections 9.2.1.2., 9.2.1.3., 9.2.1.4., and 9.2.3. 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 in question.[81]

250. Therefore, 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 in question is a potential PBT or vPvB substance.[82]

251. 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.[83]

#### (ii) The Agency did not commit an error in rejecting the Appellant's adaptation under Column 2 of Section 9.2.1.2. of Annex IX (Information Requirement 4)

252. In the present case, the Appellant sought to rely on a specific adaptation under Column 2 of Section 9.2.1.2. of Annex IX and a general adaptation under Section 3.2.(c) of Annex XI to omit the information on ultimate degradation in surface water. Both adaptations were rejected by the Agency in the Contested Decision. In the present proceedings, the Appellant did not seek to challenge the Agency's rejection of the adaptation under Section 3.2.(c) of Annex XI.

253. Under Column 2 of Section 9.2.1.2. of Annex IX, the simulation study on ultimate degradation in surface water does not need to be carried out if: '*the substance is highly insoluble in water, or the substance is readily biodegradable*'.

254. The Appellant sought to rely on this adaptation to omit this information requirement on the grounds that the Substance is highly insoluble in water.

255. However, the Agency rejected the Appellant's adaptation because '*[c]onsidering the limited sensitivity of the analytical method used to conduct the water solubility study, you have not demonstrated that a simulation study in water as described in the OECD TG 309 is not technically feasible'.*

256. For the following reasons, the Appellant's plea that the Agency committed an error in rejecting its adaptation under Column 2 of Section 9.2.1.2. of Annex IX must be rejected.

257. The Agency did not make an error of assessment in considering that high insolubility in water must be assessed in the context of the study that the registrant is seeking to omit. In the present case, according to the Contested Decision, to rely on the adaptation the solubility of the Substance in water must be so low that the test may be practically difficult or impossible to conduct at concentrations below the water solubility limit of the Substance.

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[81] Decision of the Board of Appeal of 27 September 2022, *Albemarle Europe,* A-005-2021, paragraph 62.

[82] Decisions of the Board of Appeal of 14 February 2023, *Covestro,* A-012-2021, paragraph 56 and of 27 September 2022, *Albemarle Europe,* A-005-2021, paragraph 63.

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

258. The Appellant did not present arguments capable of demonstrating that the Contested Decision is vitiated by an error in this respect.[84] In particular, the Appellant did not provide any element – for example from a Contract Research Organisation – that would establish that the level of solubility of the Substance makes OECD TG 309 study practically difficult or impossible to perform.

(iii) The Agency did not breach the fourth introductory paragraph of Annex XIII in requesting information that would not generate '*data obtained under relevant conditions*'

259. The Appellant argues that the Agency erred in requesting simulation tests in the water compartment, where the information before it showed that simulation testing in water would not generate '*data obtained under relevant conditions*' as mandated by the fourth introductory paragraph of Annex XIII.

260. However, for the reasons set out above,[85] the simulation testing on ultimate degradation in surface water is standard information under Column 1 of Section 9.2.1.2. of Annex IX. In addition, for the reasons set out above,[86] the Agency did not commit an error in rejecting the Appellant's adaptation under Column 2 of Section 9.2.1.2. of Annex IX. Consequently, the Agency had no discretion as to whether to request the Appellant to perform the simulation testing on ultimate degradation from registrants of the Substance at the Annex IX level.

261. Similarly, for the reasons set out above,[87] the Agency did not commit an error in requesting the simulation testing on ultimate degradation in surface water from registrants at the Annex VIII level.

262. Consequently, the Appellant's claim must be rejected.

(iv) Conclusion on the requests for Information Requirements 4 to 7 at the Annex IX level

263. In view of paragraphs 249 to 262 above, the Agency did not commit an error in requesting Information Requirements 4 to 7 from registrants of the Substance at the Annex IX level.

### 4.4.2. Pleas and arguments related to the request for information on non-extractable residues (NERs) in information requirements 4 to 6

264. The Appellant argues that in requesting information on NERS as part of Information Requirements 4 to 6 the Agency:

- committed an error of assessment,
- failed to take all relevant information into account, and
- breached the principle of legal certainty.

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[84] Judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraphs 65 and 86.

[85] See paragraph 249 to 251 above.

[86] See paragraphs 252 to 258 above.

[87] See paragraphs 231 to 248 above.

*Arguments of the Parties*

265. The Appellant argues that the Agency failed to take into account the Appellant's conclusion that the Substance is a PBT and vPvB substance, specifically its comments on the draft decision. The Appellant argues that, as the persistency of the Substance has already been established, the information requests on NERs would not yield new meaningful information.

266. The Appellant argues, with reference to the Board of Appeal's decision in case A-026-2015,[88] that there is currently no legal or scientific certainty as to the characterisation and interpretation of NERs for the PBT/vPvB assessment under the REACH Regulation.

267. The Appellant argues that the Contested Decision, the lack of existing guidelines, and a potential update to Guidance R.11 create significant legal uncertainty in respect of providing any meaningful information on NERs.

268. The Agency disputes the Appellant's arguments. The Agency argues that no conclusion on persistency can be reached based on the available information.

269. The Agency argues that the Contested Decision does not require the Appellant to characterise the NERs but to quantify them.

*Findings of the Board of Appeal*

270. According to the Contested Decision, for the three degradation simulation studies, '*non-extractable residues (NER) must be quantified*'.

**(a) Soil and sediment simulation testing (Information Requirements 5 and 6)**

271. For the following reasons, the Appellant's argument that the Agency committed errors in requesting information on NERs with respect to Information Requirements 5 and 6 must be rejected.

272. Section C.24 of the Annex to the Test Methods Regulation – which is equivalent to OECD TG 308 – sets out the test method to be followed for the sediment simulation testing required under Column 1 of Section 9.2.1.4. of Annex IX.

273. Paragraph 42 of OECD TG 308 states: '*…non-extractable (bound) residues in sediment are to be reported at each sampling point*'. This is repeated in point 1.9.5. of test method C.24.

274. Section C.23. of the Annex to the Test Methods Regulation – which is equivalent to OECD TG 307 – sets out the test method to be followed for the soil simulation testing required under Column 1 of Section 9.2.1.3. of Annex IX.

275. Paragraph 55 of OECD TG 307 states that the test report must include, amongst other things, '*…characterisation of non-extractable (bound) radioactivity or residues in soil…*'. This is repeated in point 3 of test method C.23. Paragraph 51 of OECD TG 307 refers explicitly to the quantification of NERs as follows: '*The amounts of test substance, transformation products, volatile substances (in % only), and non-extractable should be given as % of applied initial amount and, where appropriate, as mg·kg-1 soil (based on soil dry weight) for each sampling interval*'. This is repeated in point 2.1. of test method C.23.

[88] Decision of the Board of Appeal of 8 December 2017, *Envigo Consulting Limited and DJChem Chemicals Poland*, A-026-2015.

276. Under the first subparagraph of Article 13(3), where tests on substances are required to generate information on the intrinsic properties of substances, those tests must be carried out in accordance with the test methods laid down in the Test Methods Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.

277. Consequently, the provision of information on NERs is a requirement of both soil simulation testing and sediment simulation testing under the Test Methods Regulation. Registrants must carry out the tests in full compliance with those test methods. The Board of Appeal is not competent to decide on the legality of the Test Methods Regulation.[89]

278. In addition, for the reasons set out above,[90] it is not possible to conclude on the P/vP properties of the Substance based on the available information. Consequently, the Appellant's argument that no information on NERs is needed because the persistence of the Substance has already been established must be rejected.

279. The Appellant itself concedes that NERs are essential to assess the persistence of substances that bind faster to solid matter than they hydrolyse or degrade in water, as is the case for the Substance.

280. Third, the Appellant's arguments related to the Board of Appeal's decision in case A-026-2015 must be rejected. In particular, in that case the Board of Appeal found that '*there is at present no scientific consensus as to how the results of an OECD TG 308 study should be evaluated as regards the identity and properties of NERs*'.[91] In that case, the Board of Appeal also stated that '*there is currently no viable method to identify these NERs…*'.[92]

281. However, in the present case the Appellant is requested to 'quantify' NERs and not to evaluate the identity and properties of NERs as in case A-026-2015.

**(b) Simulation testing on ultimate degradation in surface water (Information Requirement 4)**

282. Section C.25. of the Annex to the Test Methods Regulation – which is equivalent to OECD TG 309 – sets out the test method to be followed for the simulation testing on ultimate degradation in surface water required under Column 1 of Section 9.2.1.2. of Annex IX.

283. Consequently, for the purposes of the first subparagraph of Article 13(3), to fulfil Column 1 of Section 9.2.1.2. of Annex IX a registrant must comply with the requirements of Section C.25 of the Annex to the Test Methods Regulation. In a compliance check decision under Article 41, the Agency is not competent to add additional parameters to a test guideline, as included in the Test Methods Regulation.

284. Unlike for Information Requirements 5 and 6, there is no requirement to provide information on NERs in either OECD TG 309 or test method C.25.

285. As the provision of information on NERS is not a requirement of simulation testing on ultimate degradation in surface water according to Section C.25. of the Annex to the Test Methods Regulation, the Agency exceeded its competence in requesting the Appellant to provide that information.

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[89] Decision of the Board of Appeal of 10 May 2022, *LANXESS Deutschland*, A-002-2021, paragraph 79.

[90] See paragraphs 243 and 244.

[91] See paragraph 138 of the Decision of the Board of Appeal in case A-026-2015 (cited in footnote 88).

[92] See paragraph 150 of the Decision of the Board of Appeal in case A-026-2015 (cited in footnote 88).

286. Consequently, the requirement to provide information on NERs in the simulation testing on ultimate degradation in surface water must be annulled.

### 4.5. Result

287. In view of paragraphs 154 to 178 above, the requirement to provide information on an *in vitro* cytogenicity study in mammalian cells (Section 8.4.2. of Annex VIII; OECD TG 473) or *in vitro* micronucleus study (Section 8.4.2. of Annex VIII; OECD TG 487) (Information Requirement 2) is annulled and the case remitted to the Agency for further action on that point.

288. In view of paragraphs 282 to 286 above, the requirement to provide information on simulation testing on ultimate degradation in surface water (Information Requirement 4) is annulled to the extent that it requires the Appellant to provide information on NERs generated in that study. The Appellant's other pleas in relation to Information Requirement 4 have been dismissed. Therefore, the Appellant must provide information on simulation testing on ultimate degradation in surface water (Information Requirement 4), without the quantification of NERs.

289. For the reasons given in paragraphs 37 to 101, 106 to 131, 193 to 218, 230 to 248, 249 to 263, and 271 to 281 above, the Appellant's appeal in relation to Information Requirements 1, 3, 5, 6 and 7 is dismissed.

## 5. Effects of the Contested Decision

290. The Contested Decision required the Appellant to submit information on Information Requirements 1 to 7 by 30 January 2025, which is 3 years, 3 months, and 5 days from the date of that decision.

291. 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.

292. Since Information Requirement 2 has been annulled, the Appellant must provide information on Information Requirements 1, 3, 5, 6 and 7, and Information Requirement 4, without the quantification of NERs, as requested in the Contested Decision by 11 September 2026.

## 6. Refund of the appeal fee

293. Under Article 10(4) of the Fee Regulation,[93] 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:

[93] 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).

1. **Annuls the Contested Decision insofar as it requires information on an *in vitro* cytogenicity study in mammalian cells *or in vitro* micronucleus study (Information Requirement 2).**
2. **Annuls the Contested Decision insofar as it requires information on the quantification of NERs in the simulation testing on ultimate degradation in surface water (Information Requirement 4).**
3. **Dismisses the remainder of the appeal.**
4. **Remits the case to the Agency insofar as it concerns the information on an *in vitro* cytogenicity study in mammalian cells *or in vitro* micronucleus study (Information Requirement 2).**
5. **Decides that the following information must be provided by 11 September 2026:**
   - **(i) *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII, test method: EU B.13/14 / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 (Information Requirement 1),**
   - **(ii) Long-term toxicity testing on fish (Column 2 of Section 9.1.3. of Annex VIII and Section 9.1.6. of Annex IX; OECD TG 210) (Information Requirement 3),**
   - **(iii) Simulation testing on ultimate degradation in surface water (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.2. of Annex IX; test method: EU C.25 / OECD TG 309) at a temperature of 12°C, without the quantification of NERs (Information Requirement 4),**
   - **(iv) Soil simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.3. of Annex IX; test method: EU C.23 / OECD TG 307) at a temperature of 12°C, including the quantification of NERs (Information Requirement 5),**
   - **(v) Sediment simulation testing (Column 2 of Section 9.2. of Annex VIII and Section 9.2.1.4. of Annex IX; test method: EU C.24 / OECD TG 308) at a temperature of 12°C, including the quantification of NERs (Information Requirement 6), and**
   - **(vi) Identification of degradation products (Column 2 of Section 9.2. of Annex VIII and Section 9.2.3. of Annex IX; OECD TG 307 and/or 308 and/or 309) (Information Requirement 7).**
6. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal