EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

4 May 2020

(Compliance check – Section 1.2. of Annex XI – Weight-of-evidence adaptation – Article 13 – Compliance with the relevant test method – Section 9.1. of Annex IX – Requirements for aquatic toxicity testing on fish)

Case number	A-011-2018
Language of the case	English
Appellant	Clariant Plastics & Coatings (Deutschland) GmbH, Germany
Representatives	Ruxandra Cana, Darren Abrahams and Hannah Widemann Steptoe & Johnson LLP, Belgium
Contested Decision	CCH-D-2114394043-52-01/F of 9 April 2018, adopted by the European Chemicals Agency pursuant to Article 41 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; the 'REACH Regulation')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. This appeal concerns a compliance check of the Appellant's registration dossier for the substance 3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carbox-amide (EC No 229-440-3, CAS No 6535-46-2; 'Pigment Red 112').
2. In 2010, the Appellant, acting as lead registrant, submitted a registration dossier for Pigment Red 112 at the 1 000 tonnes or more per year tonnage band.
3. On 17 August 2016, the Agency initiated a compliance check of the Appellant's registration dossier in accordance with Article 41 of the REACH Regulation (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).
4. On 28 April 2017, the Agency notified a draft decision to the Appellant in accordance with Article 50(1).
5. On 1 June 2017, the Appellant submitted comments on the draft decision. The Agency subsequently revised its draft decision, and notified the revised draft decision to the competent authorities of the Member States in accordance with Article 51(1).
6. On 9 April 2018, the Agency adopted the Contested Decision in accordance with Article 51(3).

Contested Decision

7. The operative part of the Contested Decision states:

   '*Based on Article 41 […], ECHA requests you to submit information on*

   1. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD TG 413) in rats modified to include analysis of bronchoalveolar lavage (BAL) analysis (as further specified in Appendix 1 (1)) with the registered substance [the 'first information requirement'];

   2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance [the 'second information requirement'];

   3. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a second species (rat or rabbit), oral route with the registered substance [the 'third information requirement'];

   4. Extended one-generation reproductive toxicity study (Annex X, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance [the 'fourth information requirement'] specified as follows:

   - *Ten weeks premating exposure duration for the parental (P0) generation;*
   - *Dose level setting shall aim to induce some toxicity at the highest dose level;*
   - *Cohort 1A (Reproductive toxicity);*
   - *Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation; […]*

   5. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance [the 'fifth information requirement'];

6. *Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance [the 'sixth information requirement'];*
7. *Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance [the 'seventh information requirement'];*

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI […]. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by 18 October 2021 except for the information requested under point 1 for a sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by 16 April 2019. You may only commence the extended one-generation reproductive toxicity study as requested under point 4 after 16 July 2019, unless an indication to the contrary is communicated to you by ECHA before that date. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.'

Procedure before the Board of Appeal

8. On 6 July 2018, the Appellant filed this appeal.
9. On 11 September 2018, the Agency submitted its Defence.
10. On 7 December 2018, the Appellant submitted observations on the Defence.
11. On 13 March 2019, the Agency submitted observations on the Appellant's observations on the Defence.
12. On 14 August 2019, the Appellant and the Agency submitted their respective replies to written questions from the Board of Appeal.
13. On 28 August 2019, the Agency submitted a further reply to a question from the Board of Appeal.
14. On 6 November 2019, a hearing was held at the Appellant's request. At the hearing, the Appellant and the Agency made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

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

Reasons

17. The Appellant raises eleven pleas in support of its appeal.

18. As regards the first information requirement (Section 8.6.2. of Annex IX), the Appellant argues that the Agency:

    - committed an error of assessment by requiring the Appellant to submit information on a 90-day subchronic toxicity study when this is not necessary to obtain information that is relevant to managing the risks posed by Pigment Red 112 (first plea),
    - breached Article 25 by requiring the Appellant to carry out the 90-day subchronic toxicity study by inhalation when this will not produce any useful results due to the properties of Pigment Red 112 (second plea), and
    - breached the principle of proportionality by failing to require the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would show whether it is necessary to conduct a 90-day subchronic toxicity study (third plea).

19. As regards the second, third and fourth information requirements (Sections 8.7.2. of Annexes IX and X, and Section 8.7.3. of Annex X), the Appellant argues that the Agency:

    - committed an error of assessment by requiring the Appellant to submit information on pre-natal developmental toxicity ('PNDT') studies in a first and second species, and an extended one-generation reproductive toxicity study ('EOGRTS'), when these studies will not provide information that is relevant to managing the risks posed by Pigment Red 112 (fourth plea),
    - breached Article 25 by failing to require the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would show whether it is necessary to conduct PNDT studies in a first and second species, and an EOGRTS (fifth plea), and
    - breached the principle of proportionality by failing to require the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would show whether it is necessary to conduct PNDT studies in a first and second species, and an EOGRTS, on Pigment Red 112 (sixth plea).

20. As regards the fifth and sixth information requirements (Section 9.1.2. of Annex VII and Section 9.1.5. Annex IX), the Appellant argues that the Agency:

    - committed an error of assessment in finding that two studies contained in the Appellant's registration dossier do not comply with the relevant test methods (seventh plea),
    - breached the principle of proportionality by requiring the Appellant to repeat two studies which are already contained in its registration dossier (eighth plea),
    - breached the principle of the protection of legitimate expectations by applying a guidance document which is specific to nanomaterials despite recognising that Pigment Red 112 is not a nanomaterial (ninth plea), and
    - breached the principle of equal treatment by treating Pigment Red 112 differently than two structurally similar substances (tenth plea).

21. As regards the seventh information requirement (Section 9.1.6. of Annex IX), the Appellant argues that the Agency breached Article 25 by requiring it to provide information on a study on vertebrate animals despite the fact that the Appellant's registration dossier contains a valid adaptation (eleventh plea).

22. The Board of Appeal will examine these pleas in relation to each of the information requirements addressed in the Contested Decision.

1. First, second and third pleas, concerning the first information requirement (Section 8.6.2. of Annex IX)

23. The Appellant did not submit information on a 90-day subchronic toxicity study on Pigment Red 112 under Column 1 of Section 8.6.2. of Annex IX. Instead, the Appellant submitted a weight-of-evidence adaptation under Section 1.2. of Annex XI.

24. In the Contested Decision, the Agency rejected the Appellant's adaptation. The Agency therefore required the Appellant to bring its dossier into compliance with Section 8.6.2. of Annex IX by submitting information on a 90-day subchronic toxicity study by the inhalation route or, alternatively, an acceptable adaptation.

Arguments of the Parties

25. The Appellant's first, second and third pleas, which concern the first information requirement, are supported by two lines of argument.

26. First, the Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because it failed to request the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would bring the Appellant's adaptation into compliance with Section 1.2. of Annex XI (such as a short-term inhalation study including extended recovery and the assessment of broncheoalveolar lavage).

27. Second, the Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because administering Pigment Red 112 by inhalation, as required by the Contested Decision, would cause '*lung overload effects*' on the test animals and therefore produce no useful results.

28. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

29. In order to decide on the first, second and third pleas, the Board of Appeal will examine (i) whether the Agency was entitled to conclude that the Appellant's registration dossier has a data-gap under Section 8.6.2. of Annex IX (Section 1.1. below); and (ii) the consequences of such a data-gap if one exists (Section 1.2. below).

1.1. Whether the Appellant's registration dossier has a data-gap

30. When examining the merits of a case, the Board of Appeal confines itself, in principle, to examining whether the pleas put forward by an appellant demonstrate that the contested decision is vitiated by an error (see judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraphs 64 and 65).

31. The Notice of Appeal contains no arguments contesting the Agency's finding that the Appellant's registration dossier has a data-gap under Section 8.6.2. of Annex IX. In the Notice of Appeal, the Appellant argues that this data-gap can be filled by means other than a 90-day subchronic toxicity study by the inhalation route.

32. The Appellant raised arguments contesting the Agency's finding that the Appellant's registration dossier has a data-gap only in its reply to the questions from the Board of Appeal and in the hearing. Those arguments, however, constitute a new plea that is not based on new matters of fact or law that came to light in the course of the proceedings. They are consequently inadmissible pursuant to Article 12(2) of Commission Regulation

(EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').

33. There is therefore no need for the Board of Appeal to examine the correctness of the finding, in the Contested Decision, that the Appellant's registration dossier has a data-gap under Section 8.6.2. of Annex IX.

34. In any event, the Agency was entitled to conclude that the Appellant's registration dossier has a data-gap for the following reasons.

35. A registrant who submits an adaptation must 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 (see, to this effect, Case A-004-2012, *Lanxess Deutschland*, Decision of 10 October 2013, paragraphs 92, 93, 98 and 99; Case A-006-2012, *Momentive Specialty Chemicals*, Decision of 13 February 2014, paragraphs 57 to 60; Case A-014-2014, *BASF Pigment (I)*, Decision of 1 August 2016, paragraphs 46 to 48; Case A-003-2015, *BASF Pigment (II)*, Decision of 1 August 2016, paragraphs 53 to 55, and Case A-004-2015, *Polynt*, Decision of the Board of Appeal of 19 October 2016, paragraph 123).

36. In its registration dossier, the Appellant provided the following adaptation for the information requirement set out in Section 8.6.2. of Annex IX:

'*Consistent with Section 8.6.2 of REACH Annex IX and in accordance with Section 1.2 of REACH Annex XI, there is sufficient weight of evidence from several independent sources of information leading to the conclusion that Pigment Red 112 does not cause toxicity after repeated oral administration, including the 90-day period, and thus does not have to be classified, because*

- Pigment Red 112 is a chemically unreactive substance,

- Pigment Red 112 can be considered insoluble because it has an extremely low solubility in water and n-octanol,

- due to its extremely low solubility, it is unlikely that Pigment Red 112 becomes systemically bioavailable after oral, dermal or inhalation exposure,

- Pigment Red 112 caused no systemic toxic effects in a 28-day oral gavage study in rats (NOAEL 1000 mg/kg/day) and there was no evidence of absorption of the substance,

- Pigment Red 112 does not have to be classified as skin sensitizing (referring [sic] to the pigment as such notwithstanding possible effects of impurities) or as skin or eye irritating, indicating that its chemical inertness and extremely low solubility in water and n-octanol largely prevent interaction with living cells and tissues,

- in the unlikely event of workplace exposure to aerosolized pigment in respirable form, the substance is considered likely to behave like an inert dust; from the use and exposure pattern long-term inhalation exposure is not considered relevant for the general population.

It can therefore be concluded with sufficient certainty that Pigment Red 112 will not cause toxicity after repeated oral administration, including the 90-day period, and that testing in a 90-day study is not scientifically necessary.'

37. The Appellant's adaptation for Section 8.6.2. of Annex IX is expressly based on Section 1.2. of Annex XI. It must therefore be assessed against the requirements of that provision, as it is not incumbent upon the Agency to develop or improve adaptations on

a registrant's behalf (see, to this effect, Case A-001-2012, *Dow Benelux*, Decision of 19 June 2013, paragraph 116; *Momentive Specialty Chemicals*, cited in paragraph 35 above, paragraphs 60 and 98; *BASF Pigment (I)*, cited in paragraph 35 above, paragraph 68; and *BASF Pigment (II)*, cited in paragraph 35 above, paragraph 74).

38. Section 1.2. of Annex XI provides:

'*There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.*

[…]

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

- *further testing on vertebrate animals for that property shall be omitted,*
- *further testing not involving vertebrate animals may be omitted.*

In all cases adequate and reliable documentation shall be provided.'

39. The requirements for a general adaptation under Section 1.2. of Annex XI must be read in conjunction with the specific information requirement in Annexes VII to X which the adaptation seeks to fulfil.

40. Section 8.6.2. of Annex IX requires registrants to submit information that allows the identification and characterisation of the toxicity of a substance resulting from a sub-chronic (90-day) exposure.

41. Therefore, in order to apply an adaptation under Section 1.2. of Annex XI to Section 8.6.2. of Annex IX, a registrant must demonstrate that available information is sufficient to identify and characterise the toxicity of a substance resulting from a sub-chronic (90-day) exposure.

42. First, the Appellant's adaptation refers to the results from a short-term (28-day) repeated dose toxicity study. However, given the difference in exposure duration, number of animals and investigated parameters, such a study is not sufficient on its own to characterise the toxicity of Pigment Red 112 resulting from a 90-day exposure.

43. Second, the Appellant's adaptation states that Pigment Red 112 is (i) chemically unreactive, (ii) virtually insoluble in water and n-octanol, (iii) unlikely to be absorbed due to its low solubility, (iv) not a skin sensitiser nor a skin or eye irritant, and (v) unlikely to be inhaled by the relevant population. However, (i) if a substance is chemically unreactive, this does not necessarily mean that it is toxicologically inert: it cannot be excluded that Pigment Red 112 and/or its metabolites may have toxicologically relevant effects; (ii) Pigment Red 112 has a measurable solubility in water (9.8 µg/L) and in n-octanol (3.31 mg/L); (iii) Pigment Red 112 has an octanol-water coefficient of 2.5, indicating some potential for absorption; (iv) and (v) the fact that Pigment Red 112 is neither a skin sensitiser nor a skin or eye irritant, and is unlikely to be inhaled by the relevant population, provides no information to allow characterisation of the toxicity of Pigment Red 112 resulting from a 90-day exposure.

44. Therefore, the information supporting the Appellant's adaptation is not sufficient to characterise the toxicity of Pigment Red 112 resulting from a 90-day exposure.

45. It follows that the Agency did not make an error in concluding, in the Contested Decision, that the Appellant's registration dossier has a data-gap under Section 8.6.2. of Annex IX.

1.2. Consequences of a data-gap

46. In the Contested Decision, the Agency required the Appellant to bring its dossier into compliance with Section 8.6.2. of Annex IX by submitting information on a 90-day subchronic toxicity study by inhalation or, alternatively, an acceptable adaptation.

47. The Appellant raises two lines of argument in this regard.

48. First, the Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because it failed to require the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would bring the Appellant's adaptation into compliance with the requirements of Section 1.2. of Annex XI (see paragraph 26 above).

49. In the present case, the Agency concluded, without committing an error, that the Appellant's registration dossier has a data-gap under Section 8.6.2. of Annex IX (see Section 1.1. above).

50. The consequences of this finding flow directly from the REACH Regulation. Pursuant to Article 10(a)(vi), read in conjunction with Section 8.6.2. of Annex IX and Annex XI, the Appellant is obliged to submit either information on a 90-day subchronic toxicity study or an acceptable adaptation.

51. As a consequence, the Agency was neither required nor empowered to consider whether it is proportionate, or consistent with Article 25, for the Appellant to be required to submit this information (see, to this effect, Case A-017-2014, *BASF*, Decision of 7 October 2016, paragraphs 83, 88 and 89; *Polynt*, cited in paragraph 35 above, paragraphs 137 and 138; and Case A-006-2017, *Climax Molybdenum*, Decision of 11 December 2018, paragraphs 118 to 123).

52. In any event, as stated in the operative part of the Contested Decision, the Appellant can still *'adapt the testing requested […] according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI […]'*. Therefore, the Contested Decision does not prevent the Appellant from performing the short-term studies which it proposes and consequently submitting an improved adaptation instead of information on a 90-day subchronic toxicity study. An improved adaptation would be assessed in accordance with the follow-up procedure under Article 42 (see judgment of 8 May 2018, *ESSO Raffinage* v *ECHA*, T–283/15, EU:T:2018:263, currently under appeal before the Court of Justice, paragraphs 62 and 63, and Case A-006-2018, *Emerald Kalama Chemical and Others*, Decision of the Board of Appeal of 24 March 2020, paragraph 75).

53. The Appellant's first line of argument must consequently be rejected.

54. Second, the Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because administering Pigment Red 112 by inhalation, as required by the Contested Decision, would cause '*lung overload effects*' in the test animals and therefore produce no useful results.

55. Column 1 of Section 8.6.2. of Annex IX requires registrants to carry out any study using '*[the] most appropriate route of administration, having regard to the likely route of human exposure*'.

56. Column 2 of Section 8.6.2. of Annex IX further provides that '*[t]esting by the inhalation route is appropriate if […] exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size*'.

57. The Contested Decision states, in this regard:

'*The information provided in the technical dossier and the chemical safety report on properties of [Pigment Red 112] and its uses indicate that human exposure to the registered substance by the inhalation route is likely. More specifically, the substance is considered to behave as an inert dust with a significant proportion (>1% on weight basis) of particles of inhalable size (MMAD < 50 µm). Furthermore, the substance is respirable, of low water solubility and consequently there is a potential for accumulation of the substance in the lungs*.'

58. The Appellant does not challenge the correctness of this statement. It is therefore common ground between the Parties that Pigment Red 112 is likely to behave as a dust, and that dust includes a significant proportion of solid particles of an inhalable size.

59. The Agency was consequently entitled to hold that the most relevant route of exposure to Pigment Red 112 for humans is the inhalation route.

60. This conclusion is not called into question by the Appellant's argument that Pigment Red 112 might cause '*lung overload effects*'. The current version of OECD test guideline 413 sets out ways of addressing the impact of such effects, such as lung burden measurement in the range-finding studies and in the main study.

61. The Appellant's second line of argument must consequently also be rejected.

62. The first, second and third pleas must therefore be rejected.

2. Fourth, fifth and sixth pleas, concerning the second, third and fourth information requirements (Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X)

63. The Appellant did not submit information on PNDT studies in a first and second species or an EOGRTS on Pigment Red 112 under Column 1 of Sections 8.7.2. of Annexes IX and X and Column 1 of Section 8.7.3. of Annex X. Instead, the Appellant submitted weight-of-evidence adaptations under Section 1.2. of Annex XI.

64. In the Contested Decision, the Agency rejected the Appellant's adaptations. It therefore required the Appellant to bring its dossier into compliance with Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X by submitting information on PNDT studies in a first and second species and an EOGRTS or, alternatively, acceptable adaptations.

Arguments of the Parties

65. The Appellant's fourth, fifth and sixth pleas concern the second, third and fourth information requirements. By these pleas, the Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because it failed to request the Appellant to generate, as a first step, additional information on the properties of Pigment Red 112 that would bring the Appellant's adaptations into compliance with Section 1.2. of Annex XI (such as a short-term toxicokinetic study, an *in vitro* metabolic study, a test to determine the solubility of Pigment Red 112 in biological media or simulants, a short-term inhalation study including extended recovery and the assessment of broncheoalveolar lavage, and an oral subchronic study).

66. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

67. In order to decide on the fourth, fifth and sixth pleas, the Board of Appeal will examine (i) whether the Agency was entitled to conclude that the Appellant's registration dossier has data-gaps under Section 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X (Section 2.1. below); and (ii) the consequences of such data-gaps if they exist (Section 2.2. below)**.**

2.1. Whether the Appellant's registration dossier has data-gaps

68. When examining the merits of a case, the Board of Appeal confines itself, in principle, to examining whether the pleas put forward by an appellant demonstrate that the contested decision is vitiated by an error (see paragraph 30 above).

69. The Notice of Appeal contains no arguments contesting the Agency's finding that the Appellant's registration dossier has data-gaps under Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X. In the Notice of Appeal, the Appellant argues that these data-gaps can be filled by means other than PNDT studies in a first and second species and an EOGRTS.

70. The Appellant raised arguments contesting the Agency's finding that the Appellant's registration dossier has data-gaps only in its reply to questions from the Board of Appeal and in the hearing. Those arguments, however, constitute a new plea that is not based on new matters of fact or law that came to light in the course of the proceedings. They are consequently inadmissible pursuant to Article 12(2) of the Rules of Procedure.

71. There is therefore no need for the Board of Appeal to examine the correctness of the finding, in the Contested Decision, that the Appellant's registration dossier has data-gaps under Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X.

72. In any event, the Agency was entitled to conclude that the Appellant's registration dossier has data-gaps for the following reasons.

73. A registrant who submits an adaptation must 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 (see paragraph 35 above).

- *Sections 8.7.2. of Annexes IX and X*

74. In its registration dossier, the Appellant provided the following adaptation for the information requirements set out in Sections 8.7.2. of Annexes IX and X:

'*In accordance with Section 1.2 of REACH Annex XI, there is sufficient weight of evidence from several independent sources of information leading to the conclusion that Pigment Red 112 does not cause developmental toxicity and thus does not have to be classified, because*

- *Pigment Red 112 is a chemically unreactive substance,*
- *Pigment Red 112 can be considered insoluble because it has an extremely low solubility in water and noctanol,*
- *due to its extremely low solubility, it is unlikely that Pigment Red 112 becomes systemically bioavailable after oral, dermal or inhalation exposure,*

- *Pigment Red 112 caused no systemic toxic effects in a 28-day oral gavage study in rats (NOAEL 1000 mg/kg/day) and there was no evidence of absorption of the substance,*
- *Pigment Red 112 does not have to be classified as skin sensitizing (refering to the pigment as such, notwithstanding possible effects of impurities) or as skin or eye irritating, indicating that its chemical inertness and extremely low solubility in water and n-octanol largely prevent interaction with living cells and tissues,*

It can therefore be concluded with sufficient certainty that Pigment Red 112 will not cause developmental toxicity and that testing carried out on one or two species in a Prenatal Developmental Toxicity Study is not scientifically necessary.'

75. The Appellant's adaptation for Sections 8.7.2. of Annexes IX and X is expressly based on Section 1.2. of Annex XI. It must therefore be assessed against the requirements of that provision as it is not incumbent upon the Agency to develop or improve adaptations on a registrant's behalf (see paragraph 37 above).

76. The requirements for a general adaptation under Section 1.2. of Annex XI must be read in conjunction with the specific information requirement in Annexes VII to X which the adaptation seeks to fulfil (see paragraph 39 above).

77. Sections 8.7.2. of Annexes IX and X aim to identify and characterise the toxicological properties of a substance resulting from gestational exposure of the developing (mammalian) organisms and the dam.

78. Therefore, in order to apply an adaptation under Section 1.2. of Annex XI to Sections 8.7.2. of Annexes IX and X, a registrant must demonstrate that available information is sufficient to identify and characterise the toxicological properties of a substance resulting from gestational exposure of the developing (mammalian) organisms and the dam.

79. First, the Appellant's adaptation refers to a 28-day oral gavage study in rats. However, given the difference in exposure duration, number of animals and investigated parameters, such a study is not sufficient on its own to identify and characterise the toxicological properties of a substance resulting from gestational exposure of the developing (mammalian) organisms and the dam.

80. Second, the Appellant's adaptation states, in essence, that Pigment Red 112 (i) is chemically unreactive; (ii) has an extremely low solubility in water and n-octanol and is therefore unlikely to become systemically bioavailable; and (iii) is neither a skin sensitiser nor a skin or eye irritant, indicating that its chemical inertness and extremely low solubility in water and n-octanol largely prevent interaction with living cells and tissues. However, (i) if a substance is chemically unreactive, this does not necessarily mean that it is toxicologically inert: it cannot be excluded that Pigment Red 112 and/or its metabolites may have toxicologically relevant effects; (ii) Pigment Red 112 has a measurable solubility in water (9.8 µg/L) and in n-octanol (3.31 mg/L) and an octanol-water coefficient of 2.5, indicating some potential for absorption; (iii) the fact that Pigment Red 112 is neither a skin sensitiser nor a skin or eye irritant provides no information allowing the identification and characterisation of the toxicological properties of a substance resulting from gestational exposure of the developing (mammalian) organisms and the dam.

81. Therefore, the information supporting the Appellant's adaptation is insufficient to identify and characterise the toxicological properties of Pigment Red 112 resulting from gestational exposure of the developing (mammalian) organisms and the dam.

82. It follows that the Agency did not make an error in concluding, in the Contested Decision, that the Appellant's registration dossier has data-gaps under Sections 8.7.2. of Annexes IX and X.

- *Section 8.7.3. of Annex X*

83. In its registration dossier, the Appellant provided the following adaptation for the information requirement set out in Section 8.7.3. of Annex X:

'*In accordance with Section 1.2 of REACH Annex XI, there is sufficient weight of evidence from several independent sources of information leading to the conclusion that Pigment Red 112 does not cause toxicity to reproduction and thus does not have to be classified, because*

- *Pigment Red 112 is a chemically unreactive substance,*
- *Pigment Red 112 can be considered insoluble because it has an extremely low solubility in water and n-octanol,*
- *due to its extremely low solubility, it is unlikely that Pigment Red 112 becomes systemically bioavailable after oral, dermal or inhalation exposure,*
- *Pigment Red 112 caused no systemic toxic effects in a 28-day oral gavage study in rats (NOAEL 1000 mg/kg/day) and there was no evidence of absorption of the substance,*
- *Pigment Red 112 does not have to be classified as skin sensitizing (refering to the pigment as such, notwithstanding possible effects of impurities) or as skin or eye irritating, indicating that its chemical inertness and extremely low solubility in water and n-octanol largely prevent interaction with living cells and tissues,*

It can therefore be concluded with sufficient certainty that Pigment Red 112 will not cause toxicity to reproduction and that testing is not scientifically necessary.'

84. The Appellant's adaptation for Section 8.7.3. of Annex X is expressly based on Section 1.2. of Annex XI. It must therefore be assessed against the requirements of that provision as it is not incumbent upon the Agency to develop or improve adaptations on a registrant's behalf (see paragraph 37 above).

85. The requirements for a general adaptation under Section 1.2. of Annex XI must be read in conjunction with the specific information requirement in Annexes VII to X which the adaptation seeks to fulfil (see paragraph 39 above).

86. Section 8.7.3. of Annex X requires registrants to submit information that allows the identification and characterisation of the toxicological properties of a substance to parents and their offspring resulting from a direct exposure of the adults to that substance from premating until weaning of their offspring, and direct exposure of the offspring at least from weaning until their adulthood.

87. Therefore, in order to apply an adaptation under Section 1.2. of Annex XI to Section 8.7.3. of Annex X, a registrant must demonstrate that the information already available on a substance allows to identify and characterise the toxicological properties of a substance to parents and their offspring resulting from a direct exposure of the adults to that substance from premating until weaning of their offspring, and direct exposure of the offspring at least from weaning until their adulthood.

88. First, the Appellant's adaptation refers to a 28-day oral gavage study in rats. However, given the difference in exposure duration, number of animals and investigated parameters, such a study is not sufficient on its own to allow the identification and

characterisation of the toxicological properties of a substance to parents and their offspring resulting from a direct exposure of the adults to that substance from premating until weaning of their offspring, and direct exposure of the offspring at least from weaning until their adulthood.

89. Second, the Appellant's adaptation states, in essence, that Pigment Red 112 (i) is chemically unreactive; (ii) has an extremely low solubility in water and n-octanol and is therefore unlikely to become systemically bioavailable; and (iii) is neither a skin sensitiser nor a skin or eye irritant, indicating that its chemical inertness and extremely low solubility in water and n-octanol largely prevent interaction with living cells and tissues. However, (i) if a substance is chemically unreactive, this does not necessarily mean that it is toxicologically inert, and it cannot be excluded that Pigment Red 112 and/or its metabolites may have toxicologically relevant effects; (ii) Pigment Red 112 has a measurable solubility in water (9.8 µg/L) and in n-octanol (3.31 mg/L) and an octanol-water coefficient of 2.5, indicating some potential for absorption; (iii) the fact that Pigment Red 112 is neither a skin sensitiser nor a skin or eye irritant provides no information allowing the identification and characterisation of the toxicological properties of a substance to parents and their offspring resulting from a direct exposure of the adults to that substance from premating until weaning of their offspring, and direct exposure of the offspring at least from weaning until their adulthood.

90. Therefore, the information supporting the Appellant's adaptation is insufficient to allow the identification and characterisation of the toxicological properties of a substance to parents and their offspring resulting from direct exposure of the adults to that substance from premating until weaning of their offspring, and direct exposure of the offspring at least from weaning until their adulthood.

91. It follows that the Agency did not make an error in concluding, in the Contested Decision, that the Appellant's registration dossier has a data-gap under Section 8.7.3. of Annex X.

2.1. Consequences of any data-gaps

92. In the Contested Decision, the Agency required the Appellant to bring its dossier into compliance with Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X by submitting information on PNDT studies in a first and second species and an EOGRTS or, alternatively, acceptable adaptations.

93. The Appellant argues that the Agency committed an error of assessment and breached the principle of proportionality and Article 25 because it failed to require the Appellant to generate, as a first step, information that would make the Appellant's adaptations comply with Section 1.2. of Annex XI.

94. In the present case, the Agency concluded, without committing an error, that the Appellant's registration dossier has data-gaps under Sections 8.7.2. of Annexes IX and X and Section 8.7.3. of Annex X (see Section 2.1. above).

95. The consequences of this finding flow directly from the REACH Regulation. Pursuant to Article 10(a)(vi), read in conjunction with Sections 8.7.2. of Annexes IX and X, Section 8.7.3. of Annex X, and Annex XI, the Appellant is obliged to submit either information on PNDT studies in a first and second species and an EOGRTS or, alternatively, an acceptable adaptation.

96. As a consequence, the Agency was neither required nor empowered to consider whether it is proportionate, or consistent with Article 25, for the Appellant to be required to submit this information (see paragraph 51 above).

97. In any event, as stated in the operative part of the Contested Decision, the Appellant can still *'adapt the testing requested […] according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI […]'*. Therefore, the Contested Decision does not prevent the Appellant from performing the short-term studies which it proposes and consequently submitting an improved adaptation instead of information on PNDT studies in a first and second species and an EOGRTS. Improved adaptations would be assessed in accordance with the follow-up procedure under Article 42 (see paragraph 52 above).

98. The fourth, fifth and sixth pleas must therefore be rejected.

3. Seventh to tenth pleas, concerning the fifth and sixth information requirements (Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX)

99. The Appellant included in its registration dossier an alga growth inhibition study (the 'OECD TG 201 study') and a *daphnia magna* reproduction study (the 'OECD TG 211 study') to fulfil, respectively, the information requirements set out in Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX.

100. In the Contested Decision, the Agency found that those studies were not conducted in accordance with the relevant test methods because the concentration of Pigment Red 112 in the test systems was not verified analytically at the beginning or during the conduct of the studies. The Agency therefore required the Appellant to bring its dossier into compliance with Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX by submitting information on a growth inhibition study on aquatic plants and a long-term toxicity test on aquatic invertebrates or, alternatively, acceptable adaptations.

Arguments of the Parties

101. The Appellant's seventh to tenth pleas concern the fifth and sixth information requirements.

102. By its seventh plea, the Appellant argues that the Agency committed two errors of assessment.

103. First, according to the Appellant, the Agency failed to recognise that the OECD TG 201 and 211 studies contained in the Appellant's registration dossier were conducted correctly in accordance with, respectively, OECD test guidelines 201 and 211. The studies were moreover conducted in 2010 in accordance with the principles of good laboratory practice referred to in Article 13(4), and followed the relevant guidance available at the time (*Guidance document on aquatic toxicity testing of difficult substances and mixtures*, OECD Series on testing and assessment No 23, September 2000). The studies were also assessed by the Appellant as being reliable without restriction (Klimisch score 1).

104. Second, according to the Appellant, the Contested Decision refers to an OECD guidance document that did not exist at the time the studies were carried out (*Guidance on sample preparation and dosimetry for the safety testing of manufactured nanomaterials*, OECD guidance document No 36, December 2012). Moreover, that document applies to the testing of nanomaterials whilst the substance is not a nanomaterial.

105. By its eighth plea, the Appellant argues that the Agency breached the principle of proportionality by requiring it to repeat the OECD TG 201 and 211 studies without this being necessary.

106. By its ninth plea, the Appellant argues that its legitimate expectations were infringed. The Agency recognised during the decision-making procedure that Pigment Red 112 is not a nanomaterial. Nevertheless, in its assessment of the OECD TG 201 and 211 studies contained in the Appellant's registration dossier the Agency applied OECD guidance document No 36, which is specific to nanomaterials.

107. By its tenth plea, the Appellant argues that the Agency breached the principle of equal treatment by treating Pigment Red 112 differently than two structurally similar substances, namely 1-[2,4-dinitrophenyl)azo]-2-naphtol (EC No 222-429-4, CAS No 3468-63-1; 'Pigment Orange 5'), and 1-(4-methyl-2-nitrophenylazo)-2-naphtol (EC No 219-372-2, CAS No 2425-85-6; 'Pigment Red 3'). According to the Appellant, the Agency did not apply OECD guidance document No 36 during the compliance check of the registration dossiers for those two substances.

108. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

3.1. Error of assessment in finding that the OECD TG 201 and 211 studies do not comply with the relevant test methods

109. By its seventh plea, the Appellant argues that the Agency committed an error of assessment because the Appellant's registration dossier already contained the OECD TG 201 and 211 studies required under Column 1 of Section 9.1.2. of Annex VII and Column 1 of Section 9.1.5. of Annex IX.

110. Article 13(3) provides that '*where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate*'.

111. OECD test guidelines 201 and 211 have been recognised by the Agency as being appropriate to satisfy the requirements of, respectively, Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX (see *Guidance on Information Requirements and Chemical Safety Assessment*, Chapter R.7.8.4.1. and Appendix R.7.8-2).

112. The Agency has the power to verify, under Article 41, that a study included in a registration dossier was conducted correctly in accordance with the relevant test method (see *Climax Molybdenum*, cited in paragraph 51 above, paragraphs 40 to 52).

113. The Agency was therefore entitled to examine whether the OECD TG 201 and 211 studies in the Appellant's registration dossier were performed in compliance with, respectively, OECD test guideline 201 and 211.

114. The OECD TG 201 and 211 studies were performed and submitted by the Appellant in 2010. Their compliance with the relevant test method must therefore be assessed with regard to OECD test guidelines 201 and 211 as they were in 2010.

115. The version of OECD test guideline 201, as it was in 2010, provides:

> '*[36] Provided an analytical procedure for determination of the test substance in the concentration range used is available, the test solutions should be analysed to verify the initial concentrations and maintenance of the exposure concentrations during the test*'.

116. Similarly, OECD test guideline 211, as it was in 2010, provides:

'*[46] During the test, the concentrations of test substance are determined at regular intervals.*'

117. As is apparent from the robust study summaries and full study reports submitted to the Board of Appeal, the concentration of Pigment Red 112 in the test systems was not verified analytically at the beginning or during the conduct of the OECD TG 201 and 211 studies.

118. The Appellant claims that, in 2010, there were no analytical procedures to measure the very small quantities of Pigment Red 112 which would have been present in the test systems. The Agency claims that such methods were available.

119. The burden of proof to establish that a contested decision was vitiated by an error rests on an appellant. However, an appellant cannot be required to prove that no analytical procedure was available at a certain point in time, as the burden of such proof would be excessively difficult or even impossible to discharge. Therefore, if an appellant puts forward credible evidence that there were no appropriate analytical methods available, the burden of proving that an appropriate test method was available shifts onto the Agency.

120. In the present case, however, the Appellant has not put forward credible evidence that there were no appropriate analytical methods available in 2010 for the following reasons.

121. First, the Appellant states that no appropriate method was available. In particular, according to the Appellant, certain of the possible test methods identified by the Agency (such as HPLC UV VIS, various methods developed by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers, or the use of solvents to facilitate measurements) are not sufficiently sensitive and/or would damage the testing equipment insofar as they require the use of solvents. The Appellant has not, however, submitted any evidence to support these assertions.

122. Second, the Agency pointed out in these proceedings that the Appellant's registration dossier contains a study which suggests that there were sufficiently sensitive analytical methods available in 2010. Although this study was not submitted to the Board of Appeal, the Appellant has not contradicted the Agency on this point.

123. Third, the full study reports of the OECD TG 201 and 211 studies were submitted to the Board of Appeal during the course of these proceedings. These study reports do not contain any justification showing that analytical methods, or alternative approaches such as solvents or dispersants, were considered and tried in order to verify analytically the concentration of Pigment Red 112 in the test systems. The study reports simply state that '*[n]o analytical determination of the test item was carried out, due to the low water solubility of the test item*'.

124. In these circumstances, the Appellant has not established that the Agency's finding that the OECD TG 201 and 211 studies contained in the Appellant's registration dossier did not comply with the relevant test methods was vitiated by an error.

125. Furthermore, it is irrelevant whether the studies were conducted in accordance with the principles of good laboratory practice referred to in Article 13(4), followed the relevant guidance available at the time or were assessed as being reliable without restriction. These elements cannot disprove the shortcomings identified in paragraph 117 above.

126. Finally, the reason for finding that the Appellant's registration dossier has data-gaps under Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX is that the concentration of Pigment Red 112 in the test systems was not verified analytically at the beginning or during the conduct of the OECD TG 201 and 211 studies. This finding is independent of the fact that OECD guidance document No 36 did not exist at the time

the OECD TG 201 and 211 studies were performed or submitted by the Appellant. It is therefore irrelevant that the Contested Decision refers to OECD guidance document No 36.

127. It follows that the Appellant has not established that the Agency made an error in concluding, in the Contested Decision, that the Appellant's registration dossier has data-gaps under Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX.

128. The seventh plea must consequently be rejected.

3.2. Breach of the principle of proportionality

129. By its eighth plea, the Appellant argues that the Agency breached the principle of proportionality by requiring it to repeat the OECD TG 201 and 211 studies without this being necessary.

130. In the present case, the Agency concluded, without committing an error, that the Appellant's registration dossier has data-gaps under Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX (see Section 3.1. above).

131. The consequences of this finding flow directly from the REACH Regulation. Pursuant to Article 10(a)(vi), read in conjunction with Section 9.1.2. of Annex VII, Section 9.1.5. of Annex IX, and Annex XI, the Appellant is obliged to submit either information on a growth inhibition study on aquatic plants and long-term toxicity testing on invertebrates in accordance with a relevant test method or, alternatively, an acceptable adaptation.

132. As a consequence, the Agency was neither required nor empowered to consider whether it is proportionate for the Appellant to be required to submit this information (see paragraph 51 above).

133. The eighth plea must therefore be rejected.

3.3. Breaches of the principles of the protection of legitimate expectations and equal treatment

134. By its ninth and tenth pleas, the Appellant argues that the Agency infringed the Appellant's legitimate expectations and the principle of equal treatment by applying OECD guidance document No 36 in its assessment of the OECD TG 201 and 211 studies.

135. However, OECD guidance document No 36 is not a reason for finding that the OECD TG 201 and 211 studies do not fulfil the information requirements set out in Section 9.1.2. of Annex VII and Section 9.1.5. of Annex IX (see paragraph 126 above).

136. Moreover, the operative part of the Contested Decision does not oblige the Appellant to carry out new studies in accordance with OECD Guidance Document No 36. If the Appellant chooses to carry out new studies, it is simply required to follow a test method laid down in Commission Regulation (EC) No 440/2008 or another international test method recognised by the Commission or the Agency as being appropriate.

137. The ninth and tenth pleas must therefore be rejected.

4. Eleventh plea, concerning the seventh information requirement (Section 9.1.6. of Annex IX)

138. The Appellant did not submit information on a fish early life-stage (FELS) toxicity test, a short-term toxicity test on embryo and sac-fry stages, or a juvenile growth test, under

Column 1 of Section 9.1.6. of Annex IX. Instead, the Appellant submitted a specific adaptation under Column 2 of Section 9.1. of Annex IX.

139. The Contested Decision rejected the Appellant's adaptation and therefore required the Appellant to bring its dossier into compliance with Section 9.1.6. of Annex IX by submitting information on a FELS toxicity test or, alternatively, an acceptable adaptation.

Arguments of the Parties

140. The Appellant's eleventh plea concerns the seventh information requirement. By this plea, the Appellant argues that the Contested Decision breaches Article 25 because its registration dossier contains a valid specific adaptation in accordance with Column 2 of Section 9.1. of Annex IX.

141. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

142. In its registration dossier, the Appellant provided the following adaptation for the information requirement set out in Section 9.1.6. of Annex IX:

'*Waiving according to [Column 2 of Section 9.1. of Annex IX] (long term toxicity test on daphnia available – [the chemical safety assessment carried out under Annex I] does not indicate need for further investigations)*.'

143. The Appellant's chemical safety report, which summarises the chemical safety assessment carried out under Annex I, states:

'*Derivation of PNEC is not possible. Justification: The substance was tested in concentrations far above its water solubility. No effects were observed in all test systems. Consequently, no LOEC, NOEC, or ECx-value can be calculated. Since this data is a prerequisite to estimate a PNEC it is not possible to derive this value.*'

144. The Agency rejected the Appellant's adaptation on the grounds that it does not comply with Column 2 of Section 9.1. of Annex IX. Specifically, according to the Contested Decision, the Appellant's chemical safety assessment does not establish that there is no need to carry out one of the three studies in question because '*due to the substance properties and lack of information on the short term toxicity to aquatic organisms at this stage the chemical safety assessment (CSA) is not complete*'.

145. The Appellant and the Agency therefore rely on two different interpretations of Column 2 of Section 9.1. of Annex IX.

146. On the one hand, the Appellant argues that Column 2 of Section 9.1. of Annex IX constitutes a '*trigger*' for the obligation to carry out one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX: a registrant is required to submit information on one of those studies only if its chemical safety assessment indicates the need to investigate further the effects on aquatic organisms. According to the Appellant, this '*trigger*' was not set off in the present case.

147. On the other hand, the Agency argues that Column 2 of Section 9.1. of Annex IX constitutes a possible '*waiver*' for the obligation to carry out one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX: a registrant may forgo submitting information on one of those studies if its chemical safety assessment indicates that there is no need to investigate further the effects on aquatic organisms. According to the Agency, the conditions for this '*waiver*' were not met in the present case.

148. In order to decide on the Appellant's plea concerning the seventh information requirement – namely that the Agency breached Article 25 by requiring information on a study on fish despite the fact that the Appellant's dossier contained a valid adaptation – it is therefore necessary to examine the interpretation of Column 2 of Section 9.1. of Annex IX.

149. In interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 19 September 2019, *Gesamtverband Autoteile-Handel*, C-527/18, EU:C:2019:762, paragraph 30).

- *Wording*

150. Column 2 of Section 9.1. of Annex IX provides:

'Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.'

151. This wording could bear three fundamentally different meanings.

152. First, as the Appellant argues, Column 2 of Section 9.1. of Annex IX could be read as meaning that registrants are not required to submit information on one of the studies listed in Column 1 of Section 9.1.6. of Annex IX unless their chemical safety assessment indicates that it is necessary to investigate further the effects on aquatic organisms.

153. Second, as the Agency argues, Column 2 of Section 9.1. of Annex IX could be read as meaning that registrants are required to submit information on one of the studies listed in Column 1 of Section 9.1.6. of Annex IX unless their chemical safety assessment indicates that it is necessary to investigate further the effects on aquatic organisms.

154. Third, Column 2 of Section 9.1. of Annex IX could be read as meaning that registrants are required to submit information on a further study than one of those listed in Column 1 of Section 9.1.6. of Annex IX, if their chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do.

155. In order to determine which of these interpretations is correct, it is necessary to examine the context and objectives of Column 2 of Section 9.1. of Annex IX.

- *Context*

156. The information requirements set out in Annexes VII to X are cumulative and must therefore be read as a whole (see *Lanxess Deutschland*, cited in paragraph 35 above, paragraph 72).

157. In addition to Section 9.1. of Annex IX, information requirements for aquatic toxicity are to be found in Sections 9.1. of Annexes VII, VIII, and X.

158. Sections 9.1. of Annexes VII and X do not however provide for any testing on fish and can therefore the disregarded for the purposes of the present decision. Sections 9.1. of Annexes VIII and IX, by contrast, provide for testing on fish and therefore constitute relevant context for the purposes of this decision.

159. Insofar as is relevant, Section 9.1. of Annex VIII provides:

Column 1 *Standard information required*	*Column 2* *Specific rules for adaptation from Column 1*
9.1.3. Short-term toxicity testing on fish: the registrant may consider long-term toxicity testing instead of short-term.	9.1.3. The study does not need to be conducted if: - there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, or - a long-term aquatic toxicity study on fish is available. Long-term aquatic toxicity testing as described in Annex IX shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment. The long-term aquatic toxicity study on fish (Annex IX, Section 9.1.6) shall be considered if the substance is poorly water soluble.

160. Insofar as is relevant, Section 9.1. of Annex IX provides:

Column 1 *Standard information required*	*Column 2* *Specific rules for adaptation from Column 1*
9.1. Aquatic toxicity	*9.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.* [N.b.: This is the provision under examination.]
9.1.5. […]	
9.1.6. Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements) *The information shall be provided for one of the Sections 9.1.6.1, 9.1.6.2 or 9.1.6.3.*	
9.1.6.1. Fish early-life stage (FELS) toxicity test	
9.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages	
9.1.6.3. Fish, juvenile growth test	

161. Read together, Sections 9.1. of Annexes VIII and IX give rise to the following considerations.

162. Column 1 of Section 9.1.6. of Annex IX requires registrants to provide information on a fish early-life stage (FELS) toxicity test, a fish short-term toxicity test on embryo and sac-fry stages, or a fish juvenile growth test. These three studies have a longer duration

than the short-term test required under Section 9.1.3. of Annex VIII. They have an approximate total duration, depending on the species, of 28 to 60 days (FELS test), 7 to 55 days (short-term toxicity test on embryo and sac-fry stages), and ≥ 28 days (juvenile growth test).

163. Some aquatic toxicity studies on fish have a longer duration than any of those three studies. For example, OECD test guideline 234 requires studies to continue until sexual differentiation in the control group is completed (60 days post hatching for Japanese medaka, the three-spined stickleback and zebrafish). Such studies may be needed in order to '*investigate further*' the properties of a substance in the light of prolonged exposure and/or different study designs.

164. Read as a whole – and without prejudice to the other possibilities for adaptation set out in Annexes VIII, IX, and XI – the standard information requirements for aquatic toxicity testing on fish are therefore as follows:

- short-term toxicity testing on fish (Column 1 of Section 9.1.3. of Annex VIII), or
- long-term toxicity testing on fish (Column 1 of Section 9.1.6. of Annex IX), or
- longer-term and/or more extensive toxicity testing on fish (Column 2 of Section 9.1. of Annex IX).

165. Under Sections 9.1. of Annexes VIII and IX, therefore, a registrant can forgo a certain toxicity test on fish if it provides, instead, a longer-term and/or more extensive toxicity test on fish based on the results of its chemical safety assessment.

166. This chain of cross-references between information requirements culminates in Column 2 of Section 9.1. of Annex IX, which requires registrants to submit information on a longer-term and/or more extensive toxicity test on fish – and forgo the shorter-term or less extensive tests – if the chemical safety assessment shows that this is necessary.

167. This can be illustrated with two examples.

168. As a first example, a registrant at the Annex VIII level is required to carry out, as a standard information requirement, a short-term toxicity test on fish under Column 1 of Section 9.1.3. of Annex VIII. However, if its chemical safety assessment indicates that it is necessary to investigate the effects of the registered substance on aquatic organisms further than the short-term toxicity test on fish would do, then that registrant must provide information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX. Finally, if that same chemical safety assessment shows that none of these three tests would address the effects under consideration, then the registrant must provide information on a longer-term and/or more extensive toxicity test on fish under Column 2 of Section 9.1. of Annex IX. In all cases, if the registrant provides information on a higher tier test, it may forgo the lower tier tests.

169. As a second example, a registrant at the Annex IX or X level (such as the Appellant) is required to carry out, as a standard information requirement, one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX. It may consequently forgo providing information on a short-term toxicity test on fish under Column 1 of Section 9.1.3. of Annex VIII. However, if its chemical safety assessment shows that it is necessary to investigate the effects of the registered substance on aquatic organisms further than one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX would do, then the registrant must provide information on a longer-term and/or more extensive toxicity testing on fish under Column 2 of Section 9.1. of Annex IX.

170. It is therefore clear from its context that Column 2 of Section 9.1. of Annex IX is neither a '*trigger*' (as the Appellant argues), nor a '*waiver*' (as the Agency argues) for the

requirement to submit information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX. Instead, Column 2 of Section 9.1. of Annex IX requires registrants to submit information on a further study than one of the three listed in Column 1 of Section 9.1.6. of Annex IX, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do.

- *Objectives*

171. Section 9.1. of Annex IX is part of Annexes VII to X. These Annexes require manufacturers and importers of substances to generate and submit to the Agency information on the intrinsic properties of the substances they manufacture or import.

172. This, in turn, contributes to achieving a high level of protection of human health and the environment, which is the main objective of the registration and dossier evaluation provisions in the REACH Regulation (see, to this effect, judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 45).

173. Following the interpretation of Column 2 of Section 9.1. of Annex IX set out in paragraph 162 to 170 above, registrants of substances at the Annex IX level are required to generate and submit at least the standard information set out in Column 1 of Section 9.1.6. of Annex IX, and may be required to generate and submit further information when the chemical safety assessment shows that this is necessary. Such an outcome is consistent with the objectives of Annexes VII to X.

174. The objectives of Annexes VII to X therefore confirm that Column 2 of Section 9.1. of Annex IX must be interpreted as meaning that registrants are required to submit information on a further study than one of those listed in Column 1 of Section 9.1.6. of Annex IX, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do.

- *Conclusion*

175. Based on its wording, context and objectives, Column 2 of Section 9.1. of Annex IX must be interpreted as meaning that registrants are required to submit information on a further study than one of the three listed in Column 1 of Section 9.1.6. of Annex IX, if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any one of those three studies would do.

176. In the Contested Decision, the Agency rejected the Appellant's adaptation on the grounds that it did not meet the conditions for '*waiving*' the information requirement set out in Column 1 of Section 9.1.6. of Annex IX (see paragraph 144 above). That reasoning is based on an incorrect interpretation of Column 2 of Section 9.1. of Annex IX.

177. Nevertheless, although the Agency's reasons for rejecting the Appellant's adaptation were incorrect, the Agency's conclusion was not.

178. The Appellant's adaptation states that there is no need to conduct any of the three long-term fish tests listed in Column 1 of Section 9.1.6. of Annex IX because the Appellant's chemical safety assessment '*does not indicate need for further investigations*.'

179. However, Column 2 of Section 9.1. of Annex IX does not allow registrants to forgo submitting information on one of the three studies listed in Column 1 of Section 9.1.6.

of Annex IX on the grounds that the chemical safety assessment does not establish that this information is not necessary.

180. The Agency was therefore entitled to conclude that the Appellant's adaptation does not comply with the requirements of Column 2 of Section 9.1. of Annex IX, and that the Appellant's registration dossier has a data-gap in this regard. As a consequence, the Agency did not breach Article 25 by requiring the Appellant to fill this data-gap.

181. The eleventh plea must consequently be rejected.

5. Result

182. As all the Appellant's pleas have been rejected, the appeal must be dismissed in its entirety.

Refund of the appeal fee

183. Pursuant to Article 10(4) of 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), if an appeal is dismissed the appeal fee is not refunded. As this appeal is dismissed, the appeal fee is not refunded.

Effects of the Contested Decision

184. The Contested Decision set the following deadlines:

- 16 April 2019 (one year and seven days from the date of the Contested Decision) for a 90-day subchronic toxicity study,
- 18 October 2021 (three years, six months and nine days from the date of the Contested Decision) for an EOGRTS, unless the Agency informs the Appellant by 16 July 2019 (one year, three months and seven days from the date of the Contested Decision) that an EOGRTS need not be performed, and
- 18 October 2021 (three years, six months and nine days from the date of the Contested Decision) for the remaining studies.

185. Pursuant to Article 91(2), an appeal has suspensive effect. The deadlines 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.

186. The Appellant must therefore provide the information required by the Contested Decision by:

- 11 May 2021 for a 90-day subchronic toxicity study,
- 13 November 2023 for an EOGRTS unless the Agency informs the Appellant by 11 August 2021 that an EOGRTS need not be performed, and
- 13 November 2023 for the remaining studies.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information required by the Contested Decision must be submitted by:**
   - **11 May 2021 for a 90-day subchronic toxicity study,**
   - **13 November 2023 for an EOGRTS unless the Agency informs the Appellant by 11 August 2021 that an EOGRTS need not be performed, and**
   - **13 November 2023 for the remaining studies.**
3. **Decides that the appeal fee is not refunded.**

Andrew FASEY
On behalf of the Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal