ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

19 January 2021

(Dossier evaluation – Compliance check – Section 9.1. of Annex IX – Requirements for aquatic toxicity testing on fish)

Case number	A-010-2019
Language of the case	English
Appellant	Croda Iberica SA, Spain
Representatives	Ruxandra Cana, Eléonore Mullier and Filippo Mattioli Steptoe & Johnson LLP, Belgium
Contested Decision	CCH-D-2114460730-54-01/F of 24 April 2019 adopted by the European Chemicals Agency (the '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 Antoine Buchet (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns a compliance check of the Appellant's registration dossier for the substance propane-1,2,3-triyl 3,5,5-trimethylhexanote (EC No. 260-257-1, CAS No. 56554-53-1; the 'Substance').

2. The Appellant is the lead registrant for the Substance and registered it at the 100 to 1000 tonnes per year tonnage band.

3. On 28 September 2017, 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. As regards ecotoxicological information, the Appellant's registration dossier did not contain information on a long-term toxicity testing on fish, pursuant to Section 9.1.6. of Annex IX. Instead, the Appellant submitted an adaptation of this standard information requirement on the basis of Column 2 of Section 9.1. of Annex IX. The Appellant argued that the chemical safety assessment of the Substance does not indicate a need to investigate further its effects on aquatic organisms.

5. On 10 April 2018, the Agency notified a draft decision to the Appellant in accordance with Article 50(1). In this draft decision the Agency rejected the Appellant's adaptation of the standard information requirement of Section 9.1.6. of Annex IX. The Agency stated that, based on the chemical safety report included in the Appellant's registration dossier, *'the risk for the aquatic life cannot be excluded*'.

6. On 17 May 2018, the Appellant submitted comments on the draft decision. The Agency did not revise its draft decision and notified it to the competent authorities of the Member States in accordance with Article 51(1).

7. A proposal for amendment was received from one Member State competent authority. It proposed adding a new request for a growth inhibition study on aquatic plants (OECD test guideline ('TG') 201) to the decision.

8. On 30 November 2018, the Agency invited the Appellant to comment on the proposal for amendment pursuant to Article 51(5). The Appellant did not provide further comments.

9. The Member State Committee reached unanimous agreement on the draft decision at its meeting of 5 to 7 February 2019.

10. On 24 April 2019, the Agency adopted the Contested Decision in accordance with Article 51(6).

Contested Decision

11. The Contested Decision states:

    '*Based on Article 41 […], [the Agency] requests you to submit information on:*

    1. Composition of the [Substance] (Annex VI, Section 2.3.);

    – Nature of impurities, including isomers and by-products [the 'first information requirement']

2. *Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD [421/422]) in rats, oral route with the [Substance] [the 'second information requirement'];*

3. *Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats with the [Substance] [the 'third information requirement'];*

4. *Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the [Substance] [the 'fourth information requirement'];*

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

6. *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 [Substance] [the 'sixth information requirement' or the 'FELS test'];*

You have to submit the requested information in an updated registration dossier by 2 November 2021. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.'

Procedure before the Board of Appeal

12. On 22 July 2019, the Appellant filed this appeal. In the Notice of Appeal, the Appellant contested the second, third, fourth and sixth information requirements.

13. On 21 August 2019, the Executive Director of the Agency partly rectified the Contested Decision by removing the second, third and fourth information requirements.

14. On 13 September 2019, the Registry of the Board of Appeal was informed by the Appellant that it wished to continue with the appeal with regard to the sixth information requirement, concerning the FELS test.

15. On 4 November 2019, the Agency submitted its Defence.

16. On 24 February 2020, the Appellant submitted its observations on the Defence and replied to written questions from the Board of Appeal.

17. On 6 April 2020, the Agency submitted its observations on the Appellant's observations on the Defence.

18. On 28 May 2020, the Parties were invited to submit their observations on the consequences for the present appeal of the Decision of the Board of Appeal of 4 May 2020 in Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*.

19. On 18 June 2020, the Parties submitted their respective observations on this issue.

20. On the same date, Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Sari Haukka in this case, in accordance with the first subparagraph of Article 3(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; the 'Rules of Procedure').

21. On 1 October 2020, a hearing was held at the Appellant's request. The hearing was held by video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

22. The Appellant requests the Board of Appeal to:
    - annul the Contested Decision insofar as it requires the FELS test,
    - order the refund of the appeal fee, and
    - take such other or further measures as justice may require.
23. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

1. Relevant provisions

24. The first, second and third introductory paragraphs to Annex IX provide:

    'At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(d).

    Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 12(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes VII and VIII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

    In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex XI. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annex XI.

    […].'

25. Column 1 of Section 9.1.6. of Annex IX ('*Standard information required*') sets out the standard information requirements for long-term toxicity testing on fish. This information requirement can be fulfilled by providing information on one of the following studies: Section 9.1.6.1. FELS test; Section 9.1.6.2. Fish short-term toxicity test on embryo and sac-fry stages; Section 9.1.6.3. Fish, juvenile growth test.

26. Column 2 of Section 9.1. of Annex IX ('*Specific rules for adaptation from Column 1*') 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.'

27. The second introductory paragraph to Annex XI provides:

'*In addition to the specific rules set out in column 2 of Annexes VII to X, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex. Under dossier evaluation the Agency may assess these adaptations to the standard testing regime.*'

2. Examination of the Appellant's pleas

28. The Appellant argues that the Agency erred in rejecting the adaptation submitted by the Appellant under Column 2 of Section 9.1. of Annex IX (see paragraph 4 above) and requiring the Appellant to submit information on a FELS test. By doing so, the Agency:

a) committed an error of assessment and breached Column 2 of Section 9.1. of Annex IX; and

b) breached the principle of proportionality and Article 25.

2.1. First plea: the Agency committed an error of assessment and breached Column 2 of Section 9.1. of Annex IX by rejecting the adaptation submitted by the Appellant

Arguments of the Parties

29. 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 long-term toxicity tests on fish listed in Column 1 of Section 9.1.6 of Annex IX. A registrant is required to submit information on the long-term toxicity testing on fish under Column 1 of Section 9.1.6. of Annex IX only if the chemical safety assessment of the substance indicates the need to investigate further the effects on aquatic organisms.

30. The Appellant argues that this '*trigger*' was not set off in the present case as the chemical safety assessment of the Substance does not indicate a need to investigate further the effects on aquatic organisms by a long-term fish toxicity study.

31. The Appellant argues that it was therefore entitled to omit the standard information requirement set out in Column 1 of Section 9.1.6. of Annex IX based on a specific adaptation under Column 2 of Section 9.1. of Annex IX. Consequently, the Agency committed an error of assessment and breached Column 2 of Section 9.1. of Annex IX as it required information on the FELS test.

32. The Agency argues that Column 2 of Section 9.1. of Annex IX constitutes a possible '*waiver*' of 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. Based on the chemical safety report included in the Appellant's registration dossier '*the risk for the aquatic life cannot be excluded*' and therefore the Substance must be investigated further by performing a long-term toxicity test on fish.

Findings of the Board of Appeal

33. It is not disputed that the Appellant's registration dossier does not contain standard information on long-term toxicity on fish pursuant to Column 1 of Section 9.1.6. of Annex IX.

34. The Appellant considers, however, that there is no data-gap in its registration dossier as the chemical safety assessment of the Substance does not indicate a need to

investigate further the effects on aquatic organisms by a long-term fish toxicity study; that is to say, the conditions for the *'trigger'* referred to in paragraphs 29 to 31 above are not met in the present case.

35. The Agency, on the contrary, considers that there is a data-gap in the Appellant's registration dossier as the chemical safety assessment does not exclude a risk to aquatic life; that is to say, the conditions for the *'waiver'* referred to in paragraph 32 above are not met in the present case.

36. In order to decide on the Appellant's plea it is necessary to examine the information requirements for long-term toxicity testing on fish and the interpretation of Column 2 of Section 9.1. of Annex IX in particular.

a) Interpretation of Column 2 of Section 9.1. of Annex IX

37. Column 2 of Section 9.1. of Annex IX is neither a '*trigger*' nor a '*waiver*' 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 studies 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 the information that any of those three studies would provide (*Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 18 above, paragraphs 170 and 175 of the Decision; see also Case A-010-2018, *Symrise*, Decision of the Board of Appeal of 18 August 2020, paragraphs 186 to 189).

38. Column 2 of Section 9.1. of Annex IX allows a registrant to forgo submitting information on certain long-term toxicity tests on fish, listed in Column 1 of Section 9.1.6. of Annex IX, only if it provides, instead, a longer-term and/or more extensive toxicity test on fish consequent to the results of its chemical safety assessment (see *Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 18 above, paragraphs 165 and 166 of the Decision).

b) The Appellant's arguments challenging the interpretation of Column 2 of Section 9.1. of Annex IX

39. In its reply of 18 June 2020 to a written question from the Board of Appeal and at the hearing held on 1 October 2020, the Appellant submitted a series of arguments challenging the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above.

40. For the following reasons, these arguments must be rejected.

(i) Argument based on the wording of the Annexes

41. The Appellant argues that the second introductory paragraph to Annex IX, the titles of Columns 1 and 2 of Annex IX, and the second introductory paragraph to Annex XI demonstrate that Column 2 of Section 9.1. of Annex IX should be interpreted as an adaptation rule making it possible to omit the standard information required in Column 1 of Section 9.1.6. of Annex IX.

42. Column 1 of each of Annexes VII to X contains a list of standard information requirements. Column 2 of each of those Annexes contains a series of specific adaptation rules that apply to the standard information requirements. As stated in the introductory paragraphs to each of those Annexes, including Annex IX, according to those specific adaptation rules, a registrant of a substance '*may propose to omit the required standard*

information, replace it by other information, provide it at a later stage or adapt it in another way'.

43. Some of those specific adaptation rules allow for the standard information required in Column 1 to be omitted if the conditions set out in Column 2 are fulfilled.

44. As they constitute an exception from the legal obligation to provide standard information, the specific adaptation rules of Column 2 must be interpreted restrictively as regards the conditions under which the standard information referred to in Column 1 could be omitted (see, to this effect and by analogy, judgment of 10 November 2016, *Baštová*, C-432/15, EU:C:2016:855, paragraph 59, and judgment of 27 September 2017, *Puškár*, C-73/16, EU:C:2017:725, paragraph 38; see also Case A-006-2016, *SI Group UK and Others*, Decision of the Board of Appeal of 6 June 2018, paragraph 64).

45. Specific adaptation rules that allow standard information to be omitted are set out, for example, in Column 2 of Section 9.1.3. of Annex VIII which sets out specific conditions under which short-term toxicity testing on fish '*does not need to be conducted*'. There is no such explicit wording in Column 2 of Section 9.1. of Annex IX that could be interpreted as allowing the standard information required in Column 1 of Section 9.1. of Annex IX to be omitted.

46. By contrast, other specific adaptation rules in Column 2 of Annexes VII to X do not allow the standard information requirements set out in the corresponding Column 1 to be omitted but instead indicate that the standard information requirement can be replaced by other information, provided at a later stage or adapted in another way. These include specific adaptation rules which can trigger a requirement to perform further studies that go beyond the standard information requirements. Such further studies may be required for example on mutagenicity under Column 2 of Section 8.4. of Annex VII and on sub-chronic toxicity under Column 2 of Section 8.6.1. of Annex VIII.

47. The specific adaptation rule set out in Column 2 of Section 9.1. of Annex IX is a requirement to perform a further study if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond the information any of the three studies listed in Column 1 of Section 9.1.6. of Annex IX would provide (see paragraphs 37 and 38 above).

48. Contrary to the Appellant's argument, this interpretation of Column 2 of Section 9.1. of Annex IX is consistent with the introductory paragraphs to Annex IX. Column 2 of Section 9.1. of Annex IX contains a specific adaptation rule that allows the registrant to *'replace'* the standard information required under Column 1 *'by other information'.*

49. The titles of Columns 1 and 2 of Annex IX and the second introductory paragraph to Annex XI do not put this interpretation into question. As stated in paragraphs 46 to 48 above, an *'adaptation'* is not always a '*waiver*' but may in certain cases take the form of a requirement to perform a further study going beyond what is required under the standard information requirements set out in Column 1.

(ii) Argument based on the wording of Column 2 of Section 9.1. of Annex IX

50. The Appellant argues that the term '*long-term toxicity testing*' in Column 2 of Section 9.1. of Annex IX must be interpreted as referring to the tests in Column 1 of Section 9.1. of Annex IX. The Appellant argues that the word '*further*' in Column 2 of Section 9.1. of Annex IX does not have the same meaning as it has in the last paragraph of Column 2 of Section 8.6.2. of Annex IX. The Appellant argues that, in the last paragraph of Column 2 of Section 8.6.2. of Annex IX, '*further'* means that studies additional to those referred to in the corresponding Column 1 may be required. These arguments must be rejected for the following reasons.

51. First, the wording, context and objectives of Column 2 of Section 9.1. of Annex IX have been examined in a previous decision of the Board of Appeal (see *Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 18 above, paragraphs 150 to 174 of the Decision). Based on that examination, it has been held that under Column 2 of Section 9.1. of Annex IX the words *'long-term toxicity testing'* and *'further'* mean that a registrant of a substance may be required to submit information on a study that goes beyond the information what any of the three studies listed in Column 1 of Section 9.1.6. of Annex IX would provide (see paragraphs 37 and 38 above).

52. Second, if the Appellant's interpretation was followed, there would be no difference of any kind between the information requirements flowing from the application of Column 2 of Section 9.1. of Annex IX and the corresponding rules in Annex VIII.

53. The information requirements set out in Annexes VII to X are cumulative and must therefore be read as a whole (see Case A-004-2012, *Lanxess Deutschland*, Decision of the Board of Appeal of 10 October 2013, paragraph 72).

54. Under the second paragraph of Column 2 of Section 9.1.3. of Annex VIII, long-term aquatic toxicity testing is required if the chemical safety assessment for a substance indicates the need to investigate further the effects on aquatic organisms. This specific adaptation rule means that the information requirements may go beyond the short-term toxicity testing required under Column 1 of Section 9.1.3. of Annex VIII, with the requirement to perform the long-term aquatic toxicity testing described in Column 1 of Section 9.1. of Annex IX.

55. Under the specific adaptation rule set out in Column 2 of Section 9.1. of Annex IX, a study that has a longer duration than any of the three studies listed in Column 1 of Section 9.1.6. of Annex IX may be required to investigate the effects of a substance on aquatic organisms. Such a further study is required if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond what any of those three studies would do (see *Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 18 above, paragraphs 161 to 170 of the Decision).

56. The Appellant's interpretation, on the contrary, would deprive Annex IX of a large part of its effect as regards the examination of aquatic toxicity. Column 2 of Section 9.1. of Annex IX would have exactly the same consequence, insofar as long-term aquatic toxicity testing is concerned, as that described in Column 1 of Section 9.1. of Annex IX. Information which would be required at the Annex IX level, would then in all cases be the same as that required under Column 2 of Section 9.1.3. of Annex VIII. Such an interpretation would be in contradiction with the cumulative nature of the information requirements (see paragraph 53 above).

(iii) Argument based on the limits of the powers of the Agency

57. The Appellant argues that the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above extends the Agency's powers beyond the limits set out in Article 41. The Appellant argues that under Article 41 the Agency's powers are limited to examining the compliance of a registration dossier and the Agency is not empowered to request further studies than the standard information required in Column 1. This argument is both ineffective and based on an erroneous interpretation of the powers of the Agency.

58. First, this argument is ineffective in the present case as the Contested Decision does not require the Appellant to submit information on a further study under Column 2 of Section 9.1. of Annex IX. The Appellant is required by the Contested Decision to submit

information on a FELS test which is a standard information requirement under Column 1 of Section 9.1.6.1. of Annex IX.

59. Second, whilst the Appellant's argument goes beyond the scope of the present case and addresses a situation where a registrant would be required to submit information on a further study under Column 2 of Section 9.1. of Annex IX, it must be rejected for the following reasons.

60. The Agency's powers in the compliance check procedure under Article 41 depend on the nature and content of the information requirement against which a registration dossier is being examined. When the relevant information requirement concerns information on a study, and when that study or an acceptable adaptation has not been submitted by the registrant, the Agency's powers are limited to concluding that there is a data-gap in the registrant's dossier. The consequence of a data-gap flows directly from the REACH Regulation (see *Clariant Plastics & Coatings (Deutschland),* cited in paragraph 18 above, paragraphs 49 to 51 of the Decision).

61. By contrast, when a standard information requirement may be adapted by performing a further study, as is the case in Column 2 of Section 9.1. of Annex IX, the Agency enjoys a margin of discretion as to whether information on a further study is required (see Case A-005-2011, *Honeywell*, Decision of the Board of Appeal of 29 April 2013, paragraph 70 and *Symrise*, cited in paragraph 37 above, paragraphs 189 and 190 of the Decision).

62. When the conditions to require information on a further study under a specific adaptation rule, such as the one set out in Column 2 of Section 9.1. of Annex IX, are fulfilled, and where a testing proposal has not been submitted by the registrant in this respect, the Agency is empowered to require the registrant to submit information on a further study under Article 41.

(iv) Argument based on inconsistency with the duty of care

63. According to the introductory paragraph to Annex VI, the information requirements set out in Annexes VI to XI must be considered *'as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care'*.

64. The Appellant argues that under the duty of care a registrant of a substance has a general obligation to submit information on further studies if the chemical safety assessment of that substance indicates potential effects that have to be studied further. Therefore, according to the Appellant, the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above is inconsistent with the introductory paragraph to Annex VI and is not necessary to give effect to the objective of the REACH Regulation of achieving a high level of protection of human health and the environment. In other words, the Appellant argues that the duty of care is sufficient to oblige a registrant to provide more information on a substance if there is a human health or environmental effect that needs to be studied further. This argument is both ineffective and based on an erroneous interpretation of the principle of duty of care.

65. First, this argument is ineffective in the present case as the Contested Decision does not require the Appellant to submit information on a further study under Column 2 of Section 9.1. of Annex IX. The Appellant is required by the Contested Decision to submit information on a FELS test which is a standard information requirement under Column 1 of Section 9.1.6.1. of Annex IX.

66. Second, whilst the Appellant's argument goes beyond the scope of the present case and addresses a situation where a registrant would be required to submit information on a

further study under Column 2 of Section 9.1. of Annex IX, it must be rejected for the following reasons.

67. The duty of care does not replace the requirements in the REACH Regulation for the manufacturer or importer of a substance to submit the information required for registration purposes. The duty of care also does not enable the registrant of a substance to forgo any of the information requirements set out in Annexes VII to X.

68. Therefore, the Appellant's argument cannot call into question the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above. This interpretation is necessary to establish that Column 2 of Section 9.1. of Annex IX defines a specific information requirement to be fulfilled by a registrant in cases where there is a need to investigate the effects of a substance on aquatic organisms beyond what any of the three studies referred to in Column 1 of Section 9.1.6. of Annex IX would do.

(v) Argument based on legal uncertainty

69. The Appellant argues that the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above places the Appellant in a position of legal uncertainty. This is because it would remain unclear at what point the requirement to '*investigate further the effects'* on aquatic organisms has been effectively fulfilled.

70. The principle of legal certainty requires that every measure of the European Union which produces legal effects should be clear and precise so that the persons concerned are able to know without ambiguity what their rights and obligations are and to take steps accordingly (judgment of 1 October 1998, *Langnese-Iglo* v *Commission*, C-279/95 P, EU:C:1998:447, paragraph 78, and judgment of 30 November 2009, *France and France Télécom* v *Commission*, T-427/04 and T-17/05, EU:T:2009:474, paragraph 300; see also Case A-008-2015, *Evonik Degussa*, Decision of the Board of Appeal of 12 October 2016, paragraph 36).

71. In the present case, it is not disputed that the Contested Decision requires the Appellant to submit information on a FELS test under Column 1 of Section 9.1.6.1. of Annex IX.

72. It is therefore clear from the Contested Decision what information the Appellant is required to provide in order to bring its dossier into compliance with the REACH Regulation. The Appellant is perfectly able to know, without ambiguity, what its obligations are under the Contested Decision.

73. In addition, whilst the Appellant's argument goes beyond the scope of the present case and addresses a situation where a registrant would be required to submit information on a further study under Column 2 of Section 9.1. of Annex IX, it must be rejected for the following reasons.

74. In accordance with the first introductory paragraph to Annex IX, a registrant must, at the level of this Annex, submit a testing proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 12(1)(d).

75. Under Column 2 of Section 9.1. of Annex IX, it is a registrant's obligation to determine whether there is a need to investigate further the effects of a substance on aquatic organisms. If no testing proposal is made under Article 40, the Agency may require the registrant to submit information on a further study following a compliance check under Article 41.

76. Therefore, a registrant can only carry out a further study under Column 2 of Section 9.1. of Annex IX following a decision of the Agency, either under Article 40, if a testing proposal has been made by the registrant, or under Article 41, if no such testing proposal has been made and a data gap has been identified. The registrant's rights and

the procedural requirements set out in Articles 50 and 51 apply to both of these provisions.

77. The rights and obligations of the registrants are clearly and precisely described in the provisions referred to in the previous paragraph. A decision taken by the Agency under Article 40 or Article 41 enables a registrant concerned to know without ambiguity what its rights and obligations are and what steps it has to take.

78. Therefore, the interpretation of Column 2 of Section 9.1. of Annex IX stated in paragraphs 37 and 38 above does not create any legal uncertainty in the present case or in a situation where a registrant would, under Column 2 of Section 9.1. of Annex IX, be required to submit information on a study further to one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX.

c) Conclusion on the first plea

79. In the Contested Decision, the Agency rejected the Appellant's adaptation on the ground that it did not meet the conditions for omitting the information requirement set out in Column 1 of Section 9.1.6. of Annex IX. That reasoning is based on an incorrect interpretation of Column 2 of Section 9.1. of Annex IX.

80. Column 2 of Section 9.1. of Annex IX is neither a '*trigger*' nor a '*waiver*' 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 study further to 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 the information that any of those three studies would provide (see paragraph 37 above).

81. Nevertheless, although the Agency's reasons for rejecting the Appellant's adaptation were incorrect, the Agency's conclusion was not, insofar as there is a data-gap in the Appellant's registration dossier that needs to be fulfilled by information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX.

82. Therefore, the Agency did not make an error of assessment and did not breach Column 2 of Section 9.1. of Annex IX in finding that the Appellant's registration dossier has a data-gap as regards long-term toxicity testing on fish.

83. The Appellant's first plea must consequently be rejected.

2.2. Second plea: the Agency breached the principle of proportionality and Article 25

Arguments of the Parties

84. The Appellant argues that the FELS test is not necessary as there is sufficient information in the registration dossier to conclude that long-term toxicity testing on fish is not needed.

85. The Appellant argues that the requirement to perform the FELS test is not the least onerous measure in the present case. According to the Appellant, '*any remaining uncertainties could be clarified*' by an algae growth inhibition study. Therefore the Agency should have first required the Appellant to perform an algae growth inhibition study and to update the chemical safety assessment based on the results of that study. The need to investigate further the effects of the Substance on aquatic organisms by a long-term fish toxicity study could have been considered thereafter.

86. The Appellant argues that the Agency also breached Article 25 as it required the Appellant to perform an unnecessary study on vertebrate animals.

87. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

88. The Appellant argues, in essence, that the Agency breached the principle of proportionality and Article 25 as it requested the Appellant to perform an unnecessary study on vertebrate animals.

89. In the present case, the Agency concluded, without committing an error, that the Appellant's registration dossier has a data-gap under Column 1 of Section 9.1.6. of Annex IX (see Section 2.1. above).

90. The consequences of the existence of a data-gap flow directly from the REACH Regulation. Pursuant to Article 10(a)(vi), read in conjunction with Section 9.1. of Annex IX and Annex XI, the Appellant is obliged to submit either information on one of the three long-term fish toxicity tests listed in Column 1 of Section 9.1.6. of Annex IX or an acceptable adaptation. The Appellant did not provide an acceptable adaptation. Its adaptation, based on Column 2 of Section 9.1. of Annex IX, was rejected for the reasons detailed in Section 2.1. above. In addition, the Appellant did not provide for this information requirement an adaptation under the general rules for adaptation set out in Annex XI.

91. Therefore, 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 *Clariant Plastics & Coatings (Deutschland)*, cited in paragraph 18 above, paragraphs 94 and 96 of the Decision).

92. This conclusion is not put into question by the fact that the Contested Decision requires the Appellant to submit information also on an algae growth inhibition study, which is another standard information requirement under Section 9.1.2. of Annex VII.

93. The Appellant's second plea must consequently be rejected.

Conclusion on the appeal

94. As all the Appellant's pleas have been rejected the appeal must be dismissed.

Refund of the appeal fee

95. In accordance with 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), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

Effects of the Contested Decision

96. The Contested Decision required the Appellant to submit the FELS test by 2 November 2021 which is two years, six months and seven days from the date of that Decision.

97. Pursuant to Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision to provide the FELS test must therefore be calculated starting from the date of the notification of the present decision of the Board of Appeal to the Parties.

98. The Appellant must therefore provide the information on the FELS test required by the Contested Decision by 26 July 2023.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that information on the FELS test must be submitted to the Agency by 26 July 2023.**
3. **Decides that the appeal fee is not refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal