DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

29 June 2021

(Dossier evaluation – Compliance check of a registration for a monomer – Unreacted monomer in a polymer – Monomer as a degradation product of a polymer – Exposure-based adaptation – Error of assessment – Powers of the Agency – Data-sharing – Organic or inorganic nature of a substance – Duty to state reasons)

Case number	A-001-2020
Language of the case	English
Appellant	SNF SA, France
Representatives	Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson LLP, Belgium
Contested Decision	CCH-D-2114497433-41-01/F of 6 February 2020, 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), Katrin Schütte (Technically Qualified Member) and Sakari Vuorensola (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 cyanoguanidine (EC number 207-312-8, CAS number 461-58-5; the 'Substance').

2. The Substance is a monomer. The Appellant imports into the European Union polymers which contain the Substance as a monomeric unit. The Appellant registered the Substance at the tonnage band of 100 to 1 000 tonnes per year. The Appellant submitted all information in its registration dossier separately from the other registrants of the Substance under Article 11(3) of the REACH Regulation (all references to Titles, Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).

3. In its registration dossier, the Appellant sought to fulfil the standard information requirement for a sub-chronic toxicity study (Section 8.6.2. of Annex IX) by referring to a document of the German Committee on the determination of occupational exposure limits ('*Maximale Arbeitsplatz-Konzentration'*; 'MAK'] for the Substance (*Deutsche Forschungsgemeinschaft*, *the MAK-Collection Part 1: MAK Value Documentations: Dicyanodiamide*, 2007, vol. 24; the 'MAK Value Document'). The MAK Value Document refers to, among others, the following study: Matsushima *et al.*, *Subchronic oral toxicity study of cyanoguanidine in F344 rats*, 1991 Eisei Shikensho Hokoku 109, p. 61–66 (the 'Matsushima (1991) study').

4. In its registration dossier, the Appellant sought to omit the standard information requirement for a pre-natal developmental toxicity ('PNDT') study on one species (Section 8.7.2. of Annex IX) by claiming that the Substance '*has no identified uses or exposure to man or environment'* as it *'is only imported as a monomeric unit in polymers and not manufactured or imported in the unpolymerised form'.*

5. In its registration dossier, the Appellant sought to omit the standard information requirement for simulation testing on ultimate degradation in surface water ('*simulation of ultimate degradation*', Section 9.2.1.2. of Annex IX) by claiming that the study is technically not feasible as the Substance is inorganic.

6. On 29 January 2019, the Agency initiated a compliance check of the Appellant's registration dossier in accordance with Article 41.

7. On 22 May 2019, the Agency notified a draft decision to the Appellant in accordance with Article 50(1), rejecting the three adaptations referred to in paragraphs 3, 4 and 5 above.

8. The Appellant did not submit comments on the draft decision. The Agency did not revise the draft decision and notified it to the competent authorities of the Member States in accordance with Article 51(1).

9. On 6 February 2020, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(3).

10. The Contested Decision states:

    '*Based on Article 41 […], [the Agency] requests that you submit the information listed below by the deadlines provided.*

    […]

A. Requirements applicable to all the Registrants subject to Annex IX […]

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method OECD TG 408) in rats with the Substance;

2. Pre-natal developmental toxicity [PNDT] study (Annex IX, Section 8.7.2.; test method OECD TG 414) in a first species (rat or rabbit), oral route with the Substance;

3. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method EU C.25./OECD TG 309) at a temperature of 12 °C with the Substance.

[…]

You must submit the information requested in points A.1-2 above in an updated registration dossier by 13 August 2020, and the information requested in point A.3 above by 13 November 2020.

[…].'

11. As regards the first and second information requirements (referred to as points A.1 and A.2 in the Contested Decision), the Contested Decision states:

'The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III […], you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.'

Procedure before the Board of Appeal

12. On 5 May 2020, the Appellant filed this appeal.

13. On 7 July 2020, the Agency filed its Defence.

14. On 21 September 2020, the Appellant submitted its observations on the Defence.

15. On 26 October 2020, the Agency submitted its observations on the Appellant's observations on the Defence.

16. On 30 November 2020, Katrin Schütte and Sakari Vuorensola, alternate members of the Board of Appeal, were designated to act, respectively, as technically and legally qualified members of the Board of Appeal in this case. They were designated, respectively, in accordance with the first and second subparagraphs 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').

17. On 11 and 18 January 2021, the Agency and the Appellant, respectively, replied to questions from the Board of Appeal.

18. On 24 March 2021, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure. 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

19. 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.
20. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

21. The Appellant raises the following pleas in law:
    - the Agency exceeded its powers and erred in its assessment in finding that the information provided by the Appellant did not fulfil the standard information requirement in Section 8.6.2. of Annex IX, and in requiring the Appellant to seek permission to refer to information available in the lead registrant's dossier (first plea);
    - the Agency infringed Articles 2(9), 6(3) and 41 and exceeded its powers in rejecting the Appellant's adaptation for the standard information requirement in Section 8.7.2. of Annex IX. The Agency also exceeded its powers and erred in its assessment in requiring the Appellant to seek permission to refer to information available in the lead registrant's dossier (second plea); and
    - the Agency breached its duty to state reasons, failed to take into account all relevant factors, failed to conduct its own assessment, and committed an error of assessment in finding that the Substance is organic and in rejecting the Appellant's adaptation for the standard information requirement in Section 9.2.1.2. of Annex IX (third plea).

1. First plea: The Agency exceeded its powers and erred in its assessment in finding that the information provided by the Appellant did not fulfil the standard information requirement in Section 8.6.2. of Annex IX, and in requiring the Appellant to seek permission to refer to information available in the lead registrant's dossier

Relevant legislation

22. Column 1 ('*standard information required*') of Section 8.6.2. of Annex IX provides:

    '*Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.*'

23. Article 13(3) provides:

    '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 [Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulaton (OJ L 142, 31.5.2008, p. 1); the 'Test Methods Regulation'] or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate.'

24. Section B.26 of the Annex to the Test Methods Regulation sets out the test method to be followed for sub-chronic oral toxicity (90-day) studies in rodents. It replicates OECD test guideline No 408 ('OECD TG 408').

25. Section 1.1. of Annex XI ('*Use of existing data*') provides:

'[…]

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)

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

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

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

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

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

[…]'

Relevant findings of the Contested Decision

26. In the Contested Decision, the Agency examined the information provided by the Appellant to fulfil the standard information requirement in Section 8.6.2. of Annex IX and concluded as follows:

'1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)

[…]

To be considered compliant and enable concluding whether the Substance has dangerous properties and supports the determination of the No-Observed Adverse Effect Level (NOAEL), a study has to meet the requirements of OECD TG 408. The following key parameter(s) of this test guideline include, among others:

1. *At least 10 female and 10 male animals should be used at each dose level (including control group);*
2. *Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of body weight, hematology, clinical biochemistry, and pathology of sexual (male and female) organs, full detailed gross necropsy and subsequent histopathology of both types tissues.*

The study you have provided neither provides evidence on the exact number of animals used per sex per test dose group, nor evidence for any control group animals used.

The study you have provided was not performed according to the criteria of the OECD TG 408, since the following key parameters are missing:

- *Clinical observations, ophthalmological examination, sensory reactivity to various stimuli and functional observations of the animals, recording of body weight, hematology, clinical biochemistry, and pathology of sexual (male and female) organs, full detailed gross necropsy and subsequent histopathology of both types tissues.*

Based on the above, the information you provided does not fulfil the information requirement.

Referring to the criteria provided in Annex IX, Section 8.6.2, Column 2, the oral route is the most appropriate route of administration to investigate repeated dose toxicity, because the Substance is a solid.

Therefore the sub-chronic toxicity study must be performed according to the OECD TG 408, in rats and with oral administration of the Substance.

Information on data sharing for studies involving vertebrate animals

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

[The Agency] considers six months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.'

Arguments of the Parties

27. The Appellant argues that the Agency erred in its assessment in finding that the information provided by the Appellant did not fulfil the standard information requirement in Section 8.6.2. of Annex IX, and in requesting the Appellant to seek permission to refer to the OECD TG 408 study available in the lead registrant's dossier. This plea consists of three parts.

28. First, the Appellant argues that the Agency exceeded its powers by requiring that the sub-chronic toxicity study must meet all the parameters of OECD TG 408 in order to comply with Section 8.6.2. of Annex IX. The Appellant argues that Section 8.6.2. of Annex IX does not specify any OECD test guideline according to which the sub-chronic toxicity study should be performed. The Appellant argues that the standard information requirement in Section 8.6.2. of Annex IX can therefore be fulfilled also by submitting other available and relevant information that fulfils the conditions set out in Section 1.1.2. of Annex XI.

29. Second, the Appellant argues that the Agency made an error of assessment in considering that the MAK Value Document, or the Matsushima (1991) study referred to in the MAK Value Document, did not fulfil the standard information requirement in Section 8.6.2. of Annex IX. The Appellant argues that the Agency should have taken into account, in the Contested Decision, the publicly available full version of the MAK Value Document to which the Appellant had made reference in its registration dossier.

30. The Appellant argues that the MAK Value Document is suitable for assessing the sub-chronic toxicity of the Substance. Moreover, the MAK Value Document contains a more stringent No-Observed Adverse Effect Level (NOAEL) value for the Substance than the studies referred to by the lead registrant for the Substance. The MAK Value Document is therefore '*the most relevant information*' to assess the safety of the Substance.

31. The Appellant argues that the relevance of the MAK Value Document is confirmed by the fact that the national authorities relied on it for different regulatory purposes. The Appellant argues that the Matsushima (1991) study referred to in the MAK Value Document was performed in accordance with OECD TG 408 and was considered to be the most reliable key study to assess the oral toxicity of the Substance in an assessment by the OECD.

32. Third, the Appellant argues that in a compliance check decision under Article 41 the Agency does not have the competence to prescribe the manner in which the Appellant is to obtain and submit information which is, allegedly, missing. Therefore, the Agency exceeded its powers in requesting the Appellant to seek permission to refer to the OECD TG 408 study available in the lead registrant's dossier.

33. The Appellant argues that the short deadline set in the Contested Decision to comply with the standard information requirement for the sub-chronic toxicity study means that seeking permission to refer to the OECD TG 408 study available in the lead registrant's dossier is the only option. The six-month deadline in the Contested Decision does not allow the Appellant to look for and possibly obtain data from other sources.

34. The Appellant argues that the choice of the specific study or information to be submitted lies with the registrant, as long as the registrant provides information which meets the requirements of the relevant Annex and does not duplicate vertebrate animal testing.

35. The Appellant also argues that the Agency erred in its assessment of the available data. Even if the MAK Value Document was not considered sufficient to comply with the standard information requirement, an English translation of the original Japanese Matsushima (1991) study would be more relevant than the OECD TG 408 study from 1985 that is included in the lead registrant's dossier.

36. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

1.1. First and second parts of the first plea: Compliance with Section 8.6.2. of Annex IX

37. By the first and second parts of its first plea, the Appellant argues, in essence, that the Agency exceeded its powers and made an error of assessment when it considered that the information provided by the Appellant did not fulfil the standard information requirement in Section 8.6.2. of Annex IX.

38. Under Article 41, the Agency can assess the quality and adequacy of information submitted in a registration dossier in order to determine whether that information satisfies the information requirements set out in the REACH Regulation (see Case A-006-2017, *Climax Molybdenum*, Decision of the Board of Appeal of 11 December 2018, paragraph 40).

39. 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 verifying whether there is a data-gap in the registrant's dossier (see Case A-010-2019, *Croda Iberica*, Decision of the Board of Appeal of 19 January 2021, paragraph 60, and Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, Decision of the Board of Appeal of 4 May 2020, paragraphs 49 to 51).

40. Under Section 8.6.2. of Annex IX, read in conjunction with Article 13(3) and the relevant provisions of the Test Methods Regulation, the standard information requirement for a sub-chronic oral toxicity study is information on a study performed in accordance with OECD TG 408 (see paragraphs 22 to 24 above). In order to comply with the standard information requirement in Section 8.6.2. of Annex IX, the Appellant was therefore required to submit either information on an OECD TG 408 study or, alternatively, an acceptable adaptation in accordance with the specific adaptation rules in Column 2 of Section 8.6.2. of Annex IX or the general adaptation rules in Annex XI.

41. In its registration dossier, the Appellant did not submit an OECD TG 408 study. Instead, it sought to fulfil the standard information requirement set out in Section 8.6.2. of Annex

IX by referring to the sub-chronic toxicity study data referred to in the MAK Value Document.

42. Consequently, in order to be considered equivalent to information on an OECD TG 408 study, the data submitted by the Appellant needed to fulfil the conditions set out in Section 1.1.2. of Annex XI. One of those conditions is that the data submitted by the Appellant must provide '*adequate and reliable coverage of the key parameters foreseen to be investigated*' in an OECD TG 408 study.

43. In the Contested Decision, the Agency found that the information provided by the Appellant did not cover all the key parameters investigated in a study performed in accordance with OECD TG 408, and that there was therefore a data-gap in the Appellant's registration dossier (see paragraph 26 above).

44. The Appellant argues, in essence, that the MAK Value Document and the Matsushima (1991) study referred to in the MAK Value Document are sufficient, and the most relevant available information to comply with the standard information requirement in Section 8.6.2. of Annex IX.

45. However, the Appellant has not established that the Agency erred in finding that the data submitted by the Appellant in its registration dossier did not provide adequate and reliable coverage of all the key parameters of an OECD TG 408 study and that consequently the Appellant's registration dossier did not comply with the standard information requirement in Section 8.6.2. of Annex IX. The Agency clearly identified the key parameters for which adequate and reliable coverage had not been provided in the Appellant's registration dossier, and the Appellant has not provided any evidence to contradict these findings.

46. Therefore, the Agency did not exceed its powers and did not make an error of assessment in concluding that the information submitted by the Appellant did not fulfil the conditions set out in Section 1.1.2. of Annex XI, and that there was a data-gap in the Appellant's registration dossier.

47. This conclusion is not called into question by the Appellant's argument that the Agency should have taken into account, in the Contested Decision, the publicly available full version of the MAK Value Document to which the Appellant had made reference in its registration dossier. It is the sole responsibility of registrants to generate, gather and submit to the Agency the information that they consider will fulfil the information requirements of the REACH Regulation. In the present case, it was the sole responsibility of the Appellant to include in its registration dossier the parts of the MAK Value Document that it considered to be relevant. The Agency correctly limited its examination to the information submitted by the Appellant in the relevant parts of its registration dossier, in accordance with the relevant provisions of the REACH Regulation (Articles 10(a)(vii) and 14(1), and Annex I).

48. It follows from the reasons set out in paragraphs 38 to 47 above that the first and second parts of the first plea must be rejected.

1.2. Third part of the first plea: Errors in requiring the Appellant to seek permission to refer to the information available in the lead registrant's dossier

49. By the third part of its first plea, the Appellant argues, in essence, that the Agency exceeded its powers and made an error of assessment in obliging the Appellant to seek permission to refer to the OECD TG 408 study available in the lead registrant's dossier.

50. The Appellant submitted information separately from the other registrants of the Substance under Article 11(3) (see paragraph 2 above). The Agency has not disputed the Appellant's reasons for doing so.

51. The Agency concluded that there was a data-gap in the Appellant's registration dossier with regard to the sub-chronic toxicity study required under Section 8.6.2. of Annex IX. By the Contested Decision, the Agency requested the Appellant to fill that data-gap. The Appellant has not established that the Agency exceeded its powers or made an error of assessment in this respect (see Section 1.1. above).

52. Article 25(1) provides that testing on vertebrate animals for the purposes of the REACH Regulation must be undertaken only as a last resort. The duty to avoid animal testing under Article 25(1) applies to the Agency, as well as to registrants. Checking the dossiers of the other registrants of the same substance for relevant information in the course of a dossier evaluation is a good practice and one practical way for the Agency to help ensure that testing on vertebrate animals is undertaken only as a last resort (see, to this effect, Case A-001-2014, *CINIC Chemicals Europe*, Decision of the Board of Appeal of 10 June 2015, paragraph 75, and Case A-005-2016, *Cheminova*, Decision of the Board of Appeal of 30 January 2018, paragraph 160).

53. In the present case, the Agency found that the lead registrant's dossier for the Substance contains information that would allow the Appellant to fill the data-gap with regard to the sub-chronic toxicity study required under Section 8.6.2. of Annex IX. In accordance with the good practice referred to in paragraph 52 above, and in order to avoid the duplication of a test on vertebrate animals as required under Article 25(1), the Agency informed the Appellant that the lead registrant's dossier for the Substance contains an OECD TG 408 study which is the standard information required under Section 8.6.2. of Annex IX.

54. The Agency set a deadline of six months for the Appellant to fill the data-gap as regards the sub-chronic toxicity study in its registration dossier. The Agency justified the duration of this time limit by considering that six months is *'a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report'.*

55. The Appellant argues, first, that the Agency exceeded its powers and made an error of assessment in stating, in the Contested Decision, that the Appellant *'must request [the information] from the other registrant(s)*'. The Appellant argues, second, that due to the six-month deadline set out in the Contested Decision it has no other option but to seek permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance. These arguments must be rejected for the following reasons.

56. According to Appendix A ('*Reasons for the requests to comply with Annex IX of REACH*') to the Contested Decision, the Appellant *'must request'* permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance. However, contrary to the Appellant's arguments, this wording does not mean that there is no other way for the Appellant to fill the data-gap identified by the Agency than to seek

permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance.

57. First, a registrant is entitled to adapt the standard information requirements set out in Annexes VII to X (the 'testing Annexes'), either under the specific adaptation rules in Column 2 of those Annexes, if applicable, or under the general adaptation rules in Annex XI. This possibility is set out in the introductory paragraphs of each of the testing Annexes.

58. Furthermore, Appendix C to the Contested Decision ('*Observations and technical guidance*') states that the Appellant may fulfil the information requirements of the Contested Decision by submitting *'a valid and documented adaptation'*. Therefore, the Contested Decision does not oblige the Appellant, as the only option, to seek permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance. Instead, the Contested Decision explicitly refers to the possibility of filling the data-gap by submitting an acceptable adaptation.

59. In addition, the possibility to have recourse to adaptations is not limited to the initial stage of the dossier evaluation procedure but also applies to subsequent stages of that procedure (see, to that effect, judgment of 21 January 2021, *Germany* v *Esso Raffinage*, C-471/18 P, EU:C:2021:48, paragraphs 126 to 144).

60. Second, the words *'must request'*, in the Contested Decision, are preceded by the words *'in accordance with Title III of the REACH Regulation'*. Consequently, the specific obligation to '*request [the OECD TG 408 study] from the other registrant(s)*' of the Substance must be interpreted in the context of the general obligation to avoid the duplication of studies involving testing on vertebrate animals, in accordance with the provisions of Title III. Insofar as the information to be provided by the Appellant is already available in the lead registrant's dossier for the Substance, the Appellant must comply with the relevant provisions of Title III as regards the obligation to share data concerning tests on vertebrate animals.

61. Third, as regards the time limit set out in the Contested Decision, the Appellant has not provided any argument or evidence to support its claim that six months would be insufficient to comply with the Contested Decision, either by seeking permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance, or by submitting an acceptable adaptation.

62. Fourth, the Appellant's argument that the Agency erred in its assessment as an English translation of the original Japanese Matsushima (1991) study would constitute a more relevant OECD TG 408 study than the OECD TG 408 study available in the lead registrant's dossier (see paragraph 35 above) must also be rejected. An English translation of the Japanese version of the original Matsushima (1991) study was not included in the Appellant's registration dossier and was therefore not examined by the Agency in the decision-making process leading to the Contested Decision. In addition, nothing in the Contested Decision prevents the Appellant from submitting its own study to fill the data-gap, if that study fulfils the standard information requirement at issue and on the condition that the Appellant does not duplicate the OECD TG 408 study, insofar as one relevant OECD TG 408 study is available in the lead registrant's dossier.

63. It follows from the reasons set out in paragraphs 50 to 62 above that the third part of the first plea must be rejected.

1.3. Conclusion on the first plea

64. It follows from the reasons set out in Sections 1.1. and 1.2. above that the Agency did not err in finding that the information provided by the Appellant in its registration dossier did not fulfil the standard information requirement in Section 8.6.2. of Annex IX. The Agency neither exceeded its powers nor made an error of assessment in requiring the Appellant to fill this data-gap by either seeking permission to refer to the OECD TG 408 study available in the lead registrant's dossier for the Substance or, alternatively, by providing an acceptable adaptation.

65. The first plea must therefore be rejected as unfounded.

2. Second plea: The Agency infringed Articles 2(9), 6(3) and 41 in rejecting the Appellant's adaptation for the standard information requirement in Section 8.7.2. of Annex IX, and exceeded its powers and erred in its assessment when it required the Appellant to seek permission to refer to information available in the lead registrant's dossier

Relevant legislation

66. Column 1 ('*Standard information required*') of Section 8.7.2. of Annex IX provides:

'*Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414)*.'

67. Article 2(9) provides:

'*The provisions of Titles II ['Registration of substances'] and VI ['Evaluation'] shall not apply to polymers.*'

68. Article 6 provides:

'1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency.

2. For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

(a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

[…]'

69. Article 14(1) provides:

'Without prejudice to Article 4 of [Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11)] a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.'

70. Section 3 ('*Substance-tailored exposure driven testing*') of Annex XI provides:

'3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:

(a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:

(i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;

(ii) a DNEL [derived no-effect level] or a PNEC [predicted no-effect concentration] can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;

(iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;

(b) where the substance is not incorporated in an article the manufacturer or importer demonstrates and documents for all relevant scenarios that throughout the life cycle strictly controlled conditions as set out in Article 18(4)(a) to (f) apply;

(c) where the substance is incorporated in an article in which it is permanently embedded in a matrix or otherwise rigorously contained by technical means, it is demonstrated and documented that all of the following conditions are fulfilled:

(i) the substance is not released during its life cycle;

(ii) the likelihood that workers or the general public or the environment are exposed to the substance under normal or reasonably foreseeable conditions of use is negligible; and

(iii) the substance is handled according to the conditions set out in Article 18(4)(a) to (f) during all manufacturing and production stages including the waste management of the substance during these stages.

[…]'

Relevant findings of the Contested Decision

71. In the Contested Decision, the Agency examined the adaptation provided by the Appellant for the standard information requirement in Section 8.7.2. of Annex IX and concluded as follows:

'*[PNDT] (Annex IX, Section 8.7.2.) in a first species*

[…]

You have provided adaptions in Sections 5.9.1.1 and 5.9.2.1 of your Chemical Safety Report (CSR), and you conclude that the Substance "has no identified uses or exposure to man or environment. It is only imported as a monomeric unit in polymers and not manufactured or imported in the unpolymerised form. Therefore, exposure is zero*".*

Exposure-based adaptation

While an adaptation was not specifically indicated by you, [the Agency] has evaluated the above information under the rules set in Annex XI, Section 3. Substance-tailored exposure driven testing.

[…]

We have assessed this information and identified the following issue(s):

You have considered the bound monomer in the polymer only; i.e. the quantities of the registered monomer substance which reacted during the polymerisation reaction to yield the polymer.

You have not considered the unreacted (unbound) monomer which may remain in the polymer; i.e. the quantities of the monomer substance which did not react during the polymerisation reaction and remained in the composition of the polymer.

You have neither considered the possibility that upon degradation of the polymer there may be release of the monomer.

The possible release of the monomer from the polymer can result in exposure to man. In this respect, you are also referred to the ECHA Guidance for monomers and polymers, in particular Sections 2.2, 3.2.1 and 4.2, and the judgement of the European Court of Justice in EU Case C-558/07 of 7 July 2009, paragraph 51.

However, the CSR does not contain any chemical risk assessment covering the entire lifecycle of monomer substance subject to this decision. Indeed, the CSR neither considers the possible presence of and exposure to unreacted monomers in the polymer nor considers the possible presence of and exposure to the monomer following the degradation of the polymer substance.

Reliable documentation and justification for the premise that there is no exposure to the monomer is currently missing. In particular, the following requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled:

a) you have not provided relevant exposure scenario(s) in the chemical safety report (cf. Annex XI, Section 3.1 of the REACH Regulation);

b) no rigorous exposure assessment in accordance with Annex I, Section 5 of the REACH Regulation has been developed (cf. Annex XI, Section 3.2, 2nd sentence of the REACH Regulation);

c) you have not provided relevant life-cycle information and exposure scenarios relating to the unreacted monomer (cf. Annex XI, Section 3.2.(a)(i) of the REACH Regulation); and

d) you have not demonstrated and documented that the substance (the monomer) is not released during its life cycle e.g. via decomposition or degradation (cf. Annex XI, Section 3.2.(c)(i) of the REACH Regulation).

Therefore, the adaptations of the information requirements of Annex IX, 8.7.2 (pre-natal developmental toxicity) of the REACH Regulation provided by you cannot be accepted because several requirements of Annex XI, Section 3 of the REACH Regulation are not fulfilled.

The adaptation you provided is not in line with the conditions specified in Annex XI, Section 3. Therefore your adaptation is rejected, and the information requirement is not fulfilled.

A PNDT study according to the test method OECD TG 414 must be performed in rat or rabbit as preferred species with oral administration of the Substance.

Information on data sharing for studies involving vertebrate animals

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you must request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.

[The Agency] considers six months a sufficiently reasonable time for the registrant to seek permission to refer to the other registrant's full study report.'

Arguments of the Parties

72. The Appellant argues that the Agency made several errors as it required the Appellant to provide information on the life-cycle of polymers in the registration of a monomer, and seek permission to refer to the PNDT study available in the lead registrant's dossier for the Substance. This plea consists of two parts.

73. First, the Appellant argues that under Article 41 the Agency can only request information on the substance that is subject to registration.

74. The Appellant argues that the Agency erred in considering that the Appellant was required to consider, in its registration dossier for the Substance, the exposure to the Substance as an unreacted monomer in polymers and as a degradation product of polymers.

75. The Appellant argues that the life-cycle of a monomer ends after polymerisation when the monomer becomes part of a different substance, the polymer. According to the Appellant, the obligation to register the reacted monomer under Article 6(3) cannot be extended to cover the life-cycle of a different substance, the polymer.

76. The Appellant argues that unreacted monomers are impurities of polymers within the meaning of Article 3(1) and are therefore excluded from the registration obligation.

77. Second, the Appellant argues that the Agency exceeded its powers and made an error of assessment in requiring the Appellant to seek permission to refer to the PNDT study available in the lead registrant's dossier for the Substance.

78. The Appellant argues that the choice of the specific study or information to be submitted lies with the registrant as long as the registrant provides information which meets the requirements of the relevant Annex, and does not duplicate vertebrate animal testing.

79. The Agency disputes the Appellant's arguments. The Agency argues, in essence, that reacted and unreacted monomers of polymers manufactured in, or imported into, the European Union must be registered, pursuant to Article 6(1), (2) and (3). The Agency argues that the risks resulting from unreacted monomers contained in polymers as residues after polymerisation, or from the release of monomers following the degradation of polymers, must be considered in the registration of the monomer.

80. The Agency argues that the Appellant's chemical safety report for the Substance does not contain any chemical safety assessment covering the entire life-cycle of the Substance, including the potential presence of the Substance as an unreacted monomer in the polymers and as a degradation product of the polymers. The Agency argues that in order to rely on an adaptation under Section 3 of Annex XI (an 'exposure-based adaptation'), the Appellant should have established that the imported polymers do not contain the Substance as an unreacted monomer, and that the Substance is not released from the polymers as a degradation product. The Agency argues that therefore the exposure-based adaptation submitted by the Appellant had to be rejected.

Findings of the Board of Appeal

2.1. First part of the second plea: Errors in requiring information on the monomer after polymerisation

81. The Appellant, in its capacity as importer of polymers, submitted a registration dossier for the Substance, which is a monomer used to form those polymers. By the first part of its second plea, the Appellant argues, in essence, that the registration of the Substance is based on Article 6(3) only. According to the Appellant, the life-cycle of the Substance ends upon polymerisation and the Appellant cannot be required to consider the life-cycle of another substance, the polymer, in its registration.

82. The Agency does not dispute that the conditions set out in Article 6(3) are fulfilled and that this provision is applicable to the registration of the Substance. However, the Agency argues that the potential presence of the Substance as an unreacted monomer in, or as a degradation product of, polymers is part of the life-cycle of the Substance that the Appellant was required to cover in its registration dossier.

83. According to the Agency, the Appellant's registration obligation is also covered by Article 6(1) and (2) insofar as the polymers imported by the Appellant might contain the Substance as an unreacted monomer. This position is reflected in the Agency's Guidance for monomers and polymers, to which the Contested Decision refers. In this Guidance, the Agency indicates that not only Article 6(3), but also Article 6(1), is applicable to the importer of a polymer: *'[W]here the polymer includes, in its composition, unreacted monomer (or residues from any other substance within the meaning of Article 6(3)), the quantity of that monomer (or any other substance) also needs to be registered according to Article 6(1)'* (Guidance for monomers and polymers, April 2012, version 2.0, Section 3.2.1.1., p. 14).

84. In the Contested Decision, the Agency stated that, in its registration dossier, the Appellant erroneously considered the *'bound monomer only'*, i.e. the Substance as a reacted monomer which is incorporated in polymers. According to the Contested

Decision, the Appellant should have also considered *'the unreacted (unbound) monomer which may remain in the polymer; i.e. the quantities of the monomer substance which did not react during the polymerisation reaction and remained in the composition of the polymer'* and *'the possibility that upon degradation of the polymer there may be release of the monomer'.*

85. According to the Contested Decision, the chemical safety report in the Appellant's registration dossier did not cover the entire life-cycle of the Substance, as the *'possible presence of and exposure to unreacted monomers in the polymer'* and *'the possible presence of and exposure to the monomer following the degradation of the polymer substance'* were excluded. The Agency found that the Appellant failed to establish that the Substance, which is a monomer, is not released during its entire life-cycle via decomposition or degradation of the polymer. Therefore, the Agency found that the Appellant could not rely on an exposure-based adaptation.

86. In order to decide on this part of the Appellant's second plea, it is therefore necessary to examine, first, the legal basis of the registration obligation to which the Appellant is subject in its capacity as importer of a polymer (Section 2.1.1. below), and, second, the consequences of such an obligation (Section 2.1.2. below).

2.1.1. Legal basis of the Appellant's registration obligation

87. Monomers are defined in Article 3(6). Like any other substance, monomers are subject to the general obligation to register. Unreacted monomers that are manufactured in the European Union or imported into the European Union must be registered under Article 6(1) and (2) inasmuch as they constitute substances on their own (see judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 20).

88. By contrast, polymers, as defined in Article 3(5), are excluded from the registration obligation under Article 2(9) (see *S.P.C.M. and Others*, cited in the previous paragraph, paragraph 20 of the judgment). However, manufacturers and importers of polymers must register the monomer(s) and any other substance(s) contained in their polymers if the conditions set out in Article 6(3) are fulfilled (see paragraph 68 above).

89. The concept of '*monomer substance(s)*' in Article 6(3) relates only to reacted monomers which are incorporated in polymers. Polymers are not affected by the registration obligation; only monomer substances with their own characteristics as they existed before polymerisation are subject to the registration obligation (see *S.P.C.M. and Others*, cited in paragraph 87 above, paragraphs 27 and 34 of the judgment).

90. The REACH Regulation and the case-law of the Court of Justice therefore establish a distinction between unreacted monomers as substances on their own, which are subject to the registration obligation under Article 6(1) and (2), and reacted monomers as substances incorporated in polymers after the polymerisation, which are subject to the registration obligation under Article 6(3).

91. Upon polymerisation, a monomer ceases to exist as a substance on its own and is transformed into a new substance, the polymer, which has its own life-cycle (see Case A-006-2016, *SI Group UK and Others*, Decision of the Board of Appeal of 6 June 2018, paragraph 42).

92. After polymerisation, a monomer is no longer subject to the registration obligation as a substance on its own within the meaning of Article 6(1) and (2) as interpreted by the Court of Justice (see *S.P.C.M. and Others*, cited in paragraph 87 above, paragraph 20 of the judgment).

93. Therefore, contrary to the Agency's arguments, the Appellant, in its capacity as importer of a polymer, is not subject to the obligation to register under Article 6(1) and (2). The

Appellant, in its capacity as importer of a polymer, is only subject to the obligation to register under Article 6(3).

2.1.2. Consequences of the Appellant's registration obligation

94. Under Article 6(3), the Appellant must submit and update a complete registration dossier for the Substance as a reacted monomer incorporated in the polymers which it imports.

95. When registering the Substance under Article 6(3), the Appellant was required to submit to the Agency the information set out in Article 10. As the Appellant registered the Substance at the tonnage band of 100 to 1 000 tonnes per year, it was required to submit the studies set out in Column 1 of Annexes VII to IX or, alternatively, acceptable adaptations under the specific adaptation rules set out in Column 2 of those Annexes or under the general adaptation rules set out in Annex XI.

96. Instead of submitting a PNDT study on one species under Column 1 of Section 8.7.2. of Annex IX, the Appellant sought to rely on an adaptation that was based on the absence of exposure to the Substance. The Appellant claimed, in essence, that, as it imports the Substance only as a monomeric unit of polymers, exposure to the Substance '*is zero*'.

97. Section 3 of Annex XI sets out the rules for an exposure-based adaptation that can be applied to any registered substance with a view to omitting testing in accordance with Sections 8.6. and 8.7. of Annex VIII and in accordance with Annexes IX and X. A registrant seeking to rely on an exposure-based adaptation must provide adequate justification and documentation. The justification must be based on a thorough and rigorous exposure assessment that must meet one of the criteria defined in point 3.2. of Section 3 of Annex XI.

98. In the present case, the Appellant did not submit any such justification. The Appellant argues that, due to the limits of its registration obligation under Article 6(3), it cannot be asked to provide information on any exposure occurring after the polymerisation.

99. The Appellant, in its capacity as importer of a polymer, is subject to the obligation to register under Article 6(3) (see paragraph 93 above). As stated in paragraph 94 above, a complete registration dossier is required to comply with the registration obligation under Article 6(3). This obligation does not have to be interpreted strictly; it is not an exception to the exemption from registration which applies to polymers (see *S.P.C.M. and Others*, cited in paragraph 87 above, paragraph 29 of the judgment). Therefore, in its registration dossier the Appellant was required to fulfil all the standard information requirements set out in the testing Annexes on the Substance with its own characteristics as they existed before polymerisation, including the requirement for a PNDT study on one species under Column 1 of Section 8.7.2. of Annex IX (see, to this effect, *S.P.C.M. and Others*, cited in paragraph 87 above, paragraph 34 of the judgment).

100. Under Article 14(1), the chemical safety assessment must be conducted for each substance registered in quantities of 10 tonnes or more per year (see paragraph 69 above). After polymerisation, a monomer ceases to exist as a substance on its own and is transformed into a new substance, the polymer (see paragraphs 91 and 92 above). Information on exposure to the monomer after polymerisation is therefore not part of the standard information requirements to be fulfilled in the chemical safety report of the registered monomer under Article 14(1). Consequently, the Appellant was not required to document in its chemical safety report the chemical safety assessment of the Substance after polymerisation in order to comply with Article 14(1) fulfil the standard information requirements for the registration.

101. However, in the present case, the need to provide information on exposure to the Substance after polymerisation did not stem from the registration obligation, that is to say, the obligation to fulfil any standard information requirements under the REACH Regulation. Instead, the need to provide information on exposure to the Substance after polymerisation was a direct consequence of the fact that the Appellant sought to rely on an exposure-based adaptation in order to omit a PNDT study on one species under Column 1 of Section 8.7.2. of Annex IX which is a standard information requirement that the Appellant was required to fulfil in its registration dossier.

102. As they constitute an exception from the legal obligation to provide standard information, the adaptation rules set out in Section 3 of Annex XI must be interpreted strictly as regards the conditions under which the standard information could be omitted (see, to this effect and by analogy, Case A-010-2019, *Croda Iberica,* Decision of the Board of Appeal of 19 January 2021, paragraph 44 and the case-law cited).

103. There is no provision in Section 3 of Annex XI that could be interpreted as exempting an importer of a polymer from submitting a thorough and rigorous exposure assessment of the substance at issue when that importer intends to rely on an exposure-based adaptation.

104. The fact that the exposure assessment to be submitted under Section 3 of Annex XI might oblige the importer of a polymer to provide information on the exposure to the monomer after polymerisation does not contradict the exclusion of polymers from the registration obligation under Article 2(9).

105. Article 2(9) only exempts polymers from the registration obligation. As stated in paragraph 101 above, the need to provide a thorough and rigorous exposure assessment referred to in Section 3 of Annex XI does not stem from the registration obligation. This thorough and rigorous exposure assessment is required to justify the application of an adaptation to the standard information requirements set out in the testing Annexes.

106. The exclusion of polymers from the registration obligation under Article 2(9) cannot be interpreted as granting automatically and systematically the possibility to omit the testing referred to in Section 3.1. of Annex XI in the registration dossiers of the respective monomers. Such an interpretation would partly undermine the registration obligation set out in Article 6(3), and would contradict the essential objective of the obligation to register monomer substances, which is to protect human health and the environment from the potential adverse effects of those monomers (see *S.P.C.M. and Others*, cited in paragraph 87 above, paragraph 36 of the judgment).

107. It is the responsibility of the registrant of a monomer incorporated in a polymer to demonstrate that the monomer does not pose a risk to human health and the environment due to its presence as an unreacted monomer in another substance, namely a polymer, or as a transformation or degradation product of that polymer (see, to this effect and by analogy, *SI Group UK and Others*, cited in paragraph 91 above, paragraph 50 of the decision).

108. The exposure assessment relating to a reacted monomer incorporated in a polymer, within the meaning of the exposure-based adaptation under Section 3 of Annex XI, is different from the exposure assessment under Article 14(1). Under Article 14(1), the registrant of a monomer is required to document the assessment of the monomer before polymerisation (see paragraph 100 above). Under Section 3 of Annex XI, the exposure assessment does not end upon polymerisation. In order to omit a standard information requirement under Section 3 of Annex XI the registrant of a monomer must provide adequate justification and documentation based on a thorough and rigorous exposure assessment which demonstrates that the substance at issue (the monomer) does not

pose any risk to human health and the environment because there is no exposure or no significant exposure to that substance at any stage.

109. In providing such adequate justification and documentation that the substance at issue does not pose any risk to human health and the environment because there is no exposure or no significant exposure to that substance, for the purpose of an exposure-based adaptation under Section 3 of Annex XI, the registrant of a reacted monomer incorporated in a polymer can be required to provide information on the exposure to the monomer after polymerisation.

110. It follows from paragraphs 94 to 109 above that in order to rely on an adaptation under Section 3 of Annex XI, the Appellant was required to provide a thorough and rigorous exposure assessment of the Substance covering all relevant exposures throughout the life-cycle of the Substance, including the potential exposure to the monomer as an unreacted monomer in, or as a degradation product of, polymer.

2.1.3. Conclusion on the first part of the second plea

111. The Appellant based its exposure-based adaptation for the PNDT study on one species (Section 8.7.2. of Annex IX) exclusively on the argument that the life-cycle of the Substance ended before the polymers were imported and that, therefore, the exposure to the Substance '*is zero*'. The Appellant failed to establish its adaptation with adequate justification and documentation as required under Section 3.2. of Annex XI.

112. Therefore, although the Agency's reasons for rejecting the Appellant's adaptation were partly incorrect (see Section 2.1.1. above), the Agency's conclusion was not. The Agency did not breach Articles 2(9), 6(3) and 41, and did not exceed its powers, in rejecting the Appellant's exposure-based adaptation and in finding that the Appellant's registration dossier did not comply with the standard information requirement in Section 8.7.2. of Annex IX.

113. It follows from the reasons set out in paragraphs 81 to 112 above that the first part of the second plea must be rejected.

2.2. Second part of the second plea: Errors in requiring the Appellant to seek permission to refer to information available in the lead registrant's dossier

114. By the second part of its second plea, the Appellant argues, in essence, that the Agency exceeded its powers and made an error of assessment in requiring the Appellant to seek permission to refer to the PNDT study available in the lead registrant's dossier for the Substance.

115. The second part of the second plea is based on arguments that are similar to those used by the Appellant to support the third part of the first plea (see Section 1.2. above). For the reasons set out in paragraphs 50 to 60 above with regard to the sub-chronic toxicity study, the Contested Decision does not prevent the Appellant from relying on an acceptable adaptation instead of seeking permission to refer to the PNDT study available in the lead registrant's dossier for the Substance.

116. Therefore, the second part of the second plea must be rejected.

2.3. Conclusion on the second plea

117. It follows from the reasons set out in Sections 2.1. and 2.2. above that the Agency did not err in finding that the information provided by the Appellant did not fulfil the standard information requirement in Section 8.7.2. of Annex IX. The Agency did not exceed its powers, and did not make an error of assessment in requiring the Appellant

to fill the data-gap in its registration dossier by seeking permission to refer to the data available in the lead registrant's dossier for the Substance or, alternatively, by providing an acceptable adaptation.

118. The second plea must therefore be rejected as unfounded.

3. Third plea: The Agency breached its duty to state reasons, failed to take into account all relevant factors, failed to conduct its own assessment, and committed an error of assessment in finding that the Substance is organic and in rejecting the Appellant's adaptation for the standard information requirement in Section 9.2.1.2. of Annex IX

Relevant legislation

119. *Column 1* ('*standard information required*') of Section 9.2.1.2. of Annex IX requires *'Simulation testing on ultimate degradation in surface water'.*

120. Section 2 ('*testing is technically not possible*') of Annex XI provides:

'Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. […]'

Relevant findings of the Contested Decision

121. In the Contested Decision, the Agency examined the adaptation provided by the Appellant for the standard information requirement of Section 9.2.1.2. of Annex IX, and concluded as follows:

'Simulation testing on ultimate degradation in water (Annex IX, Section 9.2.1.2.)

[…]

[The Agency] understands that you have sought to adapt this information requirement based on Annex XI, Section 2 (testing is technically not possible). You justified the adaptation by stating that the study is technically not feasible as the Substance is inorganic.

As provided in Annex XI, Section 2, you may adapt the information requirement, if it is technically not possible to conduct the study as a consequence of the properties of the substance. Biodegradability studies are not required for inorganic substances as they cannot be tested for biodegradability (ECHA Guidance R.7b Section R.7.9.5.4). Furthermore, if a substance is highly insoluble in water it may not be possible to conduct this study if the water solubility of the substance is very low (typically <1 µg/L) (ECHA Guidance R.11 Section R.11.4.1.1.3).

We have assessed this information and identified the following issue(s):

The Substance is organic.

Furthermore, you report that the Substance is very soluble in water with a water solubility of 40 g/L.

Therefore, the adaptation is rejected because [the Agency] considers that testing biodegradability is technically feasible. This is also indicated by the data in the registration that is jointly submitted for the Substance.

Therefore, your adaptation does not fulfil the information requirement.

Possibility for data sharing

The jointly submitted registration for the Substance contains data which is relevant for this endpoint. In accordance with Title III of the REACH Regulation, you may request it from the other registrant(s) and then make every effort to reach an agreement on the sharing of data and costs.'

Arguments of the Parties

122. The Appellant argues that the Agency's request for the simulation of ultimate degradation is '*scientifically and legally flawed*' for several reasons.

123. First, the Appellant argues that the Agency made an error in finding that the Substance is organic. The Appellant argues that the Substance is inorganic and therefore cannot be tested for biodegradability.

124. Second, the Appellant argues that the Agency failed to provide any reasons as to why it disagreed with the Appellant's position and found that the Substance is organic.

125. Third, the Appellant argues that the Agency failed to make its own assessment on whether biodegradability testing is feasible for the Substance and relied on the lead registrant's dossier which indicates that biodegradability testing on the Substance would be feasible. The Appellant argues that the study results in the lead registrant's dossier confirm that the Substance is inorganic.

126. Fourth, the Appellant argues that the Agency erred insofar as it justified its request by referring to the solubility of the Substance. The Appellant argues that it had grounds for waiving the simulation of ultimate degradation exclusively based on the inorganic nature of the Substance and that the solubility of the Substance is an irrelevant parameter in this context.

127. The Agency disputes the Appellant's arguments by arguing that it is '*common chemistry knowledge*' that the Substance is organic and that the Substance was defined as organic by all the other registrants of the Substance.

128. The Agency argues that it provided sufficient reasons for rejecting the Appellant's adaptation by explaining, in the Contested Decision, that biodegradability testing is feasible as the Substance is organic and is very soluble in water and by referring to the data available in the joint registration. According to the Agency, the water solubility of the Substance was addressed in the Contested Decision as the simulation of ultimate degradation can be omitted under Column 2 of Section 9.2.1.2. of Annex IX if the water solubility of the registered substance is very low.

129. The Agency argues that it is not required to elaborate on every technical detail in a decision and in the present case there was no need to further explain in the Contested Decision why it considered that the Substance is organic.

Findings of the Board of Appeal

130. In its registration dossier, the Appellant stated that testing the Substance for biodegradability is not feasible as the Substance is inorganic. As a result, the Appellant did not submit a simulation of ultimate degradation as required under Section 9.2.1.2. of Annex IX.

131. In the draft decision and in the Contested Decision, the Agency found that the Substance is organic (see paragraph 121 above). Neither the draft decision nor the Contested Decision contained any reasons for this finding. Considering the organic nature and the

high water solubility of the Substance, the Agency concluded that the Substance can be tested for biodegradability and rejected the Appellant's adaptation.

132. It is undisputed between the Parties that inorganic substances cannot be tested for biodegradation. The Parties therefore agree that, under Section 2 of Annex XI, a registrant can omit the standard information requirement for a simulation of ultimate degradation under Section 9.2.1.2. of Annex IX if the registered substance is inorganic.

133. However, the Parties disagree on whether the Substance is organic or inorganic.

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

135. A clear and unequivocal statement of reasons is a necessary part of a decision of the Agency to enable the persons concerned to ascertain the reasons for the measure in question and to enable the Board of Appeal to exercise its power of review (see Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 110).

136. The Agency argues that the duty to state reasons does not require it to elaborate on every technical detail in a decision. However, as stated in paragraph 132 above, the Parties agree that the organic or inorganic nature of the Substance is a determining factor to conclude on whether it is technically possible to perform the simulation of ultimate degradation on the Substance.

137. Therefore, the Agency was required to provide, in the Contested Decision, sufficient reasons as to why it considered that the Substance is organic and why the Appellant was incorrect in defining the Substance as inorganic. Such reasons should have been included already in the draft decision in order to allow the Appellant to effectively exercise its right to be heard in the decision-making procedure under Article 50(1).

138. In the course of these appeal proceedings the Agency raised several arguments aiming to establish that the Substance is organic. The Agency also referred to the fact that all the other registrants defined the Substance as organic. However, a failure to state reasons cannot be remedied by the fact that the person concerned learns the reasons for the decision during the appeal proceedings (see, to this effect, judgment of 1 June 2020, C-114/19 P, *Commission* v *Bernardo,* EU:C:2020:457, paragraph 51).

139. It follows from the reasons set out in paragraphs 130 to 138 above that the Agency breached its duty to state reasons when it rejected the Appellant's adaptation for the simulation of ultimate degradation without providing justifications for the finding that the Substance is organic.

140. Therefore, the third plea must be upheld and the Contested Decision annulled insofar as it requires the Appellant to submit information on simulation of ultimate degradation of the Substance.

Refund of the appeal fee

141. 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), the appeal fee is refunded if the appeal is decided in favour of an appellant.

142. As the appeal has been partially decided in favour of the Appellant, the appeal fee is refunded.

Effects of the Contested Decision

143. The Contested Decision required the Appellant to submit information on a sub-chronic toxicity study and a PNDT study on one species by 13 August 2020 which is six months and seven days from the date of that Decision. Those information requirements are upheld by the present decision of the Board of Appeal.

144. Pursuant to Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decision to provide a sub-chronic toxicity study and a PNDT study on one species must therefore be calculated starting from the date of notification of the present decision of the Board of Appeal to the Parties.

145. The Appellant must therefore provide information on a sub-chronic toxicity study and a PNDT study on one species by 5 January 2022.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it requests further information on simulation testing on ultimate degradation in water.**
2. **Remits the case to the competent body of the Agency for further action in this regard.**
3. **Dismisses the appeal for the remainder.**
4. **Decides that information on a sub-chronic toxicity study and on a PNDT study on one species must be submitted to the Agency by 5 January 2022.**
5. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal