ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

31 October 2022

(Dossier evaluation – Article 41 – Compliance check – Section 8.7.2. of Annex X – PNDT study in a second species – Section 8.7.3. of Annex X – EOGRTS – Section 8.7. of Annex X – Legal certainty – Proportionality)

Case number	A-011-2021
Language of the case	English
Appellant	Croda EU B.V., the Netherlands
Representatives	Ruxandra Cana, Eléonore Mullier, and Zanda Romata Steptoe & Johnson LLP, Belgium
Contested Decision	Decision of 4 June 2021 on a compliance check of the registration for the substance alcohols, lanolin, adopted by the European Chemicals Agency under Article 41 of the REACH Regulation The Contested Decision was notified to the Appellant under annotation number CCH-D-2114556658-33-01/F

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

1. Background to the dispute

1. This appeal concerns a compliance check of the registration for the substance alcohols, lanolin (the **Substance**).[1]

2. In 2010, the Appellant registered the Substance. Its registration is at the tonnage band of 1 000 tonnes or more per year, which corresponds to Annex X to the REACH Regulation.[2]

3. The Appellant's registration dossier included information on a pre-natal developmental toxicity (**PNDT**) study in a first species (specifically in the rat) as required under Column 1 of Section 8.7.2. of Annex IX. The Appellant's registration dossier did not include information on a PNDT study in a second species and on an extended one-generation reproductive toxicity study (**EOGRTS**). Instead, the registration dossier included the following adaptations:

   - with regard to the PNDT study in a second species, an adaptation based on Section 8.7.2. of Annex IX;
   - with regard to the EOGRTS, an adaptation based on Section 8.7.3. of Annex IX.

4. On 16 July 2020, the Agency opened a compliance check of the registration dossiers submitted for the Substance.

5. On 9 December 2020, the Agency notified to the Appellant a draft decision in accordance with Articles 41 and 50(1). In the draft decision, the Agency rejected the Appellant's adaptations and stated that the Appellant's registration dossier had several data-gaps, including under Sections 8.7.2. and 8.7.3. of Annex X.

6. On 28 January 2021, the Appellant submitted comments on the draft decision in accordance with Article 50(1). The Agency took the Appellant's comments into account and revised the draft decision in response to those comments.

7. On 22 April 2021, the Agency notified the revised draft decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1). No competent authority submitted a proposal for amendment.

8. On 4 June 2021, the Agency adopted the Contested Decision in accordance with Article 51(3).

9. In the Contested Decision, the Agency rejected the Appellant's adaptations and found that the information provided by the Appellant does not satisfy the standard information requirements of Sections 8.7.2. and 8.7.3. of Annex X. As a consequence, the Contested Decision requires the Appellant to submit information on (i) a PNDT study in a second species with the Substance in accordance with OECD test guideline 414, and (ii) an EOGRTS with the Substance in accordance with OECD test guideline 443, by 11 March 2024.

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[1] EC No 232-430-1, CAS No 8027-33-6.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

2. Procedure before the Board of Appeal

10. On 3 September 2021, the Appellant filed this appeal.

11. On 17 September 2021, Katrin Schütte, alternate member of the Board of Appeal, was designated to replace Nikolaos Georgiadis in this case, in accordance with the first subparagraph of Article 3(2) of the Rules of Procedure.[3]

12. On 5 November 2021, the Agency submitted its Defence.

13. On 14 January 2022, the Appellant submitted observations on the Defence.

14. On 23 February 2022, the Agency submitted observations on the Appellant's observations on the Defence.

15. On 31 August 2022, 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 Appellant and the Agency made oral submissions and responded to questions from the Board of Appeal.

3. Form of order sought

16. The Appellant requests the Board of Appeal to:

- annul the Contested Decision insofar as it requires the Appellant to submit information on a PNDT study in a second species and an EOGRTS,
- order the refund of the appeal fee, and
- take such other or further measures as justice may require.

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

4. Assessment of the case

18. The Appellant raises four pleas, alleging that the Agency:

- erred in its assessment, failed to take all relevant information into account, and breached Column 2 of Section 8.7.2. of Annex IX and Column 1 of Section 8.7.2. of Annex X by requesting information on a PNDT study in a second species (**first plea**),
- breached the principles of legal certainty and of the protection of legitimate expectations by requesting information on a PNDT study in a second species and an EOGRTS (**second plea**),
- erred in its assessment, failed to take all relevant information into account, failed to state reasons, and breached Column 2 of Section 8.7. of Annex X by requesting information on an EOGRTS (**third plea**), and
- breached the principle of proportionality and Article 25 by failing to take into account the Appellant's adaptations (**fourth plea**).

[3] Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

4.1. First plea: Errors of assessment, failure to take all relevant information into account, and breaches of Column 2 of Section 8.7.2. of Annex IX and Column 1 of Section 8.7.2. of Annex X by requesting information on a PNDT study in a second species

Arguments of the Parties

19. The Appellant argues that the Agency committed errors in its assessment, failed to take all relevant information into account, and breached Column 2 of Section 8.7.2. of Annex IX and Column 1 of Section 8.7.2. of Annex X by requesting information on a PNDT study in a second species.

20. First, according to the Appellant, Column 1 of Section 8.7.2. of both Annex IX and Annex X refers to the same PNDT study in a single species. Therefore, a PNDT study in a second species is not a standard information requirement under either Annex IX or Annex X. According to the Appellant, the findings of the Board of Appeal in its decision of 10 October 2013, *Lanxess Deutschland*, A-004-2012, are incorrect in this regard.

21. Second, according to the Appellant, the conditions to perform a study in a second species under Column 2 of Section 8.7.2. of Annex IX apply not only at the Annex IX level, but also to Column 1 of Section 8.7.2. of Annex X. Therefore, according to the Appellant, a PNDT study in a second species is required at Annexes IX and X only if there are indications that a substance could cause adverse developmental effects.

22. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

23. A PNDT study in a second species is a standard information requirement under Column 1 of Section 8.7.2. of Annex X. Registrants at the tonnage band of 1 000 tonnes or more per year may omit that study only if they demonstrate that the requirements for an adaptation under Column 2 of Section 8.7. of Annex X, or under Annex XI, are fulfilled.[4]

24. The Appellant challenges the conclusion on the standard requirement of PNDT study in a second species under Column 1 of Section 8.7.2. of Annex X for the following reasons.

(a) Column 1 of Section 8.7.2. of Annex X requires a PNDT study in a second species as standard information

25. The Appellant argues that Column 1 of Section 8.7.2. of Annexes IX and X refers to the same PNDT study in '*one species*', that is to say in a first species. Although Annexes VII to X are cumulative, this does not necessarily mean that Annex X requires a PNDT study in a different species than the one required under Annex IX. Therefore, according to the Appellant, a PNDT study in a second species is not a standard information requirement under either Annex IX or Annex X.

26. It is therefore necessary to examine whether Column 1 of Section 8.7.2. of Annex X requires a PNDT study in a different (second) species than the one used in the PNDT study required under Column 1 of Section 8.7.2. of Annex X.

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[4] Decisions of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraphs 71 to 87; of 29 April 2021, *LG Chem Europe*, A-014-2019, paragraphs 30 to 40; and of 23 August 2022, *Celanese Production Germany*, A-004-2021, paragraph 159.

27. In interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part.[5]

28. First, Column 1 of Section 8.7.2. of Annexes IX and X contains similar wording. Both require a PNDT study in '*one species*'. There is no reference to first or second species in those provisions. A literal interpretation therefore does not suffice to understand these provisions.

29. Second, the information requirements set out in Column 1 of Annexes VII to X are cumulative.[6] This is borne out by the first introductory paragraph to Annex VI, and the second introductory paragraph to Annexes IX and X. This is not contested by the Appellant. The Appellant argues, however, that the cumulative effect on its own does not necessitate a second species at Annex X.

30. Column 1 of Section 8.7.2. of Annex X cannot require information on the same study as Column 1 of Section 8.7.2. of Annex IX. The former provision would otherwise be a repetition of the latter. A registrant at the Annex X level would have already performed a PNDT study in one (first) species under Annex IX. It would therefore be scientifically redundant, and inconsistent with the duty under Article 25 to test on vertebrate animals only as a last resort, to require the same registrant to repeat the same study in the same species under Annex X.

31. Furthermore, Section 8.7.2. of Annex IX requires a PNDT study in '*one species*', whilst Section 8.7.2. of Annex X also requires a PNDT study in '*one species*'. If, as the Appellant argues, only a study in a single species were required under both Annexes IX and X, the standard information requirement under Column 1 of Section 8.7.2. of Annex X would be legally redundant because of the cumulative nature of Column 1 of Annexes VII to X.

32. In the present case, therefore, the Appellant's arguments are not supported by the scientific and legal context. The context of Column 1 of Section 8.7.2. of Annex X indicates that this provision requires a PNDT study in a different (second) species than the one used in the PNDT study required under Column 1 of Section 8.7.2. of Annex X.

33. Third, Column 1 of Section 8.7.2. of Annex X is part of the registration requirements. The main objective of those requirements is to ensure a high level of protection of human health and the environment.[7] Requiring registrants to carry out a PNDT study in a first species under Annex IX, and in a second species under Annex X, ensures that a potential adverse developmental effect of a substance is identified and assessed appropriately.

34. In particular, the purpose of a PNDT study in a second species is to reduce the level of uncertainty as regards the adverse developmental effects of a substance by testing it in different species (normally the rat and the rabbit in accordance with EU test method B.31/OECD test guideline 414). A PNDT study in a second species is therefore not intended to confirm, but to complement a PNDT study in a first species.

35. The objectives of Column 1 of Section 8.7.2. of Annex X therefore confirm that this provision requires a PNDT study in a different (second) species than the one used in the PNDT study required under Column 1 of Section 8.7.2. of Annex X.

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[5] Judgment of 19 September 2019, *Gesamtverband Autoteile-Handel*, C-527/18, EU:C:2019:762, paragraph 30.

[6] Decisions of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraph 72, and of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 156.

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

36. It follows that Column 1 of Section 8.7.2. of Annex X must be interpreted as requiring a PNDT study in a different (second) species than the one used in the PNDT study required under Column 1 of Section 8.7.2. of Annex X.

37. The Appellant's first argument must consequently be rejected.

(b) Column 2 of Section 8.7.2. of Annex IX does not apply to Annex X

38. The Appellant further argues that, even if Column 1 of Section 8.7.2. of Annex X were to be understood as referring to a PNDT study in a second species, Column 2 of Section 8.7.2. of Annex IX also applies to Annex X. According to the Appellant, therefore, a PNDT study in a second species is required only if there are indications that a substance has adverse developmental effects.

39. It is therefore necessary to examine whether Column 2 of Section 8.7.2. of Annex IX applies only to Column 1 of Section 8.7.2. of Annex IX, or also to Annex X.

40. In interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs, and the objectives pursued by the rules of which it is part.[8]

- *Wording*

41. Column 2 of Section 8.7.2. of Annex IX provides that '*[a] decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant and available data*'.

42. The wording '*at this tonnage level or the next*' on its own could mean (i) already at this tonnage level or only at the next, or (ii) at this tonnage level and the next. The Agency relies on the first reading whilst the Appellant relies on the second reading.

43. Furthermore, some language versions of the provision differ from the English version. The Dutch language version, for example, does not refer to Annex X at all.[9]

44. Therefore, and contrary to what the Appellant argues, a literal interpretation is not sufficient to determine the meaning of Column 2 of Section 8.7.2. of Annex IX. It is necessary to examine the context and objectives of that provision.

- *Context*

45. Column 2 of Section 8.7.2. of Annex IX must be read together with the other relevant provisions of Annexes VII to Annex X. Those annexes must be read as a whole.[10]

46. First, Column 1 of both Annexes IX and X is entitled '*Standard information required*'. Column 2 of those annexes is entitled '*Specific rules for adaptation from Column 1*'. According to the second introductory paragraph to Annexes IX and X, Column 2 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*'. In principle, therefore, Column 2 of

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[8] See paragraph 27 above.

[9] '*Op grond van de uitkomst van de eerste test en alle andere beschikbare relevante gegevens wordt besloten of onderzoek bij een tweede soort moet worden uitgevoerd*.'

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

each annex applies only to Column 1 of that same annex. Column 2 of Annex IX refers only to Column 1 of Annex IX, whilst Column 1 of Annex X has its own specific rules for adaptation under Column 2 of Annex X.[11]

47. Second, under Column 1 of Section 8.7.2. of Annex X, a PNDT study in a second species is a standard information requirement for registrants at the tonnage band of 1 000 tonnes or more per year.[12] Under Column 2 of Section 8.7.2. of Annex IX, that same study is an additional requirement for registrants at the tonnage band of 100 to 1 000 tonnes per year if an assessment of the outcome of the PNDT study in a first species and all other relevant available data show that this is necessary.[13] Column 2 of Section 8.7.2. of Annex IX is therefore not a '*waiver*' for the requirement to conduct a PNDT study in a second species under any annex, but a requirement or '*trigger*' to conduct that study already under Annex IX if available information shows that this is necessary.

48. Third, the wording '*or the next*' does not stand alone. It must be read together with the rest of Column 2 of Section 8.7.2. of Annex IX. That provision refers to '*[a] decision on the need to perform a study at this tonnage level or the next on a second species […]'.* The decision referred to in Column 2 of Section 8.7.2. of Annex IX is a decision as to whether a PNDT study in a second species should be performed at the Annex IX level or at the next. It is not a decision, as the Appellant argues, as to whether a PNDT on a second species should be performed at both the Annex IX and X levels, or not at all. If the outcome of the study in a first species and all other relevant available data show a need to perform a study in a second species '*at this level*' (Annex IX), then the PNDT study in a second species must be performed under Annex IX. If the outcome of the study in a first species and all other relevant available data do not show a need to perform a study in a second species, then the PNDT study in a second species must be performed '*only at the next [level]*' (Annex X).

49. The context of Column 2 of Section 8.7.2. of Annex IX consequently indicates that this provision applies under Annex IX only, and not under Annex X.

- *Objectives*

50. Column 2 of Section 8.7.2. of Annex IX is part of the Annexes VII to X. Those annexes require manufacturers and importers of substances to generate and submit to the Agency information on the intrinsic properties of the substances they manufacture or import. This, in turn, contributes to achieving a high level of protection of human health and the environment which is the main objective of the registration and dossier evaluation provisions in the REACH Regulation.[14]

51. Following the Appellant's interpretation, if the PNDT study in a first species and any other relevant available information do not show a need to carry out a PNDT study in a second species, then such a study is not required under either Annex IX or Annex X. In such a case, therefore, the adverse pre-natal developmental effects of a substance are in principle investigated in a first species only.

52. Consequently, following the Appellant's interpretation, substances which do not cause adverse pre-natal developmental effects in a first species are not tested in a second species under either Annex IX or Annex X, even though those substances may cause effects in one species but not in another. If, following the Appellant's argumentation, substances do cause adverse pre-natal developmental effects in a

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[11] Decision of the Board of Appeal of 29 April 2021, *LG Chem Europe*, A-014-2019, paragraph 36.

[12] See paragraphs 27 to 36 above.

[13] Decision of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-2012, paragraph 77.

[14] See paragraph 33 above.

first species, a PNDT test in second species would be conducted under Annexes IX and X. The Appellant does not demonstrate how such an 'all-or-nothing' approach helps to achieve a high level of protection of human health.

53. In addition, the Appellant's reading of Column 2 of Section 8.7.2. of Annex IX would make Column 1 of Section 9.7.2. of Annex X entirely redundant. Such an interpretation would contradict the cumulative nature of the information requirements.[15]

54. Following the interpretation of Column 2 of Section 8.7.2. of Annex IX adopted in the previous decisions of the Board of Appeal[16] and followed by the Agency in the Contested Decision, substances which do not cause adverse pre-natal developmental effects in a first species are nevertheless tested in a second species under Annex X. This interpretation is more conducive to achieving a high level of protection of human health and the environment than the one proposed by the Appellant.

55. The objectives of Column 2 of Section 8.7.2. of Annex IX therefore confirm that this provision applies only under Annex IX, and not under Annex X.

- *Conclusion on the interpretation of Column 2 of Section 8.7.2. of Annex IX*

56. It follows from the reasons set out above that Column 2 of Section 8.7.2. of Annex IX must be interpreted as applying under Annex IX only, and not under Annex X.

57. The Appellant's second argument must therefore be rejected.

(c) Conclusion on the first plea

58. The first plea must be rejected.

4.2. Second plea: Breach of the principles of legal certainty and of the protection of legitimate expectations

Arguments of the Parties

59. The Appellant argues that the Agency breached the principles of legal certainty and of the protection of legitimate expectations in two ways.

60. First, as regards the PNDT study in a second species, the Appellant argues that the meaning of Column 1 of Section 8.7.2. of Annex X is uncertain. It is not clear whether that provision requires a PNDT study in a second species. According to the Appellant, this uncertainty is further borne out by the fact that the relevant provisions have recently been amended by Commission Regulation (EU) 2022/477.[17] The Agency should therefore have refrained from applying Column 1 of Section 8.7.2. of Annex X in the present case.

61. Second, as regards the EOGRTS, the Appellant argues that the Agency is currently conducting a review of the study design, conduct and findings of past EOGRT studies, and may issue further guidance on the conduct of such studies in the future. The deadline set in the Contested Decision is too short to allow the

[15] See paragraph 29 above.

[16] See paragraph 23 above.

[17] Commission Regulation (EU) 2022/477 of 24 March 2022 amending Annexes VI to X to the REACH Regulation (OJ L 98, 25.3.2022, p. 38).

Appellant to wait until the review has been completed, and further guidance has been issued, before carrying out the EOGRTS.

62. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

(a) No breach of the principle of legal certainty

63. The principle of legal certainty requires that rules of law must be clear and precise, and that their application must be foreseeable by those subject to them.[18] In particular, acts of the administration which produce legal effects must 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.[19]

64. First, the operative part of the Contested Decision requires the Appellant to submit information on (i) a PNDT study in a second species with the Substance in accordance with OECD test guideline 414, and (ii) an EOGRTS with the Substance in accordance with OECD test guideline 443, by 11 March 2024.

65. The Appellant is therefore in a position to know what it has to do in order to comply with the Contested Decision. It must submit information on the relevant studies or, alternatively, acceptable adaptations.[20]

66. Second, as regards the PNDT study in a second species, the Appellant argues that the requirements of Column 1 of Section 8.7.2. of Annex X are not clear.

67. The Agency is neither required nor entitled to set aside a legislative provision on the grounds that its meaning may not be clear to a registrant. If the meaning of a provision is not clear, that provision must be clarified by interpretation before being applied.[21]

68. The meaning of Column 1 of Section 8.7.2. of Annex X has already been clarified in several decisions of the Board of Appeal,[22] in the Agency's guidance,[23] and in the Contested Decision. The Appellant was consequently able to know the Agency's reading of that provision.

69. Furthermore, it is irrelevant that the wording of Column 1 of Section 8.7.2. of Annex X has been clarified by Commission Regulation (EU) 2022/477. That regulation applies from 14 October 2022, which is after the adoption of the Contested Decision. In any event, Commission Regulation (EU) 2022/477 codifies the current interpretation of Column 1 of Section 8.7.2. of Annex IX.

70. Third, as regards the EOGRTS, the Appellant argues that the deadline set in the Contested Decision is too short to allow the Appellant to wait for the Agency to complete an ongoing review of existing EOGRT studies, and issue further guidance, before carrying out the required study.

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[18] Judgment of 11 September 2019, *Călin*, C-676/17, EU:C:2019:700, paragraph 50.

[19] Judgment of 1 October 1998, *Langnese-Iglo* v *Commission*, C-279/95 P, EU:C:1998:447, paragraph 78; decision of the Board of Appeal of 9 April 2019, *BrüggemannChemical*, A-001-2018, paragraph 44.

[20] Decision of the Board of Appeal of 18 August 2020, *Symrise*, A-009-2018, paragraph 136 (challenged before the General Court in Case T-29/22).

[21] Opinion of Advocate General Geelhoed of 17 March 2005, *France* v *Parliament and Council*, C-244/03, EU:C:2005:178, paragraphs 74 to 76.

[22] See paragraph 23 above.

[23] European Chemicals Agency, *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, Version 6.0, July 2017, available at https://echa.europa.eu/documents/10162/17224/information_requirements_r7a_en.pdf/e4a2a18f-a2bd-4a04-ac6d-0ea425b2567f?t=1500286622893 (last accessed on 27 September 2022).

71. As the Agency confirmed at the hearing, the Appellant is required to carry out the required study based on the relevant guidelines as they currently stand. If the Appellant carries out the study correctly based on the current version of the relevant guidelines, that study will satisfy the information requirement at issue.[24]

72. The second plea is therefore unfounded insofar as it alleges a breach of the principle of legal certainty.

(b) No breach of the principle of the protection of legitimate expectations

73. The principle of the protection of legitimate expectations is a corollary of the principle of legal certainty.[25] It presupposes that the administration gave the person concerned precise assurances, leading that person to entertain justified expectations. Information which is precise, unconditional and consistent, in whatever form it is given, constitutes such assurances.[26]

74. The Agency has not given the Appellant any assurance that it would refrain from requiring information on a PNDT study in a second species or an EOGRTS.

75. The second plea is consequently also unfounded insofar as it alleges a breach of the principle of the protection of legitimate expectations.

(c) Conclusion on the second plea

76. The second plea must be rejected.

4.3. Third plea: Failure to assess an adaptation under Column 2 of Section 8.7. of Annex X as regards the EOGRTS

Arguments of the Parties

77. The Appellant argues that it submitted an adaptation under Column 2 of Section 8.7. of Annex X. According to the Appellant, the Agency did not address that adaptation in the Contested Decision. The Agency only addressed an adaptation under Column 2 of Section 8.7.3. of Annex X. The Agency therefore committed an error of assessment, failed to take all relevant information into account, failed to state reasons, and breached Column 2 of Section 8.7. of Annex X by requesting information on the EOGRTS.

78. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

79. A registrant who submits an adaptation must set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds.[27]

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[24] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings Deutschland*, A-011-2018, paragraph 114.

[25] Judgment of 3 December 2019, *Czech Republic* v *Parliament and Council*, C-482/17, EU:C:2019:1035, paragraph 153.

[26] Judgment of 16 September 2021, *FVE Holýšov I and Others* v *Commission*, C-850/19 P, EU:C:2021:740, paragraph 34.

[27] Decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings (Deutschland)*, A-011-2018, paragraph 35; see also decisions of the Board of Appeal of 10 October 2013, *Lanxess Deutschland*, A-004-

80. It is consequently necessary, as a preliminary point, to determine whether the relevant part of the Appellant's registration dossier contained an adaptation under Column 2 of Section 8.7. of Annex X for the EOGRTS.

81. In the relevant part of its registration dossier, namely the section entitled '*Toxicity to reproduction*',[28] the Appellant stated (emphasis added):

'*In accordance with Column 1, Section 8.7.3 of Annex IX of the REACH regulation, a two-generation reproductive toxicity study has to be performed in one species, male and female, considering the most appropriate route of administration, and having regard to the likely route of human exposure, if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues. Furthermore, in accordance with Column 2 of Annex IX of the REACH regulation, the study shall be initially performed in one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available date.*

The available 90-day repeated dose toxicity study in rats revealed no effects on female and male reproductive organs or tissues up to the limit dose tested. Furthermore, a prenatal developmental toxicity study performed according to OECD 414 and tested up to the limit dose in rats showed no substance-related effects on developmental toxicity endpoints.

Thus, to account for animal welfare, the conduct of further reproduction toxicity studies according to Annex IX of the REACH regulation with Lanolin Alcohols would be scientifically unjustified.'

82. The Appellant's adaptation was therefore clearly based on Columns 1 and 2 of Section 8.7.3. of Annex IX. The Appellant confirmed during the proceedings that its dossier did not contain an explicit adaptation based on Column 2 of Section 8.7. of Annex X. The Agency is not required to speculate how an adaptation under Columns 1 and 2 of Section 8.7.3. of Annex IX might have been relevant under Column 2 of Section 8.7. of Annex X in relation to an EOGRTS.

83. Consequently, the Appellant cannot criticise the Agency for failing to address an adaptation under Column 2 of Section 8.7. of Annex X in relation to an EOGRTS. The Agency is not required to assess, and state reasons for rejecting, adaptations which are not contained in the registration dossier under evaluation.

84. The third plea must therefore be rejected.

4.4. Fourth plea: Breaches of the principle of proportionality and Article 25 by failing to take into account the Appellant's adaptations

Arguments of the Parties

85. The Appellant argues that it submitted valid adaptations and therefore the Agency breached the principle of proportionality and Article 25 by requesting the PNDT study and the EOGRTS.

86. The Agency disputes the Appellant's arguments.

2012, paragraphs 98 and 99; and of 13 February 2014, *Momentive Specialty Chemicals*, A-006-2012, paragraphs 57 to 60; and of 1 August 2016, *BASF Pigment*, A-014-2014, paragraph 47.

[28] Section 8.7.1. of the Appellant's IUCLID file.

Findings of the Board of Appeal

87. The Agency did not commit any error in rejecting the adaptations set out in the Appellant's registration dossier.[29] Consequently, in the present case, the Agency was not empowered to consider whether it is consistent with the principle of proportionality, or with Article 25, for the Appellant to be required to submit the standard information at issue.[30]

88. The fourth plea must therefore be rejected.

4.5. Result

89. As all the Appellant's pleas are rejected, the appeal must be dismissed.

5. Effects of the Contested Decision

90. The contested part of the Contested Decision required the Appellant to submit information on a PNDT study on a second species and an EOGRTS by 11 March 2024, which is 2 years, 9 months, and 7 days from the date of that decision.

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

92. The Appellant must consequently provide the information requested in the Contested Decision by 7 August 2025.

6. Refund of the appeal fee

93. Under Article 10(4) of the Fee Regulation,[31] 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.

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[29] See Sections 4.1. to 4.3. above.

[30] Decision of the Board of Appeal of 23 August 2022, *Celanese Production Germany*, A-004-2021, paragraph 160.

[31] Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6).

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information on a PNDT study in a second species and an EOGRTS required by the contested part of the Contested Decision must be provided by 7 August 2025.**
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