DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

23 February 2021

(Dossier evaluation – Article 40 – Read-across testing proposals – Conduct of the decision-making procedure – Duties of the Agency – Article 25 – Addressees of a testing proposal decision)

Case numbers	Joined Cases A-016-2018 to A-029-2019
Language of the cases	English
Appellants	Lubrizol France SAS, France Lanxess Deutschland GmbH, Germany Infineum Italia S.r.l., Italy Chevron Oronite SA M/I, France Afton Chemical S.P.R.L., Belgium Afton Chemical S.P.R.L. (Woluwe), Belgium
Representatives	Jean-Philippe Montfort and Thomas Delille Mayer Brown Europe-Brussels LLP, Belgium
Intervener	Cruelty Free Europe, Belgium
Contested Decisions	TPE-D-2114484217-44-01/F, TPE-D-2114483969-22-01/F, TPE-D-2114484220-57-01/F, TPE-D-2114484222-53-01/F, TPE-D-2114484207-45-01/F, TPE-D-2114484210-58-01/F, TPE-D-2114484212-54-01/F, TPE-D-2114483966-28-01/F, TPE-D-2114484215-48-01/F, TPE-D-2114484202-55-01/F, TPE-D-2114484204-51-01/F, TPE-D-2114484206-47-01/F, TPE-D-2114483975-29-01/F, TPE-D-2114484214-50-01/F all adopted by the European Chemicals Agency on 27 September 2019 pursuant to Article 40 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), Andrew Fasey (Technically Qualified Member and Rapporteur) and Spyridon Merkourakis (Technically Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

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Background to the dispute

1. These appeals concern testing proposals submitted by the lead registrants of the following substances (the 'Substances'):
   - [CONFIDENTIAL] ('Substance 1'),
   - [CONFIDENTIAL] ('Substance 2'),
   - [CONFIDENTIAL] ('Substance 3'),
   - [CONFIDENTIAL] ('Substance 4'),
   - [CONFIDENTIAL] ('Substance 5'),
   - [CONFIDENTIAL] ('Substance 6'),
   - [CONFIDENTIAL] ('Substance 7'),
   - [CONFIDENTIAL] ('Substance 8'),
   - [CONFIDENTIAL] ('Substance 9'),
   - [CONFIDENTIAL] ('Substance 10'),
   - [CONFIDENTIAL] ('Substance 11'),
   - [CONFIDENTIAL] ('Substance 12'),
   - [CONFIDENTIAL] ('Substance 13'), and
   - [CONFIDENTIAL] ('Substance 14').
2. The Substances were registered as substances of unknown or variable composition, complex reaction products or biological materials ('UVCB'). They consist, in essence, of three kinds of constituents: '*neutral ZDDP [zinc dialkyldithiophosphates]*', '*basic ZDDP*', and '*base oils*'.
3. Each of the Appellants is the lead registrant for one or more of the Substances.
4. On 17 November 2014, following a compliance check of the registration dossiers submitted by the lead registrant for Substances 2 and 4, the Agency adopted two decisions under Article 41 of the REACH Regulation (all references to Recitals, Articles, Chapters, Titles or Annexes hereinafter concern the REACH Regulation unless stated otherwise). In those decisions, the Agency required the lead registrant for Substances 2 and 4 to submit information on a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on those substances.
5. On 17 February 2015, the lead registrant for Substances 2 and 4 filed appeals against the two decisions in accordance with Article 91(1). The cases were assigned numbers A-001-2015 and A-002-2015 respectively.
6. On 1 April 2015, the Executive Director of the Agency rectified the two decisions, in accordance with Article 93(1), by withdrawing them in their entirety due to a procedural irregularity.
7. On 24 April 2015, the Board of Appeal consequently closed Cases A-001-2015 and A-002-2015.

8. Between 2016 and 2018, the Agency and the Appellants had several informal exchanges concerning the possibility of relying on a grouping of substances and read-across approach in accordance with Section 1.5. of Annex XI (a 'category approach'). During the course of these exchanges, the Agency repeatedly stated that, in order to justify a category approach, the Appellants should provide, amongst other things, detailed information on the composition of the Substances and the definition of the category.

9. On 31 May 2017, the Appellants submitted a '*testing strategy*' to the Agency. Following that '*testing strategy*', the Appellants proposed to:

   - carry out a repeated-dose oral toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on Substance 2; and
   - satisfy the relevant information requirements for the registration of the remaining Substances by means of a category approach, using the results of the studies to be carried out on Substance 2.

10. Between 4 October and 19 November 2018, third parties were invited by the Agency to submit information on the Appellants' testing proposals, grouped in the '*testing strategy*', in accordance with Article 40(2). No information was subsequently received from third parties.

11. On 14 December 2018, the Agency notified to each Appellant a draft decision on its own Substance or Substances in accordance with Articles 40(3) and 50(1). In the draft decisions, the Agency examined the Appellants' category approach and concluded that it did not satisfy the requirements of Section 1.5. of Annex XI. The draft decisions consequently required each Appellant to provide, amongst other information, a repeated-dose oral toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on its own Substance or Substances.

12. On 4 February 2019, the Appellants collectively submitted comments on the draft decisions. In those comments, the Appellants stated that they would revise their '*testing strategy*'.

13. On 6 March 2019, the Appellants submitted a revised '*testing strategy*'. Following that revised '*testing strategy*', the Appellants proposed to:

   - carry out a repeated-dose oral toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on Substances 1, 3, 4, and 9 (the 'Source Substances');
   - satisfy the relevant information requirements for the remaining Substances except Substance 8 (the 'Target Substances') by means of a category approach, using the results of the studies to be carried out on the four Source Substances; and
   - exclude Substance 8, for which the registrant submitted a '*waiving justification*' for the studies at issue, from their category approach.

14. The Agency subsequently revised the draft decisions and notified the revised draft decisions to the competent authorities of the Member States in accordance with Article 51(1).

15. On 27 September 2019, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decisions in accordance with Article 51(3).

Contested Decisions

16. Each of the Contested Decisions is based on Article 40. The content of those decisions is as follows.

1. Contested Decisions concerning the Source Substances

17. Contested Decisions [CONFIDENTIAL] concern the testing proposals made by the lead registrants for the four Source Substances.

18. Those decisions are challenged, respectively, in Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019.

19. In the Contested Decisions in Cases A-016-2019, A-018-2019 and A-019-2019, the Agency examined whether the studies proposed for Substances 1, 3 and 4 after 6 March 2019 (see paragraph 13 above), were necessary and sufficient to satisfy the relevant information requirements for the registration of the those Source Substances, and concluded as follows:

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

[…]

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA considers testing with the registered substance as sufficient to fulfil current information requirement. Testing with the [other three Source Substances], for the purpose of defining sub-chronic toxicity of the registered substance, is considered not needed and therefore rejected.

[…]

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

[…]

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA considers testing with the registered substance as sufficient to fulfil current information requirement. Testing with the [other three Source Substances], for the purpose of defining developmental toxicity of the registered substance, is considered not needed and therefore rejected.'

20. In each of the Contested Decisions in Cases A-016-2019, A-018-2019 and A-019-2019, the Agency therefore:

- approved the testing proposals for a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on the Source Substance concerned,

- rejected the testing proposals for a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on the other three Source Substances, and
- set out specifications for the test material to be used in the performance of the studies for the Source Substance concerned.

21. Furthermore, in the Contested Decision in Case A-024-2019, the Agency examined whether the studies proposed for Substance 9 after 6 March 2019 (see paragraph 13 above), were necessary and sufficient to satisfy the relevant information requirements for the registration of Substance 9, and concluded as follows:

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

[…]

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

You proposed testing by oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees that the oral route - which is the preferred one as indicated in ECHA Guidance on information requirements and chemical safety assessment *(version 6.0. July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure. Uses with industrial / professional spray application are reported in the chemical safety report. However, the reported concentrations forthose uses are low (<3%). Hence, the test shall be performed by the oral route using the test method OECD TG 408.*

Therefore, ECHA considers that the proposed study performed by the oral route with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

[…]

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations concluding that there were no alternative methods which could be used to adapt the information requirement(s) for which testing is proposed. ECHA has taken these considerations into account.

ECHA considers that a study performed with the registered substance according to OECD TG 414 is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.'

22. In the Contested Decision in Case A-024-2019, the Agency therefore:

- approved the testing proposals for a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on Substance 9 concerned,
- set out specifications for the test material to be used in the performance of the studies for Substance 9.

2. Contested Decisions concerning the Target Substances

23. Contested Decisions [CONFIDENTIAL] concern the testing proposals made by the lead registrants for the Target Substances.

24. Those decisions are challenged, respectively in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

25. In each of those decisions, the Agency examined the '*testing strategy*' proposed by the Appellants on 31 May 2017, as amended on 6 March 2019 (see paragraphs 9 and 13 above), including the category approach on which the '*testing strategy*' was based, and concluded as follows:

'*Conclusion on structural similarities and the grouping.*

ECHA concludes that the information provided on the category members does not reflect the inherent variability in the concentrations of the constituents and does not constitute a reliable basis to establish compositional similarities. The applicability domain does not indicate clearly the borders of the category and does not unambiguously establish for which chemicals the category does not hold.

[…]

Supporting information proposed by you to be generated in the future

You have recognized the lack of supporting information and you intend to generate more data in order to substantiate your read-across hypothesis. In particular, you have expressed the following considerations and intentions:

1. *You consider investigating the absorption potential and metabolism of 13 ZDDPs in* in vitro *toxicokinetic studies;*
2. *You intend to explore the biological reactivity of the ZDDPs to support the similarity in their mechanism of action.*
3. *You intend to carry out in vivo toxicokinetic studies (OECD TG 417) for the 4 source substances, in order to, among others, verify your hypothesis for low absorption and clarify the influence of the base oils.*

ECHA recognises your intention to generate experimental data to support your read-across hypothesis. Data on toxicokinetic properties and mechanism of action of the category members may contribute to establish similarities in these properties between the members of the category. However, ECHA is not in a position to conclude on the relevance and/or adequacy of the data obtained from these investigations for the purpose of supporting your predictions for the reasons provided below, and generation of these data is at your own discretion:

Firstly, although toxicokinetic data is in general valuable supporting information for a read across hypothesis, the inherent complexicity [sic] of the composition of UVCBs complicates its interpretation. You did not explain how you intend to address this complexity in the course of the proposed in vitro and/or in vivo experiments, in order to obtain definitive conclusions on the absorption and metabolism properties of the different constituents of the ZDDPs.

Secondly, you have not provided any details on the design of the tests that you consider to conduct. Similarly, you have not provided any criteria for the assessment of the results of these tests, including what would be considered as "low absorption". This is of utmost importance as your read-across hypothesis is based on an

anticipated low absorption of the substances and the results from these studies may or may not confirm this hypothesis.

Thirdly, with regard to the mechanistic studies that you intend to generate, it is unclear what is their relevance to your hypothesis […] other than establishing similarities in biological activity of the category members for the cellular signalling pathways tested in these assays.

Conclusion on the grouping and read-across approach

Based on the above considerations ECHA concludes that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoints in consideration. ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are not met, and consequently the testing proposed on the source substances is not appropriate to fulfil the information requirements of the substance subject to the present decision.'

26. In each of the Contested Decisions for the Target Substances, the Agency therefore:

- rejected the Appellants' category approach,
- rejected the '*testing strategy*' proposed by the Appellants on 31 May 2017, as amended on 6 March 2019 (see paragraphs 9 and 13 above),
- required a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on each of the Target Substances, and
- set out specifications for the test material to be used in the performance of the studies.

3. Contested Decision concerning Substance 8

27. Contested Decision [CONFIDENTIAL] concerns the testing proposal made by the registrant of Substance 8.

28. That decision is challenged in case A-023-2019.

29. In that decision, the Agency examined the '*testing strategy*' proposed by the Appellants on 31 May 2017 (see paragraph 9 above) as well as a '*waiving justification*' submitted by the registrant for Substance 8 after 6 March 2019 (see paragraph 13 above), and concluded as follows:

'*ECHA notes that in the updated dossiers of other substances in ZDDP category the testing strategy was changed, most importantly the new grouping excludes your registered substance.*

In your updated dossier […] you have a[c]knowledged that the new grouping and read across approach exclude your registered substance, however you have not changed your testing strategy of using [Substance 2] to fulfil the information requirements using the grouping and read across approach.

[…]

Conclusion on structural similarities and the grouping

ECHA concludes that the level of information provided on the composition of the different category members and the substance subject to this decision are not adequate to establish the similarity. There are structural and compositional dissimilarities which you did not take into account and which prevents the grouping as you proposed. The fact that the aryl ZDDP substances are included demonstrate

that the boundaries of the category are not specified. As a consequence, the applicability domain of the category is ill defined and does not support predictions.

[…]

Supporting information proposed

[…] [T]he data do not support your hypothesis of no absorption and no systemic toxicity. You seem to have recognised the lack of supporting information as you intend to test the source substance in an 'enhanced' 21-day range-finding study "to determine if the prediction of very low absorbance and no systemic exposure are valid". Generally, it is at your discretion to generate and provide any supporting information that you consider may justify your hypothesis. However, ECHA notes that it is unclear whether this objective could be fulfilled by the outcome of such a test. In particular the following is noted:

Firstly, the validity of the proposed test seems questionable as you have not indicated that you intend to follow any OECD guideline nor GLP.

Secondly, the relevance of the study protocol to the pursued objective of determining "if the prediction of very low absorbance and no systemic exposure are valid" seems questionable.

In particular, it is unclear what compositions would be tested, how many animals per sex/per dose group would be in the study, how the doses would be selected, which haematological and biochemical parameters would be measured, for which organs histopathological examinations are foreseen. Further it is not clear which target constituents or break down products would be subject to analytical determinations for toxicokinetic parameters.

Thirdly, you did not demonstrate the relevance of the proposed study performed on [Substance 2] (or on two extra source substances considered for potential future testing) for other substances in the ZDDP category, including the substance subject to the present decision. As you have not demonstrated that the source substance is representative for other substances in the ZDDP category, the results of the proposed study will provide information only for the substance tested and not for other substances in the category.

Conclusion on the grouping and read-across approach

Based on the above considerations ECHA concludes that you have not provided adequate and reliable information to demonstrate that the proposed read-across approach is plausible for the endpoints in consideration. ECHA therefore concludes that the criteria of Annex XI, Section 1.5, are not met, and consequently the testing proposed on the source substance is not appropriate to fulfil the information requirement of the substance subject to the present decision.

[…]

Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

[…]

In addition, in your updated dossier […] you have provided some arguments why you consider that testing for this standard information requirement is not needed. You have stated that the registered substance has "very low absorption potential" and that "The alkaryl ZDDPs are not expected to cause target organ/repeated dose or developmental toxicity".

ECHA has assessed the information provided and ha[s] observed the following:

To adapt standard information requirement for 90-day repeated dose toxicity, the conditions of specific adaptation based on Annex IX, Section 8.6.2, Column 2, or General adaptations, set in Annex XI have to be fulfilled.

You have not specified which of the above adaptation options you intended to use. The arguments you provided in your dossier (as cited above) do not fulfil the conditions set neither in Annex IX, Section 8.6.2, Column 2 nor in Annex XI. Hence, your adaptation is rejected, the standard information requirement is not fulfilled and further testing is necessary.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with [Substance 2]. As explained […] above, your adaptation of the information requirement is not accepted. Hence, there is a need to test the registered substance.

[…]

Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

[…]

In addition, in your updated dossier […] you have provided some arguments why you consider that testing for this standard information requirement is not needed. You have stated that the registered substance has "very low absorption potential" and that "The alkaryl ZDDPs are not expected to cause target organ/repeated dose or developmental toxicity". You have also indicated that the registered substance is already classified as Repro 1B, based on the presence of an impurity [CONFIDENTIAL]. You considered that, "according to stage 1.1 of section R.7.6.2.3.2 of Chapter R.7a, additional reproductive toxicity testing for any annex is not required".

Even though, you did not explicitly claim such adaptations, we understand that you consider the adaptations possibility according to Annex IX, Section 8.7., Column 2, third indent and the second paragraph.

ECHA has assessed the information provided and ha[s] observed the following:

A. According to Annex IX, Section 8,7., Column 2, third indent, the study does not need to be conducted if the substance is of low toxicological activity. This needs to be demonstrated with three concomitant criteria, namely:

- *That there is no evidence of toxicity seen in any of the tests available; and*
- *That it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure; and*
- *That there is no or no significant human exposure.*

None of the conditions are met. In particular:

- *You have not demonstrated that the registered substance do[es] not cause toxicity in relevant tests. There are no repeated-dose, reproductive and/or developmental studies performed with the registered substance which could provide relevant evidence.*
- *You have not provided any toxicokinetic data to show that there is no systemic absorption.*

- The uses of the Substance indicate that there is significant human exposure[.]

B. According to Annex IX, Section 8.7., Column 2, second paragraph, the study does not need to be conducted if the substance meets the criteria for classification as toxic for reproduction category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment. However, testing for developmental toxicity must be considered.

You have self-classified the Substance as Repro 1B for fertility, based on the impurity [CONFIDENTIAL]. However, you have not justified why the Repro 1B self-classification for sexual function and fertility is sufficient to protect pregnant females and their foetuses, and why information on developmental toxicity is not needed for your Substance.

Hence, your adaptations are rejected, the standard information requirement is not fulfilled and further testing is necessary.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with [Substance 2]. As explained […] above, your adaptation of the information requirement is not accepted. Hence, there is a need to test the registered substance.'

30. In the Contested Decision for Substance 8, the Agency therefore:

- rejected the '*waiving justification*' submitted for Substance 8 after 6 March 2019 (see paragraph 13 above),
- rejected the Appellants' category approach,
- rejected the '*testing strategy*' proposed by the Appellants on 31 May 2017 (see paragraph 9 above),
- required a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on Substance 8, and
- set out specifications for the test material to be used in the performance of the studies.

Procedure before the Board of Appeal

31. On 24 December 2019, the Appellants filed separate appeals against the Contested Decisions.

32. On 13 February 2020, the Board of Appeal joined the appeals for the purposes of the written and oral parts of the procedure, and the final decision.

33. On 31 March 2020, the Agency submitted its Defence.

34. On 26 May 2020, Spyridon Merkourakis, alternate member of the Board of Appeal, was designated to replace Sari Haukka in these cases, in accordance with the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; the 'Rules of Procedure').

35. On 5 June 2020, Cruelty Free Europe was granted leave to intervene in these cases in support of the Appellants.

36. On 1 July 2020, the Appellants submitted observations on the Defence.

37. On 3 August 2020, the Intervener submitted its statement in intervention.

38. On 4 September 2020, the Agency submitted its observations on the Appellants' observations on the Defence.

39. On 27 August and 4 September 2020, the Appellants and the Agency submitted their respective observations on the statement in intervention.

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

Forms of order sought

41. The Appellants, supported by the Intervener, request the Board of Appeal to annul the Contested Decisions and order the refund of the appeal fees.

42. The Agency requests the Board of Appeal to dismiss the appeals as unfounded.

Reasons

43. The Appellants raise three pleas against each Contested Decision, alleging that the Agency:

- breached Articles 40 to 43, 50 and 51 as regards the choice of legal basis for the Contested Decisions and the conduct of the decision-making procedure (first plea),
- incorrectly exercised its margin of discretion and breached Article 25 and the principle of proportionality by requiring the Appellants to conduct unnecessary studies on vertebrate animals (second plea), and
- breached Articles 40 and 50, and the principles of equal treatment and good administration, by addressing the Contested Decisions only to the lead registrants (third plea).

1. First plea: Breaches of Articles 40 to 43, 50 and 51 as regards the choice of legal basis and the conduct of the decision-making procedure

Arguments of the Parties and the Intervener

44. By the first plea, the Appellants, supported by the Intervener, argue that the Agency made several errors as regards the choice of legal basis for the Contested Decisions and the conduct of the decision-making procedure.

45. The first plea consists of three parts.

46. First, according to the Appellants, Article 40 does not allow the Agency to assess whether the information provided in a registration dossier with respect to the identity of a registered substance is adequate. Article 40 also does not allow the Agency to examine whether a category approach proposed by one or more registrants complies with the requirements of Section 1.5. of Annex XI. These issues should have been addressed in a compliance check of the Appellants' registration dossiers under Article

41. In support of this argument, the Appellants rely on paragraphs 44 and 45 of the Decision of the Board of Appeal of 30 January 2018 in Case A-005-2016, *Cheminova.*

47. Second, according to the Appellants, the Agency should either have pursued further its informal exchanges with the Appellants, or have required information on the identity and composition of the Substances by means of the compliance check procedure under Article 41. The Agency should not have sought information from the Appellants by means of informal exchanges, and then used that information against the Appellants in the assessment of their testing proposals.

48. The Intervener adds, in that regard, that Article 77(2)(j) requires the Agency to support registrants in substantiating their adaptations.

49. Third, according to the Appellants, the Agency should have clarified the identity of the Substances by means of the compliance check procedure under Article 41 before examining the Appellants' testing proposals under Article 40.

50. As the Agency's decision to apply the testing proposal procedure under Article 40 instead of the compliance check procedure under Article 41, and its failure to pursue further its informal exchanges with the Appellants, had an impact on the outcome of the cases, the Contested Decisions should be annulled.

51. The Agency disputes the Appellants' and the Intervener's arguments.

Findings of the Board of Appeal

52. By their first plea, the Appellants claim, in essence, that the Agency made several procedural errors as regards the assessment of their category approach.

53. In the Contested Decisions in Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019, the Agency approved the tests proposed for the Source Substances (see paragraphs 17 to 22 above).

54. Those decisions are not based on the assessment of the Appellants' category approach. In Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019, the first plea must therefore be rejected as inoperative.

55. In the Contested Decisions in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019, the Agency rejected the Appellants' '*testing strategy*' submitted after 6 March 2019 and required the relevant studies on each of the Target Substances (see paragraphs 23 to 26 above). Similarly, in the Contested Decision in case A-023-2019, the Agency rejected the Appellants' '*testing strategy*' of 31 May 2017 and required the relevant studies on Substance 8 (see paragraphs 27 to 30 above).

56. Those decisions are all based on the assessment of the Appellants' category approach. In Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019, it is therefore necessary to examine whether the first plea is well-founded.

57. The first plea consists of three parts. It is appropriate to examine the first and third parts of the first plea together.

1.1. First and third parts of the first plea: Choice of legal basis

58. By the first and third parts of the first plea, the Appellants argue, in essence, that the Agency was not entitled to assess and reject the category approach on which the Appellants' '*testing strategy*' was based under Article 40.

59. In order to decide on the first and third parts of the first plea, it is necessary to determine whether a registrant's proposal to rely on a study to be carried out on a different substance in order to satisfy information requirements for the registration of its own substance, by means of an adaptation under Section 1.5. of Annex XI (a 'read-across testing proposal'), constitutes a testing proposal within the meaning of Article 40.

60. First, testing proposals are only required under Annexes IX and X. The first, second and fourth introductory paragraphs to Annexes IX and X provide (emphasis added):

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

[…] Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

[…]

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

61. The first, second and fourth introductory paragraphs to Annexes IX and X therefore show that a proposal under Annex IX or X may include, or be based on, an adaptation under Section 1.5. of Annex XI.

62. Second, Article 40(1) provides that the Agency shall examine any testing proposal set out in a registration, or a downstream user report, for provision of the information specified in Annexes IX and X. Article 40(3)(c) further provides (emphasis added):

'*On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51: […] a decision in accordance with points (a), (b) or (d)* [i.e. accepting, modifying or rejecting a testing proposal] *but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI […]*.'

63. Article 40(1) and (3)(c) therefore allows the Agency to examine adaptations under Section 1.5. of Annex XI contained in a testing proposal (see Case A-015-2019, *Polynt*, Decision of the Board of Appeal of 9 February 2021, paragraph 51).

64. It follows from the provisions examined in paragraphs 60 to 63 above that a read-across testing proposal constitutes a testing proposal within the meaning of Article 40.

65. The Agency was consequently entitled to assess the Appellants' '*testing strategy*', including the category approach on which it was based, under Article 40.

66. Furthermore, Section 1.5. of Annex XI allows for an adaptation if it is established that (i) the substances in a group or category are structurally similar, (ii) the properties of the substances are likely to be similar or follow a regular pattern, and (iii) the similarity of properties or their regular pattern is the result of structural similarity (see Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 66).

67. In examining the Appellants' category approach, the Agency was consequently also required to examine whether the available information on the composition of the Substances shows that the Substances are structurally similar.

68. That conclusion is not called into question by the Appellants' reference to paragraphs 44 and 45 of the Decision of the Board of Appeal of 30 January 2018 in Case A-005-2016, *Cheminova*.

69. The appellant in *Cheminova* proposed to carry out studies on a first substance, and then rely on the results of those studies under Section 1.5. of Annex XI for the purposes of its registration of a second substance. It initially submitted a '*waiving justification*' in its registration dossier for the second substance. The Agency qualified this *'waiving justification'* as a testing proposal, leading then the appellant in *Cheminova* formally to submit a testing proposal. Eventually, the appellant in *Cheminova* stated that no further studies of any kind were needed as, meanwhile, the Agency had approved its testing proposal for the first substance (see paragraphs 1 to 16 and 39 to 43 of the Decision of the Board of Appeal in *Cheminova*).

70. In the present cases, by contrast, the Appellants submitted a '*testing strategy*' for all the Substances at the same time. That '*testing strategy*' comprised several tests under Annex IX which had not yet been approved by the Agency. Contrary to the appellant in *Cheminova*, the Appellants in the present cases intended to submit to the Agency a global approach designed to be assessed simultaneously and in a comprehensive manner.

71. The present cases must therefore be distinguished from the case that gave rise to the findings of the Board of Appeal in paragraphs 44 and 45 of the Decision of the Board of Appeal in *Cheminova*.

72. In Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019, the first and third parts of the first plea must therefore be rejected as unfounded.

1.2. Second part of the first plea: Conduct of the decision-making procedure

73. By the second part of the first plea, the Appellants claim that the Agency should either have pursued further its informal exchanges with the Appellants, or have required information on the identity and composition of the Substances by means of the compliance check procedure under Article 41, before adopting the Contested Decisions.

74. As stated in paragraphs 58 to 72 above, the Agency committed no error by examining the Appellants' testing proposals under Article 40.

75. Articles 40, 50 and 51 set out a procedure to be followed in the examination of testing proposals. In principle, the Agency is not required to seek information from registrants outside this procedure.

76. Furthermore, the Agency does not have a legal obligation, under either Article 40 or Article 41, to wait for registrants to improve their justification for an adaptation (see Case A-005-2016, *Cheminova*, Decision of the Board of Appeal of 30 January 2018, paragraph 49).

77. That finding is not called into question by Article 77(2)(j). That provision tasks the Agency with '*providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1)*'. As is apparent from its wording, that provision concerns technical assistance for the submission of registration dossiers. Article 77(2)(j) does not impose on the Agency any obligations as regards the development of a testing proposal or adaptation and helping a registrant in their preparation.

78. However, there is no rule of law preventing the Agency from discussing with, or seeking information from, registrants outside this procedure if it so chooses. If the Agency requests registrants to provide information outside the procedure set out in Article 40, 50 and 51, and information is provided as a result, the principle of good administration requires the Agency to take any information provided into account in its decision (see, for example, judgment of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438, paragraph 14).

79. In the present cases, the Agency stated clearly and repeatedly – during the course of both the informal exchanges with the Appellants and the formal decision-making procedure – the reasons why it considered that the Appellants' category approach did not satisfy the requirements of Section 1.5. of Annex XI (see paragraphs 8, 11 and 12 above).

80. Following those statements by the Agency, the Appellants had the opportunity to provide the information which was required to help substantiate their adaptation. The Appellants do not argue that the Agency failed to take into account any of the information they provided.

81. In those circumstances, the Agency committed no error by not pursuing further its informal exchanges with the Appellants, or by not requiring information on the identity and composition of the Substances by means of the compliance check procedure under Article 41, before adopting the Contested Decisions.

82. In Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019, the second part of the first plea must therefore be rejected as unfounded.

1.3. Conclusion on the first plea

83. It follows from the reasons set out in paragraph 53 and 54 above that the first plea must be rejected as inoperative in Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019.

84. It follows from the reasons set out in paragraphs 55 to 82 above that the first plea must be rejected as unfounded in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

2. Second plea: Incorrect exercise of the Agency's margin of discretion and breaches of Article 25 and of the principles of proportionality and good administration as regards the assessment of the Appellants' testing proposals

Arguments of the Parties and the Intervener

85. By the second plea, the Appellants, supported by the Intervener, argue in essence that the Agency erred in rejecting the category approach which underpinned the Appellants' testing proposals. The second plea consists of five parts.

86. First, according to the Appellants, the Agency should have '*provided its conclusions on the category approach*' before examining and rejecting the Appellants' testing proposals. By failing to do so, the Agency required the Appellants to carry out studies which it might be possible to forgo under Section 1.5. of Annex XI.

87. Second, according to the Appellants, the Agency committed numerous errors in its assessment of the Appellants' category approach. As the Appellants' category approach complies with the requirements of Section 1.5. of Annex XI, the Agency required the Appellants to conduct studies which are not necessary.

88. Third, according to the Appellants, it may be possible to establish that the conditions for an adaptation under Section 1.5. of Annex XI are fulfilled by gathering and submitting further information on the composition and properties of the Substances, and therefore forgo testing on all but the four Source Substances.

89. Fourth, according to the Appellants, the Agency failed to examine a '*waiving justification*' for Substance 8, which was submitted in March 2019 and referred to in the Appellants' comments on the draft decision. In any event, insofar as the Agency assessed that '*waiving justifification*', the Agency's assessment was materially incorrect.

90. Fifth, according to the Appellants, the Agency was inconsistent in its recommendations as to the testing materials to be used. The Agency based the selection of the testing materials on a '*worst case scenario*', whilst also refusing to accept the Appellants' adaptation under Section 1.5. of Annex XI which was also based on a '*worst case scenario*'.

91. The Agency disputes the Appellants' and the Intervener's arguments.

Findings of the Board of Appeal

2.1. First, second, third and fifth parts of the first plea: Errors in the assessment of the Appellants' category approach

92. By the first, second, third and fifth parts of the second plea, the Appellants, supported by the Intervener, argue that the Agency's rejection of the category approach which underpinned the Appellants' testing proposals is vitiated by several errors.

93. In the Contested Decisions in Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019, the Agency approved the tests proposed for the Source Substances (see paragraphs 17 to 22 above).

94. Those decisions are not based on the assessment of the Appellants' category approach. In Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019, the first, second third and fifth parts of the second plea must therefore be rejected as inoperative.

95. In the Contested Decisions in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019, the Agency rejected the Appellants' '*testing strategy*' submitted after 6 March 2019 and required the relevant studies on each of the Target Substances (see paragraphs 23 to 26 above). Similarly, in the Contested Decision in case A-023-2019, the Agency rejected the Appellants' '*testing strategy*' of 31 May 2017 and required the relevant studies on Substance 8 (see paragraphs 27 to 30 above).

96. Those decisions are all based on the assessment of the Appellants' category approach. In Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019, it is therefore necessary to examine whether the first, second, third and fifth parts of the second plea are well-founded.

97. It is appropriate to begin by examining the second part of the second plea.

2.1.1. Errors in the assessment of the Appellants' category approach

98. By the second part of the second plea, the Appellants argue, in essence, that the Agency erred in finding that the Appellants' category approach does not fulfil the requirements of Section 1.5. of Annex XI.

99. The first paragraph of Section 1.5. of Annex XI provides:

'*Substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint. […]*'

100. Section 1.5. of Annex XI therefore allows for an adaptation if it is established that (i) the substances in a group or category are structurally similar, (ii) the properties of the substances are likely to be similar or follow a regular pattern, and (iii) the similarity of properties or their regular pattern is the result of structural similarity (see Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 66).

101. As regards the first of the three cumulative conditions for an adaptation referred to in the previous paragraph, namely structural similarity, the Contested Decisions for the Target Substances conclude:

'*[T]he information provided on the category members does not reflect the inherent variability in the concentrations of the constituents and does not constitute a reliable basis to establish compositional similarities. The applicability domain does not indicate clearly the borders of the category and does not unambiguously establish for which chemicals the category does not hold.'*

102. The Appellants argue that this conclusion is incorrect.

103. When examining the merits of a case, the Board of Appeal confines itself, in principle, to examining whether the pleas put forward by an appellant demonstrate that the contested decision is vitiated by an error (see judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 65; see also Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, Decision of 4 May 2020, paragraph 30).

104. Therefore, an appellant cannot simply claim that the result of the assessment on which a contested decision is based should have been different, but must put forward arguments to show the existence of errors vitiating the scientific assessment on which the contested decision is based (see judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 86).

105. The Appellants' submissions do not contain any specific arguments challenging the Agency's finding that the first of the three cumulative conditions for an adaptation referred to in paragraph 100 above, namely structural similarity, is not fulfilled. The numerous arguments raised by the Appellants in their submissions, and in a document entitled '*Points of contention with ECHA's assessment of the category approach and testing proposal justification*', which is attached to their Notices of Appeal, relate to the Agency's findings that the Appellants' category approach does not satisfy the other two cumulative conditions for an adaptation referred to in paragraph 100 above.

106. Consequently, the Appellants' argument that the Agency's assessment as regards the first of the three cumulative conditions for an adaptation referred to in paragraph 100 above, namely structural similarity, is vitiated by error, is unsubstantiated.

107. In any event, the documentation submitted by the Appellants in these proceedings – in particular, the several documents justifying the Appellants' '*testing strategy*' – shows that the Appellants have provided average concentrations for the content of '*neutral ZDDP*', '*basic ZDDP*' and '*base oils*' in the composition of the Substances. The Appellants have not, however, provided information on the variability in the concentrations of these constituents for each individual Substance, nor on the exact identity of the '*base oils*' in question. The Agency therefore committed no error in finding that the information provided by the Appellants does not establish that the Substances are structurally similar.

108. It follows from the reasons set out in paragraphs 99 to 107 above that the Appellants have not established that the Agency committed an error in finding that the first of the three cumulative conditions for an adaptation referred to in paragraph 100 above, namely structural similarity, is not fulfilled.

109. As a consequence, there is no need to examine the Appellants' arguments concerning the two remaining conditions for an adaptation referred to in paragraph 100 above.

110. The second part of the second plea must therefore be rejected as unfounded in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

2.1.2. Request to gather, generate and submit further information to substantiate the Appellants' category approach

111. By the first and third parts of the second plea, the Appellants argue, in essence, that their adaptations would comply with Section 1.5. of Annex XI if further information on the composition and properties of the Substances were generated, gathered, and submitted. By failing to request that information from the Appellants, the Agency committed an error of assessment and breached Article 25, the principle of proportionality and the principle of good administration.

112. In order to decide on those arguments, it is necessary to examine the respective duties of registrants and of the Agency as regards the submission and development of adaptations.

113. First, Title II (Articles 5 to 24) provides that manufacturers of substances on their own, in mixtures or in articles in quantities above one tonne per year may not place their substances on the market in the European Union unless they have been registered with the Agency.

114. In order to register a substance with the Agency, a manufacturer or importer must submit a registration containing the information set out in Article 10. This information includes the information on the intrinsic properties of substances derived from the application of Annexes VII to XI. That information includes vertebrate animal studies under Column 1 of Annexes VII to X or, alternatively, adaptations under Column 2 of those Annexes or adaptations under Annex XI.

115. It follows from Recitals 16 and 19, and Articles 1(3) and 5, that it is the responsibility of registrants to provide information capable of satisfying the information requirements of the REACH Regulation.

116. Furthermore, it follows from Recital 47 and Articles 13(1) and 25(1) that testing on vertebrate animals required under Annexes VII to X should be carried out only if it is not possible to provide the required information on the intrinsic properties of a substance by means of an adaptation (see, to this effect, judgment of 21 January 2021, *Germany* v *ESSO Raffinage*, C-471/18 P, EU:C:2021:48, paragraphs 130 to 132; see also Case A-005-2011, *Honeywell Belgium*, Decision of the Board of Appeal of 29 April 2013, paragraph 90).

117. Registrants are consequently obliged to submit to the Agency registration dossiers which comply with all the information requirements set out in, amongst other provisions, Annexes VII to X. Where those Annexes require information from testing on vertebrate animals, registrants are also obliged to ensure that such testing is only carried out if the conditions for an adaptation cannot be fulfilled.

118. Second, Chapter 1 of Title VI, which is entitled '*Dossier evaluation*', provides for two procedures: the examination of testing proposals (Article 40) and the compliance check of registrations (Article 41).

119. In addition, Chapter 1 of Title VI provides for a follow-up procedure (Article 42), which is a continuation of the procedures under Articles 40 and 41 (see judgment of 8 May 2018, *ESSO Raffinage* v *ECHA*, T–283/15, EU:T:2018:263, paragraph 62).

120. The procedures under Articles 40 and 41 pursue the same objective, namely to allow the Agency to assess the quality and adequacy of the information provided by registrants in their registration dossier in order to verify that the information requirements of the REACH Regulation have been fulfilled (see Case A-015-2019, *Polynt*, Decision of the Board of Appeal of 9 February 2021, paragraph 51).

121. The procedures under Articles 40 and 41, and the follow-up under Article 42 to decisions taken by the Agency under Articles 40 and 41, ensure that registrants have the possibility to comply with their duties, including providing adaptations instead of vertebrate animal studies whenever possible.

122. To that end, registrants may submit adaptations not only in their registration dossiers in lieu of the results from a study, but also in testing proposals (see paragraph 64 above) and in the follow-up under Article 42 to decision taken by the Agency under Articles 40 or 41 (see judgments of 21 January 2021, *Germany* v *ESSO Raffinage*, C-471/18 P, EU:C:2021:48, paragraphs 135 and 136, and of 8 May 2018, *ESSO Raffinage* v *ECHA*, T–283/15, EU:T:2018:263, paragraphs 62 and 63).

123. Furthermore, during the conduct of both of the dossier evaluation procedures the Agency is required to examine carefully and impartially all the relevant aspects of the individual case (see judgment of 21 November 1991, *Technische Universität München*, C-269/90, EU:C:1991:438). The Agency's assessment is carried out as thoroughly as possible on the basis of the principles of scientific excellence, transparency and independence (see judgment of 11 September 2002, *Pfizer Animal Health* v *Council*, T-13/99, EU:T:2002:209, paragraph 172; see also Case A-010-2018, *Symrise*, Decision of the Board of Appeal of 18 August 2020, paragraph 202).

124. The procedures and safeguards referred to in paragraphs 121 to 123 above ensure that studies – and especially studies on vertebrate animals – are carried out only if no adaptation is possible. Without prejudice to those safeguards, it is not the role of the Agency to develop or improve adaptations on a registrant's behalf (see, to that effect, Case A-006-2012, *Momentive Specialty Chemicals*, Decision of the Board of Appeal of 13 February 2014, paragraph 60, and Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, Decision of the Board of Appeal of 4 May 2020, paragraph 37).

125. Furthermore, as regards the information required under Annexes IX and X, the powers conferred on the Agency under Article 40(3) are limited to the drafting and adoption of one of the following decisions: (i) approve a testing proposal, (ii) approve a testing proposal but modify the conditions under which the test is to be carried out, (iii) approve, modify or reject a testing proposal whilst requiring registrants to carry out studies set out in Annexes IX or X although the registrants did not propose them, (iv) reject a testing proposal, or (v) determine which of several registrants must carry out a certain study. Article 40 does not empower the Agency to require registrants to generate, gather and submit information to substantiate an adaptation.

126. It follows from the reasons set out in paragraphs 113 to 125 above that it is the responsibility of registrants to generate, gather and submit to the Agency such information as will substantiate an adaptation in accordance with the requirements of the REACH Regulation. The Agency is neither required nor empowered to oblige registrants to generate, gather and submit information to substantiate an adaptation.

127. Consequently, contrary to the Appellants' arguments, the Agency did not commit an error of assessment or breach Article 25, the principle of proportionality or the principle of good administration by failing to require the Appellants to submit further information in order to substantiate their adaptations.

128. The first and second parts of the second plea must therefore be rejected as unfounded in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

2.1.3. Inconsistency between the assessment of the Appellants' category approach and the selection of testing materials

129. By the fifth part of the second plea, the Appellants argue that the Agency was inconsistent in its recommendations as to the testing materials to be used in the present cases.

130. Specifically, the Appellants argue that their category approach was based on a '*worst case scenario*' as regards the properties of the Substances. The Agency rejected that assumption, but then contradicted itself by stating, in the Contested Decisions, that each Appellant should '*select a composition of the test material for the conduct of the requested studies, which represents a worst case in terms of expected absorption and expected toxicity for the possible constituent ratios*'.

131. That argument must be rejected. There is no connection between the reasons for rejecting the Appellants' category approach for all the Substances, and the selection of testing materials for each individual Substance. There cannot, therefore, be any inconsistency between the Agency's assessment of the Appellants' category approach and its recommendation as to the test materials to be used.

132. In any event, the Appellants have not demonstrated that the first of the three cumulative conditions for an adaptation referred to in paragraph 100 above, namely structural similarity, is fulfilled (see paragraph 107 above). As a consequence, there is no need to address the Appellants' arguments concerning the properties of the Substances.

133. The fifth part of the second plea must consequently be rejected as unfounded in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

2.1.4. Conclusion on the first, second, third and fifth parts of the second plea

134. It follows from the reasons set out in paragraphs 93 and 94 above that the first, second, third and fifth parts of the second plea must be rejected as inoperative in Cases A-016-2019, A-018-2019, A-019-2019 and A-024-2019.

135. It follows from the reasons set out in paragraphs 95 to 133 above that the first, second, third and fifth parts of the second plea must be rejected as unfounded in Cases A-017-2019, A-020-2019, A-021-2019, A-022-2019, A-023-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019, and A-029-2019.

2.2. Fourth part of the second plea: Failure to take into account a '*waiving justification*'

136. By the fourth part of the second plea, the Appellants claim that the Agency failed to recognise that, following the receipt of the Agency's draft decision, the registrant for Substance 8 did not update its '*testing strategy*'. Instead, it submitted a '*waiving justification*' for that substance.

137. First, this argument relates solely to Case A-023-2019, which is directed against the Contested Decision for Substance 8. In all the other cases, the fourth part of the second plea is inoperative.

138. Second, the registrant for Substance 8 submitted a testing proposal for that substance on 31 May 2017 (see paragraph 9 above). As that testing proposal remained in place during the entire course of the decision-making procedure, the Agency was entitled to examine it under Article 40.

139. Third, the registrant for Substance 8 submitted a '*waiving justification*' on 6 March 2019, setting out why it considered that testing on Substance 8 was not scientifically necessary (see paragraph 13 above). At pages 3, 22 and 23 of the Contested Decision concerning Substance 8, the Agency addressed that '*waiving justification*' against the requirements of the first and second paragraphs of Column 2 of Section 8.7. of Annex IX. The Agency has not, therefore, failed to assess the '*waiving justification*' submitted for Substance 8.

140. In addition, in their observations on the Defence, the Appellants argued that the Agency's assessment of the '*waiving justification*' submitted for Substance 8 is materially incorrect. This argument constitutes a new plea that was not contained in the Notice of Appeal.

141. Pursuant to Article 12(2) of the Rules of Procedure, no new plea may be introduced after the first exchange of written pleadings unless it is based on new matters of law or of fact that come to light in the course of the proceedings

142. The argument in question constitutes a new plea which was submitted after the first exchange of written pleadings. Furthermore, it is not based on a new matter of law or fact that came to light during the course of the proceedings.

143. The argument that the Agency's assessment of the '*waiving justification*' submitted for Substance 8 was materially incorrect must therefore be rejected as inadmissible.

144. The fourth part of the second plea must consequently be rejected as unfounded in Case A-023-2019, and as inoperative in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-025-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019.

2.3. Conclusion on the second plea

145. The first, second, third and fifth parts of the second plea are inoperative in Cases 016-2019, A-018-2019, A-019-2019 and A-024-2019, and unfounded in the remaining cases (see paragraphs 134 and 135 above).

146. The fourth part of the second plea is unfounded in Case A-023-2019, and inoperative in the remaining cases (see paragraph 144 above).

147. In each case, all parts of the second plea are therefore either inoperative or unfounded.

148. The second plea must consequently be rejected in all cases.

3. Third plea: breach of Articles 40 and 50 and of the principles of equal treatment and good administration as regards the choice of addressees

Arguments of the Parties and the Intervener

149. The Appellants, supported by the Intervener, argue that each Contested Decision should have been addressed to all registrants of the Substance in question and not only to the lead registrant.

150. The Agency argues that a decision on a testing proposal need only be addressed to the registrant who submitted the testing proposal, which in each of these cases is the Appellant who is the lead or sole registrant for each substance. In any event, according to the Agency, addressing the decisions only to the Appellants had no effect on their rights and obligations. The Appellants will be able to share the studies, and their costs, with the other registrants of each of the Substances in accordance with the data and cost-sharing rules in the REACH Regulation.

Findings of the Board of Appeal

151. In order to decide on the third plea it is necessary to examine, first, the interpretation of Article 40(3) and 50(1) insofar as they provide that a decision on a testing proposal should be addressed to the '*registrant(s) […] concerned*' and, second, the application of those provisions in the present case.

3.1. Interpretation of Articles 40(3) and 50(1)

152. Articles 40(3) and 50(1) provide that a decision on a testing proposal should be addressed to the '*registrant(s) […] concerned*'.

153. It is not clear from the wording '*registrant(s) […] concerned*' whether a decision under Article 40 should be addressed only to the registrant who included the testing proposal in its registration dossier, or whether – and under which conditions – it should also be addressed to other registrants of the same substance.

154. Therefore, in interpreting the provision in question, 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 (see judgment of 4 February 2016, *C&J Clark International and Puma*, C-659/13 and C-34/14, EU:C:2016:74, paragraph 124).

155. As regards the context, pursuant to Articles 10(a)(ix) and 12, registrants must submit testing proposals under Annexes IX and X in their registration dossiers when registering a substance. Similarly, pursuant to Article 22(1)(h), registrants must submit testing proposals if they identify the need to perform a test required under Annexes IX and X after registering a substance.

156. In addition, the REACH Regulation contains provisions on the submission of data and the sharing of the costs of those data between registrants of the same substance. Some of those provisions also apply to the submission of testing proposals.

157. Specifically, the second subparagraph of Article 11(1), read in conjunction with Article 10(a)(ix), provides that testing proposals must be submitted by the lead registrant for a substance not only on its own behalf, but also on behalf of the '*assenting registrants*'.

158. The term '*assenting registrants*' must be read in light of Article 11(3), which provides that registrants may only submit information (and testing proposals) separately by doing so expressly in their registration dossiers, and only for specific reasons (see, to that effect, Case A-022-2013, *REACheck Solutions*, Decision of the Board of Appeal of 15 March 2016, paragraph 73). Registrants of a substance to whom an information requirement applies and whose lead registrant submits a testing proposal to the Agency are therefore deemed to have assented to that testing proposal unless they have decided to submit information separately in accordance with Article 11(3).

159. When the Agency takes a decision on a testing proposal submitted by a lead registrant in accordance with Article 40, that decision therefore affects not only the lead registrant who submitted the proposal in its own registration dossier, but also all those other registrants of the substance to whom an information requirement applies and who have not decided to submit information separately from the submission of the testing proposal in accordance with Article 11(3).

160. For example, if the Agency modifies a testing proposal, or requires a further study, in accordance with Article 40(3), the effects of the Agency's decision will affect not only the lead registrant who submitted the testing proposal, but also the assenting registrants. Assenting registrants may be required to contribute to the costs of carrying out a different study than the one to which they initially assented.

161. All registrants to whom an information requirement applies and who have not decided to submit information separately from the submission of the testing proposal in accordance with Article 11(3) are therefore concerned by the Agency's eventual decision under Article 40.

162. The context of Articles 40(3) and 50(1) therefore indicates that the '*registrant(s) […] concerned*' are all those registrants of the same substance to whom an information

requirement applies and who have not decided to submit the information in question separately in accordance with Article 11(3).

163. As regards the objectives, the procedural rules in Articles 40(3) and 50(1) concern both the involvement of concerned registrants in the decision-making procedure and the question of who should be the addressees of the Agency's eventual decision. The procedural rules in Articles 40(3) and 50(1) pursue three objectives.

164. In the first place, those rules allow the Agency to acquire information on a substance so that it can carry out its assessment of a testing proposal in the fullest possible knowledge of the facts of a case (see, to that effect, judgments of 4 June 2020, *EEAS* v *De Loecker*, C-187/19 P, EU:C:2020:444, paragraph 69, and of 11 December 2014, C-249/13, *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, EU:C:2014:2431, paragraph 37).

165. In the second place, those rules ensure the effective protection of the registrants who will eventually be bound by the Agency's decision, allowing them to submit such information as will argue in favour of the adoption or non-adoption of a decision, or of its having a specific content (see, to that effect, the case-law cited in the previous paragraph).

166. In the third place, those rules allow the registrants in question to know of the adoption and content of the Agency's decision, so that they may comply with it or challenge it, as the case may be (see, to that effect, judgments of 5 December 1963, *Lemmerz-Werke and Others* v *High Authority*, 53/63 and 54/63, EU:C:1963:54, p. 248, and of 15 June 2005, *Olsen* v *Commission*, T-17/02, EU:T:2005:218, paragraph 74).

167. These objectives are served only if all those registrants of the same substance to whom an information requirement applies and who have not decided to submit the information in question separately, in accordance with Article 11(3), are involved in the decision-making procedure under Articles 40, 50 and 51, and the Agency's final decision is addressed to them.

168. The objectives of Articles 40(3) and 50(1) therefore confirm that the '*registrant(s) […] concerned*' are all those registrants of the same substance to whom a certain information requirement applies and who have not decided to submit the information in question separately in accordance with Article 11(3).

169. It follows from the reasons set out in paragraphs 152 to 168 above that a decision on a testing proposal under Article 40 must be addressed to all those registrants of the same substance to whom an information requirement applies and who have not decided to submit separately the information in question in accordance with Article 11(3).

3.2. Application to the present cases

170. First, it is not contested that Substance 8 has only one registrant, who is the addressee of the relevant Contested Decision and the Appellant in Case A-023-2019. The third plea must consequently be rejected in that case.

171. Second, it is not contested that, although Substance 10 was registered twice for two different compositions, both registration dossiers were submitted as part of the same joint registration by the same registrant. That sole registrant is the addressee of the relevant Contested Decision and the Appellant in Case A-025-2019. The third plea must consequently also be rejected in that case.

172. Third, it is not contested that, in all the other cases, there are other registrants than the lead registrant to whom the relevant Contested Decision is addressed. Furthermore, none of the Parties submit that the other registrants, or some of them, have decided to submit the information in question separately in accordance with Article 11(3), or that the relevant information requirements do not apply to those registrants. Those other registrants must therefore be considered to be assenting registrants within the meaning of Article 11(1).

173. As each Contested Decision in those cases was addressed only to the lead registrant for the relevant substance, and not to the other registrants, Articles 40(3) and 50(1) were breached.

174. The Agency argues that that breach should not lead to the annulment of the Contested Decisions as it did not affect the relevant Appellants' legal position adversely. This argument must be rejected for the following reason.

175. Article 53 sets out mandatory data and cost-sharing rules following the adoption of a decision pursuant to Title VI, which includes Articles 40 and 50. It provides:

    '*1. Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.*

    2. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

    3. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

    4. The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.'

176. By addressing the relevant Contested Decisions only to the lead registrants of the relevant Substances, the Agency therefore deprived each lead registrant – that is, each Appellant – of the benefit of Article 53 in relation to the other registrants of the relevant Substance.

177. As a consequence, the Agency's argument that breaching Articles 40(3) and 50(1) did not affect the relevant Appellants' legal position adversely cannot be accepted.

178. It follows from all the reasons set out above that the third plea must be upheld in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019.

3.3. Conclusion on the third plea

179. It follows from the reasons set out in paragraphs 170 and 171 above that the third plea must be rejected in Cases A-023-2019 and A-025-2019.

180. It follows from the reasons set out in paragraphs 172 to 178 above that the third plea must be upheld in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019.

4. Result

181. In Cases A-023-2019 and A-025-2019, all the Appellants' pleas have been rejected. The appeals in those cases must consequently be dismissed.

182. In Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019, the third plea has been upheld. The Contested Decisions in those cases must consequently be annulled.

183. Pursuant to Article 93(3), if it considers an appeal to be well-founded, the Board of Appeal may exercise any power that lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

184. In the exercise of that power, the Board of Appeal must not only examine whether it has at its disposal all the information allowing it to adopt its own decision, but it must also take into account the rules governing the procedure provided for the adoption of the initial decision by the Agency (see, to that effect, judgments of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, paragraph 118, and *Germany* v *ECHA*, T-755/17, EU:T:2019:647, paragraphs 88 and 89).

185. In the present cases, it cannot be excluded that the assenting registrants of the relevant Substances, if involved in the procedure, may be able to contribute to the assessment of the testing proposals with relevant information. That information would then have to be examined by the Agency's competent body and the competent authorities of the Member States, in accordance with Articles 40, 50 and 51.

186. As a consequence, it is not possible for the Board of Appeal to replace the Contested Decisions in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019 with its own decision.

187. Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019 must therefore be remitted to the competent body of the Agency for further action.

Refund of the appeal fees

188. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee must be refunded if the appeal is decided in favour of an appellant.

189. As the appeals are dismissed in Cases A-023-2019 and A-025-2019, the appeal fees in those cases are not refunded.

190. As the Contested Decisions are annulled in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019, the appeal fees in those cases must be refunded.

Effects of the Contested Decisions in Cases A-023-2019 and A-025-2019

191. The Contested Decisions in Cases A-023-2019 and A-025-2019, which are upheld by the present decision, required the registrants for Substances 8 and 10 to submit information on a 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX) and a pre-natal developmental toxicity study (Section 8.7.2. of Annex IX) on those substances by 4 April 2022, which is two years, six months and eight days from the date of those Contested Decisions.

192. Pursuant to Article 91(2), an appeal has suspensive effect. The deadline set in the Contested Decisions in Cases A-023-2019 and A-025-2019 must therefore be calculated starting from the date of notification of the present decision of the Board of Appeal.

193. The information required by the Contested Decisions in Cases A-023-2019 and A-025-2019 must therefore be provided by 31 August 2023.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeals in Cases A-023-2019 and A-025-2019.**
2. **Decides that the information required in those cases must be provided by 31 August 2023.**
3. **Decides that the appeal fees in those cases are not refunded.**
4. **Annuls the Contested Decisions in Cases A-016-2019, A-017-2019, A-018-2019, A-019-2019, A-020-2019, A-021-2019, A-022-2019, A-024-2019, A-026-2019, A-027-2019, A-028-2019 and A-029-2019.**
5. **Remits those cases to the competent body of the Agency for further action.**
6. **Decides that the appeal fees in those cases are refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Luca BOLZONELLO
On behalf of the Registrar of the Board of Appeal