EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

10 May 2022

(Substance evaluation – Error of assessment – Good administration – Proportionality – Equal treatment and non-discrimination – Right to be heard)

Case number	A-002-2021
Language of the case	English
Appellants	LANXESS Deutschland GmbH, Germany Schirm GmbH, Germany
Representatives	Ursula Schliessner and Preslava Dilkova Jones Day, Belgium
Intervener	The Finnish Safety and Chemicals Agency ('Tukes')
Contested Decision	Decision of 26 October 2020 on the substance evaluation of diuron adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46 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 Contested Decision was notified to LANXESS Deutschland GmbH under the annotation number SEV-D-2114528603-52-01/F and to Schirm GmbH under the annotation number SEV-D-2114526004-64-01/F.

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman), Nikolaos Georgiadis (Technically Qualified Member and Rapporteur) and Laura De Sanctis (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. The Agency included diuron (EC number 206-354-4; CAS number 330-54-1) in the Community rolling action plan ('CoRAP') for substance evaluation in 2014. This was on the basis of an opinion of the Member State Committee and due to initial grounds for concern relating to '*human health/potential endocrine disruptor, exposure/wide dispersive use, ground and surface water pollutant*'. The updated CoRAP including diuron was published on the Agency's website on 26 March 2014 in accordance with Article 44(2) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). The Competent Authority of Finland was appointed as the evaluating Member State Competent Authority (the 'eMSCA').

2. In the course of the evaluation, the eMSCA identified additional concerns regarding endocrine disruption in the environment.

3. On 10 June 2016, the Agency adopted a decision under Article 46 (the 'first substance evaluation decision') requesting the Appellants to provide, by 18 December 2017, information on a Fish Sexual Development Test ('FSDT'; test method: OECD[1] test guideline ('TG') 234) with one of the following species: Japanese medaka *Oryzias latipes* or zebrafish *Danio rerio* or three-spined stickleback *Gasterosteus acuelatus*.

4. The first substance evaluation decision stated that the need for potential further information requests, targeted at endocrine disrupting effects in wildlife related to modes of actions (for example the thyroid) not examined in the FSDT, would be assessed based on the results of the FSDT and all other available information.

5. On 28 June 2018, the Appellants updated their registration dossiers for diuron with the information requested in the first substance evaluation decision.

6. Following an examination of the information submitted by the Appellants in response to the first substance evaluation decision, and the other available information, the eMSCA decided that there was not enough information to conclude that diuron is not an endocrine disruptor due to the (anti)androgenic and (anti)estrogenic modes of action. In addition, the eMSCA concluded that there was a concern related to the thyroid mode of action. The eMSCA therefore prepared a draft decision and, on 28 June 2019, submitted it to the Agency.

7. On 8 July 2019, in accordance with Article 50(1), the Agency notified the draft decision to the Appellants and invited them to provide comments. The draft decision requested the Appellants to provide information on a Larval Amphibian Growth and Development Assay ('LAGDA') according to OECD TG 241, including measurements of plasma vitellogenin.

8. On 29 July 2019, the Appellants requested an extension of the deadline to provide comments on the draft decision.

9. On 30 July 2019, the Agency informed the Appellants that it was not possible to extend the deadline to provide comments and recommended them to contact the eMSCA about the possibility of submitting a dossier update.

10. On 7 August 2019, the eMSCA informed the Appellants that they could submit a dossier update which would, nonetheless, need to support the comments submitted on the draft decision and be received within 60 days of the receipt of that draft.

11. On 13 August 2019, the Appellants provided comments to the Agency on the draft decision. The Appellants argued that the LAGDA was not sufficiently validated and that alternative test methods were available to address the concerns identified by the eMSCA (see paragraph 6 above).

[1] Organisation for Economic Co-operation and Development.

12. On 2 October 2019, the Appellants informed the Agency and the eMSCA that they had been able to submit their comments on the draft decision within the 30-day deadline. The Appellants also stated that they would update their registration dossier.

13. On 8 October 2019, the eMSCA informed the Appellants that, due to the workload and resources of the eMSCA, the draft decision would be sent to the competent authorities of the other Member States during the first half of 2020 and, at the latest, before the end of August 2020. The eMSCA also asked the Appellants to provide it with a list of the sections of the dossier updated.

14. On 28 November 2019, the eMSCA informed the Appellants that it had not received the dossier updates referred to by the Appellants earlier in the decision-making procedure. The eMSCA added that it was no longer necessary to update the registration dossier for diuron because, according to the Agency's policy, dossier updates are not considered during the decision-making procedure.

15. On 27 August 2020, the eMSCA notified the draft decision and the Appellants' comments on that draft to the competent authorities of the other Member States and the Agency in accordance with Article 52(1).

16. On 26 October 2020, as no proposals for amendment were submitted by the competent authorities of the Member States, the Agency adopted the Contested Decision in accordance with Article 51(3).

17. The Contested Decision requires the Appellants to update their registration dossier by 3 May 2022 with information on a LAGDA, including measurements of plasma vitellogenin.

Procedure before the Board of Appeal

18. On 22 January 2021, the Appellants filed this appeal.

19. On 25 March 2021, the Agency filed its Defence.

20. On 5 May 2021, the Appellants filed their observations on the Defence.

21. On 7 June 2021, the Agency filed its observations on the Appellants' observations on the Defence.

22. On 24 June 2021, Laura De Sanctis, alternate member of the Board of Appeal, was designated to act as legally qualified member of the Board of Appeal in this case in accordance with the second 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').

23. On 25 June 2021, the Appellants filed a corrigendum to their observations on the Defence.

24. On 30 June 2021, the eMSCA was granted leave to intervene in support of the Agency.

25. On 26 July 2021, the eMSCA filed its statement in intervention.

26. On 6 August 2021, the Agency submitted comments on the Appellants' corrigendum and replied to questions from the Board of Appeal.

27. On 2 September 2021, the Appellants filed their observations on the statement in intervention.

28. On 3 September 2021, the Agency filed its observations on the statement in intervention.

29. On 23 September 2021, the Appellants submitted their observations on certain aspects of the Agency's submission of 6 August 2021.

30. On 24 November 2021, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure. The hearing took place via video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Parties and the eMSCA made oral submissions and answered questions from the Board of Appeal.

Form of order sought

31. The Appellants request the Board of Appeal to annul the Contested Decision and order the refund of the appeal fee.

32. The Agency, supported by the eMSCA, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

1. Admissibility of the evidence in Annexes A5 to A12 to the Notice of Appeal

Arguments of the Parties

33. The Agency objects to the admissibility of the following eight annexes submitted with the Appellants' Notice of Appeal:

    (a) Ibacon Expert Statement of 19 January 2021 on the substance evaluation decision on diuron (Annex A5).

    (b) Martin *et al*, '*Data collection in support of the Endocrine Disruption (ED) assessment for non-target vertebrates*', EFSA Supporting Publication, (2020) 17(5), p. 1849 (Annex A6).

    (c) Fraunhofer IME Expert Statement, *'Scientific support for appeal against the substance evaluation decision of ECHA on the substance diuron'*, 14 January 2021 (Annex A7).

    (d) Couderq *et al*, *'Testing for thyroid hormone disruptors, a review of non-mammalian in vivo models'*, Molecular and Cellular Endocrinology, (2020), p. 110779 (Annex A8).

    (e) Letters from three laboratories to LANXESS Deutschland GmbH regarding capacity and experience with the amphibian metamorphosis assay ('AMA') and the LAGDA (Annex A9).

    (f) Awkerman *et al*, '*Cross-taxa distinctions in mechanisms of developmental effects for aquatic species exposed to trifluralin*', Environmental Toxicology and Chemistry, (2020) 39(9), pp. 1797-1812 (Annex A10).

    (g) Knapen *et al*, '*Toward an AOP network-based tiered testing strategy for the assessment of thyroid hormone disruption*', Environmental Science & Technology, (2020), 54(14), pp. 8491-8499 (Annex A11).

    (h) Reinwald *et al*, '*Toxicogenomic fin(ger)prints for thyroid disruption AOP refinement and biomarker identification in zebrafish embryos*', Science of the Total Environment, (2020) (Annex A12).

34. The Agency argues that Annexes A5 to A11 are inadmissible because they were not submitted to the Agency during the substance evaluation process leading to the adoption of the Contested Decision. The Agency argues that Annex A12 is inadmissible because it was published only after the adoption of the Contested Decision.

35. The Appellants dispute the Agency's claim that the evidence produced as Annexes A5 to A12 is inadmissible.

Findings of the Board of Appeal

36. Under Article 12(1) of the Rules of Procedure, no further evidence may be introduced after the first exchange of written pleadings – the notice of appeal submitted by the appellant and the defence submitted by the Agency – unless the Board of Appeal decides that the delay in offering the evidence is duly justified.

37. When examining whether evidence submitted in support of the Notice of Appeal that was not available to the Agency during the substance evaluation process is admissible, it must also be ascertained whether such information or evidence supports new facts or supports facts already alleged during the Agency's decision-making procedure (see Case A-001-2012, *Dow Benelux*, decision of the Board of Appeal of 19 June 2013, paragraph 46).

38. Annexes A5 and A7 are expert statements which were commissioned by the Appellants to support their appeal. Those expert statements assess the relevant information available before the adoption of the Contested Decision. Annex A9 contains letters to the Appellants from three laboratories which the Appellants use to support its arguments related to the appropriateness of the Amphibian Metamorphosis Assay ('AMA'). Annexes A5, A7 and A9 were not publicly available. Annexes A6, A8, A10, and A11 are articles published in journals after the date on which the Appellants submitted their comments on the draft decision but before the adoption of the Contested Decision. Annex A12 is an article published in a journal after the adoption of the Contested Decision.

39. Annexes A5 to A12 were submitted with the Notice of Appeal in accordance with Article 6(1)(f) of the Rules of Procedure. There was therefore no delay in offering that evidence within the meaning of Article 12(1) of the Rules of Procedure.

40. Annexes A5 to A12 were not available to the Agency during the decision-making procedure leading to the adoption of the Contested Decision. However, those Annexes were introduced by the Appellants in the present appeal proceedings to support arguments already raised during that decision-making procedure. Those arguments were that the LAGDA was not sufficiently validated for the thyroid mode of action and that there are more appropriate test methods to address the concerns identified by the Agency.

41. In view of paragraphs 36 to 40 above, the Agency's claim that the evidence produced in Annexes A5 to A12 to the Appellants' Notice of Appeal is inadmissible is rejected.

2. Substance

42. The Appellants raise the following pleas in law:

- First plea: The Agency committed a manifest error of assessment and infringed its duty of good administration under Article 41 of the Charter of Fundamental Rights of the European Union ('the Charter');
- Second plea: The Agency breached the principle of proportionality;
- Third plea: The Agency breached the principle of equal treatment and non-discrimination; and
- Fourth plea: The Agency breached the Appellants' right to be heard.

43. The Appellants' first plea is divided into three parts:

- First part: The Agency failed to take into account information that became available during the period between the Appellants' comments on the draft decision and the adoption of the Contested Decision;
- Second part: The Agency disregarded in its assessment the suitability of the LAGDA for examining the thyroid mode of action; and
- Third part: The Agency failed to assess the suitability of alternative testing methods to the LAGDA.

44. The first and second parts of the first plea will be examined in turn. The third part of the first plea will then be examined together with the second plea as the arguments raised under those pleas are similar.

2.1. First part of the first plea: The Agency failed to take into account information that became available during the period between the Appellants' comments on the draft decision and the adoption of Contested Decision

Arguments of the Parties and Intervener

45. The Appellants argue that the LAGDA is not sufficiently validated and that there are more appropriate alternative test methods to address the concerns identified in the Contested Decision.

46. The Appellants argue that the Agency failed to take into account certain published scientific articles, submitted as Annexes A6, A8, A10, and A11 to the Notice of Appeal, which were relevant to deciding whether the LAGDA is suitable to address the concerns identified in the Contested Decision (the 'new scientific information'). That information came to light during the more than 14-month period between the date on which the Appellants submitted their comments on the draft decision (13 August 2019) and the date of the adoption of the Contested Decision (26 October 2020). The Appellants argue that, by failing to take into account the new scientific information, the Agency committed a manifest error of assessment and infringed its duty of good administration under Article 41 of the Charter.

47. The Appellants argue that the Agency is required to base its decisions on the most up-to-date information. The Appellants also argue that, because of the new scientific information that came to light during the decision-making procedure, the Appellants should have been heard again and granted the opportunity to submit additional information.

48. The Appellants argue that, in the present case, the new scientific information constitutes substantial new information. However, the Appellants state that they did not submit that information to the Agency in the present case because, based on the Agency's communications, they understood that, by the time that information came to light, the deadline to submit dossier updates had expired. The Appellants argue that, even if they had submitted that information, the Agency would not have taken it into account in the substance evaluation process.

49. The Agency, supported by the eMSCA, disputes the Appellants' arguments.

50. The Agency argues that if a registrant's comments, which are received within the 30-day time-limit set out in Article 50(1), include study reports and study summaries not addressed in the initial draft decision, those will be taken into account by the Agency.

51. The Agency argues that it takes into account substantial new information which is submitted to the Agency by a registrant, or otherwise comes to its attention, after the expiry of the 30-day time-limit set out in Article 50(1) until the adoption of the final decision. The Agency argues, however, that registrants must submit such information by email or through the webform available for commenting on draft decisions. The Agency argues that a dossier update is not the correct channel for communicating substantial new information during the decision-making procedure, unless such a possibility is granted by the eMSCA.

52. The Agency argues that, in any case, the information that came to light during the decision-making procedure referred to by the Appellants in the present appeal is not capable of affecting the Agency's conclusions.

Findings of the Board of Appeal

Agency's obligation to take into account all relevant facts of a case

53. Under the right to good administration, which is codified in Article 41 of the Charter, the Agency is required to examine carefully and impartially all the relevant facts of the individual case, to gather all the factual and legal material necessary for the exercise of its discretion, and to ensure the proper conduct and the efficiency of the procedures it was implementing (see judgment of 3 October 2019, *BASF* v *ECHA*, T-805/17, EU:T:2019:723, paragraph 57 and judgment of 3 October 2019, *BASF and REACH & colours* v *ECHA*, T-806/17, EU:T:2019:724, paragraph 75).

54. With regards to the Appellants' argument that the Agency committed a manifest error of assessment, the General Court has confirmed that the review by the Board of Appeal of an Agency decision is not limited to verifying the existence of manifest errors. By relying on the legal and scientific competences of its members, the Board of Appeal must examine whether the arguments put forward by an appellant are capable of demonstrating that the considerations on which the Agency's decision is based are vitiated by error (see, for example, judgment of 20 September 2019, *BASF Grenzach* v *ECHA*, T-125/17, EU:T:2019:638, paragraph 89).

55. As part of the examination of arguments that the Agency committed an error of assessment, it is necessary to examine whether the Agency took into account all the relevant facts of the individual case (see, by analogy, judgment of 19 January 2012, *Xeda International and Pace International* v *Commission*, T-71/10, EU:T:2012:18, paragraph 71; see Case A-006-2017, *Climax Molybdenum*, decision of the Board of Appeal of 11 December 2018, paragraph 38).

Possibility to submit information during the Agency's decision-making procedure

56. Establishing and implementing an administrative cut-off point in a decision-making procedure with the aim of ensuring administrative efficiency may fall within the Agency's margin of discretion (see Joined Cases A-006-2020 and A-007-2020, *BASF Colors & Effects GmbH and BASF SE*, decision of the Board of Appeal of 9 November 2021, paragraph 49).

57. However, in order to ensure that it has exercised its discretion correctly when establishing and implementing an administrative cut-off point, the Agency must balance the need for administrative efficiency with other relevant considerations. In particular, the Agency, when exercising its discretion, must take into consideration all the relevant factors and circumstances of the situation the act was intended to regulate. The Agency's refusal to take into account dossier updates after the draft decision has been sent to the registrant under Article 50(1) could lead to a situation in which the final decision adopted by the Agency is not based on all relevant factors and circumstances (see *BASF Colors & Effects GmbH and BASF SE*, cited in the previous paragraph, paragraph 50).

58. After an administrative cut-off point, the Agency may exceptionally limit to substantial new information its obligation to take into account all relevant factors and circumstances of a particular case. For this reason, the Agency must have mechanisms in place to take into account substantial new information coming to light after that administrative cut-off point (see *BASF Colors & Effects GmbH and BASF SE*, cited in paragraph 56 above, paragraph 51).

59. The requirement to take into account substantial new information which comes to light after the expiry of the deadline to provide comments on the draft decision foreseen in Article 50(1) may also mean that the Agency is required to re-start, or repeat certain steps of, the decision-making procedure set out in Articles 50 to 52 (see, for example, Case A-023-2015, *S.A. Akzo Nobel Chemicals and Others*, decision of the Board of Appeal of 13 December 2017, paragraph 306).

Communications regarding the possibility to submit information during the decision-making procedure

60. In the present case, the Appellants received the following communications on the possibility to submit information during the decision-making procedure:

    - On 8 July 2019, the Appellants received a letter from the Agency, by which the draft decision was notified to them. This letter indicated that '*by default, […] updates of the registrations received after the day on which the draft decision was notified […] will normally not be taken into consideration. However, such an update may be taken into consideration if agreed in advance with the [eMSCA]. […] Dossier updates received after the deadline agreed with the [eMSCA] will not be taken into account*'.
    - On 7 August 2019, the eMSCA indicated to the Appellants that they should respect the following instructions to update their dossier: updates should support the comments made on the draft decision and be received within 60 days of the receipt of the draft decision.
    - On 28 November 2019, the eMSCA informed the Appellants that it was no longer necessary to update the registration dossier for diuron because, according to the Agency's policy, dossier updates are not considered during the decision-making procedure.

61. The Contested Decision states:

    '*You were exceptionally given extra time to update the dossier after the draft decision was notified to you, but no updates were received by the deadline given*.'

62. The Agency's news item of 31 March 2020 referred to in the Defence ('*Updates to registration dossiers not taken into account during substance evaluation decision making*' – ECHA/NR/20/12) states:

    '*If registrants have new relevant information on their substance after receiving a draft decision, they will need to submit it through their comments to the draft decision. Authorities will consider the comments and amend the draft decision, if needed*.'

63. The Agency's '*Registrant's guide – How to act in substance evaluation'* (February 2018) states:

    - *'Due to the tight decision-making timelines foreseen by REACH, the deadline for delivering the comments on the draft decision cannot be extended unless there are technical reasons […] or if the commenting period falls during closure periods of the Agency […]'*;
    - *'In general, updates of the registration dossier cannot be taken into consideration if they are received after the day on which you receive the draft decision. However, if you have agreed in advance with the eMSCA to submit such an update, it must (i) support the comments you submitted within the 30-day commenting period and (ii) be received within 60 days of the receipt of the draft decision*.'

Conclusions on the respect of the right to good administration

64. The possibility to submit comments on the draft decision and the possibility to update the registration dossier were clearly defined by the guidance and the communications referred to in paragraphs 60 to 63 above. However, neither the possibility to submit substantial new information after the expiry of the deadlines set for those comments and updates, nor the Agency's or the eMSCA's obligation to take such substantial new information into account, were clearly communicated to the Appellants. Both the Agency and the eMSCA were entirely silent on the rights and obligations described in paragraphs 56 to 59 above.

65. In this regard, the Agency's argument that substantial new information coming to light during the decision-making procedure should not be submitted in the form of a dossier update (see paragraph 51 above) must be rejected. The Agency is required to take into account all substantial new information during a decision-making procedure irrespective of the means chosen to bring that information to its attention, provided that such means of transmission ensure that the Agency is informed in a clear and comprehensive way.

66. Furthermore, it is not unlikely that substantial new information relevant to a substance evaluation will arise during the decision-making procedure. In the present case, more than 14 months passed between the Appellants' comments on the draft decision and the adoption of the Contested Decision. According to the eMSCA, this delay was due to the workload and resources of the eMSCA (see paragraph 13 above). This delay was not related to the decision-making procedure itself. In this respect, the longer the delay in adopting an evaluation decision the more likely it is that substantial new information will arise and which the Agency is required to take into account (see Case A-001-2018, *BrüggemannChemical, L. Brüggemann GmbH & Co. KG, Germany*, decision of the Board of Appeal of 9 April 2019, paragraph 71).

67. However, for the following reasons, the lack of clarity in the guidance and the communications referred to in paragraphs 60 to 63 above regarding the possibility to submit substantial new information during the decision-making procedure and the obligation for the Agency and the eMSCA to take such information into account does not affect the validity of the Contested Decision.

68. First, the Agency's obligation to take substantial new information into account after any cut-off points has been clearly and repeatedly underlined by a number of decisions of the Board of Appeal, adopted and published before the start of the decision-making procedure in the present case (Case A-023-2015, *S.A. Akzo Nobel Chemicals and Others*, decision of the Board of Appeal of 13 December 2017, paragraphs 151 and 152, and Case A-001-2014, *CINIC Chemicals Europe*, decision of the Board of Appeal of 10 June 2015, paragraphs 68 to 104). Under Articles 76(1)(h) and 94(1), the decisions of the Board of Appeal are Agency decisions and can only be challenged before the Court of Justice of the European Union. The decisions of the Board of Appeal are published on the Agency's website and were therefore available to the Appellants.

69. Second, the Agency and the eMSCA established a clear line of communication with the Appellants during the substance evaluation decision-making procedure. The Appellants, whose primary responsibility is to determine whether substantial new information is available, could have contacted the Agency or the eMSCA to clarify whether it would have been possible to submit such substantial new information. This line of communication could have been used, in particular, during the more than 14-month period between the Appellants' comments on the draft decision and the adoption of the Contested Decision.

70. Third, the Appellants had been informed by the eMSCA of the delays in the substance evaluation process and the timeline for its completion (see paragraph 13 above). The Appellants were therefore aware that there would be a delay before the Contested Decision was adopted. Once informed of this delay, the Appellants could have used the line of communication referred to in the previous paragraph.

71. Fourth, certain of the Appellants' communications with the eMSCA were themselves unclear and may have created confusion regarding the Appellants' intention to update their dossier. In particular, in an email of 2 October 2019, the Appellants indicated that they would update their dossier (see paragraph 12 above). As acknowledged by the Appellants during the present proceedings, this may have created a misunderstanding that the Appellants intended to submit additional information relevant to the substance evaluation. However, such a dossier update did not take place despite an email from the eMSCA of 8 October 2019 asking the Appellants to clarify which sections of their dossier they were intending to update (see paragraph 13 above).

72. The Appellants did not submit to the Agency any new scientific information during the decision-making procedure which could be considered as substantial. Furthermore, contrary to the Appellants' argument, the Agency and the eMSCA were not required to monitor the availability of new scientific publications relevant to the substance evaluation in question. For these reasons, the Appellants' argument that they should have been heard again by the Agency during the decision-making procedure and granted the opportunity to submit additional information must be rejected.

73. In view of paragraphs 53 to 72 above, the Appellants' argument that the Contested Decision should be annulled on the grounds that the Agency made an error of assessment and breached the right to good administration by failing to take into account the new scientific information is rejected.

2.2. Second part of the first plea: The Agency disregarded in its assessment the suitability of the LAGDA for examining the thyroid mode of action

Arguments of the Parties and Intervener

74. The Appellants argue that the Agency failed to demonstrate that the LAGDA has a realistic possibility of clarifying the concerns identified in the Contested Decision. According to the Appellants, this is because the LAGDA was not validated with specific thyroid disrupting substances and, as such, is not suitable for assessing the thyroid mode of action. The Appellants argue that this is confirmed by the new scientific information that came to light during the substance evaluation decision-making procedure.

75. The Appellants argue that testing laboratories do not have sufficient experience with conducting the LAGDA which might lead to false outcomes.

76. The Agency, supported by the eMSCA, disputes the Appellants' arguments.

Findings of the Board of Appeal

77. For the following reasons, the Appellants' argument that the Agency disregarded in its assessment the suitability of the LAGDA must be rejected.

78. First, the suitability of the LAGDA to clarify the concerns identified is clearly considered in the Contested Decision. This is clear, for example, from Section A.6. of the Contested Decision entitled '*Considerations on the test method*' in which the Agency responded to the Appellants' comments regarding the validation of the LAGDA and the experience of testing laboratories in performing that test. The Contested Decision stated that '*the LAGDA is a validated test method and therefore should be considered fit to provide the information needed*'.

79. Second, the LAGDA was adopted by the OECD on 28 July 2015 and was included in Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1; the 'Test Methods Regulation') on 16 October 2019. According to the LAGDA, as included in the Test Methods Regulation, that test method is capable of examining the concern related to the thyroid mode of action identified in the Contested Decision. By contesting the validity or suitability of the LAGDA for the modes of action in question, the Appellants contest the legality of the Test Methods Regulation, as it is that Regulation that recognised the LAGDA as a valid test, suitable for these modes of action. However, the Board of Appeal is not competent to decide on the legality of the Test Methods Regulation, which is a Commission regulation (see Case A-006-2016, *SI Group UK Ltd and others*, decision of the Board of Appeal of 6 June 2018, paragraph 202).

80. Third, the fact that there is a possibility for the LAGDA to be reviewed and, if necessary, revised in the light of experience gained, does not call into question the current validity or suitability of LAGDA, as it is set out in the Test Methods Regulation.

81. Fourth, the limited experience of testing laboratories with conducting the LAGDA does not call into question the suitability of the LAGDA in the present case and does not mean that an alternative test should be requested to clarify the concern identified in the Contested Decision.

2.3. Third part of the first plea and the second plea: The Agency failed to assess the suitability of alternative test methods and breached the principle of proportionality

Arguments of the Parties and Intervener

82. The Appellants argue that the Agency failed to assess the suitability of alternative test methods by incorrectly rejecting the alternative testing methods proposed by the Appellants to address the thyroid mode of action. The Appellants argue that the Amphibian Metamorphosis Assay ('AMA'; OECD TG 231) and the Xenopus Eleutheroembryonic Thyroid signalling Assay ('XETA'; OECD TG 248) are more suitable alternatives for detecting thyroid-mediated activity and/or endocrine modes of action. The Appellants argue that the XETA and the AMA are both Level 3 studies (OECD 2018a; the 'OECD Conceptual Framework'[2]) in the Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (guidance adopted by ECHA and EFSA on 5 June 2018) and therefore appropriate for detecting thyroid-mediated activity and/or modes of action.

83. The Appellants argue that the suitability of the AMA for examining the thyroid mode of action has been confirmed by testing laboratories contacted by the Appellants and the new scientific information that came to light during the decision-making procedure.

84. The Appellants argue that it would be more appropriate to seek to clarify the concern identified in the Contested Decision through additional tests on fish due to the lower sensitivity of amphibians compared to fish.

85. The Appellants argue that the Fish Sexual Development Test ('FSDT'), which was performed in response to the first substance evaluation decision, already addressed the (anti)androgenic and (anti)estrogenic ('EA') modes of action and no additional information on those modes of action could be obtained by performing the LAGDA.

86. The Appellants argue that the Agency breached the principle of proportionality. This is because:

- the LAGDA will not bring more clarity in relation to the EA modes of action which were already examined in the FSDT;
- the LAGDA is not sufficiently validated with thyroid disrupting substances to examine the thyroid mode of action and therefore cannot achieve the objectives pursued by the Agency in the substance evaluation of diuron; and
- less onerous and more appropriate alternative test methods are available to address the concerns identified by the Agency.

87. The Agency, supported by the eMSCA, disputes the Appellants' arguments.

Findings of the Board of Appeal

88. To comply with the principle of proportionality, measures adopted by the Agency must not exceed the limits of what is appropriate and necessary to attain the objectives legitimately pursued by that measure; when there is a choice between several

[2] The OECD Conceptual Framework lists OECD test guidelines and standardised test methods that can be used to evaluate chemicals for endocrine disruption.

appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (Case A-007-2019, *Chemours Netherlands*, decision of the Board of Appeal of 12 January 2021, paragraph 109).

89. To demonstrate the necessity of a request for information under substance evaluation, the Agency must establish that:

- there are grounds for considering that, based on a combination of exposure and hazard information, a substance constitutes a potential risk to human health or the environment,
- the potential risk needs to be clarified, and
- the requested information, needed to clarify the concern, has a realistic possibility of leading to improved risk management measures (see, for example, *BASF Grenzach* v *ECHA*, cited in paragraph 54 above, paragraph 276 of the judgment, and Case A-008-2018, *Taminco and Performance Additives Italy*, decision of the Board of Appeal of 29 January 2020, paragraphs 45 and 46).

90. The Contested Decision states that, based on the information in the registration dossier and in published literature, there is a concern that diuron may be an endocrine disruptor in the environment. The Contested Decision states that available *in vitro* and *in vivo* data indicates that diuron might affect the endocrine system therefore potentially causing endocrine disruption effects in wild-life species.

91. The Contested Decision states that, although no endocrine disruption mediated adverse effects were observed in the FSDT, there remains insufficient information to conclude that diuron is not an endocrine disruptor. This is because the main mode of action may be via thyroid hormone receptors or because effects caused via the EA modes of action may occur during life stages which are not covered by the FSDT, for example the reproductive phase of the life cycle. In the Contested Decision, the Agency also considered that diuron may be more potent in other species or, with regard to systemic toxicity, the zebrafish used in the FSDT might be more sensitive to the systemic effects of diuron than other species. Therefore, there is a need to clarify an endocrine disruption concern through both the EA modes of action and the thyroid mode of action.

92. The Contested Decision also states that the LAGDA is the most appropriate test method to clarify the identified concerns. This is because, unlike the alternative tests proposed by the Appellants, the LAGDA is capable of providing information on both the thyroid mode of action and the EA modes of action, and also informs about population relevance of the effects (Level 4[3] of the OECD Conceptual Framework, *in vivo* assays providing data on adverse effects on endocrine relevant endpoints). However, the alternatives proposed by the Appellants are only at Level 3 (*In vivo* assays providing data about selected endocrine mechanism(s)/pathway(s)) of the OECD Conceptual Framework (see paragraph 82 above). According to the OECD Conceptual Framework, tests at Level 4 can provide a more thorough assessment than Level 3 tests of the possible or actual endocrine disrupting effects and endocrine mechanism(s)/pathways of a chemical in developing or adult organisms.

93. In the present proceedings, the Appellants agree that it is necessary to clarify whether diuron is an endocrine disruptor via the thyroid mode of action. However, the Appellants argue that it is not necessary to examine the concern in relation to the EA modes of action as that specific concern was already examined in the FSDT conducted following the first substance evaluation decision. The Appellants also argue that the LAGDA is not appropriate to examine the thyroid mode of action.

[3] In the Conceptual Framework for Testing and Assessment of Endocrine Disrupting Chemicals, tests are placed on Levels from 1 to 5. Level 4 includes *in vivo* assays providing data on adverse effects on endocrine-relevant endpoint.

2.3.1. Need to clarify the endocrine disruptor concern through the EA modes of action

94. In the present case, the results of the FSDT submitted by the Appellants in response to the first substance evaluation decision did not show any endocrine disruption mediated adverse effects.

95. According to the OECD Conceptual Framework, where the results of an FSDT do not show any endocrine disruption mediated adverse effects, careful consideration of any existing data is needed before additional information is requested.

96. The Contested Decision states that the results of the FSDT submitted by the Appellants in response to the first substance evaluation decision did not clarify the concern for endocrine disruption properties via the EA modes of action. As a result, further information was needed to clarify the concern related to the EA modes of action in addition to the concern related to thyroid mode of action.

97. However, for the following reasons, the Agency failed to demonstrate in the Contested Decision that, based on the available information, there is a potential hazard, and therefore a potential risk, related to the EA modes of action.

98. First, as stated in paragraph 94 above, the results of the FSDT submitted by the Appellants in response to the first substance evaluation decision did not show any endocrine disruption mediated adverse effects. Furthermore, to justify a potential hazard related to the EA modes of action, the Contested Decision does not refer to any other information which would suffice on its own to contradict the FSDT study findings and maintain the concern. Therefore, in the Contested Decision, the only additional information related to the EA modes of action was the results of the FSDT in which no endocrine disruption mediated adverse effects were observed.

99. Second, in the OECD Conceptual Framework, the FSDT is placed at the same Level – Level 4 – as the LAGDA and can address endocrine related adverse effects at population level.

100. Third, the FSDT was performed according to the criteria set out in OECD TG 234. As a result, the FSDT conducted by the Appellants is a valid study.

101. In this respect, the Agency argued that there were deficiencies in the conduct of the FSDT regarding (i) the choice of species, (ii) the number of test concentrations without mortality, and (iii) the chosen test concentrations (dose setting). Those arguments must be rejected for the following reasons.

102. With regard to the choice of species, the first substance evaluation decision provided the Appellants with a choice between three species (Japanese medaka *Oryzias latipes*, zebrafish *Danio rerio*, or three-spined stickleback *Gasterosteus acuelatus*). The Appellants cannot be criticised for having performed the requested study with one of those species.

103. With regard to mortality, it must be noted that mortality did not occur at any dose levels during the sexual developmental phase but only during early life stages. Consequently, all remaining fish, at all dose levels, could be used for the identification of the endocrine disrupting properties of diuron.

104. With regard to the chosen test concentrations, those concentrations were based on relevant data from the literature, on a dose range finding study performed with zebrafish, and following the recommendation of the OECD TG 234. The chosen test concentrations were also agreed with the eMSCA.

Conclusion on the endocrine disruption concern through the EA modes of action

105. In view of paragraphs 94 to 104 above, the Agency breached the principle of proportionality by failing to demonstrate that it is necessary to clarify the endocrine disruption concern through the EA modes of action.

106. The Contested Decision is therefore annulled in so far as it concludes that there is a concern related to the EA modes of action.

2.3.2. Endocrine disruption concern related to the thyroid mode of action

107. The Appellants and the Agency agree that it is necessary to clarify whether diuron is an endocrine disruptor in the environment through the thyroid mode of action. However, the Appellants argue that the LAGDA is not appropriate to clarify that concern.

108. As stated in paragraph 106 above, the Contested Decision is annulled in so far as it concludes that there is a concern related to the EA modes of action. In these circumstances, under Article 93(3), the Board of Appeal is competent to replace a substance evaluation decision with its own decision or remit the case to the Agency for further action (see *BASF Grenzach* v *ECHA*, cited in paragraph 54 above, paragraph 117 of the judgment). In the present case, the Board of Appeal would therefore be competent to replace the Contested Decision with a decision seeking to clarify the concern related to the thyroid mode of action only.

109. However, before replacing a substance evaluation decision with its own decision, the Board of Appeal must examine whether the available evidence allows it to do so. In addition, when examining whether it can replace an Agency decision, the Board of Appeal must bear in mind the procedure for adopting Agency decisions under the substance evaluation process set out in Articles 50 to 52, and in particular the role of the various actors in that procedure (see *BASF Grenzach* v *ECHA*, cited in paragraph 54 above, paragraph 118 of the judgment).

110. In the Contested Decision, the appropriateness of the LAGDA to meet the objectives of the Contested Decision was assessed on the basis of potential hazards related to both the EA modes of action and the thyroid mode of action. The Agency requested the LAGDA in the Contested Decision because, amongst other reasons, it considered that the test is the most appropriate to clarify the concerns related to both the EA modes of action and the thyroid mode of action. More specifically, one of the reasons the Agency rejected the AMA as an alternative test method was that, although it investigates the thyroid mode of action, that study does not investigate the EA modes of action.

111. A test that would only address the concern related to the thyroid mode of action was not discussed during the decision-making procedure in the present case.

112. The Agency and the eMSCA argued during the present proceedings that, even if the Board of Appeal were to find that the Agency had not demonstrated a concern related to the EA modes of action, the LAGDA would still be the most appropriate test in the present case to address the concern for the thyroid mode of action. This is because, in particular, the LAGDA is the only validated study that can clarify the thyroid mode of action and the population relevance of the effects.

113. However, the possibility to request the LAGDA to clarify only the thyroid mode of action has not been examined in the process leading to the adoption of the Contested Decision. Likewise, as it is stated in paragraph 111 above, the possibility of requesting a test that would only address the concern related to the thyroid mode of action has not been examined in the process leading to the adoption of the Contested Decision.

114. The arguments made by the Appellants during the present proceedings that less onerous and more appropriate test methods are available to address only the concern related to the thyroid mode of action have not been assessed. In particular, the possibility to clarify the population relevance of the effects by the AMA, modified by extending the dose regime, has not been examined. The relevance and appropriateness of alternatives to the LAGDA to assess only the thyroid mode of action must therefore be assessed, taking elements such as animal welfare into account.

115. In view of paragraphs 107 to 114 above, considering the procedure for adopting Agency decisions under the substance evaluation process set out in Articles 50 to 52, and in particular the role of the various actors in that procedure, the case must be remitted to the Agency for further action.

2.4. Result

116. The Contested Decision is annulled in its entirety. As a result, there is no need to examine the remaining pleas.

Refund of the appeal fee

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

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision.**
2. **Remits the case to the competent body of the Agency for further action.**
3. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal