DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

25 April 2023

(Dossier evaluation – Compliance check – Section 8.7.3. of Annex IX – EOGRTS – Additional investigations on learning and memory function)

Case numbers	Joined Cases A-002-2022 and A-003-2022
Language of the cases	English
Appellants	BASF Lampertheim GmbH, Germany (A-002-2022) Represented by Michael Raupach BASF SE, Germany Metall-Chemie GmbH & Co. KG, Germany (A-003-2022) Represented by Christoph Rung and Michael Wenzel Rittershaus Rechtsanwälte, Germany
Contested Decision	Decision of 14 January 2022 on a compliance check of the registration for the substance O,O,O-triphenyl phosphorothioate, adopted by the European Chemicals Agency under Article 41 of the REACH Regulation The Contested Decision was notified to the Appellants under annotation numbers CCH-D-2114580865-34-01/F (A-002-2022) and CCH-D-2114580866-32-01/F (A-003-2022)

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

1. Background to the dispute

1. This appeal concerns a compliance check of the registration for the substance O,O,O-triphenyl phosphorothioate (the **Substance**).[1]

2. BASF Lampertheim GmbH registered the Substance on 25 July 2014. Metall-Chemie GmbH & Co. KG registered the Substance on 12 December 2017.

3. Both Appellants registered the Substance at the tonnage band of 100 to 1 000 tonnes per year, which corresponds to the volume of manufacture or import referred to in Annex IX to the REACH Regulation.[2]

4. On 18 September 2020, the Agency initiated a compliance check under Article 41.

5. On 21 January 2021, the Agency notified to the Appellants a draft decision in accordance with Articles 41(3) and 50(1). The draft decision required the Appellants to submit information on an extended one-generation reproductive toxicity study (**EOGRTS**) under Column 1 of Section 8.7.3. of Annex IX, including cohort 1B with extension to mate the cohort 1B animals to produce the F2 generation, cohorts 2A and 2B, and cohort 3 under Column 2 of Section 8.7.3. of Annex IX.

6. On 25 February 2021, the Appellants submitted comments on the draft decision in accordance with Article 50(1).

7. On 2 September 2021, the Agency notified a revised draft of the decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1).

8. On 4 October 2021, the competent authority of the Netherlands submitted a proposal for amendment to the Agency in accordance with Article 51(2). According to that proposal, cohorts 2A and 2B of the EOGRTS (developmental neurotoxicity) should include additional investigations of learning and memory function as described in paragraph 37 of test guideline 426 of the Organisation for Economic Co-Operation and Development (**OECD**), corresponding to European Union (**EU**) test method B.53 set out in the Annex to the Test Methods Regulation.[3]

9. On 5 November 2021, the Appellants submitted comments on the proposal for amendment in accordance with Article 51(5). The Appellants' comments were submitted, together with the revised draft of the decision, to the Member State Committee.

10. On 14 January 2022, following the unanimous agreement of the Member State Committee, the Agency adopted the Contested Decision in accordance with Article 51(6).

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1 EC No 209-909-9; CAS No 597-82-0.

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

3 Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1). All references to EU test methods hereinafter are to test methods set out in the Annex to the Test Methods Regulation.

2. Contested Decision

11. The Contested Decision requires the Appellants to submit, by 22 April 2025, information on an EOGRTS (OECD test guideline 443, corresponding to EU test method B.56) under Section 8.7.3. of Annex IX, including:

- cohort 1A (reproductive toxicity),
- cohort 1B (reproductive toxicity) with extension to mate the cohort 1B animals to produce the F2 generation which shall be followed to weaning,
- cohorts 2A and 2B (developmental neurotoxicity),
- investigations on learning and memory function as described in paragraph 37 of OECD test guideline 426, corresponding to EU test method B.53, and
- cohort 3 (developmental immunotoxicity).

3. Procedure before the Board of Appeal

12. On 11 April 2022, BASF Lampertheim GmbH filed appeal A-002-2022.

13. On 14 April 2022, Metall-Chemie GmbH & Co. KG filed appeal A-003-2022.

14. On 24 May 2022, the Board of Appeal joined the two appeals for the purposes of the written and oral parts of the procedure, and the final decision, in accordance with Article 15(1) and (2)(a) of the Rules of Procedure.[4]

15. On 20 June 2022, the Agency submitted its defence.

16. On 27 and 28 June 2022, BASF Lampertheim GmbH and Metall-Chemie GmbH & Co. KG submitted their respective observations on the defence.

17. On 29 August 2022, the Agency submitted its observations on the Appellants' observations on the defence.

18. On 1 February 2023, a hearing was held as the Board of Appeal considered it necessary in accordance with Article 13(1) of the Rules of Procedure. The hearing was held at the Agency's premises. At the hearing, the Parties made oral submissions and responded to questions from the Board of Appeal.

4. Form of order sought

19. BASF Lampertheim GmbH requests the Board of Appeal to:

- annul the Contested Decision insofar as it requires investigations on learning and memory function as described in paragraph 37 of OECD test guideline 426, corresponding to EU test method B.53, and
- order the refund of the appeal fee.

20. Metall-Chemie GmbH & Co. KG requests the Board of Appeal to:

- annul the Contested Decision insofar as it requires investigations on learning and memory function as described in paragraph 37 of OECD test guideline 426, corresponding to EU test method B.53,
- order the refund of the appeal fee, and
- as a subsidiary plea, in case the other pleas are dismissed, extend the deadline set in the Contested Decision.

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[4] 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).

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

5. Assessment of the case

5.1. The Appellants' single plea: The Agency exceeded its powers by requiring investigations on learning and memory function

Arguments of the Parties

22. The Appellants raise, in essence, a single plea in support of their appeals. They argue that investigations on learning and memory function as described in paragraph 37 of OECD test guideline 426, corresponding to EU test method B.53, are not part of the information which is required under Section 8.7.3. of Annex IX. In particular, those investigations are not part of the information required for cohorts 2A and 2B. The Agency therefore exceeded the powers conferred on it under Article 41 by requiring those investigations. According to the Appellants, the Agency was not empowered, in a compliance check process, to verify the registration dossier beyond the information required under Annex IX.

23. The Agency disputes the Appellants' arguments. The Agency argues that the investigations required under cohorts 2A and 2B are described in paragraphs 47 to 50 of EU test method B.56, which is the test method for an EOGRTS.

24. First, the Agency argues that paragraph 50 of that test method requires registrants to integrate other functional testing for developmental neurotoxicity in the study design under cohorts 2A and 2B if existing information shows that there is a need to do so. Among the other functional testing for developmental neurotoxicity, paragraph 50 of EU test method B.56 refers to cognitive testing.

25. Second, the Agency argues that the sixth introductory paragraph of Annex IX provides that where a test method offers flexibility in the study design, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment. This is consistent with the main objective of the obligation to register substances, which is to achieve a high level of protection of human health and the environment.

26. Third, the Agency argues that the Board of Appeal has held, in previous decisions, that the Agency may specify the study design of an EOGRTS, such as the choice of the route of administration. The Agency relies, in this regard, on the decisions of the Board of Appeal of 18 August 2020 in Cases A-009-2018 and A-010-2018, *Symrise*.

27. Fourth, the Agency argued, at the hearing, that its interpretation of paragraph 50 of EU test method B.56 is consistent with the approach taken by the European Commission in compliance check decisions adopted under Articles 51(7) and 133(3). In one of those decisions, which was challenged before the General Court in Case T-868/19, *Nouryon Industrial Chemicals and Others* v *Commission*, the European Commission required the same investigations on learning and memory function as in the present case.

28. Fifth, the Agency argued, at the hearing, that its interpretation of paragraph 50 of EU test method B.56 is consistent with the interpretation given by the Board of Appeal to Column 2 of Section 9.1. of Annex IX.[5]

[5] Decisions of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings*, A-011-2018, paragraph 175; of 18 August 2020, *Symrise*, A-010-2018, paragraph 186; and of 19 January 2021, *Croda Iberica*, A-010-2019, paragraphs 37 and 38.

29. Finally, the Agency argues that, in the present cases, there are indications that the Substance may affect learning and memory function. This is not contested by the Appellants. That potential effect, which may be linked to developmental neurotoxicity, needs to be investigated under cohorts 2A and 2B, in accordance with paragraph 50 of EU test method B.56. The appropriate way to investigate it is to integrate into cohorts 2A and 2B investigations on learning and memory function as described in paragraph 37 of EU test method B.53.

Findings of the Board of Appeal

(a) Preliminary remarks

30. The Contested Decision requires the Appellants to provide information on an EOGRTS, including inter alia cohorts 2A and 2B and investigations on learning and memory function in accordance with paragraph 37 of EU test guideline B.53.

31. The operative part of the Contested Decision states that the legal basis for this request is Article 41 in conjunction with Section 8.7.3. of Annex IX.[6] Those provisions explicitly refer to an EOGRTS and cohorts 2A and 2B, and to OECD test guideline 443, corresponding to EU test method B.56. They do not refer to investigations on learning and memory function.

32. The reasoning of the Contested Decision further refers to paragraph 51 of OECD test guideline 443, which corresponds to paragraph 50 of EU test method B.56, in the context of the investigations on learning and memory function.[7] As EU test method B.56 is laid down in the Test Methods Regulation, it is the test to be carried out to generate information on an EOGRTS in accordance with Article 13(3). At the hearing, the Agency explained that paragraph 50 of EU test method B.56 is part of the legal basis for the request to conduct investigations on learning and memory function.

33. Therefore, the legal basis used by the Agency for requiring the contested investigations on learning and memory function in the present cases was Article 41 in conjunction with the second paragraph of Column 2 of Section 8.7.3. of Annex IX, Article 13(3) and paragraph 50 of EU test method B.56.[8]

34. The Appellants argue, in essence, that the legal basis stated in the previous paragraph is inadequate as the mentioned provisions, read together, do not empower the Agency to require investigations of learning and memory function.

35. The Appellants do not contest that they must submit information on an EOGRTS (Column 1 of Section 8.7.3. of Annex IX) and that the EOGRTS must include cohorts 2A and 2B (developmental neurotoxicity, second paragraph of Column 2 of Section 8.7.3. of Annex IX). Furthermore, the Appellants do not contest in the present case the fact that there might be a need to investigate the effects of the Substance on learning and memory function.

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6 See p. 1 of the Contested Decision.

7 See pp. 6 and 7 of the Contested Decision.

8 The Agency referred to paragraph 51 of OECD test method No 443, which corresponds to paragraph 50 of EU test method B.56.

36. Under Article 41, the Agency can assess the quality and adequacy of information submitted in a registration dossier in order to determine whether that information satisfies the information requirements set out in the REACH Regulation.[9] Specifically, under Article 41(3), the Agency may require registrants to submit any information needed to bring a registration into compliance with the relevant information requirements.

37. In order to decide on the present case, it is therefore necessary to determine whether investigations on learning and memory function are information which the Appellants are required to submit, or the Agency may require, under the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56.

(b) Interpretation of the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56

38. The second paragraph of Column 2 of Section 8.7.3. of Annex IX, Article 13(3) and paragraph 50 of EU test method B.56 are rules of EU law. In interpreting rules of EU law, their wording, context and objectives must all be taken into account.[10]

39. First, as regards the wording and the context, the second paragraph of Column 2 of Section 8.7.3. of Annex IX does not refer to investigations on learning and memory function. That provision requires the inclusion of cohorts 2A and 2B (developmental neurotoxicity) in the study design of an EOGRTS if certain conditions are fulfilled.

40. The developmental neurotoxicity investigations to be performed under cohorts 2A and 2B are described in paragraphs 47 to 50 of EU test method B.56, which is the applicable test method under Article 13(3).

41. Paragraph 47 of EU test method B.56 sets out general considerations for the conduct of investigations under cohorts 2A and 2B, such as the selection of animals and test conditions. Paragraphs 48 and 49 of EU test method B.56 provide for an auditory startle test, a functional observational battery and an automated test of motor activity. Although paragraphs 48 and 49 of EU test method B.56 contain some references to EU test method B.53, as the investigations referred to in those paragraphs should be carried out so as to be '*consistent with*' EU test method B.53, they are clearly distinct from and different than the investigations on learning and memory function at issue in this case.

42. Paragraph 50 of EU test method B.56 provides:

'*If existing information indicates the need for other functional testing (e.g. sensory, social, cognitive), these should be integrated without compromising the integrity of the other evaluations conducted in the study. If this testing is performed in the same animals as used for standard auditory startle, functional observational battery and motor activity testing, different tests should be scheduled to minimise the risk of compromising the integrity of these tests. Supplemental procedures may be particularly useful when empirical observation, anticipated effects, or mechanistic/mode-of-action indicate a specific type of neurotoxicity*.'

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[9] Decision of the Board of Appeal of 29 June 2021, A-001-2020, *SNF*, paragraph 38.

[10] See, for example, decision of the Board of Appeal of 31 October 2022, *Croda EU*, A-011-2021, paragraph 27.

43. By contrast to paragraphs 48 and 49 of EU test method B.56, paragraph 50 of that test method does not explicitly refer to specific further investigations and/or other EU test methods. In particular, that provision does not explicitly refer to investigations of learning and memory function in accordance with paragraph 37 of EU test method B.53.

44. Paragraph 50 of EU test method B.56 does not state that additional investigations must be conducted if existing information shows that this is necessary. The provision merely states that, if any other functional testing than the one prescribed in paragraphs 47 to 49 of EU test method B.56 is conducted, such testing should be integrated without compromising the integrity of the other evaluations.

45. Paragraph 50 of EU test method B.56 does not exclude that additional investigations on learning and memory function might be conducted, and that it might be necessary to include those investigations in cohorts 2A and 2B. However, the fact that it may be possible to investigate learning and memory function does not mean that a registrant under paragraph 50 of EU test method B.56 is obliged to conduct them as an information requirement under the second paragraph of Column 2 of Section 8.7.3. of Annex IX.

46. Therefore, the wording and the context of the second paragraph of Column 2 of Section 8.7.3. of Annex IX and paragraph 50 of EU test method B.56 indicate that investigations on learning and memory function are not an information requirement for the Appellants' registration of the Substance under those provisions.

47. Second, the Agency argues that its interpretation of Column 2 of Section 8.7.3. of Annex IX and paragraph 50 of EU test method B.56 is supported by the objectives of the REACH Regulation.[11]

48. It is true that the main objective of the information requirements for registration is to achieve a high level of protection of human health and the environment.[12] However, that main objective is not, on its own, sufficient to justify an interpretation that goes against the wording and the context of the provisions in question.

49. The wording and context of the second paragraph of Column 2 of Section 8.7.3. of Annex IX and paragraph 50 of EU test method B.56 clearly indicate that those provisions do not impose investigations on learning and memory function. More specifically, the objective of paragraph 50 of EU test method B.56 is to ensure that the integrity of the evaluations conducted on cohorts 2A and 2B is not compromised by any potential other functional testing.[13]

50. Furthermore, the REACH Regulation therefore provides for other ways in which the potential effect of the Substance on learning and memory function can be investigated. For example, the Agency has the power to require information that goes beyond the information requirements of Annexes VII to X in the course of the substance evaluation process under Article 46(1).

51. Therefore, the objectives of the REACH Regulation are not sufficient to conclude that investigations on learning and memory function are an information requirement for the Appellants' registration of the Substance under the second paragraph of Column 2 of Section 8.7.3. of Annex IX and paragraph 50 of EU test method B.56.

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[11] See paragraph 25 above.

[12] Judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 45; and decision of the Board of Appeal of 27 September 2022, Case A-005-2021, *Albemarle Europe*, paragraph 65.

[13] See paragraph 42 *et seq*. above.

52. It follows from the reasons set out in paragraphs 38 to 51 above that investigations on learning and memory function in accordance with paragraph 37 of EU test method B.53 are not an information requirement for the Appellants' registration of the Substance under the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56.

(c) The Agency's remaining arguments

53. The conclusion set out in the preceding paragraph is not called into question by the Agency's remaining arguments.

54. First, the Agency refers to the sixth introductory paragraph to Annex IX.[14] That provision states that where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

55. However, the investigations of learning and memory function at issue in the present case are not part of the flexibility offered by the EU test method B.56. They constitute investigations that are additional to the investigations required by that test method, and are an integral part of the investigations to be conducted in a different test method, namely EU test method B.53.

56. The sixth introductory paragraph to Annex IX is consequently not relevant to the present case.

57. Second, the Agency refers to Case T-868/19, *Nouryon Industrial Chemicals and Others* v *Commission*, which was pending before the General Court during the written and oral part of the present appeal proceedings.[15] However, this reference is not relevant in the present case for the following reasons.

58. In the first place, the additional investigations of learning and memory function were not challenged in Case T-868/19. Therefore, the General Court did not rule on the legality of those additional investigations.[16]

59. In the second place, and in any event, a decision adopted by the European Commission under Articles 51(7) and 133(3) does not constitute an interpretation of the REACH Regulation that is binding on the Board of Appeal.

60. Third, the Agency refers to the interpretation given by the Board of Appeal of Column 2 of Section 9.1. of Annex IX.[17] This is not relevant in the present case. The wording of Column 2 of Section 9.1. of Annex IX clearly sets out an obligation to conduct testing, and only the conditions of that obligation were subject to the interpretation of the Board of Appeal in the decisions referred to by the Agency.[18] By contrast, paragraph 50 of EU test method B.56 only provides for the integration of potential other functional testing without setting out an obligation to conduct that testing.[19]

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[14] See paragraph 25 above.

[15] See paragraph 27 above.

[16] Judgment of 29 March 2023, *Nouryon and others v Commission*, T-868/19, EU:T:2023:168.

[17] See paragraph 28 above.

[18] See decision of the Board of Appeal of 4 May 2020, *Clariant Plastics & Coatings*, A-011-2018, paragraph 150 *et seq.*

[19] See paragraphs 42 *et seq*. above.

(d) Conclusion on the Appellants' single plea

61. Article 41(3) empowers the Agency to require registrants to submit any information needed to bring a registration into compliance with the relevant information requirements.[20]

62. Investigations on learning and memory function are not an information requirement for the Appellants' registration of the Substance under the second paragraph of Column 2 of Section 8.7.3. of Annex IX in conjunction with Article 13(3) and paragraph 50 of EU test method B.56.

63. By requiring those investigations on that legal basis in the Contested Decision, the Agency therefore exceeded its powers under Article 41(3) in conjunction with the second paragraph of Column 2 of Section 8.7.3. of Annex IX, Article 13(3) and paragraph 50 of EU test method B.56.

64. The Appellants' single plea must therefore be upheld.

5.2. Result

65. The Appellants request the Board of Appeal to annul the request for an EOGRTS in the Contested Decision insofar as that request encompasses investigations on learning and memory function. The remainder of the request for an EOGRTS in the Contested Decision is not challenged.

66. The Appellants and the Agency confirmed in the course of the present proceedings that the annulment of the contested investigations on learning and memory function would not affect the remainder of the request.

67. The Contested Decision can and must therefore be annulled only insofar as it requires investigations on learning and memory function.

6. Effects of the Contested Decision

68. Under Article 91(2), an appeal has suspensive effect. In principle, that suspensive effect applies only to the contested parts of a contested decision.[21] However, in the present case the contested investigations on learning and memory function were designed, in the Contested Decision, to be carried out together with the rest of the EOGRTS. The suspensive effect of this appeal therefore extended to the whole request for an EOGRTS.

69. Insofar as the Contested Decision is only partly annulled, it still requires the Appellants to submit information on an EOGRTS, including the extensions to cohort 1B with extension to mate the cohort 1B animals to produce the F2 generation, cohorts 2A and 2B, and cohort 3, under Columns 1 and 2 of Section 8.7.3. of Annex IX.

70. The deadline set in the Contested Decision was 22 April 2025, which is 3 years, 3 months and 8 days from the date of notification of that decision. The Appellants must therefore provide information on an EOGRTS, as required by the Contested Decision with the specifications described in the previous paragraph, by 2 August 2026.

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[20] See paragraph 36 above.

[21] See, for example, decision of the Board of Appeal of 19 January 2021, *Croda Iberica*, A-010-2019, paragraphs 11, 22 and 97.

7. Refund of the appeal fee

71. Under Article 10(4) of the Fee Regulation[22] the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is upheld, the appeal fee is refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision insofar as it requires the Appellants to conduct investigations on learning and memory function as described in paragraph 37 of EU test method B.53.**
2. **Decides that information on an EOGRTS, including the extensions to cohort 1B with extension to mate the cohort 1B animals to produce the F2 generation, cohorts 2A and 2B, and cohort 3, must be provided by 2 August 2026.**
3. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal

[22] 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).