EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

28 May 2024

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Addressees – Good administration – Equal treatment – Non-discrimination – Article 25 of the REACH Regulation)

Case number	A-003-2023
Language of the case	English
Appellant	Jungbunzlauer Ladenburg GmbH, Germany Represented by Kristian Fischer SZA Schilling, Zutt & Anschütz Rechtsanwaltsgesellschaft mbH, Germany
Contested Decision	Decision of 9 December 2022 on the follow-up to a compliance check of a registration for the substance tributyl O-acetylcitrate, adopted by the European Chemicals Agency under Article 42(1) of the REACH Regulation The Contested Decision was notified to the Appellant under annotation number CCH-D-2114620385-53-01/F

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

1. Background to the dispute

1. This appeal concerns the follow-up to the compliance check of a registration dossier for tributyl O-acetylcitrate (the **'Substance'**).[1]

2. On 22 July 2010, the Appellant submitted its registration for the Substance at the 1 000 or more tonnes per year tonnage band (the '**Annex X level**'). The Appellant is the lead registrant of the Substance.

1.1. The compliance check decision of 24 July 2017 addressed to the Appellant

3. On 5 October 2016, the Agency initiated a compliance check of the Appellant's registration dossier, acting as lead registrant, for the Substance.

4. On 24 July 2017, the Agency adopted a compliance check decision under Article 41(3) of the REACH Regulation[2] (the '**initial compliance check decision**') requesting the Appellant to provide information on various human health and environmental endpoints by 31 January 2019, including information on:

   - Pre-natal developmental toxicity (**PNDT**) study (Section 8.7.2. of Annex IX; test method: EU B.31/OECD test guideline (**TG**) 414) in a first species (rat or rabbit), oral route, and
   - PNDT study (Section 8.7.2. of Annex X; test method: EU B.31/OECD TG 414) in a second species (rat or rabbit), oral route.

5. The initial compliance check decision was only addressed to the Appellant, acting as lead registrant.

6. The letter notifying the initial compliance check decision to the Appellant states that the Agency '*expects that you, as the lead registrant of the joint submission for this substance, will share the relevant requirements and reasoning of the enclosed decision with the members of your joint submission. [The Agency] also expects that you will coordinate any testing with them*.'

7. At the time of the adoption of the initial compliance check decision, the joint submission for the Substance included the Appellant, four other registrants subject to the Annex IX information requirements and one other registrant subject to the Annex X information requirements. In addition, at that time, there was one registrant of the Substance subject to the Annex X information requirements which had opted-out of the joint submission under Article 11(3) (the '**first opt-out registrant**').

1.2. Compliance check decision addressed to the first opt-out registrant

8. On 8 December 2017, the Agency addressed a separate compliance check decision under Article 41 to the first opt-out registrant requesting it to provide information on various human health endpoints by 17 June 2019, including information on PNDT studies in the first and second species.

9. On the same date, the Agency sent a letter to the Appellant informing it that the first opt-out registrant had been required by the Agency to provide information on the Substance. The Agency also reminded the Appellant of its obligation under Article 53 to reach an agreement with the other registrants of the Substance on who will perform the tests on the Substance and on cost sharing.

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[1] CAS No 77-90-7, EC No 201-067-0.

[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 or Annexes hereinafter concern the REACH Regulation unless stated otherwise.

10. On 14 March 2018, the first opt-out registrant informed the Agency that '*[the Appellant] as lead registrant for the [Substance] will take over the responsibility on behalf of the joint registration members for the fulfilment of the relevant requirements according to [the Agency's] decision...'*.

1.3. Change of the Agency's policy regarding the addressees of dossier evaluation decisions

11. From 1 January 2019, the Agency started initiating compliance check processes with respect to all affected members of the joint submission for a substance. Prior to that date, the Agency's practice had been to initiate the compliance check process with respect to lead registrants only.

12. According to the page of the Agency's website entitled '*Progress in evaluation 2019*':

'*Since 2019, [the Agency] has started sending its draft decisions to all affected members of the joint submission with non-compliant dossiers. This is a change to the earlier practice when only the lead registrant of the joint submission was contacted and expected to inform other relevant members on the outcome of [the Agency's] assessment.*

By contacting all affected members of the joint submission and setting out clearly how the information requirements apply at each tonnage band, [the Agency] gives registrants better legal certainty on what their individual legal obligations are, which helps ensure a level-playing field for all registrants in the joint submission. All recipients are required to comply with their respective information requirements, and need to share existing/new data while respecting their legal obligation to avoid unnecessary (vertebrate animal) testing.'

1.4. Information submitted by the Appellant in response to the initial compliance check decision

13. In response to the initial compliance check decision, the Appellant sought to waive the information requirements on PNDT studies in a first and second species, in particular through a weight-of-evidence adaptation under Section 1.2. of Annex XI.

1.5. Decision on the follow-up to the compliance check decision addressed to the first opt-out registrant

14. On 13 April 2021, the Agency informed the competent national enforcement authority that the first opt-out registrant had failed to provide any information concerning the requested PNDT studies by the deadline set in the compliance check decision addressed to it.

1.6. Decision on the follow-up to the compliance check decision addressed to the Appellant (the 'Contested Decision')

15. On 7 April 2022, the Agency sent a draft follow-up decision to the Appellant under Articles 42(1) and 50(1). In the draft follow-up decision, the Agency found that the Appellant's weight-of-evidence adaptation did not comply with the requirements of Section 1.2. of Annex XI.

16. On 11 May 2022, the Appellant submitted comments on the draft follow-up decision. The comments included a statement that, in relation to the PNDT study, '*it would be appropriate to adapt the information requirements based on exposure considerations according to Annex XI, section 3 in order to avoid unnecessary animal testing*'.

17. On 1 September 2022, the Agency notified the draft follow-up decision to the competent authorities of the Member States in accordance with Articles 50(1) and 51(1).

18. On 9 December 2022, 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). The Contested Decision was addressed to the Appellant only.

19. At the time of the adoption of the Contested Decision, the joint submission included the Appellant, seven other registrants subject to the Annex IX information requirements and one other registrant subject to the Annex X information requirements. In addition, at that time, there were two opt-out registrants: the first opt-out registrant, which was subject to the Annex X information requirements, and a second opt-out registrant, which was subject to the Annex IX information requirements (the '**second opt-out registrant**'). The registration for the second opt-out registrant was submitted in 2018.

20. In the Contested Decision, the Agency rejects the Appellant's weight-of-evidence adaptation based on Section 1.2. of Annex XI and concludes that the Appellant's registration still does not comply with Section 8.7.2. of Annex IX (PNDT study in a first species) and Section 8.7.2. of Annex X (PNDT study in a second species).

21. The Contested Decision states that the Appellant is still required to submit the information requested in the initial compliance check decision and that the Agency will inform the competent national authority with a view to taking enforcement action.

22. On 30 January 2023, the Appellant's representative sent an inquiry to the Agency stating that a follow-up decision according to Article 42 has been addressed to the Appellant, but not to the other registrants of the Substance in the joint submission. The Appellant's representative asked the Agency whether the Contested Decision can be extended to the other registrants of the Substance.

23. On 21 February 2023, the Agency replied to the Appellant's representative that only the recipients of a decision are bound by that decision. The Agency added that it cannot alter a decision, including the addressees of that decision, because it is unanimously agreed by the Member State Committee.

2. Procedure before the Board of Appeal

24. On 3 March 2023, the Appellant lodged this appeal.

25. On 8 May 2023, the Agency lodged its Defence.

26. On 5 June 2023, the Board of Appeal closed the written procedure and requested the Agency to provide certain documents related to the Agency's policy on the addressees of dossier evaluation decisions.

27. On 20 June 2023, the Agency submitted the documents requested by the Board of Appeal.

28. On 23 and 25 October 2023 respectively, the Appellant and the Agency responded to written questions from the Board of Appeal.

29. On 23 April 2024, a hearing was held as the Board of Appeal considered it to be necessary in accordance with Article 13(1) of the Rules of Procedure[3]. The hearing took place via video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Appellant and the Agency made oral submissions and responded to the questions from the Board of Appeal.

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

3. Form of order sought

30. The Appellant requests that the Board of Appeal:

- annuls the Contested Decision,
- remits the case to the competent body of the Agency to adopt an amended decision addressed to all registrants of the Substance that are affected by the requirements of the Contested Decision, and
- orders the refund of the appeal fee.

31. In the alternative, the Appellant requests that the Board of Appeal:

- amends the Contested Decision so that it is addressed to all registrants of the Substance that are affected by the requirements of the Contested Decision, and
- orders the Agency to refund the appeal fee.

4. Assessment of the case

32. The Appellant argues that, in addressing the Contested Decision only to the Appellant as the lead registrant of the Substance, and not to the other registrants of the Substance at the relevant tonnage bands, the Agency infringed:

(i) Article 42, in conjunction with the right to good administration as set out in Article 41 of the Charter of Fundamental Rights[4] (the '**Charter**'), and

(ii) the principles of equal treatment and non-discrimination.

33. The Appellant argues that the Agency also infringed Article 25 by failing to ensure that testing on vertebrate animals is undertaken only as a last resort.

4.1. Alleged infringements related to the Agency's failure to address the Contested Decision to other registrants of the Substance

4.1.1. Article 42 and the right to good administration

Arguments of the Parties

34. The Appellant argues that, under Articles 41(3) and 42, compliance check decisions must be addressed to all registrants of a substance so that compliance of all registrations is achieved. According to the Appellant, neither Article 11, nor Articles 41 and 42 foresee that the lead registrant should be the only addressee of compliance check decisions.

35. The Appellant argues that under Article 41(3), the Agency must prepare a draft decision requiring 'the registrant(s)' to submit any information needed to bring the 'registration(s)' into compliance with the relevant information requirements. According to the Appellant, this also applies to decisions adopted under Article 42 so that a decision adopted in follow-up to a compliance check decision must be addressed to all registrants.

36. The Appellant argues that, in the context of testing proposal examinations under Article 40, the Board of Appeal rejected the Agency's policy of addressing decisions only to the lead registrant.[5] The Appellant argues that the Board of Appeal's findings in that decision should also apply to the compliance check process.

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[4] OJ C 83, 30.3.2010, p. 389.

[5] Decision of the Board of Appeal of 23 February 2021, *Lubrizol France and others*, Joined Cases A-016-2019 to A-029-2019, paragraphs 151 to 177.

37. The Appellant states that since 1 January 2019 the Agency addresses compliance check decisions to all registrants of a substance with the aim of creating legal certainty and a level playing field between registrants. According to the Appellant, by addressing the Contested Decision only to the Appellant following that change of policy, the Agency did not act in good faith and violated Article 41 of the Charter.

38. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

39. Article 41(1) of the Charter provides that '*[e]very person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions, bodies, offices and agencies of the Union'.* Under Article 41(2)(a) of the Charter, the right to good administration includes '*the right of every person to be heard, before any individual measure which would affect him or her adversely is taken*'.

40. Under Article 42(1) of the REACH Regulation, '*[t]he Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary'*.

41. For the following reasons, the Appellant has not demonstrated that the Agency breached Article 42 or infringed the right to good administration in adopting the Contested Decision.

(a) The follow-up decision as a continuation of the initial compliance check decision

42. The Contested Decision is a follow-up decision adopted on the basis of Article 42(1). The check carried out by the Agency following the initial compliance check decision requiring the registrant to bring its dossier into compliance is merely the continuation of the same, single procedure.[6] The scope of the follow-up decision – including the information identified as missing from the registrant's dossier and the addressees of the decision – is defined in the initial check decision adopted under Article 41.

43. A follow-up compliance check decision under Article 42(1) is intended to determine whether the information provided by the addressee of the initial compliance check decision either corresponds to the information requested in that decision or constitutes compliant adaptations under the rules laid down in the relevant annexes to the REACH Regulation.

44. In the present case, the initial compliance check decision was addressed only to the Appellant. The initial compliance check decision has not been appealed and is therefore final. The Appellant was therefore bound to provide information on PNDT studies in the first and second species, or acceptable adaptations, by the deadline set in the initial compliance check decision.

45. The other registrants of the Substance were not addressees of the initial compliance check decision. As the Board of Appeal previously found in Case A-009-2020[7], in such circumstances, it was therefore legally impossible for the Agency to involve the other registrants of the Substance in the follow-up process that led to the Contested Decision. The addressees of follow-up decisions under Article 42(1) cannot include registrants who were not addressees of the corresponding initial compliance check decision under Article 41 and who have not, therefore, benefited from the procedural guarantees foreseen in Article 41 and Articles 50 and 51.

46. The Appellant has not provided any convincing argument that could justify why the Board of Appeal's findings in Case A-009-2020 regarding the addressees of follow-up compliance check decisions should not apply fully to the present case. In both the present case and in Case A-009-2020 the Agency's policy on addressees of compliance check decisions described in paragraphs 11 and 12 above took effect between the date of adoption of the initial compliance check decision and the date of adoption of the follow-up decision.

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6 Judgment of 8 May 2018, *Esso Raffinage* v *ECHA*, T-283/15, EU:T:2018:263, paragraph 62.

7 Decision of the Board of Appeal of 9 November 2021, *Polynt*, A-009-2020 paragraphs 81 and 82.

(b) Procedural obstacles to the involvement of other registrants at the stage of the follow-up decision

47. The Appellant did not demonstrate how it would be legally possible to include other registrants of the Substance as addressees of the Contested Decision when those registrants were not included as addressees of the initial compliance check decision.

48. To be the subject of a follow-up compliance check decision under Article 42, registrants must firstly be subject to an initial compliance check decision under Article 41. Including registrants directly as addressees of a follow-up decision under Article 42 would constitute a breach of Article 41 and the procedural rights set out in Articles 50 and 51, in particular the right to be heard.

49. In this respect, the Appellant stated during the present proceedings that it did not consider that there is a cut-off point after which new registrants of a substance could not be included in a follow-up decision under Article 42 prior to the adoption of that decision. Since new registrations of a substance could be submitted at any point, and since those registrants must be afforded the procedural guarantees set out in the REACH Regulation, such an approach could potentially lead to endless delays in the decision-making procedure. This could in turn prevent the Agency from obtaining information missing from registrants' dossiers and therefore jeopardise the achievement of the primary objectives of the REACH Regulation.[8]

(c) The change of addressee policy does not apply to the follow-up decision

50. The Appellant's argument that the Agency did not act in good faith and violated Article 41 of the Charter by addressing the Contested Decision solely to the Appellant despite the Agency's change of policy on addressees must also be rejected.

51. The Agency's policy to address compliance check decisions to all registrants of a substance concerned by the information requirements in question – which applied from January 2019 – was designed to change the way the Agency initiates initial compliance check processes under Article 41 and with regard to whom initial compliance check decisions are addressed. That policy does not concern the situation of a change of addressee at the stage of a follow-up to the initial compliance check decision under Article 42. The Agency did not change its policy regarding the addressees of follow-up decisions. Therefore, the Agency's change of policy regarding the addressees of initial compliance check decisions did not mean that the Agency was obliged to address the Contested Decision to other registrants of the Substance.

52. The Appellant's registration dossier remains non-compliant with regards to Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X regardless of the change of the Agency's addressee policy. In this respect, during the present proceedings, the Appellant did not contest the Agency's conclusion that its dossier contains a data-gap with regards to those information requirements.

(d) The non-relevance of the Board of Appeal's previous decision concerning initial decisions on testing proposals

53. The Appellant's argument[9] that the Board of Appeal's decision in Joined Cases A-016-2019 to 029-2019 applies equally to the present case must also be rejected. In those joined cases, the Board of Appeal decided that a decision on a testing proposal under Article 40 must be addressed to all the registrants of the same substance to whom an information requirement applies and who have not decided to submit separately the information in question under Article 11(3). However, the present case concerns a different legal framework – namely the compliance check procedure under Article 41 and the follow-up procedure under Article 42.

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8 See, by analogy, decision of the Board of Appeal of 9 September 2015, *Altair Chimica and others*, A-004-2014, paragraph 141.

9 See paragraph 36 above.

54. In view of paragraphs 39 to 53 above, the Appellant's first plea must be rejected.

4.1.2. Equal treatment and non-discrimination

Arguments of the Parties

55. The Appellant argues that the Contested Decision violates the principles of equal treatment and non-discrimination. The Appellant argues that the principle of equal treatment, which is embodied in Article 20 of the Charter, requires that like cases are treated alike and a difference of treatment of comparable situations is allowed only if there is an objective reason for doing so.

56. According to the Appellant, to respect the equality of economic opportunities, the principle of equal treatment requires that the Agency must not alter the equality of economic opportunities of one company for the benefit of competitors without compelling grounds. The Appellant argues that, in the present case, the Agency gave a competitive advantage to the other registrants of the Substance by addressing compliance check decisions only to the lead registrant.

57. The Appellant argues that there are economic and legal consequences of compliance check decisions. The addressee of the decision is obliged to perform the requested study and to bear the related costs. Other registrants, who are not addressees of the compliance check decision, have the possibility to cease manufacturing or reduce their tonnage band to avoid fulfilling the information requirements. In addition, the Appellant argues that in case of non-compliance, only the lead registrant, as the only addressee of the decision, might be the subject of possible enforcement actions of national authorities.

58. The Appellant argues that there is no objective reason for such unequal treatment of the lead registrant. According to the Appellant, the Agency is obliged to address compliance check decisions to all registrants to ensure a level playing field for those registrants.

59. The Appellant argues that data and cost-sharing under the REACH Regulation must be non-discriminatory. Therefore, since there is no justification for different treatment of the Appellant and the other registrants of the Substance, the Agency breached the principle of non-discrimination.

60. The Agency disputes the Appellant's arguments.

Findings of the Board of Appeal

61. The principle of equal treatment is a general principle of European Union law, enshrined in Articles 20 and 21 of the Charter.

62. The principle of equal treatment requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.[10]

63. Furthermore, a breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all elements which characterise them. The elements which characterise different situations, and hence their comparability, must in particular be determined and assessed in the light of the subject-matter and purpose of the European Union act which makes the distinction in question. The principles and objectives of the field to which the act relates must also be taken into account.[11]

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[10] Judgment of 14 September 2010, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission*, C-550/07 P, EU:C:2010:512, paragraph 55. Decision of the Board of Appeal of 8 September 2017, *Envigo Consulting and DJChem Chemicals Poland*, A-026-2015, paragraph 158.

[11] Judgment of 18 June 2014, *Spain* v *Commission,* T-260/11, EU:T:2014:555, paragraph 93.

64. In the present case, the Appellant argues that the Contested Decision is the legal act which makes the alleged distinction in question.

65. However, at the time of the adoption of the Contested Decision, the Appellant was not in a comparable situation to the other registrants of the Substance. This is because the Appellant is the only addressee of the initial compliance check decision finding that there is a data-gap in its registration dossier with regards to the PNDT studies required under Section 8.7.2. of Annex IX and Section 8.7.2. of Annex X.

66. Furthermore, for the reasons set out above,[12] the Agency could not address the Contested Decision to other registrants of the Substance as those registrants were not addressees of the initial compliance check decision. As a result, with respect to the adoption of the Contested Decision, there was no unequal treatment between the Appellant and the other registrants of the Substance.

67. The Appellant's plea that the Agency breached the principles of equal treatment and non-discrimination must therefore be rejected.

4.2. Article 25

Arguments of the Parties

68. The Appellant argues that the Agency breached Article 25(1) by failing to ensure that testing on vertebrate animals is undertaken only as a last resort. According to the Appellant, this is because the Agency failed to examine whether the registration dossier of the second opt-out registrant contained the information requested in the Contested Decision.

69. The Agency disputes the Appellant's argument. According to the Agency, the registration dossier of the second opt-out registrant was considered by the Agency but that dossier does not contain any information relevant to the information requirements addressed in the Contested Decision.

Findings of the Board of Appeal

70. Article 25(1) states that '*in order to avoid animal testing, testing on vertebrate animals for the purposes of [the REACH Regulation] shall be undertaken only as a last resort*'.

71. According to the Appellant, the Agency breached Article 25(1) as it did not examine the dossier of the second opt-out registrant to verify whether there was information available which would entail that the PNDT studies requested in the initial compliance check decision are not necessary.

72. However, the Agency stated during the present appeal proceedings that it did examine the dossier of the second opt-out registrant and found that no relevant information was available. The Appellant did not contest the Agency's statement.

73. At the hearing, in response to the Agency's statement set out in the previous paragraph, the Appellant argued that the Agency did not treat it equally since it did not open a compliance check process against the second opt-out registrant despite being aware of the non-compliance with regards to the PNDT studies. However, that argument is not capable of demonstrating a breach of Article 25 in the Contested Decision, which is only addressed to the Appellant. Furthermore, for the reasons set out in Section 4.1.2. above, the Agency did not breach the principles of equal treatment and non-discrimination by addressing the Contested Decision only to the Appellant.

74. The Appellant's plea that the Agency breached Article 25 must therefore be rejected.

[12] See Section 4.1.1. above.

5. Result

75. As all the Appellant's pleas have been rejected, the appeal must be dismissed.

6. Refund of the appeal fee

76. Under Article 10(4) of the Fee Regulation[13], the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**

2. **Decides that the appeal fee is not refunded.**

Antoine Buchet
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal

[13] 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).