

**DECISION OF THE CHAIRMAN OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

16 September 2019

*(Follow-up to dossier evaluation – Failure to respond to a dossier evaluation decision –
Admissibility – Competence of the Board of Appeal)*

Case number	A-013-2019
Language of the case	English
Appellant	Symrise AG, Germany
Representatives	Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson LLP, Belgium
Contested Act	CCH-C-2114472349-39-01/F of 21 May 2019 entitled <i>'Information of a failure to respond to a dossier evaluation decision'</i>

THE CHAIRMAN OF THE BOARD OF APPEAL

gives the following

Decision

Background to the dispute

1. On 14 December 2016, the Agency adopted a testing proposal decision concerning 2-phenylethanol (EC number 200-456-2, CAS number 60-12-8; the 'Substance'). The Appellant was requested to provide, amongst other things, information on an extended one-generation reproductive toxicity study ('EOGRTS') in rats, oral route with certain specifications (Section 8.7.3. of Annex IX to 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; corrected by OJ L 136, 29.5.2007, p. 3; the 'REACH Regulation').
2. The Appellant was required to provide the information on the EOGRTS by 21 December 2018.
3. On 17 March 2017, the Agency adopted a compliance check decision concerning the Appellant's dossier for the Substance. The Appellant was requested to provide information on the following using the Substance:
 - Composition of the Substance – concentration values (Section 2.3. of Annex VI to the REACH Regulation);
 - Spectral data – nuclear magnetic resonance or mass spectrum (Section 2.3.5. of Annex VI to the REACH Regulation);
 - Surface tension (Section 7.6. of Annex VII to the REACH Regulation); and
 - Pre-natal developmental toxicity study (Column 2 of Section 8.7.2. of Annex IX to the REACH Regulation; 'PNDT study') in a second species (rabbit), oral route.
4. The Appellant was required to provide the information by 26 March 2018.
5. On 23 March 2018, the Appellant provided information on the first three requests for information contained in the compliance check decision (see paragraph 3 above). With regard to the PNDT study, the Appellant submitted to the Agency a letter from the contract research organisation ('CRO') explaining that the delivery of the study was delayed. The letter also set out the overall testing strategy.
6. On 18 December 2018, the Appellant updated its dossier with another letter from the CRO outlining the timing of the PNDT study. The Appellant also submitted a '*Proposed Step-Wise Annex IX Testing Strategy*' (the 'testing strategy') for the Substance in response to both the testing proposal decision and the compliance check decision.
7. In the testing strategy, the Appellant requested the Agency to re-evaluate the need to perform the EOGRTS based on the results of the PNDT study, when those results became available. The Appellant also requested the Agency to consider requiring the Appellant to perform an OECD test guideline 421 screening study before requesting the EOGRTS. The Appellant also informed the Agency that the final report of the PNDT study was further delayed.
8. On 4 March 2019, a representative of the Appellant informed the Agency that the final report of the PNDT study was expected on 19 April 2019.
9. On 15 April 2019, a representative of the Appellant informed the Agency that the final report of the PNDT study was further delayed until 8 May 2019.
10. On 21 May 2019, the Agency sent the Contested Act to the German REACH Competent Authority and the German (MSCA/NEA) Focal Point. The Appellant received a copy of the Contested Act.
11. The Contested Act concludes that no information was submitted by 26 March 2018 in response to the request in the compliance check decision for a PNDT study.

12. Due to the failure to provide the requested information on a PNDT study, the Contested Act requests the German competent authorities '*... to take appropriate actions to address this failure to respond by the deadline set in the decision*'.
13. In the Annex to the Contested Act, under the heading '*Explanation*', it is stated that '*the Registrant claims the study is ongoing (the registrant has indicated several provisional completion dates which have all passed)*'.
14. On 19 August 2019, the Appellant lodged the present appeal. The Appellant requests the Board of Appeal to annul the Contested Act and refund the appeal fee.

Admissibility – Competence of the Board of Appeal

Arguments of the Appellant

15. The Appellant argues that, although the Contested Act was not adopted on the basis of one of the Articles listed in Article 91(1) of the REACH Regulation, the Board of Appeal is competent to rule on the present appeal.
16. The Appellant argues that, in its decision of 29 July 2015 in Case A-019-2013, *Solutia*, the Board of Appeal found that it is competent to rule on Agency decisions under dossier evaluation that should have been adopted under Article 42(1) of the REACH Regulation, even if the decision in question was not in fact based on that Article.
17. The Appellant argues that the facts of the present case are similar to those in Case A-019-2013, *Solutia*. In particular, the Contested Act is an Agency decision which requires enforcement action to be taken against the Appellant based on the Agency's assessment that the information submitted by the Appellant did not comply with the initial dossier evaluation decision.
18. The Appellant argues that, following the General Court's judgment of 8 May 2018 in T-283/15, *Esso Raffinage v European Chemicals Agency* (EU:T:2018:263), the Agency was required to adopt a decision under Article 42(1) of the REACH Regulation, following the procedure in Article 51 of that Regulation. The Agency was required to assess the information provided by the Appellant as that information was not manifestly unreasonable and did not therefore amount to an abuse of procedure. In the present case, the Appellant did not fail to respond to the compliance check decision. The Appellant provided information on three of the four information requirements. The Appellant also provided explanations for the delay in providing the results of the PNDT study.
19. The Appellant argues that the General Court is not competent in this case. Pursuant to Article 94 of the REACH Regulation, the General Court is competent to rule on actions against Agency decisions when no right of appeal lies before the Board of Appeal. In the present case, the Board of Appeal is competent as the Contested Act should have been adopted on the basis of the procedure laid down in Article 51 of the REACH Regulation.
20. The Appellant argues that, at the time the Esso Raffinage case was brought, the Board of Appeal had not yet ruled on whether it was competent for appeals against such acts. As a result, there was uncertainty as to whether the Board of Appeal was competent. As the applicant in the Esso Raffinage case had only challenged the case before the General Court, the applicant would have been left without a remedy had the General Court declined competence.

Findings of the Chairman of the Board of Appeal

21. Pursuant to Article 93(2) of the REACH Regulation, the Chairman of the Board of Appeal may dismiss an appeal within 30 days of it being filed if he considers the appeal to be inadmissible.

22. According to Article 91(1) of the REACH Regulation, '*[a]n appeal may be brought [before the Board of Appeal] against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51*'.
23. Pursuant to Article 11(1)(c) 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. 1, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4), an appeal is inadmissible if it is not brought against a decision referred to in Article 91(1) of the REACH Regulation.
24. Article 94(1) of the REACH Regulation provides that '*[a]n action may be brought before the [General Court] or the Court of Justice, in accordance with Article [263 TFEU], contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency*'.
25. In the present case, it is uncontested by the Appellant that the Contested Act was not adopted on the basis of any of the Articles listed in Article 91(1) of the REACH Regulation. As such, the Board of Appeal is not competent to decide on an appeal against the Contested Act.
26. This finding is not affected by the Appellant's argument (see paragraph 16 above) that, based on the Board of Appeal's decision in A-019-2013, *Solutia*, the Board of Appeal is competent for the present appeal on the grounds that the Contested Act should have been adopted on the basis of the procedure set out in Article 51 of the REACH Regulation, which is one of the Articles listed in Article 91(1) of that Regulation.
27. Since the Board of Appeal's decision in Case A-019-2013, *Solutia*, the General Court has declared itself competent to determine actions against acts of the Agency similar to that at issue in the present case (see paragraphs 33 to 37 of the Esso Raffinage judgment cited in paragraph 18 above).
28. In this respect, contrary to the Appellant's claims, there is no indication in the judgment in the Esso Raffinage case that the General Court decided to take jurisdiction in order to address a temporary uncertainty, and redress a potential gap, regarding the availability of legal remedies against decisions of the Agency issued in follow-up to a dossier evaluation decision. The General Court held that it had jurisdiction because, based on Article 91(1) of the REACH Regulation, the Board of Appeal did not have competence to rule on the action brought in the Esso Raffinage case.
29. In addition, the Appellant would not be devoid of a remedy in the present case if the Board of Appeal did not accept competence for the appeal. The Appellant was entitled to bring an action to the General Court against the Contested Act. In such an action, as occurred in the Esso Raffinage case, the applicant could have raised the argument that the Agency should have adopted the challenged measure on the basis of Article 42(1) of the REACH Regulation, following the procedure set out in Article 51 of that Regulation. The General Court could have then evaluated whether the Agency had committed an error in that regard.
30. Furthermore, as set out in Article 94(1) of the REACH Regulation, the Appellant may challenge any Board of Appeal decision, including a decision of the Chairman, before the General Court.
31. Having regard to the foregoing, it must be held that the present case does not fall within the competence of the Board of Appeal. This appeal must consequently be dismissed as inadmissible.

Refund of the appeal fee

32. In accordance with Article 10(3) of Commission Implementing Regulation (EU) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), if the appeal is considered inadmissible, the fee shall not be refunded.
33. As the appeal is dismissed as inadmissible, the appeal fee is not refunded.

On those grounds,

THE CHAIRMAN OF THE BOARD OF APPEAL

hereby:

- 1. Dismisses the appeal as inadmissible.**
- 2. Decides that the appeal fee will not be refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal