

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

15 December 2017

Application to intervene

*(Interest in the result of the case –
Registrant of a similar substance)*

Case number	A-006-2017
Language of the case	English
Appellant	Climax Molybdenum B.V., the Netherlands
Representatives	Scott Megregian and Zanda Romata K&L Gates LLP, United Kingdom
Contested Decision	CCH-D-2114356486-40-01/F of 13 March 2017 adopted by the European Chemicals Agency pursuant to Article 41(3) of Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')
Applicant	Plansee SE, Austria
Representatives	Scott Megregian and Zanda Romata K&L Gates LLP, United Kingdom

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman and Rapporteur), Sari Haukka (Legally Qualified Member) and Jonna Sunell-Huet (Technically Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 9 June 2017, the Appellant filed an appeal against the Contested Decision. The Contested Decision is a compliance check of the Appellant's registration dossier for the substance disodium molybdate (EC No 231-551-7, CAS No 7631-95-0 (anhydrous) and 10102-40-6 (dihydrate), the 'Substance').
2. The Contested Decision requires the Appellant to perform a pre-natal developmental toxicity ('PNDT') study in accordance with Section 8.7.2. of Annex IX to the REACH Regulation (all references to Articles, Recitals, Titles, Chapters and Annexes hereinafter concern the REACH Regulation unless stated otherwise).
3. On 28 July 2017, an announcement was published on the Agency's website in accordance with Article 6(6) 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').
4. On 1 August 2017, the Applicant applied for leave to intervene in the proceedings in support of the Appellant.
5. On 8 September 2017, the Appellant informed the Registry of the Board of Appeal that it did not object to the application for leave to intervene.
6. On 11 September 2017, the Agency submitted observations on the application for leave to intervene requesting the Board of Appeal to dismiss the application to intervene.

Arguments

Arguments of the Applicant

7. The Applicant claims to have an interest in the result of the case because it is the lead registrant of the substances molybdenum sulphide, roasted (CAS No 86089-09-0, EC No 289-178-0), and slags, ferromolybdenum-manufg., silicothermic (CAS No 84144-95-6, EC No 282-217-2) different substances than the one registered by the Appellant. The Applicant relies through read-across on the pre-natal developmental toxicity study ('PNDT') performed by Dr. Tyl in 2013 (the 'Tyl 2013 study') that was submitted by the Appellant in the registration dossier. The Agency found in the Contested Decision that the Tyl 2013 study did not meet the specifications of OECD Test Guideline 414, did not meet the requirements of Article 13(3) and is insufficient to fulfil the information requirement in Section 8.7.2. of Annex IX.
8. Should the appeal be dismissed, according to Article 53, the Applicant will have to share the costs of the further PNDT study that the Appellant would have to perform as requested in the Contested Decision. The decision of the Board of Appeal will therefore have a direct effect on the Applicant.
9. The Applicant also claims that it is a '*concerned registrant*' within the meaning of Article 50(1) since that Article does not specify that it applies only to the registrants of the substance subject to a draft decision. The Applicant considers that it should have been notified by the Agency of the Contested Decision.
10. The Applicant also claims that it relies on the Tyl 2013 study through read-across which the Agency considered in the Contested Decision as insufficient to fulfil information requirements of section 8.7.2. of Annex IX. The Agency should have been aware that the Applicant was relying on the Tyl 2013 study as it has full knowledge of the registrants which rely on studies from registration dossiers other than their own.

Arguments of Agency

11. The Agency objects to the application. It claims that the Applicant has not established an interest in the result of this case for the following reasons. The Applicant is not a registrant of the Substance. Moreover, the Applicant is not an addressee of the Contested Decision, nor the addressee of any decision concerning the PNDT endpoint for its own substance. Therefore, neither Article 53 nor the Contested Decision impose any obligation on the Applicant.

Reasons

12. In accordance with Article 8(1) of the Rules of Procedure, any person establishing an interest in the result of a case submitted to the Board of Appeal may intervene in the proceedings.
13. When assessing whether an interest in the result of the case exists, the Board of Appeal follows the test developed by the Court of Justice according to which the concept of an interest in the result of the case must be defined in the light of the precise subject-matter of the dispute and be understood as meaning a direct, existing interest in the ruling on the forms of order sought. It is necessary, in particular, to ascertain whether the Applicant is directly affected by the Contested Decision and whether its interest in the result of the case is established (see case A-001-2016, Decision of the Board of Appeal of 6 April 2016 on the application to intervene of Thor GmbH, paragraph 10).
14. The Applicant argues in support of its application that it is a '*concerned registrant*' within the meaning of Article 50(1). As a result, the Applicant argues, it would be bound by Article 53 to share the costs of further testing with the Appellant should the appeal be dismissed.
15. Article 50(1) provides that '*[t]he Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt*'.
16. The terms '*concerned registrants*' used in Article 50(1) refers to registrants that are concerned in so far as they are subject to any of the procedures described under Articles 40, 41 and 46.
17. Article 41 which concerns compliance check of registrations provides amongst other things that the Agency may examine any registration in order to verify that information in the technical dossiers comply with the information requirements of Annexes VI to X. These Annexes in turn specify the information which shall be submitted for registration and evaluation purposes. Annex VI states explicitly that registrants should gather '*all existing available test data on the substance to be registered*.' Throughout this Annex, it is made clear that registrants are only required to provide information in their dossier on the one substance for which they have submitted a registration dossier.
18. As regards those required to provide the information on a registered substance, Recital 19 states that '*the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import*'.
19. It follows from the previous paragraph that the Agency only assesses registrations dossiers pertaining to one substance at a time and that the obligation to generate and provide information on a dossier under evaluation is only on the registrant(s) for the registered substance. This is clear from the wording used throughout the REACH Regulation.
20. Therefore, the concerned registrants to be notified in the course of a compliance check within the meaning of Article 50(1) are only the registrants of the particular substance subject to a draft decision and not the registrants of another substance.
21. The argument of the Applicant that it is a concerned registrant within the meaning of Article 50(1) is therefore rejected as it registered different substances than the Appellant.

22. In conclusion, as the registrant of different substances than the Appellant, the Applicant is not a concerned registrant to the effects of Article 50(1). The Agency did not therefore disregard the Applicant's procedural rights in adopting the Contested Decision.
23. In addition, the Applicant's argument regarding the breach of its procedural rights would have been rejected by the Board of Appeal even if the application to intervene had been accepted. In this respect, the Board of Appeal follows the practice of the European Court of Justice according to which an intervener may '*set out arguments as well as pleas independently, in so far as they support the form of order sought by one of the main parties and are not entirely unconnected with the issues underlying the dispute, as established by the applicant and defendant, as that would otherwise change the subject-matter of the dispute*' (judgment of 14 March 2013, Case T-587/08 *Fresh Del Monte Produce v Commission*, EU:T:2013:129, paragraph 537). In the present application, the Applicant's argument is clearly unconnected from the issues raised by the Appellant and would therefore have been rejected also for this reason.
24. The Applicant also argues that according to Article 53 it would be bound to share the costs of any further studies requested by the Agency, should the appeal be dismissed.
25. Following the same reasoning as explained in paragraph 23 above as regards Article 50(1), Article 53(2), setting out mandatory cost sharing between registrants in the context of Title VI, is equally only applicable to registrants of the same substance. The Appellant and the Applicant therefore do not have a legal obligation to share costs as a result of the Contested Decision. The argument of the Applicant according to which it would have to share the costs of further testing with the Appellant is therefore rejected.
26. In addition, the Applicant has not provided any evidence that the Appellant, should the appeal be dismissed, would contractually require the Applicant to share the cost of a new PNDT study. Moreover, as stated in Section 1 of the Contested Decision, the Appellant has always the possibility to adapt the requested testing according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI.
27. In conclusion, the Applicant has not established a direct and existing interest in the outcome of the present appeal.
28. Since the application for leave to intervene does not comply with the requirements of Article 8(1) of the Rules of Procedure, it must be dismissed.

On those grounds,

THE BOARD OF APPEAL

hereby:

Dismisses the application to intervene.

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal