EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	15 March 2024
Case	A-002-2024
Appellant	Grace GmbH, Germany
Appeal received on	8 February 2024
Subject matter	A decision taken by the European Chemicals Agency under Article 41 of the REACH Regulation[2]
Keywords	*Dossier evaluation – Compliance check – Read-across – Proportionality – Equal treatment – Articles 13(1) and 25*
Contested Decision	CCH-C-2114668710-46-01/F
Language of the case	English

Background and remedy sought by the Appellant

As part of the compliance check of the Appellant's registration dossier for lanthanum chloride, anhydrous (the **Substance**)[3], initiated on 7 December 2021, the Agency notified a draft decision to the Appellant requiring it to provide the following information:

1. *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII; test method: OECD TG 471, 2020);
2. Growth inhibition study aquatic plants (Section 9.1.2. of Annex VII; test method: EU C.3./OECD TG 201);
3. *In vitro* gene mutation study in mammalian cells (Section 8.4.3. of Annex VIII; test method: OECD TG 476 or TG 490);
4. Justification for an adaptation of a short-term repeated dose toxicity study (28 days) based on the results of the sub-chronic toxicity study (90 days) requested below (Section 8.6.1. of Annex VIII);
5. Screening for reproductive/developmental toxicity (Section 8.7.1. of Annex VIII; test method: EU B.64/OECD TG 422) by oral route, in rats;
6. Short-term toxicity testing on fish (Section 9.1.3. of Annex VIII; test method: EU C.1./OECD TG 203);
7. Sub-chronic toxicity study (90-day) (Section 8.6.2. of Annex IX; test method: OECD TG 408) by oral route, in rats;

[1] Announcement published 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).

[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 concern the REACH Regulation unless stated otherwise.

[3] EC No 233-237-5; CAS No 10099-58-8.

8. Pre-natal developmental toxicity study (Section 8.7.2. of Annex IX; test method: OECD TG 414) by inhalation route, in one species (rat or rabbit);
9. Long-term toxicity testing on fish (Section 9.1.6. of Annex IX; test method: EU C.47./OECD TG 210); and
10. Pre-natal developmental toxicity study (Section 8.7.2. of Annex X; test method: OECD TG 414) by oral/inhalation route, in a second species (rat or rabbit).

In its comments on the draft decision, the Appellant proposed a read-across adaptation under Section 1.5. of Annex XI to the Substance from other lanthanum salts (lanthanum carbonate and lanthnum carbonate actahydrate, lanthanum oxide, lanthanum hydroxide, lanthanum nitrate, and lanthanum acetate; '**the source substances**').

On 9 November 2023, the Agency adopted the Contested Decision rejecting the proposed read-across and requiring the Appellant to provide the information set out above by 16 August 2027.

The Appellant requests the Board of Appeal to partially annul the Contested Decision as regards information requirements 4, 5, 7, 8 and 10. The Appellant also requests the Board of Appeal to order the Agency to refund the appeal fee.

Pleas in law and main arguments

In support of its appeal, the Appellant raises three pleas in law.

By its first plea, the Appellant argues that the Agency committed a manifest error of assessment by rejecting the proposed read-across in relation to information requirements 4, 5, 7, 8 and 10.

In this respect, the Appellant argues that its proposed read-across adaptation meets the criteria set out in Section 1.5. of Annex XI due to the structural similarities between the Substance and the source substances resulting in the similarity of their properties and transformation process in the digestive system. The Appellant argues further that it provided adequate and reliable evidence to support its proposed adaptation.

The Appellant argues that, considering the viability of its proposed read-across adaptation:

- As regards information requirements 4 and 7, there is an adequate and reliable 90-day study on lanthanum carbonate therefore satisfying these two endpoints.

- As regards information requirement 5, it is already fully satisfied by a reliable OECD TG 422 study on lanthanum acetate, which was accepted by the Agency as the basis for a separate proposed read-across from lanthanum acetate to lanthanum nitrate.

- As regards information requirement 8, the requested study is not feasible with the Substance without specific adjustments, which would transform the Substance into lanthanum hydroxide. As acknowledged by the Agency, there is sufficient data on lanthanum hydroxide for this endpoint. Therefore, this study is unnecessary.

- As regards information requirement 10:
  - Related to the testing by inhalation route, the Appellant raises the same difficulties in performing the test as those identified for information requirement 8; and
  - Related to the testing by oral route, the Appellant emphasises that reliable source data on lanthanum carbonate satisfies this endpoint.

By its second plea, the Appellant argues that the Agency breached the principle of proportionality by requiring further animal studies despite the read-across adaptation proposed by the Appellant, which is, according to it, well-established and well-evidenced.

By its third plea, the Appellant argues that the Agency breached the principle of equal treatment as it has accepted a read-across adaptation between some of the source substances. According to the Appellant, the adaptation previously accepted by the Agency must be fundamentally the same as the read-across proposed in the present case. The Appellant argues that the Agency therefore treated comparable situations differently.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

https://echa.europa.eu/web/guest/regulations/appeals