

To the co-registrants of lanthanum oxide

Subject: Communication on final compliance check decision
Our reference: Rare Earth Consortium
Project number: 30165730
Date: 24 January 2024

Dear co-registrants of lanthanum oxide,

On 9th of November, the final decision of the lanthanum oxide dossier CAS: 1312-81-8, EC: 215-200-5) has been released by the ECHA – see: <http://www.rare-earth-consortium.eu/sites/default/files/substances/lanthanum-oxide/dev-cch-1decfinalregpubliccch.pdf>

The Rare Earth Consortium is currently in the process of fine-tuning its strategy regarding the final decision. This includes discussion on potential disagreement with the content of the final decision as well as discussion on potential future endpoint coverage, which could be:

- Solving reporting issues
- Covering the endpoint or strengthening the endpoint by newly identified literature
- Establishing new read across approaches
- Set up or strengthening of weight-of-evidence approaches
- Testing

Please note that the read across approach among the different La substances (which are considered as a category by the ECHA) is currently being revised and may entail testing as well to generate the required evidence.

Further, it is important to mention that the ECHA omitted the Extended One Generation Reproductive Toxicity study including learning and memory testing from the compliance check decision, although it was present in the draft decision. This is the result of comments of the Rare Earth Consortium and other Lead Registrants/sector organisations on this type of requests in compliance check decisions, as well as the Board of Appeal's decision in cases A-002-2022 and A-003-2022 (as mentioned in Appendix 2 to the final decision). Industry was heard on this topic during the MSC meeting of October, and as a result of this discussion, the EOGRTS & learning and memory testing requirement has been removed from the final decision in its entirety. Nevertheless, this testing requirement will be addressed later "in the context of the category approach", as specified in the minutes of the MSC meeting: [minutes_msc-83_en \(europa.eu\)](#). Similarly, in Appendix 2 to the final decision, it is mentioned that "This information requirement may be addressed in a separate decision". Currently, the Rare Earth Consortium, however, has no view on the expected timeline for this.

As the Consortium is still in the process of evaluating the way forward and this way forward may also entail multiple consecutive steps (tiers) depending on the endpoint(s) under consideration, several communications might follow once there is clarity on potential costs that are expected to be incurred (e.g., testing costs, costs incurred for revision or strengthening of the endpoints, waivers, read across, etc.) and would require cost-sharing between all co-registrants in the different tonnage bands.

Impact on LoA costs

The current costs of the LoA per tonnage band already include a provision for future work on the dossier. See: <http://www.rare-earth-consortium.eu/sites/default/files/substances/lanthanum-oxide/may-2017-sief-communication-loas-available-for-lanthanum-oxide-cas-1312-81-8-ec-215-200-5.pdf>

Part of this provision has already been used. The balance will of course be used to finance the abovementioned work on the dossier. Depending on the total cost for this update, the remaining provision may be insufficient. In such case, the cost of the LoA per tonnage band shall be adapted accordingly and an additional invoicing to all the co-registrants can be deemed necessary.

The deadline provided by ECHA to comply with the requirements is 14th of June, 2027.

If you have any urgent questions, please contact the Rare Earth Consortium using the Consortium mailbox mentioned below.

With kind regards,
Arcadis Belgium nv/sa, for the Rare Earth Consortium

Contact: Rare Earth Consortium mailbox
E-mail: rare-earth-consortium@arcadis.com