

Subject: Communication on testing and dossier update in view of compliance check  
Our reference: Rare Earth Consortium  
Project number: 30263212  
Date: 20 March 2025

Dear co-registrants of lanthanum fluoride,

As communicated in 2024, a final compliance check decision was received on 9<sup>th</sup> of November 2023 for lanthanum fluoride (CAS: 13709-38-1, EC: 237-252-8).

This communication provides further news on the scheduled dossier update which is due 15<sup>th</sup> of February 2027.

- **Water solubility** (An VII, Section 7.7 – test method OECD GD 29)
  - ➔ The Consortium has **ordered transformation/dissolution testing from ECTX/BioXQ**. This testing consists of a 24-h screening test at 1 mg/L and 2 pH levels (pH 6 and 8). Depending on the results of this 24-h screening study, the need for and benefit to proceed to a full 28-d study will be decided upon. The T/D testing will be finalised in 2025.
  - ➔ **Related study cost: 5792 EUR for screening test / between 8195-11075 EUR for a full 28-d study** (depending on number of sampling occasions – to be determined).
- **Skin sensitisation** (An VII, Section 8.3 – in vitro testing (OECD TG 442C/D/E) and/or in vivo testing (OECD TG 429))
  - ➔ The comments given by ECHA can be addressed by adding further information from the study report to the IU entry.
- **Growth inhibition study aquatic plants** (An VII, Section 9.1.2 – test method OECD TG 201)
  - ➔ The Consortium has **ordered an algal growth inhibition study from Labcorp**. This study will be performed with La(NO<sub>3</sub>)<sub>3</sub> and will be used in the different La compound dossiers under compliance check. In addition, an expert statement will be added on the interpretation of algal growth inhibition test results for rare earth compounds (written in 2018 based on all available data at that time and supported by equilibrium speciation modelling). Also, the Consortium is reviewing data from peer-reviewed literature (including on fluoride for the counter anion assessment) and will consider adding the most relevant data to the dossier.
  - ➔ **Related study cost: approximately 26100 EUR.**
- **Long-term toxicity testing on aquatic invertebrates** (An VII, Section 9.1.1, column 2 (if T/D test confirms the substance is poorly soluble) or An IX, Section 9.1.5 – test method OECD TG 211)
  - ➔ The endpoint will be covered by a **reliable OECD 211 study performed with LaCl<sub>3</sub>**. In addition, the Consortium is reviewing data from peer-reviewed literature (including on fluoride for the counter anion assessment) and will consider adding the most relevant data to the dossier. No testing will be required.
- **Long-term toxicity testing on fish** (An VIII, Section 9.1.3, column 2 (if T/D test confirms the substance is poorly soluble) or An IX, Section 9.1.6 – test method OECD TG 210).
  - ➔ As no reliable data could be identified, the Consortium has **ordered a Fish Early Life Stage test from Labcorp**. This study will be performed with La(NO<sub>3</sub>)<sub>3</sub> and will be used in the different La compound dossiers under compliance check that require the study. In addition, the Consortium is reviewing data from peer-reviewed literature (including on fluoride for the counter anion assessment) and will consider adding the most relevant data to the dossier.
  - ➔ **Related study cost: approximately 88150 EUR.**
- **Oral sub-chronic toxicity study (90-day)** (An IX, Section 8.6.2 – OECD TG 408)

- ➔ The endpoint will be covered by an **existing reliable OECD 408 study performed with La carbonate**. In the absence of specific experimental evidence on bioavailability differences between source and target substance, ECHA considers water solubility in pure water (as determined in OECD 105 study) as a proxy for the difference in bioavailability. As LaF<sub>3</sub> and La carbonate have similar water solubility, it is anticipated that ECHA would not reject the read across. In addition, publicly available data on fluoride are being considered for inclusion as well.
- **Oral pre-natal developmental toxicity study in one species** (An IX, Section 8.7.2 – test method OECD TG 414)
  - ➔ The endpoint will be covered by a **reliable OECD 414 study performed with La carbonate** from US FDA (publicly available). It is also anticipated that this read across would not be rejected by ECHA because of the similar water solubility of source and target substance in pure water. In addition, publicly available data on fluoride are being considered for inclusion as well.
- **Short-term toxicity to terrestrial invertebrates** (An IX, Section 9.4.1 – test method OECD TG 207)
  - ➔ The Consortium has ordered an OECD 207 study from Labcorp. This study will be performed with LaF<sub>3</sub>.
  - ➔ **Related study cost: approximately 12663 EUR.**
- **Effects on soil microorganisms** (An IX, Section 9.4.2 – test method OECD TG 216)
  - ➔ The endpoint will be covered by a **reliable OECD 216 and OECD 217 study performed with LaCl<sub>3</sub>**. In addition, the Consortium is reviewing data from peer-reviewed literature on fluoride for the counter anion assessment and will consider adding the most relevant data to the dossier.
- **Short-term toxicity on terrestrial plants** (An IX, Section 9.4.3 – test method OECD TG 208)
  - ➔ The endpoint will be covered by available literature data on La toxicity to terrestrial plants as well as data on fluoride for the counter anion assessment.

For the **ecotoxicological endpoints, information on fluoride** will be added to the dossier in view of the counter anion assessment and the overall conclusion on the respective endpoints. Identified data is from peer-reviewed publications or no longer data protected.

For the **subchronic repeated dose toxicity and prenatal developmental toxicity endpoints**, the **data on fluoride** are US NTP data which are publicly available, as well as literature data.

Other updates to the dossier might be needed to bring it in compliance with current best practices under REACH as well as the most recent IUCLID version. Also, relevant literature important for solidifying endpoint coverage might be added to the dossier for several endpoints.

In addition, if the T/D testing and additional long-term toxicity testing in fish results in classification for the aquatic environment, generic exposure scenarios will be developed, and a Chemical Safety Assessment will be added to the dossier.

### **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-fluoride/may-2017-sief-communication-loas-available-for-lanthanum-fluoride-cas-13709-38-1-ec-237-252-8.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.

A recalculation of LoA prices for this substance is foreseen to account for expiry of the 12 years data protection period under EU REACH, to update the number of co-registrants, and include the costs associated with testing and preparation of the dossier update.

If additional invoicing to co-registrants who purchased an LoA is necessary, those companies will be informed individually and presented with a justification of the additional costs.

Concerning the testing costs mentioned above:

- The testing costs for the T/D testing and the growth inhibition study in algae are considered relevant for all An VII or higher registrants.
- The testing costs for the FELS study are considered relevant for all An VIII or higher registrants (assuming confirmation of poor solubility in the T/D screening test).
- The testing costs for the short-term toxicity test in terrestrial invertebrates are considered relevant for all An IX or higher registrants.

Apart from the testing costs, all study monitoring costs and administrative costs for preparing the dossier update will be divided over the respective tonnage bands for which the endpoints under consideration are mandatory information requirements.

With kind regards,

Arcadis Belgium nv/sa  
on behalf of the members of the Rare Earth Consortium

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