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Subject: Update of boundary composition and endpoint coverage / re-submissions of joint dossier / change of Lead Registrant
Our reference: Rare Earth Consortium
Project number: 30199549
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Dear co-registrant of diyttrium trioxide (Y₂O₃, CAS 1314-36-9; EC 215-233-5),

As per our communication on 4th of October 2023, we informed the co-registrants that ECHA requested additional information on substance identity. With this new communication, we would like to provide further information and provide a status update concerning the dossier updates related to this request as well as future dossier updates.

On the 5th of April 2024, the lead dossier of the substance diyttrium trioxide was re-submitted by the Lead Registrant (Traxys Europe SA).

This re-submission was a direct follow-up to the previous dossier re-submission at the end of November 2023, for which ECHA requested additional information during the manual completeness check.

The re-submitted dossier includes the following updates:

- 1) The boundary composition was included in the Lead Registrant dossier (re-submission end of November 2023). The corresponding updated SIP (Substance Identification Profile) has been published in annex to this communication as well as on the [REC website](#). Each registrant has the obligation to check if its legal entity's composition(s) falls within the boundaries set by the boundary composition in the joint dossier. As announced in the communication of 4th of October 2023, this boundary composition excludes doped yttria and currently does not cover nanomaterials. In a future dossier update the LR would like to include nano grade Y₂O₃.
- 2) Additionally, the following data was included in the dossier (re-submission on 5th of April 2024):
 - A testing proposal for a sub-chronic toxicity study (90-day) in rats via the inhalation route according to the OECD guideline 413, using the test substance diyttrium trioxide, to address the rejected endpoint coverage for the sub-chronic repeated dose toxicity endpoint.
 - Data from publications, to address the rejected endpoint coverage for the long-term toxicity to fish and the long-term toxicity to aquatic invertebrates endpoints.
 - Data from publications, to avoid rejection of the endpoint coverage strategy for the adsorption endpoint during the announced compliance check (see below).

The inclusion of this data in the dossier, as well as the inclusion of diyttrium trioxide in [ECHA's assessment of regulatory needs of 31-03-2023 \(announcing a compliance check for the substance\)](#), will lead to a general revision and update of the dossier in the near future. For this reason, the CSR was not yet updated in the current dossier

submission, as the foreseen updates will further impact the CSR. These updates will be planned and discussed amongst the involved members of the Rare Earth Consortium. The exact timeline of the compliance check is currently unknown and it will determine the timeline for the next dossier update.

Change of Lead Registrant

After the dossier re-submission on 5th of April 2024, the Lead Registrant role was transferred from Traxys Europe SA to Treibacher Industrie AG

Impact on the LoA costs (Letter of Access)

The cost for work performed on the joint dossier, as well as the planned updates, will have an impact on future costs of the Letter of Access (LoA).

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/yttrium-oxide/may-2017-sief-communication-loas-available-for-yttrium-oxide-cas-1314-36-9-ec-215-233-5.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 to cover all costs. In such a case, the cost of the LoA per tonnage band shall be adapted accordingly and an additional invoicing to all co-registrants can be deemed necessary.

In case there are any questions, please do not hesitate to contact us at the email address listed below.

With kind regards,
Arcadis Belgium nv/sa

Arcadis, as Consortium manager of the Rare Earth Consortium

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