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Subject: Letter of ECHA on substance identity in the Y2O3 dossier  
Our reference: Rare Earth Consortium  
Project number: 30165730  
Date: 04 October 2023

Dear co-registrant of diyttrium trioxide (Y2O3),

On the 19<sup>th</sup> of September, the lead registrant and co-registrants for diyttrium trioxide (Y2O3, CAS 1314-36-9; EC 215-233-5) received a letter from ECHA concerning the substance identity profile of the substance.

Arcadis, as a Consortium manager, already had a brief discussion with the Lead Registrant (Traxys Europe SA) on the questions from ECHA and would like to communicate the following to all co-registrants of the substance:

- 1) Regarding Y2O3 as nanomaterial: ECHA, through its reviews of nano-registers and the information in the European Observatory for Nanomaterials (EUON), is aware that Y2O3 nanomaterials are on the EEA market. ECHA therefore requests all registrants to check whether their marketed grades are nanomaterials or not. If this is the case, this should also be reflected in the dossier. **The current joint dossier does NOT cover Y2O3 as nanomaterial.** The Consortium has discussed this a few years ago and at that time decided that it would not update the Y2O3 dossier to include nanomaterials (no specific need for the registrants within the Consortium). This **evaluation will be re-done around and during the next Consortium management meeting which will take place in October, 2023.** Should the decision change, this will be announced to the co-registrants. Regardless of the decision of the Consortium, all registrants of Y2O3 are recommended to investigate the potential nano-status of their fine powder grades on the EEA market. This can be done by determining the constituent particle size distribution, which is recommended to be determined using TEM and using the counting rules specified in the latest JRC document ([JRC Publications Repository - Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial \(europa.eu\)](#)). Additionally, (V)SSA could be determined using the BET method and a density determination.
- 2) Regarding doped Y2O3 materials: ECHA, through its review of the compositional and analytical data given in the registrants' dossiers, is concerned that there might be doped Y2O3 materials covered by the Y2O3 dossiers. With 'dopants', ECHA means substances that are intentionally included in the crystal lattice of the material to adjust its properties, typically by adjustments in the crystallographic structure or phase composition. Such doped substances should be considered as separate substances and cannot be covered by the Y2O3 dossier. **The current joint dossier does NOT cover doped Y2O3 forms. This will be clearly specified in a new SIP.** All registrants should therefore check if they have intentionally added substances in their compositions for Y2O3 that can be considered as 'dopants' and if so, they should take the necessary steps to re-attain compliance through revision of their registration strategy. Note that there is currently no decision to prepare dossiers for doped/stabilised yttria within the Consortium. Should this change, this will be communicated. Please contact the Consortium in case you have questions (or for data sharing agreements).

- 3) Regarding the boundary composition: Each registrant has the obligation to check if its legal entity composition(s) falls well within the boundaries set by the boundary composition in the joint dossier. This **boundary composition will be re-specified by the end of November 2023** (i.e., when the Lead Registrant needs to re-submit the dossier) **and will be distributed** to all co-registrants **together with an updated SIP** (Substance Identification Profile).

In case there are further questions, please do not hesitate to **contact us before 1<sup>st</sup> of November, 2023**. Further communication can be expected in October/November, after the Rare Earth Consortium meeting took place (October) and the Consortium finalised any potential follow-up actions specified during the meeting.

#### Impact on the LoA costs (Letter of Access)

All co-registrants need to perform the checks indicated in the 3 points above. The costs associated with those checks are for account of each co-registrant and have today no impact on the lead dossier. Therefore, no impact today on the cost of the LoA.

Of course, any cost exposed for work performed on the lead registration dossier will have an impact on the total costs of the Letter of Access (LoA).

With kind regards,  
Arcadis Belgium nv/sa

Arcadis, as Consortium manager of the Rare Earth Consortium

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