

To the co-registrants of ytterbium oxide

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Subject: Decision on YbO<sub>3</sub>  
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Dear co-registrants,

The Ytterbium oxide registration (EC 215-234-0, CAS 1314-37-0) has been updated as of 09 April 2024. Following a final decision from ECHA (for further information, please refer to our previous [SIEF communication](#)), an [in vivo mutagenicity study according to OECD 489](#) was conducted and concluded negative. Therefore, an updated dossier and a new CSR version have been submitted to incorporate the new endpoint coverage for genotoxicity.

A follow-up in vivo genotoxicity study on somatic cells is required to cover the in vivo genetic toxicity endpoint under REACH in case positive results are obtained from in vitro studies. Although the in vivo genetic toxicity endpoint under REACH is an Annex IX endpoint, this endpoint must also be covered for lower tonnage bands if positive results are obtained from in vitro studies.

In the case of ytterbium oxide, positive results were obtained in the in vitro chromosome aberration study, therefore this follow-up in vivo Comet assay is now part of the information requirements for the Annex VIII tonnage band and an impact on future LoA costs for the Annex VIII tonnage band is anticipated.

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/ytterbium-iii-oxide/march-2018-loas-costs-and-detailed-calculations-ytterbium-iii-oxide.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.

There are no actions required for now from your side.

In the meantime, if there are specific questions, please send an e-mail to the Consortium's mailbox, hosted by Arcadis (see below for the e-mail address).

With kind regards,

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

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