To the co-registrants of Praseodymium (III, IV) Oxide

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Subject: Status update Q2 2020
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Dear co-registrants,

The Lead Registrant for the substance Praseodymium (III, IV) Oxide EC No 234-857-9 (CAS No 12037-29-5), NPM Silmet OÜ, received in 2017 a notification of a draft decision on a compliance check. The Lead Registrant and the SIEF members shared their comments to ECHA.

The **final decision on a testing proposal issued by ECHA on January 31st, 2017** concluded on the necessity to conduct a series of additional tests in order to meet the requirements for the tonnage band 100-1000 tpy.

The following tests are currently conducted in order to meet with the requests from ECHA:

• Transgenic rodent somatic gene mutation assays (Annex IX*, Section 8.4., column 2; test method: EU B.58./OECD TG 488); in transgenic mice, via the oral route, on the following tissues: liver and glandular stomach using the registered substance. An oral toxicokinetics study was conducted as well as part of the additional investigations considered for data interpretation.

* Although this test is related to the Annex IX (100-1000 tpy) data requirements, it is relevant for lower tonnage bands as well.

- The OECD 488 test is relevant for Annex VIII co-registrants (rationale: As stated in REACH Annex VIII: Appropriate *in vivo* mutagenicity studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex VII or VIII).
- Although this test is not explicitly required in the final decision issued by ECHA, the toxicokinetics study is part of the testing strategy for the Transgenic Rodent Gene Mutation Assay, and is therefore relevant for all Annex VIII co-registrants.

As mentioned in the previous SIEF communication related to the notification of this draft decision, additional testing and update of the registration dossier imply an increase of costs considered in the LoA calculation and of the costs of the LoA itself (in consideration of the tonnage band).

The **additional testing costs** are estimated at approximately **187.000 €.** Note that these costs do not include the costs linked to the study monitoring, dossier update,

update of CSR and project management; these costs will also be integrated in the LoA calculation at a later stage, likely triggering an increase of the cost of the LoA.

The LoA costs will be re-assessed during 2020 at the occasion of the yearly exercise. If the impact of these additional costs is significant on the LoA-costs, additional amounts could be invoiced to the co-registrants who purchased a LoA. Those companies will be informed individually.

Please check our website for the latest information: http://www.rare-earth-consortium.eu. Should you have any comment or question on the status of the ongoing tests or the dossier update for the substance Praseodymium (III, IV) Oxide EC No 234-857-9 (CAS No 12037-29-5), you can reach us at rare-earth-consortium@arcadis.com.

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

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