

Announcement of appeal¹

Published on	12 October 2021
Case	A-011-2021
Appellant	Croda EU B.V., the Netherlands
Appeal received on	3 September 2021
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 41 of the REACH Regulation
Keywords	<i>Compliance Check – Sections 8.7.2. and 8.7.3. of Annex X – Legal certainty – Proportionality – Error of assessment</i>
Contested Decision	Decision No CCH-D-2114556658-33-01/F of 4 June 2021 on the compliance check on lanolin alcohols (EC No 232-430-1; CAS No 8027-33-6)
Language of the case	English

Remedy sought by the Appellant

On 4 June 2021, the Agency adopted the Contested Decision following the compliance check of the Appellant's registration dossier for the substance lanolin alcohols. The Appellant is the lead registrant for that substance and has registered it at the tonnage band of 1000 tonnes or more per year.

The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires information a pre-natal developmental toxicity (PNDT) study in a second species and an extended one-generation reproductive toxicity study (EOGRTS) under Annex X of the REACH Regulation. The Appellant also requests the Board of Appeal to order the Agency to refund the appeal fee and take such other or further measures as justice may require.

¹ Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency as amended by Commission Implementing Regulation (EU) 2016/823.

Pleas in law and main arguments

The Appellant argues that the Agency erred in its assessment, failed to take all relevant information into account and breached Column 2 of Section 8.7.2. of Annex IX and Column 1 of Section 8.7.2. of Annex X to the REACH Regulation by requesting the PNNDT study on a second species. According to the Appellant, these provisions require a registrant to carry out a PNNDT study on a second species only if a PNNDT study in a first species has been conducted and the results show that there is a need for a PNNDT study in a second species. The Appellant argues that the available data on lanolin alcohols does not indicate that a second PNNDT study is necessary.

The Appellant also argues that the Agency breached the principle of legal certainty and the principle of protection of legitimate expectations by requesting the PNNDT on a second species and the EOGRTS.

The Appellant further argues that by requesting the EOGRTS, the Agency erred in its assessment, failed to take all relevant information into account, failed to state reasons and breached Column 2 of Section 8.7. of Annex X to the REACH Regulation.

According to the Appellant, the Agency also breached the principle of proportionality and Article 25 of the REACH Regulation by failing to take the Appellant's proposed adaptations into account.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

<http://echa.europa.eu/web/guest/regulations/appeals>