

Announcement of appeal¹

Published on	18 May 2021
Case	A-004-2021
Appellant	Celanese Production Germany GmbH & Co. KG, Germany
Appeal received on	9 April 2021
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 42(1) of the REACH Regulation
Keywords	<i>Compliance check – Follow-up procedure – Sections 8.7.2. and 8.7.3. of Annex X – Rejection of an adaptation under Sections 1.2. and 1.5. of Annex XI</i>
Contested Decision	CCH-D-2114538555-43-01/F
Language of the case	English

Background to the case and remedy sought by the Appellant

On 14 July 2017 the Agency adopted an initial compliance check decision pursuant to Article 41 of the REACH Regulation. In this decision, the Agency held that there are data-gaps in the Appellant's registration dossier for the substance butyl glycollate (EC No 230-991-7). By that decision, the Agency consequently required the Appellant to submit a pre-natal developmental toxicity study in a second species and an extended one-generation reproductive toxicity study (Sections 8.7.2. and 8.7.3. of Annex X to the REACH Regulation) or, alternatively, a valid adaptation.

In response to that initial compliance check decision, the Appellant provided an adaptation for the information requirements at issue pursuant to Sections 1.2. and 1.5. of Annex XI to the REACH Regulation.

By the Contested Decision, adopted on 12 January 2021, the Agency assessed and rejected that adaptation pursuant to Article 42 of the REACH Regulation.

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.

The Appellant requests the Board of Appeal to annul the Contested Decision, take other or further measures as justice may require and order the refund of the appeal fee. In the alternative, the Appellant requests the Board of Appeal to set a deadline for the provision of the information at issue.

Pleas in law and main arguments

In support of its appeal, the Appellant argues that the Agency's rejection of its adaptation is vitiated in several regards. In particular, the Agency:

- committed several errors in its scientific assessment and breached the requirements of Sections 1.2. and 1.5. of Annex XI to the REACH Regulation by rejecting the Appellant's adaptation,
- infringed the principle of legal certainty and the principle of the protection of legitimate expectations by assessing the Appellant's adaptation on the basis of different criteria than the ones applied in the initial compliance check decision, and by failing to extend the deadline for the provision of the information at issue set in the initial compliance check decision,
- infringed the principle of proportionality by requiring the Appellant to perform unnecessary studies which are unlikely to provide meaningful results, and
- infringed the provisions of the REACH Regulation concerning the welfare of vertebrate animals by requiring the Appellant to perform unnecessary studies.

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>