ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

**SUMMARY OF DECISION OF 23 AUGUST 2022 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-004-2021**

*(Article 42(1) – Follow-up to a compliance check decision – Sections 8.7.2. and 8.7.3. of Annex X – Adaptations from standard information requirements – Section 1.5. of Annex XI – Consistency between a compliance check decision and the related follow-up decision – Deadline to provide information after a follow-up decision)*

*Factual background*

The appeal concerned the follow-up to the compliance check of a registration dossier for butyl glycollate (the Substance).[1]

The Appellant registered the Substance at the tonnage band of 1000 tonnes or more per year. On 14 July 2017, the Agency adopted a compliance check decision under Article 41 of the REACH Regulation.[2] By that decision, the Agency required the Appellant to submit information on a PNDT study in a second species and an EOGRTS in order to bring its dossier into compliance with Sections 8.7.2. and 8.7.3. of Annex X.

In consequence of the compliance check decision of 14 July 2017, the Appellant included in its registration dossier an adaptation for the two studies at issue. According to the Appellant's adaptation, the Substance is rapidly transformed, once ingested, primarily into same break-down product as would result from the ingestion of an analogue substance, ethylene glycol (the Source Substance). It is therefore possible to predict the reproductive and developmental toxicity of the Substance based on existing information on the Source Substance.

On 14 January 2021, the Agency issued the Contested Decision, which was a follow-up decision under Article 42(1). In that decision, the Agency assessed the Appellant's adaptation and found that it did not comply with the requirements of Section 1.5. of Annex XI. It therefore rejected the adaptation and informed the competent national enforcement authority accordingly. It did not set a new deadline for the Appellant to provide the required information.

The Appellant requested the Board of Appeal to annul the Contested Decision, and in any event set a deadline for the Appellant to provide the PNDT study in a second species and the EOGRTS.

*Main findings of the Board of Appeal*

1. *Requirements for read-across adaptations under Section 1.5. of Annex XI*

The Appellant argued that its adaptation complied with Section 1.5. of Annex XI. According to the Appellant, the Agency had applied that provision too stringently by requiring the Appellant to exclude that the properties of the Substance and the Source Substance might be different.

The Board of Appeal recalled that Section 1.5. of Annex XI allows the registrant of a substance to rely on the information on another substance if it is established that (a) the substances in

[1] EC No 230-991-7, CAS No 7397-62-8.
[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles hereinafter concern the REACH Regulation unless stated otherwise.

a group or category are structurally similar, (b) the properties of the substances are likely to be similar or follow a regular pattern, and (c) the similarity of properties or their regular pattern is the result of structural similarity. Those similarities may be based on the likelihood of common breakdown products.

The Board of Appeal held that the Contested Decision showed that the Agency had adequately verified whether the submitted information showed that the properties of the Substance and the Source substance were likely to be similar or follow a regular pattern. The Agency therefore did not commit an error in that regard. Furthermore, the Board of Appeal examined the Appellant's scientific arguments in detail and concluded that the Agency had not committed errors in its scientific assessment.

*2. A follow-up decision need not set a new deadline for providing the required information*

The Appellant argued that in the Contested Decision the Agency should have extended the deadline set in the initial compliance check decision, so that the Appellant could now provide the information without fear of enforcement action. The Appellant further argued that, in any event, the Board of Appeal should set a new deadline.

As regards extending the previous deadline, the Board of Appeal highlighted that, by the time of the adoption of the Contested Decision, the deadline set in the initial compliance check decision had already expired. The Agency could not therefore have extended that deadline.

As regards setting a new deadline, the Board of Appeal recalled that a follow-up decision under Article 42(1) is strictly limited to examining whether a registrant has complied with the initial compliance check decision or not. A follow-up decision does not require any further information from a registrant than what was already required in the initial compliance check decision. Furthermore, the absence of a new deadline in a follow-up decision is consistent with the principle of legal certainty as the possibility that an adaptation may be rejected, and that enforcement measures might ensue, is foreseeable to a registrant. As a consequence, there was no need to grant to Appellant a new deadline.

*3. Result*

As all the Appellant's arguments were held to be unfounded, the appeal was dismissed.

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