EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 31 OCTOBER 2022 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-011-2021

(Dossier evaluation – Article 41 – Compliance check – Section 8.7.2. of Annex X – PNDT study in a second species – Section 8.7.3. of Annex X – EOGRTS – Section 8.7. of Annex X – Legal certainty – Proportionality)

Factual background

The appeal concerned a compliance check of the registration for the substance alcohols, lanolin (the Substance).[1]

In 2010, the Appellant registered the Substance at the tonnage band of 1000 tonnes or more per year, which corresponds to Annex X to the REACH Regulation.[2] The registration dossier included information on a pre-natal development toxicity (PNDT) study in a first species as required under Column 1 of Section 8.7.2. of Annex IX. However, instead of testing information on a PNDT study in a second species and on an extended one-generation reproductive toxicity study (EOGRTS), the registration dossier included two adaptations based on Section 8.7.2. of Annex IX and on Section 8.7.3. of Annex IX to adapt from Sections 8.7.2. and 8.7.3. of Annex X.

On 4 June 2021, the Agency adopted the Contested Decision in accordance with Article 51(3) of the REACH Regulation. In the Contested Decision, the Agency rejected the Appellant's adaptations and found that the information provided by the Appellant does not satisfy the standard information requirements of Sections 8.7.2. and 8.7.3. of Annex X. As a consequence, the Contested Decision required the Appellant to submit information on (i) a PNDT study in a second species with the Substance in accordance with OECD test guideline 414, and (ii) an EOGRTS with the Substance in accordance with OECD test guideline 443, by 11 March 2024.

The Appellant requested the Board of Appeal to annul the Contested Decision insofar it required the Appellant to submit information on a PNDT study in a second species and an EOGRTS.

Main findings of the Board of Appeal

In its Decision of 31 October 2022, the Board of Appeal dismissed the appeal.

The Board of Appeal confirmed that Column 1 of Section 8.7.2. of Annex X must be interpreted as requiring a PNDT study in another (second) species than the one used in the PNDT study required under Column 1 of Section 8.7.2. of Annex IX. Furthermore, it found that the adaptation on the need to perform a PNDT study in a second species under Column 2 of Section 8.7.2. of Annex IX applies only under Annex IX, and therefore a PNDT study in a second species is a standard information requirement under Annex X.

[1] EC No 232-430-1, CAS No 8027-33-6.
[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.

The Board of Appeal rejected the Appellant's plea that the Agency breached the principles of legal certainty and of the protection of legitimate expectations. First, the Board of Appeal held that the Agency is neither required nor entitled to set aside a legislative provision on the ground that its meaning may not be clear to a registrant. If the meaning of a provision is not clear, that provision must be clarified by interpretation before being applied. In this regard, the meaning of Column 1 of Section 8.7.2. of Annex X has already been clarified in several decisions of the Board of Appeal, in the Agency's guidance, and in the Contested Decision. Second, the Agency did not give the Appellant any assurance that it would refrain from requiring information on a PNDT study in a second species or an EOGRTS, and, therefore, the Agency did not breach the principle of the protection of legitimate expectations.

The Board of Appeal further held that the Agency is not required to assess, and state reasons for rejecting, adaptations which are not contained in the relevant part of its registration dossier under evaluation. Thus, the Appellant could not criticise the Agency for failing to address an adaptation under Colum 2 of Section 8.7. of Annex X in relation to an EOGRTS, since the Appellant's adaptation was clearly based on Columns 1 and 2 of Section 8.7.3. of Annex IX and its dossier did not contain an explicit adaptation based on Colum 2 of section 8.7. of Annex X.

Finally, the Board of Appeal held that, since the Agency did not commit any error in rejecting the adaptations set out in the Appellant's registration dossier, the Agency was not empowered to consider whether it is consistent with the principle of proportionality, or with Article 25, for the Appellant to be required to submit the standard information at issue.
