EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	19 September 2019
Case	A-010-2019
Appellant	Croda Iberica SA, Spain
Appeal received on	22 July 2019
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation – Compliance check – Testing on vertebrate animals – Cosmetic ingredient – Error of assessment – Proportionality*
Contested Decision	CCH-D-2114460730-54-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision, insofar as it requires information on:

- screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD [421/422]) in rats, oral route;
- a sub-chronic toxicity study (90-day) oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats;
- a pre-natal developmental toxicity ('PNDT') study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route; and
- long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: fish early-life stage (FELS) toxicity study, OECD TG 210).

The Appellant also requests the Board of Appeal to order the refund of the appeal fee and take other such measures as justice may require.

Pleas in law and main arguments

The Agency adopted the Contested Decision on 24 April 2019 following a compliance check of the Appellant's dossier for the substance propane-1,2,3-triyl 3,5,5-trimethylhexanoate (EC

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No 260-257-1, CAS No 56554-53-1, the 'Substance'). The Appellant registered the Substance exclusively for use as an ingredient in cosmetic products and sought to adapt the information requirements for the contested human health endpoints by read-across approach.

The Appellant claims that, in adopting the Contested Decision, the Agency committed errors of assessment, exceeded its competence under the compliance check procedure, failed to take all relevant information into account, and breached the principle of proportionality, the principle of legal certainty and the principle of protection of legitimate expectations. In essence, the Appellant argues that the Agency cannot require a substance to be tested on vertebrate animals when that substance is exclusively used in cosmetic products, as this would be against the testing ban set out in Regulation (EC) No 1223/2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59) and, therefore, lead to a marketing ban under the same Regulation.

The Appellant also argues that the Agency failed to adequately consider the read-across approach proposed by the Appellant, and in any event, breached Column 2 of Section 8.7.2. of Annex VIII to the REACH Regulation by requiring the Appellant to conduct both the reproductive/developmental toxicity screening study and the pre-natal developmental toxicity study on the Substance.

Moreover, the Appellant argues that the Agency breached Column 2 of Section 9.1. of Annex IX to the REACH Regulation, committed an error of assessment and breached the principle of proportionality by requiring the Appellant to conduct the fish early-life stage toxicity study. According to the Appellant long-term toxicity testing on fish is not necessary because the available data on the Substance did not indicate a need to investigate further its potential effects on acquatic organisms.

The Appellant also claims that all the contested information requirements are contrary to Article 25(1) of the REACH Regulation according to which testing on vertebrate animals should be undertaken only as a last resort.

Other information

On 26 August 2019, the Executive Director of the Agency, in accordance with Article 93(1) of the REACH Regulation, rectified the Contested Decision insofar as it required the Appellant to submit the information on screening for reproductive/developmental toxicity, the sub-chronic toxicity study and the PNDT study.

On 13 September 2019, the Appellant informed the Board of Appeal that it wished to continue the appeal proceedings insofar as they concern the requirement to submit information on long-term toxicity testing on fish since this information requirement was not affected by the rectification decision of the Agency's Executive Director.

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