EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-013-2016
Appellant	BASF Personal Care and Nutrition GmbH, Germany
Appeal received on	16 December 2016
Subject matter	A decision adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 40 of the REACH Regulation
Keywords	*Testing proposal – Read-across – Error of assessment – Testing on vertebrate animals – Regulation (EC) 1223/2009 on cosmetic products*
Contested Decision	Decision TPE-D-2114344602-56-01/F of 21 September 2016 on a testing proposal concerning the substance Reaction mass of sodium hydrogen N-(1-oxooctadecyl)-L-glutamate and stearic acid (EC No 939-201-1; hereinafter the 'Substance')
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision, to remit the case to the competent body of the Agency for re-evaluation of the Appellant's testing proposal and to order the refund of the appeal fee.

Pleas in law and main arguments

The Substance is a fatty acid derivate which is used as an ingredient in cosmetic products. The Appellant submitted a registration dossier for the Substance, including a testing proposal for the pre-natal developmental toxicity ('PNDT') endpoint. It proposed to perform a PNDT study on an analogue substance, namely L-glutamic acid, N-coco acyl derivs., disodium salts (CAS No 68187-30-4, EC No 269-085-1); hereinafter the 'Analogue Substance'), on the basis of a read-across from the Analogue Substance to the Substance.

The Contested Decision rejects the proposed read-across on the ground that it does not fulfil the requirements of Section 1.5 of Annex XI to the REACH Regulation. The Contested Decision states, in essence, that the Appellant has not established that the physicochemical, toxicological and eco-toxicological effects of the Analogue Substance and the Substance are likely to be similar or follow a regular pattern as a result of structural similarity.

[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 Contested Decision therefore requires the Appellant to perform a PNDT study on the Substance.

The Appellant claims, first, that the Agency wrongly rejected the proposed read-across, thereby breaching Article 13(1) in conjunction with Section 1.5 of Annex XI as well as Article 25(1) and the principle of proportionality.

Second, the Appellant further argues that, although it must fulfil the registration requirements of the REACH Regulation, the Appellant cannot be obliged to do so by performing the vertebrate animal study at issue. According to the Appellant, the Substance is used exclusively as an ingredient in cosmetic products, and testing the Substance on vertebrate animals would cause it to incur a marketing ban under Article 18(1)(b) of Regulation (EC) No 1223/2009 on cosmetic products.

Third, the Appellant claims that the Agency made an error of assessment by failing to take into account the fact that the Substance is used exclusively as an ingredient for cosmetic products. Since the Appellant had raised this point in its comments, but the Contested Decision makes no mention of it, the Appellant also alleges a violation of the obligation to state reasons.

The Appellant finally alleges a violation of the principle of good administration insofar as the Agency adopted a decision on the testing proposal for the Substance before deciding on the related testing proposal for the Analogue Substance.

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