EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-021-2015
Appellant	Carus Europe S.L., Spain
Appeal received on	28 September 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency'), pursuant to Article 41(3) of the REACH Regulation, in accordance with Articles 50 and 51 of the REACH Regulation
Keywords	*Compliance check – Request for further information - Adaptation*
Contested Decision	CCH-D-2114303249-55-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision and refund the appeal fee and, as a subsidiary claim, to extent the time limit for submitting the requested information.

Pleas in law and main arguments

The Contested Decision was adopted on 30 June 2015 following a compliance check under the dossier evaluation procedure of the registration submitted by the Appellant for potassium permanganate (hereinafter the 'Substance').

The Contested Decision requests the Appellant to provide information on a sub-chronic toxicity study (90-day), oral route (Section 8.6.2 of Annex IX to the REACH Regulation; test method: EU B.26/OECD 408) in rats. According to the Contested Decision, the registration dossier for the Substance contained an adaptation proposal to meet the information requirement in Section 8.6.2 of Annex IX. The adaptation was based on the presumption that, pursuant to the fourth introductory paragraph of Annex IX to the REACH Regulation, it was not necessary to perform the test due to the corrosivity and poor systemic absorption of the Substance. The adaptation proposal was, however, rejected in the Contested Decision on the grounds, in particular, that non-corrosive concentration(s) can be tested and the fourth introductory paragraph of Annex IX to the REACH Regulation is not a legal basis for adapting standard information requirements.

[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.

The Appellant argues in its appeal that although the initial adaptation proposal was rejected, the requested test still does not need to be conducted on the basis of the adaptation foreseen in the first indent of Column 2 of Section 8.6.2 of Annex IX to the REACH Regulation. Specifically, the Appellant argues that the information requirement could be met by an extrapolation of existing data on a 28-day sub-acute toxicity test via the oral route and proposing to classify the Substance as Specific Target Organ Toxicity-Repeated Exposure Category 2 with the liver as the target organ. The Appellant claims that the Contested Decision therefore breaches Article 41(3) read together with Section 8.6.2 of Annex IX to the REACH Regulation.

The Appellant claims that the Contested Decision also breaches the principle of proportionality as a less onerous measure would have been to obtain the requested information through the adaptation set out in the first indent of Column 2 of Section 8.6.2 of Annex IX to the REACH Regulation.

The Appellant also argues that since the adaptation set out in the first indent of Column 2 of Section 8.6.2 of Annex IX to the REACH Regulation is applicable in this case the Agency breached Article 13 of the REACH Regulation by failing to ensure that information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods. The Appellant argues that the Agency also breached 25(1) of the REACH Regulation by failing to ensure that testing on vertebrate animals is undertaken only as a last resort.

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