EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-012-2016
Appellant	Zschimmer & Schwarz Italiana S.p.A., Italy
Appeal received on	28 November 2016
Subject matter	Statement of non-compliance following a dossier evaluation decision under Regulation (EC) No 1907/2006 (the 'REACH Regulation')
Keywords	*Statement of non-compliance – Testing proposal – Testing on an analogue substance*
Contested Decision	TPE-C-2114344590-53-01/F of 30 September 2016
Language of the case	English

Remedy sought, pleas in law and main arguments

The Contested Decision, addressed to the Italian REACH Competent Authority and the Italian (MSCA/NEA) Focal Point with the Appellant in copy, was taken by ECHA as follow-up to a testing proposal decision addressed to the Appellant concerning the substance sodium hydrogen N-(1-oxododecyl)-L-glutamate (EC No 249-958-3, CAS No 29923-31-7; hereinafter 'the Substance'). The testing proposal decision had requested the Appellant to provide information on a test performed on an analogue substance (I-Glutamic acid, N-coco acyl derivs., disodium salts, EC No 269-085-1, CAS No 68187-30-4) by 28 March 2016.

According to the Contested Decision, the Appellant did not provide the information requested in the testing proposal decision by the deadline set. The Contested Decision concludes that, as a result, the Appellant has not met its obligations following from the testing proposal decision and therefore is in breach of Article 40(4) of the REACH Regulation. The Contested Decision requests the national authority of the member state '*to address the non-compliance in [its] own competence by means of enforcement to execute ECHA's decision*'.

In its appeal the Appellant claims that it was unable to submit the information requested in the testing proposal decision because the lead registrant of the analogue substance was still discussing some points relating to the proposed testing with ECHA. The Appellant states that the lead registrant of the analogue substance therefore could not perform the test requested in the Contested Decision within the deadline set. The Appellant states that it informed the Agency of this situation in a dossier update of 30 March 2016.

[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 Appellant argues that, whilst it could perform the test requested in the Contested Decision itself on the Substance, such an approach could be contrary to Article 25 of the REACH Regulation, according to which testing on animals should be performed only where strictly necessary, as an approved read-across could be employed in this case.

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