EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-016-2014
Appellant	Oxiteno Europe SPRL (OR2), Belgium
Appeal received on	17 December 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Evaluation – Compliance check – Request for further information*
Contested Decision	CCH-D-0000004054-83-06/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the rectification of the Contested Decision in favour of the Appellant as well as the refund of the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 18 September 2014 following a compliance check under the dossier evaluation procedure of the registration submitted by the Appellant for isopentyl acetate (hereinafter the 'Substance').

The Contested Decision requests the Appellant to provide information on hydrolysis as a function of pH in accordance with Section 9.2.2.1 of Annex VIII to the REACH Regulation (test method: Hydrolysis as a function of pH, EU C.7/OECD 111). According to the Contested Decision, the information available in the registration dossier did not meet this standard information requirement.

The Appellant claims that its registration dossier contains a summary of a study report demonstrating that the Substance is readily biodegradable (OECD TG 301 F, GLP, Study No. 99-E70, Givaudan). The Appellant claims that data demonstrating that a substance is readily biodegradable represents a valid alternative to the information requested in the Contested Decision. According to the Appellant, this information was included in a registration dossier

[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.

update after the adoption of the Contested Decision. The Appellant claims further that the registration dossier also contains data of another study on the biodegradability of the Substance (OECD TG 301 C, Muckle, 2013) which points to the conclusion that the Substance would only be inherently biodegradable. The Appellant concludes that in a weight of evidence approach, taking into consideration the results of both studies, the Substance is readily biodegradable.

The Appellant states that the registration dossier was updated with the data demonstrating that the Substance is readily biodegradable (OECD TG 301 F, GLP, Study No. 99-E70, Givaudan) only after the adoption of the Contested Decision due to a change in the status of the joint submission. The Appellant states that in order to make this change it was required to obtain the consent of all co-registrants which took longer than expected.

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