EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-014-2014
Appellant	BASF Pigment GmbH, Germany
Appeal received on	11 December 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Articles 50 and 51 of Regulation (EC) 1907/2006 (the 'REACH Regulation').
Keywords	*Dossier evaluation - Compliance check – Weight of evidence - Pre-natal developmental toxicity study*
Contested Decision	CCH-D-0000005112-88-02/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

– annul the Contested Decision; and
– order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 16 September 2014 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the substance chrome antimony titanium buff rutile, CAS No 68186-90-3 (EC-No 269-052-1). By the Contested Decision the Agency requested the Appellant to conduct a pre-natal developmental toxicity study to satisfy the endpoint at Annex IX, Section 8.7.2 of the REACH Regulation.

The Appellant submits that the Agency only applied the criteria of Annex IX, Section 8.7, column 2 of the REACH Regulation when assessing whether the Appellant satisfied the waiving requirement for that endpoint. The Appellant argues that it employed a weight of evidence approach according to Annex XI, Section 1.2 of the REACH Regulation in order to satisfy the pre-natal developmental toxicity study endpoint. It submits that data justifying this approach were included in the IUCLID dossier. The Appellant contends that its 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.

therefore conforms to the provisions of the REACH Regulation and that the Contested Decision therefore lacks a legal basis.

The Appellant further argues that, by neglecting to assess whether the data submitted by the Appellant satisfies the waiving criteria under Annex XI, Section 1.2 of the REACH Regulation, the Agency failed to exercise its discretion correctly.

The Appellant also considers that the Contested Decision violates good administrative practice and the Appellant's legitimate expectations. The Appellant submits that it was led to believe that a weight of evidence approach would be assessed and approved by the Agency as the Agency held a webinar in 2013 recommending the use of a weight of evidence approach for substances that the Appellant considers to be of the same kind as antimony chrome titanium buff rutile. The Appellant further submits that this webinar established criteria for a weight of evidence approach that the Appellant claims to fulfil.

The Appellant further submits that the request for the pre-natal developmental toxicity study breaches Article 25(1) and Recital 47 of the REACH Regulation pertaining to the need for testing on vertebrate animals to be a 'last resort' and animal welfare respectively.

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