EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-003-2015
Appellant	BASF Pigment GmbH, Germany
Appeal received on	24 February 2015
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41 of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation .
Keywords	*Dossier evaluation - Compliance check – Weight of evidence - Pre-natal developmental toxicity study*
Contested Decision	CCH-D-0000004057-77-06/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 26 November 2014 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for antimony nickel titanium oxide yellow (hereinafter the 'Substance'). By the Contested Decision the Agency requested the Appellant to conduct a pre-natal developmental toxicity study to satisfy the endpoint at Section 8.7.2 of Annex IX.[2]

The Appellant submits that the Agency only applied the criteria of Section 8.7.2 of Annex IX 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 Section 1.2 of Annex XI in order to satisfy the pre-natal developmental toxicity study endpoint. It

[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.

[2] All references are to the REACH Regulation unless stated otherwise.

submits that data justifying this approach were included in its registration dossier. The Appellant contends that its dossier 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 Section 1.2 of Annex XI, 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 the Substance. 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 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