EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-013-2015
Appellant	Evonik Degussa GmbH, Germany
Appeal received on	23 April 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 the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation – Compliance check – Request for further information – Rejection of an update from substance to intermediate*
Contested Decision	CCH-D-2114289967-22-01/F
Language of the case	English

Remedy sought by the appellant

The Appellant requests the Board of Appeal to:

- order the Agency to refund the appeal fee; and
- annul the Contested Decision in its entirety.

Subsidiarily, if the Board of Appeal concludes that the Contested Decision is valid, the Appellant requests that the Board of Appeal amends or interprets any valid parts of the Contested Decision, in a manner that will allow the Appellant to build an analogue or weight of evidence approach by conducting relevant other studies, in so far as necessary in deviation of the requirements in the Contested Decision to perform studies involving vertebrate animals.

Pleas in law and main arguments

The Contested Decision was adopted on 27 January 2015 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the substance buta-1,2-diene (hereinafter the 'Substance'). In the Contested Decision the Agency requested the Appellant to, among others, perform certain studies involving the vertebrate animals and aquatic toxicity studies.

The Appellant states that it attempted to update its registration dossier from substance to intermediate, but the Agency unlawfully blocked the intended change until the adoption of the Contested Decision. The intended change was based on the Appellant's assessment, performed

[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.

after the submission of the registration dossier, concluding that the Substance is used only as intermediate.

The Appellant argues that, in the circumstances of the present case, the Agency's position that an update cannot be processed without a formal written agreement of all registrants of the joint submission lacks a rationale and fails to meet standards of good administration. Moreover, this Agency's requirement is arbitrary and manifestly contrary to the REACH Regulation and general principles of equal treatment, proportionality and legal certainty.

The Appellant also claims that the Agency misconstrued the provisions of Articles 50(2) and (3) of the REACH Regulation. The Appellant argues that in the context of previously mentioned articles the term 'substance' must be interpreted as excluding an 'intermediate'. As a result, a change from full substance to intermediate is equivalent to discontinuing the manufacture of the substance concerned. Consequently, the Appellant's unsuccessfull attempt to update its registration dossier prior to the issuance of the Contested Decision should have been interpreted as a notification of the cessation of the manufacture of the Substance. As a result, the Agency was not permitted to adopt the Contested Decision.

Considering the above, the Appellant additionally claims that if the Board of Appeal were to find that Articles 50(2) and (3) of the REACH Regulation do not apply in the present case, although this would be inconsistent with the REACH Regulation, the Contested Decision must be annulled as it violates the principles of equal treatment and proportionality. The Appellant argues that it must be treated in the same way as other registrants of an intermediate, other registrants that cease manufacturing the substance upon receipt of a draft compliance check decision, registrants that benefit from a data waiver, such as an exposure-based waiver and the other registrant of the Substance which registered the Substance as an intermediate.

The Appellant further submits, as regards the requirements in the Contested Decision to perform studies involving vertebrate animals, that those should be waived based on an analogue/read-across approach or a weight of evidence approach by using toxicological data on chemically closely related substances that degrade into related metabolites. Considering that the adequate and reliable documentation has been provided to support the analogue approach, the Appellant claims that the Contested Decision violates Sections 1.2. and 1.5. of Annex XI to the REACH Regulation.

Finally, as regards the requirement for the information obtained by, in the Contested Decision specified aquatic toxicity studies, the Appellant claims that those studies should have been waived because the Substance is a gas. Therefore, aquatic toxicity, if any, is unlikely to occur and any testing is technically unfeasible. The Contested Decision therefore violates column 2, Sections 9.1.2. of Annex VII and 9.1.3. of Annex VIII to the REACH Regulation.

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