EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-001-2014
Appellant	CINIC Chemicals Europe Sàrl, France
Appeal received on	15 January 2014
Subject matter	Decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 40 of the REACH Regulation
Keywords	Testing proposal – Third-party consultation procedure - Ordering of tests - Information contained in other registration dossiers - Duties of the Agency
Contested Decision	TPE-D-0000003219-74-05/F of 15 October 2013
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

(a) annul the Contested Decision in so far as it requests the Appellant to carry out an extended one-generation reproductive toxicity study in rats, oral route (OECD 443); and
(b) order the opening of a new testing proposal examination procedure for the same end-point, or re-open the testing evaluation procedure for the same end-point; and
(c) order the refund of the appeal fee and take such other measures as justice may require.

Pleas in law and main arguments

The Appellant submitted an inquiry to the Agency with a view to submitting a registration dossier for the substance 3,6-bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione (hereinafter 'the Substance'). According to the Appellant, in response to the inquiry the Agency provided the Appellant with the contact details of companies that had already registered the Substance and informed the Appellant that the reproductive/developmental toxicity screening study required by Section 8.7.1 of Annex VII of the REACH Regulation was not available in the other registrants' dossiers.

The Appellant therefore commissioned a reproductive/developmental toxicity screening study. In view of the results of that study, the Appellant included a testing proposal in its registration dossier for the Substance regarding the performance of an extended one-generation reproductive study in rats, oral route.

According to the Appellant, after the submission of the Appellant's registration dossier, the Agency initiated a third party consultation pursuant to Article 40(2) of the REACH Regulation, for a two-generation reproductive toxicity study concerning the Substance.

[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.

Following the third party consultation, the Contested Decision was adopted requiring the Appellant to perform an extended one-generation reproductive toxicity study in rats, oral route.

The Appellant claims however that between the time the draft decision was sent to the Member State Committee and the adoption of the Contested Decision the Appellant became aware that one of the other registration dossiers submitted for the Substance contained an alternative and recent reproductive/developmental toxicity screening study which contained different results to those observed in the Appellant's study. Following a letter from the Appellant asking whether the results of that study had been taken into account in the decision-making process the Agency informed the Appellant that it based the Contested Decision only on the information included in the Appellant's registration dossier.

The Appellant submits that the Agency's decision requesting it to perform an extended one-generation reproductive toxicity study is unlawful for the following reasons:

- The Agency was obliged to assess whether information submitted in other registration dossiers for the Substance was relevant before reaching its conclusion. This obligation stems from the REACH Regulation, including Article 10 and the introduction to Annexes VI, VII and VIII, as well the Agency's duties as a European Union body, including the duty of sound administration, and the duty not to frustrate the Appellant's legitimate expectations. In addition, the Agency infringed the principle of proportionality as the study requested was not demonstrated to be necessary on the basis of all relevant information;

- If the Board of Appeal considers that the provisions of the REACH Regulation do not clearly create an obligation for the Agency to take into account information on the relevant end-point included in other registration dossiers submitted for the Substance, those provisions must be given a teleological interpretation which achieves the objective of avoiding vertebrate animal studies;

- By requesting the Appellant to perform the requested study without having taken into account the information available to the Agency in other registration dossiers for the Substance, the Agency breached Article 25 of the REACH Regulation; and

- By opening a third party consultation on a testing proposal other than the testing proposal included in the Appellant's registration dossier, the Agency breached an essential procedural requirement and acted contrary to Article 40(2) of 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