EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 13 FEBRUARY 2014
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-006-2012

(Compliance check of a registration – Adaptation of standard information requirements – Justification for the use of read-across – Duty to state reasons)

Factual background

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by Momentive Specialty Chemicals (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision in which it rejected the read-across adaptations proposed by the Appellant on the grounds that they did not meet the requirements of Section 1.5 of Annex XI to the REACH Regulation[1]. In addition, the Agency requested the Appellant to perform a number of studies and to update the dossier for the substance concerned by the registration with the relevant information.

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the Agency's decision to the extent that it requested the Appellant to perform several studies.

Main findings of the Board of Appeal

In its Decision of 13 February 2014, the Board of Appeal noted that it is the registrant of a substance who bears the responsibility to provide 'adequate and reliable documentation of the applied method' for any read-across proposal in accordance with Section 1.5 of Annex XI to the REACH Regulation. The Board of Appeal added that for a read-across adaptation to be assessed and potentially accepted by the Agency, registrants have to show with clear reasoning and supporting data, set out in the appropriate section of the registration dossier, that the substances involved in the read-across are structurally similar and are likely to have similar properties (or follow a similar pattern). Registrants should also explain how and why the similarity of properties is the result of the structural similarity. The Board of Appeal explained that inclusion of the above information in the dossier is essential to allow the Agency to carry out its role of evaluating whether the read-across proposal complies with the relevant provisions of the REACH Regulation.

The Board of Appeal further observed that whilst registrants can expect a certain level of expertise within the Agency, it is not the task of the Agency to develop, or improve, read-across adaptations on behalf of the registrants. The Board of Appeal also noted that it is impossible for the Agency to inform individual registrants what exactly should be included in their justification for a read-across adaptation as it is the registrant who knows its substances best, who understands the basis for a read-across approach, and who has the responsibility to communicate that information in such a manner that the Agency can then verify the approach proposed.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3).

Having regard to the circumstances of this particular case, the Board of Appeal concluded that the Agency was justified in concluding that the Appellant had not demonstrated the structural similarity and similarity of toxicological properties of the target and source substances, and that the read-across adaptation had not been sufficiently justified in order to meet the requirements of Section 1.5 of Annex XI to the REACH Regulation. The Board of Appeal therefore found that the Appellant had not demonstrated that, in rejecting the Appellant's read-across approach, the Agency had incorrectly interpreted the REACH Regulation requirements on read-across.

The Board of Appeal further observed that, although one of the main purposes of the provisions of the REACH Regulation related to read-across is to ensure that testing on vertebrate animals is undertaken only as a last resort, the Agency is entitled to reject a read-across proposal if a registrant's proposed use of read-across does not comply with the requirements of Section 1.5 of Annex XI to the REACH Regulation. The Appellant's cliam that the Agency had infringed Article 25(1) of the REACH Regulation was therefore rejected.

The Board of Appeal also dismissed the other pleas put forward by the Appellant which concerned *inter alia* the alleged violation of the Appellant's procedural rights by the Agency. After examination of the facts in the present case, the Board of Appeal found that the Agency had not violated the Appellant's right to be heard and had not infringed the duty to state reasons for the Contested Decision.

In consideration of all the above, the Board of Appeal dismissed the appeal. The Board of Appeal further decided that due to the suspensive effect of appeals, and considering the circumstances of the case at hand, a new time-limit should be set for the Appellant to submit the information requested in the contested part of the Contested Decision, starting from the date of notification of the Board of Appeal's decision in the case.
