EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 19 JUNE 2013
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2012

(Compliance check of a registration – Request to submit further information – Rejection of proposed read-across approach – Agency's margin of discretion)

Factual background

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by Dow Benelux B.V. (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision in which it rejected the read-across approach proposed by the Appellant, and it requested the Appellant to submit information for the substance concerned by the registration following the conduct of a pre-natal developmental toxicity study in the rat by the oral route.

The Appellant lodged an appeal before the Board of Appeal seeking the annulment of the Agency's decision.

Main findings of the Board of Appeal

In its Decision of 19 June 2013, the Board of Appeal noted that it is the registrant of a substance who bears the responsibility to demonstrate that its proposed adaptations of the standard testing requirements using a grouping or read-across approach conform to the criteria set out in Annex XI, section 1.5 of the REACH Regulation[1]. In addition, the Agency has a margin of discretion when it assesses the proposed read-across methods. This margin of discretion applies when the Agency assesses whether it is possible, from the information available for the reference or source substance(s), to predict the effects on human health or the environment of another (target) substance for a particular end-point.

The Board of Appeal added that it can be inferred from Annex XI to the REACH Regulation that the application of read-across as a way to adapt the standard testing regime always entails a degree of uncertainty which the Agency has to assess. The Board of Appeal recognised that it is for the Agency to consider whether this uncertainty is acceptable or not taking into account the precautionary principle which underpins the REACH Regulation.

Having regard to the circumstances of this particular case, the Board of Appeal concluded that the Agency had acted within its margin of discretion in rejecting the read-across approach proposed by the Appellant as the Appellant's proposal did not satisfy the requirements set-out in Annex XI, section 1.5 of the REACH Regulation. In particular, the Appellant had not managed to adequately rebut the fact that its read-across proposal for the endpoint on pre-natal developmental toxicity contains an unacceptable level of

[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).

uncertainty. Consequently, the Agency had acted within its margin of discretion in requesting information on pre-natal developmental toxicity.

The Board of Appeal also dismissed the other claims 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 Agency's duty to state reasons.

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 requested information, starting from the date of notification of the Board of Appeal's decision in the case.
