EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

**SUMMARY OF DECISION OF 10 OCTOBER 2013**
**OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-004-2012**

*(Compliance check of a registration – Request to submit further information - Section 8.7.2 of Annexes IX and X – Duty to state reasons – Assessment of waiving arguments)*

*Factual background*

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by Lanxess Deutschland GmbH (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting the Appellant to submit additional information on sub-chronic toxicity (Section 8.6.2 of Annex IX to the REACH Regulation) and on developmental toxicity on a second species (Section 8.7.2 of Annex X) for the substance concerned by the registration (hereinafter the 'Contested Decision'). With regards to the latter information requirement, the Contested Decision stated that the Appellant's registration dossier contained an information gap as it did not include any information on the pre-natal developmental toxicity endpoint, nor did it include any adequate adaptation.

The Appellant lodged an appeal against the Contested Decision in which it requested the Board of Appeal to extend the deadline set by the Agency for the submission of information on sub-chronic toxicity to allow the Appellant to take into consideration the results of a study which was planned under the United States National Toxicology Programme (hereinafter the 'NTP Study'). The Appellant also requested the Board of Appeal to annul the Contested Decision to the extent that it required the Appellant to provide information on developmental toxicity in a second species.

*Main findings of the Board of Appeal*

In its Decision of 10 October 2013, the Board of Appeal firstly dismissed the Appellant's request for the Board of Appeal to revise the Contested Decision to allow it to take into account the results of the NTP Study. After examining the specific facts of the case, the Board of Appeal found that the timing of the NTP Study was outside the control of the Appellant. The Board of Appeal also noted that the evidence submitted in the case provided no certainty that the results of the NTP Study would be available in the near future. The Board of Appeal therefore concluded that the performance of a study at some unspecified time in the future cannot justify the revision of the Contested Decision with respect to the information required on sub-chronic toxicity.

The Board of Appeal also noted that, in accordance with the REACH Regulation[1], the information on sub-chronic toxicity requested in the Contested Decision should have already been made available to the Agency in the Appellant's registration dossier. The Board 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).

Appeal added that the provision of the information on sub-chronic toxicity should not be further delayed by uncertain future events which are outside the control of the Appellant.

The Board of Appeal also dismissed the pleas put forward by the Appellant concerning the Agency's request for information on developmental toxicity. In particular, the Board of Appeal rejected the Appellant's plea that, in requiring information on developmental toxicity in a second species as a standard information requirement the Agency had incorrectly interpreted Section 8.7.2 of Annex X of the REACH Regulation, read in light of Section 8.7.3 of Annex IX, given that the Appellant had already provided information on a pre-natal developmental toxicity study in one species.

The Board of Appeal concluded that the provisions of the REACH Regulation, when read as a whole, mean that, in accordance with Section 8.7.2 of Annex X to the REACH Regulation, registrants manufacturing or importing substances at 1000 or more tonnes per year are required to perform a developmental toxicity study also on a second species, unless the adaptations set out in Column 2 of Section 8.7 of Annex X and Annex XI mean that such a study is not necessary.

The Board of Appeal also stressed that registrants must clearly set out the reasons for their decision not to perform a study on the second species, in order to allow the Agency to assess the validity of the registrant's decision not to perform such a test.

In the present case, the Board of Appeal found that the Appellant did not clearly put forward adaptation or waiving arguments in the appropriate section of its registration dossier. Thus, the Agency was not in a position to assess those arguments. Furthermore, according to the Board of Appeal, the Agency should not be required to compile adaptation arguments on behalf of registrants from the information set out in other parts of the registration dossier. In addition, after examination of the facts in the present case, the Board of Appeal found that the Agency had not infringed its duty to state reasons.

In consideration of all the above, the Board of Appeal dismissed the appeal. The Board of Appeal decided further that, due to the suspensive effect of appeals, and considering the circumstances of the case at hand, a new time-limit, equal to that set in the Contested Decision, 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.

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