EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-004-2012
Appellant	Lanxess Deutschland GmbH, Leverkusen, Germany
Appeal received on	5 July 2012
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	*Evaluation – Compliance check – Request to submit further information - Tests involving vertebrate animals*
Contested decision	CCH-D-0000002044-86-04/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

- revise the contested decision so as to allow the Appellant to properly take into account future United States National Toxicology Program (NTP) results of a 13-week study on mice, by 31 December 2014;
- annul the contested decision imposing a pre-natal developmental toxicity study on a second species via the oral route based on the Agency's erroneous interpretation of Annex X, Column 1, 8.7.2. to the REACH Regulation, the breach of the duty to state reasons, the erroneous assessment of the Appellant's waiving arguments, and the failure to consider available data on the very low consumer exposure to the substance concerned for waiving; and
- reimburse the Appellant the fees for, and costs arising from, the appeal proceedings.

Pleas in law and main arguments

The contested decision was adopted by the Agency pursuant to Article 41(3) of the REACH Regulation following a compliance check, under the dossier evaluation procedure, of the Appellant's registration submitted for the substance triphenyl phosphate (hereinafter 'TPP').

In the contested decision, the Agency concluded that the registration did not comply with the requirements of Articles 10, 12, 13 and 14, as well as with Annexes I and IX to X of the REACH Regulation. The Agency requested the Appellant to submit information using the following test methods:

- Sub-chronic toxicity (90-day) in the rat via the oral route (Annex IX, 8.6.2; EU Method B.26 or OECD test guideline 408); and

[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

- Developmental toxicity study in the rabbit via the oral route (Annex X, 8.7.2; EU Method B.31 or OECD test guideline 414).

The Agency's reasoning can be summarised as follows:

1. Regarding the request to submit information on sub-chronic toxicity (90-day) in the rat via the oral route, the Agency stated that additional information provided by the Appellant in response to ECHA's draft decision does not meet, either on its own or in a combined (with the information submitted in the initial registration dossier) weight-of-evidence approach, as defined in Annex XI, 1.2 to the REACH Regulation, the criteria set out in Annex IX, Column 2, 8.6.2 and Annex XI, 1.1.2 and 3.2;
2. Regarding the request to submit information on a developmental toxicity study in the rabbit via the oral route, the Agency stated that there is an information gap as no information has been provided for the pre-natal developmental toxicity test on a second species, nor is there any adequate adaptation of the information requirement.

The Appellant contests the Agency's decision requesting it to submit the above-mentioned information for the registered substance. The Appellant's arguments can be summarised as follows:

1. Sub-chronic toxicity (90-day) in the rat via the oral route: the Appellant should be permitted to rely on the results of a future NTP 90-day sub-chronic test on B6C3F1/N mice instead of having to 'duplicate' a 90-day sub-chronic test on another rodent. The Appellant should be entitled to submit an updated dossier once the NTP study results become publicly accessible.
2. Developmental toxicity study in the rabbit via the oral route: this part of the contested decision is being challenged on four grounds, namely, (i) erroneous interpretation of Annex X, 8.7.2, (ii) breach of the duty to state reasons, (iii) wrongful assessment of the Appellant's waiving arguments, and (iv) absence of consideration of available data on the very low consumer exposure to TPP for waiving. The principal grounds of appeal, as stated by the Appellant, is that no mention of a default information requirement on two species is made in Column 1 of Annexes VII to X of the REACH Regulation. With respect to endpoint 8.7.2, reference is systematically made to one species only. If the REACH drafters required a two-species information requirement under Annex X Column 1, *a contrario* they would have mentioned a two-species study requirement directly in the text of that provision. Furthermore, Annex IX, Column 2, 8.7.2, states that the Agency may impose a study on a second species not only at Annex IX tonnage level but also at Annex X tonnage level, contingent upon *'the outcome of the first test and all other relevant available data'*. If the Agency's reasoning for this part of the contested decision was applied, the text of Annex IX, Column 2 would become redundant and be stripped of its effectiveness with regard to the 1000 tonnage band since the second-species study, based on the Agency's view, would in any event have to be carried out as a standard information requirement under Annex X regardless of any individual 'adaptation' assessment.

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