EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-003-2012
Appellant	THOR GmbH, Speyer, Germany
Appeal received on	25 May 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 – Updated dossier – Waiving*
Contested decision	CCH-D-0000001752-76-06/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests that the Board of Appeal should order the Agency to use its updated registration dossier as basis for the final decision.

Pleas in law and main arguments

The contested decision was taken following a compliance check of a registration dossier regarding an organic nitrogen-phosphorous compound.

The contested decision requests the Appellant to provide, in the IUCLID format, a robust study summary on the following endpoint:

- Skin sensitisation: local lymph node assay (Annex VII, Section 8.3. of the REACH Regulation).

The contested decision also requests the Appellant to submit information using the following test methods:

1. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2. of the REACH Regulation), rodents, by the oral route (EU test method B.26);

[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 (OJ L 206, 2.8.2008, p. 5).

2. Screening for reproductive/developmental toxicity, one species (Annex VIII, 8.7.1. of the REACH Regulation) (OECD 421 test method); and

3. Pre-natal development toxicity (Annex IX, 8.7.2. of the REACH Regulation), one species, by the oral route (EU test method B.31).

The Appellant states that although it had been informed by the Agency that an update of the registration dossier is possible at any time during the decision-making process its update had not been taken into account by the Agency on the grounds that the decision-making process was at its final stages at the time the update was received. The Appellant claims therefore that the contested decision was adopted on the basis of an old and obsolete version of its registration dossier and that it does not know if and how its registration dossier update would have affected the contested decision.

More specifically, the Appellant claims that prior to the adoption of the contested decision it had submitted an updated dossier which contained an exposure-based waiving strategy. The Appellant concludes that it needs an evaluation of this waiving concept in order to be able to decide on whether to initiate the requested studies.

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