EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-012-2014
Appellant	Huntsman Holland BV, Botlek-Rotterdam, The Netherlands
Appeal received on	21 November 2014
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*
Contested Decision	CCH-D-0000004262-82-05/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

a. annul the part of the Contested Decision requiring the Appellant to submit certain additional information using pre-natal developmental toxicity study and any other of its parts, which are contested expressly or impliedly with the appeal;
b. order the reimbursement of costs incurred by the Appellant in the appeal proceedings; and
c. order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted on 22 August 2014 following a compliance check under the dossier evaluation procedure of the Appellant's registration submitted for the registered substance (propylene carbonate).

In the Contested Decision the Agency requested the Appellant to among others submit, for the registered substance, the information using pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31/OECD 414) in rabbits, oral route (the 'contested study').

The Appellant claims firstly that the Contested Decision was adopted without taking into account the update to the registration dossier. It argues that the Agency has no legal

[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.

authority, ability or power to disregard and not take into account updates to a REACH registration dossier.

The Appellant claims secondly that it was never given any opportunity to respond or make any comments on the amendments that the Agency made to the Contested Decision and which did not relate to the proposals for amendment that the Appellant had the opportunity to comment upon. The Appellant argues that the Agency's amendments were highly significant in the decision-making process as they formed the basis of the final decision and the justification for Agency's rejection of the read-across and requiring the contested data. The Appellant argues that the addition of that text in the body of the Contested Decision meant that the final (i.e. the Contested Decision) and the draft decision that the Appellant had the opportunity to comment on substantially differed.

The Appellant submits thirdly that the Contested Decision requires that the sample of the substance chosen and used for the contested study is acceptable to all other registrants of the registered substance. It claims that the Agency legally cannot require the Appellant to provide data using a test sample of the registered substance which is or will be acceptable to all registrants, as this is outside of the Appellant's control and authority to ensure compliance with. As a result, the Agency committed a manifest error in the exercise of its discretionary powers, misused its powers and acted outside of the limits of its discretionary powers.

The Appellant fourthly disagrees with the Agency's interpretation of the legal provisions regarding Section 8.7.2. of Annex X to the REACH Regulation to mean that a second species testing is a standard information requirement. The Appellant argues that it clearly and expressly informed the Agency of its adaptation to Section 8.7.2. second species provision and therefore provided the due justification not to undertake that testing. The Appellant also argues that the proposed read-across adaptation satisfies the requirements of Section 1.5 of Annex XI to the REACH Regulation governing grouping of substances and read-across approach.

The Appellant also claims that by adopting the Contested Decision the Agency disregarded the legal requirements regarding animal welfare by, amongst others, not considering or balancing in its assessment the requirement to undertake vertebrate animal testing as a last resort. As a result, the Agency has not adhered to the requirements under Article 25(1) of the REACH Regulation, Article 13 of the Treaty on Functioning of the European Union and the principles codified under Directive 2010/63/EU on the protection of animals used for scientific purposes.

Moreover, the Appellant contends that the Contested Decision has been adopted in breach of the principle of legal certainty, protection of legitimate expectations and proportionality.

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