EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-018-2014
Appellant	BASF Grenzach GmbH, Germany
Appeal received on	17 December 2014
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 52 of the REACH Regulation
Keywords	*Evaluation – Substance evaluation – Request for further information*
Contested Decision	Decision on substance evaluation for triclosan of 19 September 2014. The Contested Decision was notified to the Appellant through the annotation number SEV-D-2114285478-33-01/F.
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to:

a. modify the Contested Decision insofar as it obliges the Appellant to conduct testing on the persistence of triclosan (hereinafter the 'Substance') and permit the Appellant to conduct OECD TG 309, as further specified by the Appellant, instead;
b. annul the Contested Decision insofar as it requires the Appellant:
    a) to conduct and submit information for the Substance using an Enhanced Developmental Neurotoxicity Study (OECD TG 426 with relevant elements of a Extended One-Generation Reproductive Toxicity Study, OECD TG 443);
    b) to conduct a Fish Sexual Development Test (OECD TG 234); and
    c) to conduct a cardiotoxicity literature review; and
c. order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 19 September 2014 following a substance evaluation for triclosan by the Dutch Competent Authority in cooperation with the Danish Competent Authority.

The Appellant claims, as regards the requirement in the Contested Decision to submit information on the persistence of the Substance, that the requirement violates Annex

[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.

XIII to the REACH Regulation and the Guidance on information requirements and chemical safety assessment because it did not comply with the requirement to collect data about the Substance under relevant environmental conditions. The Appellant also submits that by requiring additional persistency testing, performed as a pelagic test, the Agency ignored relevant information on the Substance's behaviour in the environment that was in the registration dossier. As a result, the Agency breached Article 47 of the REACH Regulation since it did not base its decision on all relevant submitted or available information. The Appellant claims, in addition, that the Agency failed to state reasons for ignoring an alternative testing strategy thereby breaching Article 130 of the REACH Regulation and, furthermore, that the Contested Decision violates the principles of proportionality and good administrative practice.

The Appellant claims, as regards the requirement in the Contested Decision to submit information for the Substance using an Enhanced Developmental Neurotoxicity Study (OECD TG 426 with relevant elements of the Extended One-Generation Reproductive Toxicity Study, OECD TG 443) (hereinafter the 'Study'), that the Agency did not base its decision on all relevant submitted or available information. In relation to neurotoxicity testing, the Appellant contends, amongst other arguments, that the Agency ignored a study funded by the Danish Competent Authority, which revealed that the neurological effects that the Contested Decision seeks to investigate do not exist. The Appellant concludes that, by failing to assess the relevancy of specific information considered in that study, the Contested Decision breached Article 47 of the REACH Regulation.

The Appellant further claims that the Contested Decision breaches Article 130 of the REACH Regulation as the Agency failed to provide an adequate scientific rationale for requiring the Study, in particular by failing to explain why the test was requested despite the doubts as to the applicability of results on rats to humans. In relation to the requirements of the Study related to certain additional reproductive toxicity endpoints, the Appellant claims that the Contested Decision fails to adequately assess the relevancy of the submitted data and therefore breaches Article 47, as well as Article 130 of the REACH Regulation.

The Appellant concludes that, taking into account all relevant submitted or available information, the Study is unlikely to provide scientifically meaningful results. As a result, this requirement in the Contested Decision breaches Article 25(1) of the REACH Regulation as well as the principle of proportionality.

The Appellant claims, as regards the requirement in the Contested Decision to conduct a Fish Sexual Development Test (OECD TG 234) (hereinafter the 'FSDT'), that existing studies already sufficiently demonstrated the absence of adverse effects on fish. The Contested Decision would therefore effectively lead to a duplication of results and the unnecessary sacrifice of animals thereby violating both Article 25 of the REACH Regulation and the principle of proportionality.

Finally, the Appellant claims, as regards the requirement in the Contested Decision to conduct and submit the results of a literature review on the effects of the Substance on the cardiovascular system, that the Agency failed to state reasons for ordering the review, thereby breaching Article 130 of the REACH Regulation. In addition, since the review was requested without any reasonable scientific indication that the Substance may have a cardiotoxic effect on humans, the Contested Decision violates the principle of proportionality. The Appellant concludes by claiming that the requirement of a literature review breaches the principle of good administration since the Agency failed to properly scrutinize the proposal of a Member State Competent Authority to include the cardiotoxicity endpoint in the Contested Decision.

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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