EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-006-2017
Appellant	Climax Molybdenum B.V., The Netherlands
Appeal received on	9 June 2017
Subject matter	A decision adopted by the European Chemicals Agency (hereinafter 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	*Dossier evaluation - Compliance check – Pre-natal developmental toxicity study – OECD Mutual Acceptance of Data status – Proportionality – Animal welfare – Good administration*
Contested Decision	CCH-D-2114356486-40-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requested the Board of Appeal to annul the Contested Decision and to order the refund of the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 13 March 2017 following a compliance check for the substance disodium molybdate (CAS No 7631-95-0). The Contested Decision requests to submit information derived from a pre-natal developmental toxicity study performed on the registered substance (OECD Test Guideline (TG) 414; EU B.31) in a first species by the oral route (Annex IX, Section 8.7.2) by 20 March 2018.

The Appellant claims that the Contested Decision, by requiring it to submit of a pre-natal developmental toxicity study is contrary to the letter and the spirit of the REACH Regulation. The Appellant considers that the information request does not respond to real information needs because its dossier already contains a pre-natal developmental study performed in accordance with OECD TG 414. Also new information provided with the Notice of Appeal demonstrates, in the Appellant's view, that human health has been highly protected.

[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, as amended by Commission Implementing Regulation (EU) 2016/823.

The Appellant further claims that the Contested Decision is in breach of the Decision of the OECD Council on Mutual Acceptance of Data (MAD) in the Assessment of Chemicals and Protocol No 1 to the Convention on OECD. As a result of these provisions, data generated in any OECD member country in accordance with OECD guidelines shall be accepted in other member countries. The Appellant claims that the Agency's statement that one of the studies submitted by the Appellant, does not meet the specifications of OECD TG 414 is not accurate because that study was granted OECD MAD status. That study should be, in the Appellant's view, recognised as valid and conforming with OECD TG 414.

The Appellant also claims that the Contested Decision breaches the principle of proportionality. The studies already provided on the dossier show, in the Appellant's view, a clear NOAEL for reproductive toxicity. The higher dose to be applied in the study requested by the Agency is unnecessary and would cause excessive toxicity in contradiction with OECD TG 414 and would entail the sacrifice of too great a number of animals.

For the same reason, the Appellant considers that the Contested Decision also breaches Article 13(1) of the REACH Regulation and is contrary to the principle of protection of animal welfare.

The Appellant further claims that the Agency erred in its assessment in preparing the Contested Decision because the Appellant had already submitted a study that complied with the applicable OECD test guidelines and the Agency has not carried out a professional and scientific assessment of the arguments put forward by the appellant.

The Appellant also claims that by ignoring the OECD MAD status of the study submitted in its registration dossier, the Agency did not take into account all relevant facts available and therefore breached the principle of good administration.

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