

Announcement of appeal¹

Case	A-008-2018
Appellants	Taminco BVBA, Belgium, Performance Additives Italy S.p.A., Italy
Appeal received on	14 May 2018
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46(1) of the REACH Regulation
Keywords	<i>Substance evaluation – Statement of reasons – Error of assessment – Proportionality – Animal welfare</i>
Contested Decision	Decision of 13 February 2018 on the substance evaluation of Ziram (EC No 205-288-3, CAS No 137-30-4)
Language of the case	English

Remedy sought by the Appellants

The Appellants request the annulment of the Contested Decision in so far as it requires the submission of information on a combined developmental neurotoxicity study (OECD TG 426) and neurotoxicity study in rats (OECD TG 424), oral route via feed, including additional investigations in the OECD TG 424 part of the study. In the alternative, the Appellants requests the annulment of the additional investigation parameters of the study (number and sex of animals, dose level setting, dosing period, functional tests, and histopathology).

The Appellants also request the Board of Appeal to order the Agency to pay the costs of the proceedings.

Pleas in law and main arguments

The Appellants claim that the Agency failed to identify the correct legal basis to justify the requirement for further information. Although Article 46 of the REACH Regulation provides the legal basis to request the information, the Agency is still required to identify a specific Article or Section of the Annexes to the REACH Regulation justifying the need for that information. The Agency also failed to provide an adequate statement of reasons in this regard.

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 Appellants argue that the Agency failed to fulfil the conditions for requesting information under Article 46 of the REACH Regulation. In particular, the Agency failed to demonstrate that there is an actual, and not only theoretical, risk posed by Ziram related to developmental neurotoxicity and parkinsonian disorders. The Agency also failed to demonstrate that there are real information needs to address that risk, and that the information required in the Contested Decision will lead to an improvement in the risk management measures in place. The Appellants argue that the Agency also failed to provide an adequate statement of reasons in this regard.

The Appellants argue that the Contested Decision is based on an error of assessment in the Agency's application of the weight-of-evidence approach to justify the need for the requested information and the additional investigation parameters.

The Appellants argue that the Contested Decision breaches the principles of proportionality and animal welfare, as well as Article 13 of the REACH Regulation, as it requires testing on a large number of animals without considering the less severe, non-animal testing, means proposed by the Appellants.

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>

The CoRAP list of substances is available here:

<https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-list-of-substances>