

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

4 October 2018

Application to intervene

(Interest in the result of the case – Accredited Stakeholder Organisations)

Case number	A-008-2018
Language of the case	English
Appellants	Taminco BVBA, Belgium, and Performance Additives Italy S.p.A., Italy
Representatives	Claudio Mereu and Simon Englebert, Fieldfisher (Belgium) LLP, Belgium
Contested Decision	Decision of 13 February 2018 on the substance evaluation of Ziram adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 46 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3, the 'REACH Regulation')
Applicant	PETA International Science Consortium Ltd. ('PISC'), United Kingdom

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 14 May 2018, the Appellants filed an appeal against the Contested Decision which was adopted following the substance evaluation of Ziram (EC No 205-288-3, CAS No 137-30-4). 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 request the annulment of the additional investigation parameters of the study.
2. On 28 June 2018, an announcement of the appeal was published on the Agency's website in accordance with Article 6(6) of Commission 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4; the 'Rules of Procedure').
3. On 19 July 2018, PISC applied for leave to intervene in the proceedings in support of the Appellants. PISC states that its objectives include the reduction, and ultimately the elimination, of the use of animals in regulatory testing and other scientific procedures. PISC argues that its interest in the result of the case is demonstrated, amongst other things, by the fact that it is an accredited stakeholder organisation and that the case raises questions of principle which may affect its interests and those of its members to an appreciable extent. PISC argues that the case raises questions of principle related to how the Agency (i) demonstrates a risk for the purposes of Article 46 of the REACH Regulation, (ii) assesses inconclusive data to justify requests for animal testing and (iii) assesses whether the requirements of the REACH Regulation can be satisfied through the use of alternative testing methods.
4. On 21 August 2018, the Appellants informed the Board of Appeal that they do not oppose PISC's application for leave to intervene.
5. On 24 August 2018, the Agency requested the Board of Appeal to dismiss the application for leave to intervene on the grounds that PISC has not demonstrated an interest in the result of the case. The Agency argues that PISC has not shown that the case raises questions of principle regarding animal testing which have consequences beyond the specific circumstances of the present case.

Reasons

6. The application to intervene complies with Article 8(2), (3) and (4) of the Rules of Procedure. The Board of Appeal will therefore examine whether PISC has established an interest in the result of the present case for the purposes of the first subparagraph of Article 8(1) of the Rules of Procedure.
7. Accredited stakeholder organisations of the Agency, such as PISC, have an established interest in the field of the REACH Regulation and the work of the Agency in general. Furthermore, they are representative of those who have an interest in the avoidance of animal testing for regulatory purposes.
8. An accredited stakeholder organisation has an interest in the result of a case before the Board of Appeal for the purposes of the first subparagraph of Article 8(1) of the Rules of Procedure if that case raises questions of principle capable of affecting its interests (see Case A-001-2018, *Brüggemann Chemical, L. Brüggemann GmbH & Co. KG*, Decision of the Board of Appeal of 29 June 2018 on the application to intervene by The European Coalition to End Animal Experiments, paragraphs 17 to 24).
9. PISC's interests include the reduction, and ultimately the elimination, of the use of animals in regulatory testing and other scientific procedures. The Board of Appeal will therefore examine whether the present case raises questions of principle capable of affecting those interests.

10. In the present case the Appellants seek the annulment of the Agency's decision requiring testing on vertebrate animals (see paragraph 1 above). Based on the Appellants' pleas, the issues that may be examined in the present case include whether:
- the Agency demonstrated that there is an actual, and not only theoretical, risk posed by Ziram related to developmental neurotoxicity and parkinsonian disorders,
 - the Agency demonstrated that the requested information is necessary to meet real information needs regarding the risk identified,
 - the Agency demonstrated that the information required in the Contested Decision will lead to an improvement in the risk management measures in place,
 - the Contested Decision is based on an error of assessment in the Agency's application of the weight-of-evidence approach, and
 - the Contested Decision breaches the principle of proportionality and the requirements of the REACH Regulation related to vertebrate animal testing, as it requires testing on a large number of animals rather than the alternatives proposed by the Appellants.
11. The present case therefore raises questions of principle which directly relate to the way the Agency reaches its decisions requiring testing on vertebrate animals and how the Agency applies the rules in the REACH Regulation to ensure such testing is a last resort. For example, the Board of Appeal may be required to examine the Agency's application of the weight-of-evidence approach in relation to possible animal testing and how it considers alternatives to animal testing. These questions of principle may have consequences beyond the circumstances of the present case in relation to how substance evaluations are conducted and how the Agency assesses available data before requesting tests on vertebrate animals.
12. PISC, as an accredited stakeholder organisation in a case which raises questions of principle related to testing on vertebrate animals, therefore has an interest in the result of this appeal within the meaning of the first subparagraph of Article 8(1) of the Rules of Procedure. PISC's application to intervene must therefore be granted.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by PISC in Case A-008-2018 in support of the Appellants.**
- 2. Instructs the Registrar to arrange for copies of the non-confidential versions of the Notice of Appeal and the Defence to be served on the Intervener.**
- 3. Allows the Intervener a period of one month, following the serving of the Notice of Appeal and the Defence, to lodge a statement in intervention.**

Mercedes Ortuño
Chairman of the Board of Appeal

Alen Močilnikar
Registrar of the Board of Appeal