

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

19 December 2018

Application to intervene

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

Case number	A-006-2018
Language of the case	English
Appellants	Emerald Kalama Chemical B.V., the Netherlands, Lanxess Deutschland GmbH, Germany, and Valtris AO Belgium NV (previously Ineos Chloro Toluenes Belgium NV), Belgium
Representatives	Neil Baylis, Raminta Dereskeviciute and Clare Reynolds, K&L Gates LLP, United Kingdom
Contested Decision	CCH-D-2114378524-42-01/F of 18 December 2017 adopted by the European Chemicals Agency pursuant to Article 41 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 Rapporteur) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

1. On 19 March 2018, the Appellants filed this appeal.
2. The appeal is directed against a decision following a compliance check of the dossier submitted by Emerald Kalama Chemical B.V. as lead registrant for benzaldehyde (EC No 202-860-4, CAS No 100-52-7). The Contested Decision rejected several read-across adaptations proposed by Emerald Kalama Chemical B.V and required it to provide, amongst other information, first and second species pre-natal developmental toxicity ('PNDT') studies and an extended one generation reproductive toxicity study ('EOGRTS').
3. On 16 June 2018, an announcement of the appeal was published on the website of the European Chemicals Agency (the 'Agency') 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').
4. On 3 July 2018, PISC applied for leave to intervene in the proceedings in support of the Appellants. PISC states that it is a non-governmental organisation and an accredited stakeholder organisation of the Agency. Its objectives include the reduction, and ultimately the elimination, of vertebrate animal testing for regulatory purposes. PISC argues that the case raises questions of principle which have a direct impact on issues related to animal testing. These questions of principle are related to, among others, how the Agency applies Article 25(1) of the REACH Regulation when evaluating read-across adaptations including how the Agency manages conflicts of opinion with other European Union bodies.
5. On 20 August 2018, the Appellants filed their observations on the application for leave to intervene. The Appellants support the application.
6. Also on 20 August 2018, the Agency filed its observations on the application for leave to intervene. The Agency opposes the application. The Agency argues that the Appellants' arguments on the relationship between vertebrate animal testing requirements and read-across adaptations are case specific. As a result, any question of principle in this regard will not be addressed in these proceedings. The Agency further argues that issues associated with the prevention of conflicts of opinion between the Agency and other European Union bodies has neither a direct nor certain link with questions of principle related to animal testing. As a consequence, the case does not raise issues of principle capable of affecting PISC's interests.

Reasons

7. According to Article 8(1) of the Rules of Procedure, any person establishing an interest in the result of a case may intervene in the proceedings before the Board of Appeal.
8. 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. Furthermore, they are representative of those who have an interest in the avoidance of animal testing for regulatory purposes.
9. An accredited stakeholder organisation has an interest in the result of a case before the Board of Appeal if that case raises questions of principle capable of affecting its interests (see Case A-001-2018, *BrüggemannChemical*, Decision of the Board of Appeal of 29 June 2018 on the application for leave to intervene by The European Coalition to End Animal Experiments, paragraphs 17 to 24).

10. The present case raises at least one question of principle capable of affecting the interests of PISC's members. Namely, how the Agency applies the principle that testing on vertebrate animals must be undertaken only as a last resort (Article 25(1) of the REACH Regulation) when it evaluates a proposed read-across adaptation. The Board of Appeal may be required to examine the Agency's application of the last resort principle in relation to the grouping of substances and the implications this has for requesting new tests on vertebrate animals. The findings of the Board of Appeal may have consequences beyond the circumstances of the present case in relation to how substances can be grouped, the use of data in a group for read-across purposes, and the implications this has under compliance checks for requesting tests on vertebrate animals (see also Case A-013-2016, *BASF Personal Care and Nutrition*, Decision of the Board of Appeal of 3 May 2017 on the application for leave to intervene by PISC, paragraph 37).
11. It follows that PISC has established an interest in the result of this case within the meaning of Article 8(1) of the Rules of Procedure.
12. As the application also complies with Article 8(2), (3) and (4) of the Rules of Procedure, it must be allowed.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application for leave to intervene by PISC in Case A-006-2018 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