

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

**8 November 2022**

**Application to intervene**

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

<b>Case number</b>	A-008-2022
<b>Language of the case</b>	English
<b>Appellant</b>	Dragon Chemical Europe GmbH, Germany
<b>Representatives</b>	Ruxandra Cana, Eléonore Mullier, and Hannah Widemann Steptoe & Johnson LLP, Belgium
<b>Contested Decision</b>	Decision of 24 May 2022 on the substance evaluation of 5-amino-o-cresol adopted by the European Chemicals Agency pursuant to Article 46 of the REACH Regulation <sup>1</sup>  The Contested Decision was notified to the Appellant under annotation number SEV-D-2114596741-38-01/F
<b>Applicant</b>	PETA Science Consortium International e.V. ('PSCI'), Germany

**THE BOARD OF APPEAL**

composed of Antoine Buchet (Chairman), Nikolaos Georgiadis (Technically Qualified Member),  
and Marijke Schurmans (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

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<sup>1</sup> 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).

## Decision

### Summary of the facts

1. On 23 August 2022, the Appellant filed its appeal against the Contested Decision. The Appellant seeks the annulment of the Contested Decision requesting the submission of information on an *in vivo* mammalian alkaline comet assay test (OECD test guideline 489) in liver, gastro-intestinal tract (glandular stomach and duodenum) and urinary bladder performed in rats via the oral route.
2. On 27 September 2022, an announcement was published on the Agency's website in accordance with Article 6(6) of the Rules of Procedure<sup>2</sup>.
3. On 13 October 2022, PSCI applied for leave to intervene in the proceedings in support of the remedy sought by the Appellant. PSCI argues that its objectives include the reduction, and ultimately the elimination, of the use of animals in regulatory testing and other scientific procedures. PSCI argues that it is an Accredited Stakeholder Organisation with the Agency.
4. PSCI argues that the case raises questions of principle related to:
  - (a) the circumstances under which the Agency may request additional tests on animals if the information requested is unlikely to lead to improved risk management measures;
  - (b) how the Agency meets the requirements of proportionality and animal welfare as well as Article 25(1) of the REACH Regulation, which requires that information must be generated wherever possible by means other than tests on vertebrate animals;
  - (c) the circumstances under which the Agency rejects *in vivo* data already provided in the registration dossier;
  - (d) how the Agency balances animal welfare considerations with the objectives of the requested information when assessing available tests to fulfil information requirements; and
  - (e) how the Agency fulfils its obligation under Article 95(3) of the REACH Regulation to solve fundamental conflicts over scientific or technical points with other scientific committees.
5. On 27 and 28 October 2022 respectively, the Appellant and the Agency submitted their observations on the application to intervene. The Appellant and the Agency did not object to PSCI's application.

### Reasons

6. Under the first subparagraph of 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.
7. PSCI is included in the list of Accredited Stakeholder Organisations published on the Agency's website. An Accredited Stakeholder Organisation, such as PSCI, has an interest in the result of a case if that case raises questions of principle capable of affecting its interests<sup>3</sup>.

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<sup>2</sup> 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).

<sup>3</sup> See decision of the Board of Appeal of 29 June 2018 on the application to intervene by the European Coalition to End Animal Experiments, *BrüggemannChemical*, A-001-2018, paragraphs 17 to 24 and decision of the Board of Appeal of 11 March 2020 on the application for leave to intervene by Cruelty Free Europe, *Polynt*, A-015-2019, paragraph 9.

8. PSCI's interests include the reduction, and ultimately the elimination, of the use of animals in testing under the REACH Regulation. The present case raises questions of principle which relate directly to Agency decisions requiring testing on vertebrate animals. In particular, those questions of principle relate to how the Agency reaches its decisions requiring testing on vertebrate animals under substance evaluation and how it applies the REACH Regulation to ensure such testing is used as a last resort. Those questions of principle are therefore capable of affecting PSCI's interests.
9. PSCI therefore has an interest in the result of the present case within the meaning of the first subparagraph of Article 8(1) of the Rules of Procedure.
10. As the application for leave to intervene also complies with Article 8(2), (3) and (4) of the Rules of Procedure, it must be granted.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by PSCI in Case A-008-2022 in support of the Appellant.**
- 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. The Chairman of the Board of Appeal will prescribe a period within which PSCI may submit a statement in intervention.**

Antoine BUCHET  
Chairman of the Board of Appeal

Marc Goodacre  
On behalf of the Registrar of the Board of Appeal