ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

29 November 2022

Application to intervene

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

Case number	A-009-2022
Language of the case	English
Appellants	Nouryon Functional Chemicals B.V., the Netherlands ARKEMA GmbH, Germany PERGAN Hilfsstoffe für industrielle Prozesse GmbH, Germany United Initiators GmbH, Germany
Representatives	Ruxandra Cana, Eléonore Mullier, and Hannah Widemann Steptoe & Johnson LLP, Belgium
Contested Decision	Decision of 8 June 2022 on a compliance check of the registration for the substance di-tert-butyl 1,1,4,4-tetramethyltetramethylene diperoxide, adopted by the European Chemicals Agency pursuant to Article 41 of the REACH Regulation[1] The Contested Decision was notified to the Appellants under annotation number CCH-D-2114597796-22-01/F
Applicant	PETA Science Consortium International e.V. ('PSCI'), Germany

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

[1] 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 8 September 2022, the Appellants filed their appeal against the Contested Decision. The Appellants seek the annulment of the Contested Decision insofar as it requests information on an extended one-generation reproductive toxicity study (OECD test guideline 443) to be performed on rats, by the oral route, with the following specifications:

   – Ten weeks premating exposure duration for the parental (P0) generation;
   – Dose level setting shall aim to induce systemic toxicity at the highest dose level;
   – Cohort 1A (Reproductive toxicity);
   – Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;
   – Cohorts 2A and 2B (Developmental neurotoxicity); and
   – Investigations on learning and memory function as described in paragraph 37 of the OECD TG 426.

2. On 17 October 2022, an announcement was published on the Agency's website in accordance with Article 6(6) of the Rules of Procedure[2].

3. On 1 November 2022, PSCI applied for leave to intervene in the proceedings in support of the remedy sought by the Appellants. 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) how the Agency meets the requirements of proportionality and animal welfare as well as Article 25(1) of the REACH Regulation, which require that information shall be generated wherever possible by means other than tests on vertebrate animals;

   (b) how the Agency determines the circumstances under which additional tests on animals may be requested based on the results of previous tests with limited validity;

   (c) how the Agency balances animal welfare concerns with the objectives of the requested information;

   (d) the Agency's ability to request studies which are subject to several scientific and technical limitations and controversies;

   (e) the Agency's ability to base its requests for additional tests on its own guidance documents, rather than on the relevant Annexes of the REACH Regulation; and

   (f) the extent of the Agency's responsibility to make use of the best possible scientific and technical knowledge when accomplishing its tasks.

5. On 10 and 22 November 2022 respectively, the Appellants and the Agency submitted their observations on the application to intervene. The Appellants and the Agency did not object to PSCI's application.

[2] 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).

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[3].

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 compliance check 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-009-2022 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. **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

Alen MOČILNIKAR
Registrar of the Board of Appeal

[3] 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.