

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

11 December 2020

Application to intervene

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

Case number A-005-2020

Language of

English

the case
Appellant

S. Goldmann GmbH & Co. KG, Germany

Representatives Claudio Mereu and Sandra Sáez Moreno

Fieldfisher (Belgium) LLP, Belgium

Contested Decision

Decision of 12 March 2020 on the substance evaluation of

2,5,7,10,11,14-hexaoxa-1,6-distibabicyclo[4.4.4]tetradecane

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; the 'REACH Regulation')

Applicant PETA International Science Consortium Ltd. ('PISC'),

United Kingdom

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Ángel M. Moreno (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

- On 12 June 2020, the Appellant filed its appeal against the Contested Decision. The
 Appellant seeks the annulment of the Contested Decision requesting the submission
 of information on a 90-day (subchronic) toxicity study in rats, oral route (test method:
 OECD test guideline 408) on 2,5,7,10,11,14-hexaoxa-1,6distibabicyclo[4.4.4]tetradecane, including the evaluation of cardiovascular effects and
 the assessment of toxicokinetics.
- 2. On 24 August 2020, an announcement 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; the 'Rules of Procedure').
- 3. On 10 September 2020, PISC applied for leave to intervene in support of the Appellant. 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 with the Agency and that the case raises questions of principle which may affect its interests and those of its members to an appreciable extent.
- 4. PISC argues that the case raises questions of principle related to:
 - (i) The circumstances under which the Agency uses the substance evaluation procedure to request additional tests on animals;
 - (ii) 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;
 - (iii) 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;
 - (iv) 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;
 - (v) Whether the compliance check procedure should be followed before the substance evaluation procedure is initiated or concluded; and
 - (vi) The circumstances under which the Agency rejects read-across and weight-of-evidence adaptations.
- 5. On 22 September 2020, the Appellant informed the Board of Appeal that it supports PISC's application for leave to intervene.
- 6. On 7 October 2020, the Agency submitted its observations on PISC's application to intervene. The Agency did not raise any objections to PISC's application.

Reasons

- 7. Pursuant to 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.
- 8. An Accredited Stakeholder Organisation, such as PISC, has an interest in the result of a case 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 to intervene by the European Coalition to End Animal Experiments, paragraphs 17 to 24 and Case A-015-2019, *Polynt*, Decision of the Board of Appeal of 11 March 2020 on the application for leave to intervene by Cruelty Free Europe, paragraph 9).

- 9. PISC'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 directly relate to the way the Agency reaches its decisions requiring testing on vertebrate animals under substance evaluation and how it considers alternatives to such testing. Those questions of principle are therefore capable of affecting PISC's interests.
- 10. As a result, PISC 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.
- 11. 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 PISC in Case A-005-2020 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 PISC may submit a statement in intervention.

Antoine BUCHET Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal