

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

**24 September 2019**

**Application to intervene**

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

<b>Case number</b>	A-001-2019
<b>Language of the case</b>	English
<b>Appellant</b>	Solvay Fluor GmbH, Germany
<b>Representatives</b>	Ruxandra Cana, Eléonore Mullier and Filippo Mattioli, Steptoe & Johnson LLP, Belgium
<b>Contested Decision</b>	CCH-D-2114450985-37-01/F of 15 November 2018 adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 42(1) 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')
<b>Applicant</b>	PETA International Science Consortium Ltd. ('PISC'), United Kingdom

**THE BOARD OF APPEAL**

composed of Antoine Buchet (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 5 February 2015, pursuant to Article 41(3) of the REACH Regulation, the Agency adopted a decision (the 'initial compliance check decision') following a compliance check of the Appellant's dossier for the substance sulphur hexafluoride. In that decision, the Agency requested the Appellant to update its registration dossier by 12 August 2016 with information on a pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex IX to the REACH Regulation), and a sub-chronic toxicity study (90 day), inhalation route (Section 8.6.2. of Annex IX to the REACH Regulation).
2. With regard to the PNDT study, the Appellant updated its registration dossier with a weight-of-evidence adaptation according to Section 1.2. of Annex XI to the REACH Regulation.
3. On 15 November 2018, after the follow-up evaluation of the Appellant's dossier pursuant to Article 42(1) of the REACH Regulation, the Agency adopted the Contested Decision. In the Contested Decision, the Agency rejected the Appellant's weight-of-evidence adaptation. The Agency concluded that the Appellant's registration dossier still does not comply with Section 8.7.2. of Annex IX to the REACH Regulation.
4. According to the Contested Decision, *'the respective Member State competent authority (MSCA) and national enforcement authority (NEA) will be informed of [the Agency's] decision [...]. They may consider enforcement actions to secure the implementation of [the initial compliance check decision]'*.
5. On 12 February 2019, the Appellant filed an appeal against the Contested Decision.
6. On 23 April 2019, 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').
7. On 13 May 2019, PISC applied for leave to intervene in the proceedings 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.
8. PISC argues that the case raises questions of principle related to:
  - (i) how the Agency assesses updates to registration dossiers in the follow-up to a compliance check decision;
  - (ii) how much time a registrant should be given to update a registration dossier in a follow-up compliance check;
  - (iii) how the Agency assesses weight-of-evidence adaptations pursuant to Section 1.2. of Annex XI to the REACH Regulation;
  - (iv) how the Agency meets the requirements of the principles of legal certainty and legitimate expectations, as well as the Appellant's right to be heard; and
  - (v) how the Agency meets the requirements of proportionality and animal welfare as well as Article 13, which require that information must be generated wherever possible by means other than tests on vertebrate animals.
9. On 20 June 2019, the Appellant informed the Board of Appeal that it has no comments on PISC's application for leave to intervene.
10. On 20 June 2019, the Agency stated that the question of principle in the present case is whether the Agency correctly adopted the Contested Decision in accordance with Article 42(1) of the REACH Regulation. The Agency argues that it is unclear from the application to intervene whether PISC has understood the question of principle in this case. The Agency

argues that PISC incorrectly states that the case concerns the Agency's refusal to take into account the Appellant's updated weight-of-evidence adaptation. The Agency stated that it therefore leaves it to the Board of Appeal to decide on PISC's application to intervene.

### Reasons

11. 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.
12. 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, PISC is representative of those who have an interest in the avoidance of animal testing for regulatory purposes.
13. 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, *BrüggemannChemical, 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).
14. 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.
15. In the present case, the Appellant seeks the annulment of the Agency's decision finding that the information submitted by the Appellant in response to the initial compliance check decision is insufficient to meet the requirements of Section 8.7.2. of Annex IX to the REACH Regulation (see paragraphs 1 to 3 above). Based on the Appellant's pleas, the issues that may be examined in the present case include whether the Agency:
  - breached Articles 41 and 42(1) of the REACH Regulation and exceeded its powers as the Contested Decision is limited to a statement of non-compliance and does not require the Appellant to submit any information and does not specify a time-limit for the Appellant to submit that information;
  - should have based the Contested Decision on Article 41 of the REACH Regulation;
  - breached the Appellant's right to be heard and its rights of defence by including substantial new information in the Contested Decision on which the Appellant did not have an opportunity to comment;
  - committed an error of assessment, failed to consider all relevant information and breached Annex XI of the REACH Regulation in rejecting the Appellant's weight-of-evidence adaptation;
  - breached Article 25 of the REACH Regulation, as well as the principle of proportionality, in finding that a PNDT study was still required despite the fact that the Appellant had fulfilled the endpoint in question using a weight-of-evidence adaptation.
16. 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 REACH Regulation to ensure such testing is used as a last resort. For example, the Board of Appeal may be required to examine the Agency's assessment of weight-of-evidence adaptations in relation to possible animal testing and how the Agency considers alternatives to animal testing. These questions of principle may have consequences beyond the circumstances of the present case in relation to how compliance checks are conducted and how the Agency assesses available data before requesting tests on vertebrate animals.

17. 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-001-2019 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. 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.**

Antoine Buchet  
Chairman of the Board of Appeal

Alen Močilnikar  
Registrar of the Board of Appeal