

**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)

Case number	A-001-2019
Language of the case	English
Appellant	Solvay Fluor GmbH, Germany
Representatives	Ruxandra Cana, Eléonore Mullier and Filippo Mattioli, Steptoe & Johnson LLP, Belgium
Contested Decision	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')
Applicant	European Coalition to End Animal Experiments ('ECEAE'), 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 updated registration 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, ECEAE applied for leave to intervene in the proceedings in support of the Appellant. ECEAE states that it is Europe's leading alliance of animal protection organisations, representing many millions of people in the European Union who are concerned about animal testing. It claims to have an interest in the result of the case because it has been an Accredited Stakeholder Organisation of the Agency from the outset and has worked with the Agency to improve its guidance to industry, in particular on the avoidance of animal testing.
8. ECEAE claims to have an interest in the result of the appeal for the following reasons:
 - ECEAE has been granted leave to intervene in Case C-471/18 P, *Germany v Esso Raffinage*, in which some of the issues discussed in this appeal will also be examined,
 - ECEAE has concerns about the Agency's approach to weight-of-evidence adaptations, an issue which will be examined in the present case, and
 - a PNDT study has a significant impact on animal welfare and ECEAE has an interest in ensuring that such a test does not take place if it is not legally warranted.
9. On 20 June 2019, the Appellant informed the Board of Appeal that it has no comments on ECEAE'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 ECEAE has not explained how its involvement in Case C-471/18 P, *Germany v Esso Raffinage*, establishes an interest in the result of the present case. The Agency stated that it therefore leaves it to the Board of Appeal to decide on ECEAE'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 ECEAE 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 ECEAE, have an established interest in the field of the REACH Regulation and the work of the Agency in general. Furthermore, ECEAE 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 ECEAE, paragraphs 17 to 24).
14. ECEAE's interests include the avoidance of animal testing. 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. ECEAE, 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. ECEAE's application to intervene must therefore be granted.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by ECEAE 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