

Announcement of appeal¹

Published on	10 January 2023
Case	A-010-2022
Appellant	BASF SE, Germany
Appeal received on	7 November 2022
Subject matter	A decision taken by the European Chemicals Agency ('the Agency') pursuant to Article 46(1) of the REACH Regulation ²
Keywords	<i>Substance Evaluation – Principle of Proportionality – Margin of discretion – Legal certainty – Right to be heard</i>
Contested Decision	Decision of 8 August 2022 on the substance evaluation of the substance bis (2-propylheptyl) phthalate (EC No 258-469-4; CAS No 53306-54-0)
Language of the case	English

Background and remedy sought by the Appellants

By the Contested Decision, the Agency required the registrants of bis (2-propylheptyl) phthalate (the **Substance**) to submit information on an amphibian metamorphosis assay (**AMA**) according to the OECD test guideline 231. The study was requested to clarify concerns related to endocrine disruption.

The Contested Decision requests the Appellant to perform the AMA with the following specifications:

- The test material must be representative for the Substance, in particular with respect to the concentrations of isomers, constituents and impurities.
- The AMA must be conducted with dietary exposure and include a number of non-standard adaptations of the OECD TG 231.

¹ Announcement published 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).

² 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). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

The Appellant requests the Board of Appeal to annul the Contested Decision.

The Appellant also requests the Board of Appeal to order the Agency to refund the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

In support of its appeal, the Appellant raises the following pleas in law. According to the Appellant, the Agency breached:

- Article 46 and the principle of proportionality;
- Article 13(3);
- the principle of legal certainty; and
- the Appellant's right to be heard.

The Appellant supports its pleas in law with the following main arguments.

First, the Appellant argues that the Agency failed to demonstrate the necessity of the request for further information by failing to demonstrate that the Substance poses a potential risk to the environment, that there is a real need for the information and that the information requested has a realistic possibility of leading to improved risk management measures. Moreover, the Appellant argues that the Agency also failed to adopt an appropriate and least onerous information request capable of clarifying the alleged potential risk.

Second, the Appellant argues that the Agency incorrectly exercised its margin of discretion in requiring that the requested study be conducted in a way that is not foreseen in OECD test guideline 231, and failed to demonstrate that the required changes to the study design meet the conditions set out in Article 13(3) and, by reference, Section 2 of Annex XI.

Third, the Appellant argues that the Agency breached the principle of legal certainty as regards the conduct and feasibility of the AMA requested. The Appellant argues that the many adaptations to the AMA imposed by the Agency in the Contested Decision create a great uncertainty about the possibility to comply with that decision. The Appellant also argues that the Agency failed to provide sufficient clarification and guidance regarding the conduct of the study requested and to address the Appellant's concerns on its feasibility.

Finally, the Appellant argues that the Agency failed to take into account some of the comments of the Appellant on the initial Draft Decision, and that this breach of the right to be heard should result in an annulment of the Contested Decision.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

<http://echa.europa.eu/web/guest/regulations/appeals>