EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	09 January 2024
Case	A-012-2023
Appellant	DSM Nutritional Products GmbH, Germany
Appeal received on	9 November 2023
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 46 of the REACH Regulation[2]
Keywords	*Substance evaluation – Follow-up – Error of assessment – Legitimate expectations*
Contested Decision	Decision of 10 August 2023 on the substance evaluation of 1-[4-(1,1-dimethylethyl)phenyl]-3-(4-methoxyphenyl)propane-1,3-dione[3]
Language of the case	English

Background and remedy sought by the Appellant

Due to initial grounds of concern relating to suspected persistent, bioaccumulative and toxic (**PBT**) or very persistent and very bioaccumulative (**vPvB**) properties, consumer use, exposure of the environment, high (aggregated) tonnage and wide dispersive use, the Substance was included in the Community rolling action plan (**CoRAP**) to be evaluated in 2015.

On 23 March 2017, the Agency adopted a substance evaluation decision on the Substance (**first substance evaluation decision**) requesting information on aerobic mineralisation in surface water, aerobic and anaerobic transformation in aquatic sediment systems, long-term toxicity testing on aquatic invertebrates and long-term toxicity testing on fish.

In 2021, the Appellant submitted information in response to the first substance evaluation decision. Based on the available information, the evaluating member state competent authority (**eMSCA**) considered that the Substance is potentially PBT.

[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 concern the REACH Regulation unless stated otherwise.

[3] EC number 274-581-6; CAS number 70356-09-1.

During the follow-up of the first substance evaluation decision, the eMSCA identified an additional concern related to endocrine disrupting properties in the environment. This additional concern was based on new information available in academic literature.

On 10 August 2023, to clarify the concern relating to endocrine disruption in the environment, the Agency adopted the Contested Decision requesting the Appellant and other registrants of the Substance to submit, by 16 February 2026, information on an amphibian metamorphosis assay (OECD TG 231) using the Substance.

The Appellant requests the Board of Appeal to annul the Contested Decision and order the refund of the appeal fee.

Pleas in law and main arguments

The Appellant argues that, in adopting the Contested Decision, the Agency breached Article 46(3) and (4), as well as the Appellant's legitimate expectations.

The Appellant argues that, under Article 46(3), the eMSCA should have completed its assessment within 12 months of the submission of the information in response to the first substance evaluation decision. According to the Appellant, as it submitted all the information required by the first substance evalulation decision by 26 November 2021, the eMSCA should have completed its assessment by 26 November 2022. However, the Agency issued the draft decision based on the eMSCA's assessment only on 1 December 2022.

The Appellant also argues that the Agency breached Article 46(3) and the Appellant's legitimate expectations by adopting the Contested Decision to address concerns relating to endocrine disruption based on information other than that submitted in response to the initial substance evaluation decision.

The Appellant argues that substance evaluation decisions adopted on the basis of information other than that submitted in response to a substance evaluation decision must be adopted under Article 47(1). According to the Appellant, adopting a decision under Article 47(1) would have entailed the restart of the substance evaluation procedure, including another inclusion of the Substance on CoRAP.

The Appellant also argues that the Agency made an error of assessment in relying on unreliable studies to justify the concern relating to endocrine disruption, and not concluding, instead, on the basis of reliable information that there is no remaining concern.

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