ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

6 March 2024

Application to intervene

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

Case number	A-012-2023
Language of the case	English
Appellant	DSM Nutritional Products GmbH, Germany Represented by Ruxandra Cana, Zanda Romata and Roman Spangenberg Steptoe LLP, Belgium
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[1] ('the Substance'), adopted by the European Chemicals Agency pursuant to Article 46 of the REACH Regulation[2] The Contested Decision was notified to the Appellant under annotation number SEV-D-2114649046-48-01/F
Applicant	The European Federation for Cosmetic Ingredients ('EFfCI'), Belgium Represented by Ruxandra Cana, Zanda Romata and Roman Spangenberg Steptoe LLP, Belgium

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Nikolaos Georgiadis (Technically Qualified Member) and Marijke Schurmans (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

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

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.

Decision

Summary of the facts

1. 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.

2. 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.

3. 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.

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

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

6. On 9 November 2023, the Appellant filed its appeal seeking the annulment of the Contested Decision.

7. In its appeal, the Appellant argues that the Agency breached Article 46(3) by exceeding the time limit to complete its assessment of the information submitted in response to the first substance evaluation decision. The Appellant argues that the Agency also breached Article 46(3) by basing its decision on information other than that submitted in response to the first substance evaluation decision. According to the Appellant, 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). 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.

8. On 9 January 2024, an announcement was published on the Agency's website in accordance with Article 6(6) of the Rules of Procedure[3].

9. On 30 January 2024, EFfCI applied for leave to intervene in the proceedings in support of the remedy sought by the Appellant.

10. In support of its application, EFfCI claims that it has an interest in the result of the case as it represents the interests of registrants of the Substance, including addressees of the Contested Decision. According to the Applicant, the outcome of the appeal will affect whether registrants of the Substance are required to submit additional information on the Substance to the Agency.

11. EFfCI also argues that it fulfils the criteria set by the Court of Justice of the European Union and referred to by the Board of Appeal in its previous decisions for assessing applications to intervene by representative associations.

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[3] 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).

12. In this respect, EFfCI states that it represents the collective interests of an appreciable number of manufacturers of ingredients used in cosmetics products (over 100 companies), including the Appellant and other registrants of the Substance. In addition, EFfCI submits that, as indicated in its Statutes, its object includes the representation and defence of the interests of its members. EFfCI adds that, as an Accredited Stakeholder Organisation with the Agency, it has already demonstrated its legitimate interest in the areas of work of the Agency.

13. EFfCI further argues that the case raises the following questions of principle:

    (a) Whether, during the follow-up to a substance evaluation procedure, an eMSCA may rely on information obtained outside the framework of the initial procedure to establish additional concerns and whether the Agency may adopt a decision to address those concerns;

    (b) Whether the eMSCA can exceed the 12-month deadline set in Article 46(4) to complete the evaluation; and

    (c) Whether the studies relied on by the Agency and the eMSCA to substantiate their concerns are subject to any qualitative thresholds.

14. On 12 February 2024, the Appellant informed the Board of Appeal that it welcomed EFfCI's application for leave to intervene.

15. On 19 February 2024, the Agency informed the Board of Appeal that it did not object to EFfCI's application.

Reasons

16. Under 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.

17. EFfCI is included in the list of Accredited Stakeholder Organisations published on the Agency's website. An Accredited Stakeholder Organisation, such as EFfCI, has an interest in the result of a case if that case raises questions of principle capable of affecting its interests[4].

18. According to EFfCI's Statutes, its interests include the representation of its members before, *inter alia*, official authorities and public organisations, as well as the defence of their interests. Furthermore, EFfCI aims at coordinating '*the activities of its members to ensure the uniform protection of their interests*'. It also aims at defining, promoting and defending '*common positions concerning the problems arising from the manufacture and use of ingredients used in cosmetic products*'.

19. The present case raises questions of principle related to the conditions under which the Agency may request additional information under the substance evaluation procedure from registrants of substances, including those represented by EFfCI. More specifically, those questions of principle relate to the duration of the substance evaluation procedure, the procedure the Agency should follow to address additional concerns identified during the follow-up to a substance evaluation procedure and the information that the Agency may rely on to establish those concerns. Those questions of principle are therefore capable of affecting EFfCI's interests, as well as those of its members.

20. Therefore, EFfCI 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.

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[4] See decision of the Board of Appeal of 29 June 2018 on the application to intervene by the European Coalition to End Animal Experiments, *BrüggemannChemical,* A-001-2018, paragraphs 17 to 24, and decision of the Board of Appeal of 8 November 2022 on the application for leave to intervene by PETA Science Consortium International e.V., *Dragon Chemical Europe*, A-008-2022, paragraph 7.

21. 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 EFfCI in Case A-012-2023 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 EFfCI may submit a statement in intervention.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal