

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

5 March 2024

Application to intervene

(Interest in the result of the case – Member State competent authority)

Case number A-010-2023

Language of the case English

Appellant Sumitomo Chemical Agro Europe SAS, France

Represented by

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Fieldfisher (Belgium) LLP, Belgium

Contested Decision TAP-C-1665698-01-00/F adopted on 6 June 2023 by the

European Chemicals Agency under Article 54(4) of the

Biocidal Products Regulation¹

Applicant Agence nationale de sécurité sanitaire de l'alimentation, de

l'environnement et du travail (ANSES), France

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1). All references to Articles hereafter concern the Biocidal Products Regulation unless stated otherwise.

Decision

Summary of the facts

- 1. On 11 August 2022, the Appellant submitted to the Agency a request for a decision on whether *bacillus thuringiensis* subsp. *israelensis* Serotype H14, Strain AM65-52 ('BTI AM65-52'), manufactured by the Appellant, and *bacillus thuringiensis* subsp. *israelensis* Strain BMP 144 ('BTI BMP 144'), manufactured by the *Compagnie Européene de Réalisations Antiparasitaires SAS* (CERA), are technically equivalent.
- 2. On 6 June 2023, the Agency adopted the Contested Decision rejecting the Appellant's request. The Agency found, in the Contested Decision, that the technical equivalence at issue had already been carried out by ANSES and concluded that there was no legal necessity for the Appellant to obtain a technical equivalence decision from the Agency as a condition for authorising a biocidal product under Article 19(1)(c).
- 3. On 4 September 2023, the Appellant lodged an appeal requesting the annulment of the Contested Decision.
- 4. On 12 October 2023, an announcement was published on the Agency's website in accordance with Article 6(6) of the Rules of Procedure.²
- 5. On 31 October 2023, ANSES applied for leave to intervene in these proceedings in support of the Agency.
- 6. ANSES claims that it has a direct interest in the result of the present case as it has already carried out the technical equivalence at issue in the context of three national authorisations granted to CERA for the latter's biocidal products containing BTI BMP 144. In addition, ANSES claims that the Appellant's request for technical equivalence relates to an ongoing litigation in France, in which the Appellant has challenged the abovementioned authorisations.
- 7. On 17 November 2023, the Agency informed the Board of Appeal that it has no objections to the application for leave to intervene. On the same day, the Appellant objected to that application.
- 8. The Appellant argues that ANSES has not explained how its legal or economic situation may be directly affected by the operative part of the Board of Appeal's decision. According to the Appellant, the interest in being informed of the outcome of the case, as expressed by ANSES in its application for leave to intervene, does not constitute an interest within the meaning of Article 8(1) of the Rules of Procedure.
- 9. The Appellant argues that ANSES and the Agency have created a conflict of interest. According to the Appellant, the fact that the Agency consulted ANSES in order to submit its Defence and that ANSES thus had access to the documents relating to the present proceedings, renders Article 8(5) of the Rules of Procedure ineffective and inoperative.
- 10. The Appellant argues that, since it is challenging the Contested Decision on the admissibility of its request for technical equivalence and not a decision on technical equivalence itself, it is not possible for ANSES to have a direct interest in the result of the present case at this stage of the proceedings.
- 11. The Appellant argues that the need for ANSES to set out the background and the arguments relating to the ongoing litigation in France, as expressed by ANSES in its application for leave to intervene, cannot be regarded as constituting an interest in the outcome of the case.

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).

Reasons

- 12. 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.
- 13. The concept of interest in the result of a case, within the meaning of the first subparagraph of Article 8(1) of the Rules of Procedure, must be defined in the light of the subject matter of the dispute and be understood as meaning a direct, existing interest in the ruling on the form of order sought, and not as an interest in relation to the pleas in law or arguments put forward. The words 'result of a case' refer to the final decision sought, as set out in the operative part of the future decision. In principle, an interest in the result of the case can be regarded as sufficiently direct only in so far as that result is capable of altering the legal position of the applicant for leave to intervene.³
- 14. ANSES is the competent authority of France, and, as all the competent authorities of the Member States, plays an important role under the Biocidal Products Regulation. For example, under Article 8 those competent authorities are responsible for evaluating applications for the approval of an active substance and for sending an assessment report and the conclusions of the evaluation to the Agency.
- 15. In the present case, ANSES has already carried out the assessment of technical equivalence between BTI AM65-52 and BTI BMP 144 in the context of the authorisation procedure for three CERA's biocidal products containing BTI BMP 144. In the Contested Decision, the Agency's reasoning for rejecting the Appellant's request to carry out the technical equivalence assessment is partly based on the assessment already carried out by ANSES.
- 16. ANSES is involved in ongoing litigation in France in which the authorisations granted by it to CERA are being challenged.⁴
- 17. In its Notice of Appeal, the Appellant argues that ANSES was not competent to carry out the technical equivalence at issue. In particular, the Appellant argues that CERA submitted the application for authorisation of its biocidal products containing BTI BMP 144 after the entry into force of the Biocidal Products Regulation, and therefore the assessment and establishment of technical equivalence no longer fell within the competence of ANSES but of the Agency instead, under Article 91.
- 18. In its future decision in the present proceedings, the Board of Appeal will assess the above arguments and will therefore decide whether ANSES or the Agency was competent to establish the technical equivalence between BTI AM65-52 and BTI BMP 144. In this respect, the outcome of the present proceedings will produce legal effects capable of affecting the particular interests of ANSES, by calling into question its competence to establish the technical equivalence between BTI AM65-52 and BTI BMP 144.⁵
- 19. Moreover, the outcome of the present proceedings may lead to a new assessment of the technical equivalence, and might therefore lead to a decision that would contradict the assessment already carried out by ANSES.
- 20. Therefore, the Board of Appeal's decision on the Appellant's request to annul the Contested Decision is capable of altering ANSES's legal position. It must therefore be

See decision of the Board of Appeal of 13 March 2023 on the application to intervene by Armosa Tech SA, *Biofa GmbH*, A-011-2022, paragraph 14.

⁴ See paragraph 6 above.

⁵ See, to this effect and by analogy, order of the President of the Court of Justice of 17 September 2021, European Parliament v European Commission, C-144/21, EU:C:2021:757, paragraph 11.

- concluded that ANSES 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.
- 21. For the following reasons, this conclusion is not called into question by the other Appellant's arguments.
- 22. First, the expression that ANSES "has an interest in being kept informed of the outcome of this appeal", used in the application for leave to intervene, cannot be read in isolation, but must be interpreted in the context of the application for leave to intervene, which clearly establishes the interest of ANSES in the result of the present case, as it has been held in paragraphs 12 to 20.
- 23. Second, the mere fact that the Agency has consulted ANSES to prepare its Defence does not prevent ANSES from intervening in the present proceedings. Moreover, the alleged transmission of procedural documents by the Agency to ANSES is not substantiated and would be, in any event, irrelevant for the assessment of the existence of an interest in the result of the present case.
- 24. As the application for leave to intervene also complies with the requirements of Article 8(2) to (4) of the Rules of Procedure, it must be allowed.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by ANSES in case A-010-2023 in support of the Agency.
- 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 ANSES may submit a statement in intervention.

Antoine BUCHET Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal