

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

5 March 2024

Application to intervene

(Interest in the result of the case)

Case number	A-010-2023
Language of the case	English
Appellant	Sumitomo Chemical Agro Europe SAS, France Represented by: Koen Van Maldegem, Peter Sellar and Maud Grunchard 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 Regulation ¹
Applicant	Compagnie Européenne de Réalisations Antiparasitaires SAS (CERA), France Represented by Peter Kugel VVGB Advocaten/Avocats, Belgium

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

¹ 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 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 the French authority competent under the Biocidal Products Regulation (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, CERA applied for leave to intervene in these proceedings in support of the Agency.
6. CERA claims that it has a direct interest in the result of the present case as the Board of Appeal's decision on the Appellant's request to annul the Contested Decision may lead the Agency to carry out a new technical equivalence assessment between BTI AM65-52 and BTI BMP 144, thereby jeopardising the assessment already carried out by ANSES and on the basis of which CERA holds the national marketing authorisations for its biocidal products containing BTI BMP 144.
7. In addition, CERA claims that its legal position is likely to be directly affected by the outcome of the present appeal proceedings as the authorisations referred to in paragraph 6 above have been challenged by the Appellant in ongoing litigation in France, in which CERA intervenes.
8. 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.
9. The Appellant argues that, contrary to CERA's arguments, the subject matter of the present appeal proceedings is not the technical equivalence assessment carried out by ANSES, but the Agency's decision on the admissibility of the Appellant's request for technical equivalence. Consequently, CERA would only have had an interest in the result of the case if the subject matter of the appeal had been a substantive decision on technical equivalence taken by the Agency.
10. The Appellant argues that, since it is challenging a decision on the admissibility of its request for technical equivalence and not a decision on technical equivalence itself, it is not possible for CERA to have a direct interest in the result of the present case at this stage of the proceedings.
11. The Appellant argues that the fact that CERA intervenes in ongoing litigation in France cannot lead to the conclusion that CERA has an interest in the outcome of the present case, since the subject matter is different from that of the present appeal

² 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).

proceedings and there is therefore no need for CERA to repeat the arguments put forward in the national proceedings.

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 An interest in the result of the case can be recognised where the future decision is likely to have a negative effect on the economic situation of the applicant for leave to intervene.⁴
14. 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.
15. CERA has been included in the list of suppliers of active substances and biocidal products maintained by the Agency pursuant to Article 95 for the Appellant's BTI AM65-52 strain following, *inter alia*, the assessment of ANSES establishing the technical equivalence between BTI AM65-52 and BTI BMP 144.
16. CERA entered into a data sharing agreement with the Appellant in order to obtain permission to refer to certain studies owned by the Appellant in support of its product authorisation dossiers.
17. CERA has been authorised to market its biocidal products containing BTI BMP 144 in several Member States on the basis of the authorisations it had obtained in France, which in turn were based on the technical equivalence assessment carried out by ANSES.
18. CERA is involved in ongoing litigation in France in which the authorisations granted to it by ANSES are being challenged.⁵
19. 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.
20. 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

³ 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, by analogy, order of the President of the General Court of 11 August 2021, *Symrise AG v ECHA*, T-655/20, EU:T:2021:516, paragraphs 26 and 30.

⁵ See paragraph 7 above.

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 interests of CERA, by calling into question ANSES's competence to establish the technical equivalence between BTI AM65-52 and BTI BMP 144.⁶

21. Moreover, the outcome of the present proceedings may lead to a new technical equivalence assessment, and might therefore lead to a decision that would contradict the assessment already carried out by ANSES.
22. Therefore, the Board of Appeal's decision on the Appellant's request to annul the Contested Decision is capable of altering CERA's legal position and having a negative effect on CERA's economic situation. It must therefore be concluded that, contrary to the Appellant's arguments,⁷ CERA 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.
23. 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 CERA 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 CERA may submit a statement in intervention.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal

⁶ See decision of the Board of Appeal of 5 March 2024 on the application to intervene by ANSES, *Sumitomo Chemical Agro Europe SAS*, A-010-2023, paragraph 18.

⁷ See paragraphs 9, 10 and 11 above.