EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	12 October 2023
Case	A-010-2023
Appellant	Sumitomo Chemical Agro Europe SAS, France
Appeal received on	4 September 2023
Subject matter	A decision taken by the European Chemicals Agency under Article 54(4) of the Biocidal Products Regulation[2]
Keywords	*Biocidal products – Strains of micro-organisms – Necessity and competence to establish technical equivalence – Manifest error of assessment – Scope of Article 54*
Contested Decision	TAP-C-1665698-01-00/F
Language of the case	English

Background and remedy sought by the Appellant

Bacillus thuringiensis subsp. *israelensis* Serotype H14, Strain AM65-52 ('**BTI AM65-52**'), manufactured by the Appellant, is an active substance approved for use in biocidal products of product-type 18 under Commission Directive 2011/78/EC.[3]

In the preparation of the renewal of its active substance, the Appellant has been informed by the Agency that a successful renewal would also cover another strain (*bacillus thuringiensis* subsp. *israelensis* Strain BMP 144; '**BTI BMP 144**'), which is manufactured by another company, due to the latter having received a positive technical equivalence decision from the *Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail* (ANSES), the Competent Authority of France.

On 11 August 2022, the Appellant submitted to the Agency a request for a decision on whether BTI AM65-52 and BTI BMP 144 are technically equivalent.

On 6 June 2023, the Agency adopted the Contested Decision rejecting the Appellant's request.

In the Contested Decision, the Agency concluded that the technical equivalence assessment between BTI AM65-52 and BTI BMP 144 is not necessary. First, the Agency found that there was no legal necessity for the Appellant to obtain a technical equivalence decision from the

[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 (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; the 'BPR'). All references to Articles concern the BPR unless stated otherwise.

[3] OJ L 243, 21.9.2011, p. 7–9.

Agency as a condition for authorising a biocidal product under Article 19(1)(c). Second, the Agency found that the technical equivalence at issue had already been carried out by ANSES.

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

Pleas in law and main arguments

The Appellant makes the following claims.

- The Agency infringed Article 54 by adding conditions that are not provided in the BPR. According to the Appellant, the Agency erred in limiting the need for a technical equivalence decision to applications under Article 19 because Article 54 does not contain a condition that limits its application to Article 19.
- The Agency misinterpreted the meaning of the word "necessary" contained in Article 54 and committed a manifest error of assessment by not considering the Appellant's application for technical equivalence as necessary. According to the Appellant, the BPR does not specify the conditions under which the establishment of technical equivalence is considered necessary, and therefore the necessity of a decision on technical equivalence has to be assessed on a case-by-case basis. In this respect, the Appellant argues that, under Article 54, it is for the applicant, and not for the Agency, to determine whether or not the establishment of technical equivalence is necessary.
- The Agency committed a manifest error of assessment by (i) considering that ANSES had already established that BTI AM65-52 and BTI BMP 144 were technically equivalent, and (ii) failing to take into account that ANSES was not competent to assess technical equivalence and that BTI AM65-52 and BTI BMP 144 could not be considered as equivalent. According to the Appellant, the application for authorisation of the products using BTI BMP 144 was submitted after the entry into force of the BPR, 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.
- The Agency committed a manifest error of assessment by deviating from its document entitled 'Recommendation for applicants on information requirements and assessment of applications for technical equivalence of active micro-organisms', published on the Agency's website in September 2020. According to the Appellant, the Agency disregarded that that document provides that two different strains, as in the case of BTI AM65-52 and BTI BMP 144, correspond to different active substances. Therefore, the Agency should have considered that the renewal of the approval of BTI AM65-52 and BTI BMP 144 was to be sought through the submission of two distinct applications.
- The Agency infringed Article 54 by relying on arguments concerning the completeness of the Appellant's technical equivalence application in order to reject its admissibility. According to the Appellant, the Agency should have taken into account the specificities of the present case and therefore should have considered the completeness of the Appellant's technical equivalence application only at a later stage of the procedure.

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