EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	6 October 2022
Case	A-007-2022
Appellant	SoftOx Solutions AS, Norway
Appeal received on	5 August 2022
Subject matter	A decision taken by the European Chemicals Agency under Article 54(4) of the Biocidal Products Regulation[2]
Keywords	*Biocidal products – Technical equivalence – Rectification of a decision by the Executive Director*
Contested Decision	TAP-D-1571123-32-00/F
Language of the case	English

Background and remedies sought by the Appellant

Active chlorine released from hypochlorous acid (the **Active Substance**) is an active substance approved for use in biocidal products of product-types 1, 2, 3, 4 and 5 under Commission Implementing Regulations (EU) No 2021/347[3] and No 2021/365[4] (the **Implementing Regulations**).

On 9 September 2021, the Appellant that manufactures the Active Substance filed an application with the Agency to establish the technical equivalence of its alternative source of the Active Substance with the reference source of the Active Substance as defined in the Implementing Regulations.

On 13 May 2022, the Agency adopted the Contested Decision rejecting the Appellant's application. In that decision, the Agency found that technical equivalence could not be established because in the Appellant's application the maximum concentration for one of the impurities (the **Concerned Impurity**) was too high when compared to the reference specification.

[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).

[3] OJ L 68, 26.2.2021, p. 170.

[4] OJ L 70, 1.3.2021, p. 9.

On 5 August 2022, the Appellant filed an appeal against the Contested Decision, requesting the Board of Appeal to annul the Contested Decision and to replace it with a decision establishing technical equivalence. In the alternative, the Appellant requested the Board of Appeal to remit the case to the competent body of the Agency and order the Agency to grant the Appellant the opportunity to update its application with new information.

In addition, the Appellant requested the Board of Appeal to order the Agency to exchange with the Appellant further information on:

- the analytical methods used to establish the reference specification;
- the chemical name and concentration limit of the Concerned Impurity; and
- the Agency's assessment underlying the Contested Decision.

The Appellant also requested the Board of Appeal to order a refund of the appeal fee.

Pleas in law and main arguments

The Appellant argued that the Agency breached the Appellant's rights of good administration and defence. According to the Appellant, the Agency prevented the Appellant from defending itself in the course of the decision-making procedure by refusing access to necessary information on the reference specification.

The Appellant also argued that the Agency breached the Appellant's legitimate expectations by incorrectly applying its own Guidance on Technical Equivalence in the assessment of the Appellant's application.

The Appellant also argued that the Agency exceeded its powers in several respects.

First, the Appellant argued that the Agency misinterpreted the technical equivalence criteria set out in Article 3(1)(w) of the Biocidal Products Regulation and that its assessment was scientifically flawed.

Second, the Appellant argued that the Contested Decision is disproportionate and unlawful insofar as it imposed on the Appellant requirements which went beyond the scope of the reference specification set out in the Implementing Regulations.

Rectification, withdrawal of the appeal and closure of the case

Pursuant to Article 93(1) of the REACH Regulation[5], which is applicable to the present case in accordance with Article 77 of the Biocides Products Regulation, the Acting Executive Director of the Agency rectified the Contested Decision by withdrawing it. Subsequently, the Appellant withdrew the appeal and the Chairman of the Board of Appeal closed the case on 6 October 2022.

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

[5] 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).