EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	23 April 2019
Case	A-004-2019
Appellant	ARKEMA France, Colombes, France
Appeal received on	6 March 2019
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 54(4) of the Biocidal Products Regulation ('the BPR')
Keywords	*Technical equivalence – Hazard profile – Error of assessment – Duty to state reasons – Good administration – Legitimate expectations – Principle of proportionality*
Contested Decision	TAP-D-1340769-21-00/F
Language of the case	English

Background and remedy sought by the Appellant

'*Active chlorine released from sodium hypochlorite*' has been approved as an existing active substance for use in biocidal products of product-types 1, 2, 3, 4 and 5 under Commission Implementing Regulation (EU) No 2017/1273 of 14 July 2017 (the 'Implementing Regulation'). The Implementing Regulation states that the degree of the purity of '*active chlorine released from sodium hypochlorite*' that had been evaluated for the purposes of approval amounted to ≤ 18% w/w in a aqueous solution with active chlorine concentration and that '*[t]he active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance*.'

The Appellant manufactures '*active chlorine released from sodium hypochlorite*' and filed an application before the Agency to establish the technical equivalence of its alternative source of the active substance with the reference source of the active substance approved under the Implementing Regulation (the 'alternative source of the active substance' and the 'reference source of the active substance').

On 7 December 2018, the Agency adopted the Contested Decision which rejects the Appellant's application.

In the Contested Decision, the Agency found that technical equivalence cannot be established because it cannot be excluded that the alternative source of the active substance has a different hazard profile from the reference source of the active substance. This was because the alternative source of the active substance had a higher concentration of active chlorine than the reference source.

[1] Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, as amended by Commission Implementing Regulation (EU) 2016/823.

ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Remedy sought by the Appellant

The Appellant requests the Board of Appeal:

- to annul the Contested Decision,
- replace the Contested Decision with a decision establishing the technical equivalence of the alternative source of the active substance and the reference source of the active substance, and
- to refund the appeal fee.

Pleas in law and main arguments

The Appellant makes the following claims.

- The Agency made an error of assessment and breached Article 54(4) of the BPR for the following reasons:
    - The Agency did not take into consideration scientific data on corrosion submitted by the Appellant during the proceedings showing that skin corrosion cannot differ depending on the different concentrations of active chlorine in the alternative source and the reference source of the active substance, and
    - the Agency did not take into consideration that the hazard classification was the same for both the reference source and the alternative source of the active substance under the CLP Regulation.
- The Agency breached the duty to state reasons because it did not justify why the information provided by the Appellant was insufficient. The Agency considered that more information was needed to determine that changes in the composition in the Appellant's alternative source of the active substance did not result in an unacceptable change of the hazard profile compared to the reference source.
- The Agency breached the duty of good administration because it did not specify what information the Appellant should have submitted to address concerns on the toxicity of the alternative source of the active substance.
- The Agency breached the Appellant's legitimate expectations because it acted contrary to the Guidance on Technical Equivalence which states that only an unacceptable change in the hazard profile would prevent a decision approving technical equivalence.
- The Agency breached Article 62 of the BPR and its own Guidance for human health risk assessment because the Contested Decision implicitly requires additional vertebrate animal testing when the active substance, predicted to be corrosive, should not be tested on animals.
- The Agency breached the principle of proportionality because the Contested Decision requires additional animal studies that are not necessary and appropriate because all studies performed on the sources of the active substance with a concentration equal or above 5% of active chlorine (as was the case for both the alternative and the reference source of the active substance) would result in the same findings as regards the hazard profile of the active substance.

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