

**SUMMARY OF DECISION OF 24 NOVEMBER 2020 OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-004-2019

(Biocidal Products Regulation – Technical equivalence – Similarity of hazard profiles – Right to good administration – Duties of the Agency)

Factual background

The Appellant is a manufacturer of active chlorine released from sodium hypochlorite which is used as an active substance in biocidal products.

On 14 July 2017, the Commission adopted Implementing Regulation (EU) 2017/1273 (the 'Implementing Regulation') by which it approved active chlorine released from sodium hypochlorite as an existing active substance for use in biocidal products in certain product-types.

On 18 May 2018, the Appellant submitted an application to the Agency under Article 54(1) of the Biocidal Products Regulation (the 'BPR') seeking to establish technical equivalence between its alternative source of active chlorine released from sodium hypochlorite and the reference source as defined in the Implementing Regulation.

The active chlorine concentration of the Appellant's alternative source exceeds the maximum concentration limit set out in the Implementing Regulation. In the contested decision the Agency found that the Appellant had not provided sufficient evidence to show that this difference in the composition does not result in an unacceptable change of the hazard profile. The Agency therefore rejected the Appellant's application.

The Appellant requested the Board of Appeal to annul the contested decision and establish the technical equivalence.

Main findings of the Board of Appeal

The Board of Appeal found that the Agency had breached the Appellant's right to good administration in two respects.

First, the Agency failed to specify clearly and comprehensively the additional information needed to assess the Appellant's application.

If the Agency considers that an application for technical equivalence does not contain all the necessary information for the assessment of technical equivalence it must, under Article 54(5) of the BPR, request the applicant to provide additional information. Any such additional information request must be sufficiently clear and comprehensive as to allow the applicant to gather and submit the additional information needed. In the present case, the Agency failed to comply with this requirement as it merely stated that the Appellant should provide more information on 'local toxicity' without specifying what information was needed and on which effects.

Second, the Agency failed to respect the Appellant's right to be heard by rejecting the application partly on considerations on which the Appellant did not have an actual opportunity to make known its views.

The Agency referred to the need for information on respiratory irritation for the first time in an informal teleconference that took place only eight days before the expiry of the deadline granted to the Appellant to submit comments on the draft decision. Therefore, the Appellant had no actual opportunity to make known its views on the need for information on respiratory irritation before the adoption of the contested decision.

The Board of Appeal annulled the contested decision but considered that it was not possible to assess the technical equivalence before giving the Appellant the opportunity to submit additional information which has been clearly and comprehensively specified by the Agency. Therefore, the Board of Appeal remitted the case to the Agency for further action.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 77 of the BPR. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

*The full text of the decision is available on the Board of Appeal's section of ECHA's website:
<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>*