

**SUMMARY OF THE DECISION OF 9 NOVEMBER 2021 OF THE BOARD OF APPEAL  
OF THE EUROPEAN CHEMICALS AGENCY**

**Joined Cases A-006-2020 and A-007-2020**

*(Dossier evaluation – Compliance Check – Tonnage downgrade – Cut-off point for considering dossier updates – Substantial new information – Duties of the Agency – Proportionality – Article 25)*

*Factual background*

The appeal concerned the compliance check of the Appellants' registration dossiers for the substance reaction product of [29H, 31 H-phthalocyaninato (2-)-N29, N30, N31, N32] zinc, sulphuric acid and caustic soda (EC No 939-524-8; the 'Substance').

The Appellants are the only registrants of the Substance. They initially registered it at the tonnage band of 100 to 1000 tonnes per year. After having received the Agency's draft decision on the compliance check of their dossiers, both Appellants downgraded their tonnage band from 100 to 1000 tonnes per year to 10 to 100 tonnes per year (the 'tonnage downgrades').

By the contested decision, the Agency requested information on studies under Annexes VII, VIII and IX of the REACH Regulation. The Appellants requested the Board of Appeal to annul the contested decision insofar as it concerned the information requirements set out in Annex IX to the REACH Regulation. The Appellants argued that the REACH Regulation does not define any cut-off point that would allow the Agency to disregard new facts in the decision-making process. Following the tonnage downgrades, the Appellants argued that the Annex IX requirements should not have applied to their respective dossiers.

*Main findings of the Board of Appeal*

In its decision of 9 November 2021, the Board of Appeal annulled the contested decision insofar as it concerned the information requirements set out in Annex IX of the REACH Regulation and remitted the case to the Agency for further action.

The Board of Appeal held that the REACH Regulation does not preclude the Agency from taking into account tonnage downgrades during a compliance check process. The Agency's refusal to take into account the tonnage downgrades was based on an administrative cut-off point set by the Agency. When establishing and implementing this cut-off point, the Agency must balance the need for administrative efficiency with other relevant considerations, in particular the obligation to take into account all the relevant factors and circumstances of the case. Also, the Agency should have set up a mechanism to take into account substantial new information coming to light after the cut-off point.

The Agency's powers under Article 41 of the REACH Regulation aim, first, at identifying the potential data-gaps in the evaluated registration dossier at the time of the adoption of the compliance check decision, and, second, at requiring that the registrant submits the information needed to fill those data-gaps. Therefore, the fact that the Appellants initially registered the Substance at a higher tonnage band did not allow the Agency to refuse to take

into account the tonnage downgrades that occurred after the Appellants received the compliance check draft decision.

In the present case, the Board of Appeal found that the tonnage downgrades constituted substantial new information that the Agency should have taken into account during the decision-making process. The tonnage downgrades must be subject to an individual assessment in order to determine whether they rely on objective industrial or commercial considerations or are primarily triggered by the receipt of the draft compliance check decision and therefore amounted to an abuse of procedure.

By refusing to assess the tonnage downgrades, the Agency breached, first, its duty to take into consideration all the relevant factors and circumstances of the case and, second, its duty to ensure that the Appellants carry out studies on vertebrate animals only as a last resort under Article 25(1) of the REACH Regulation.

**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 91(1) of the REACH Regulation and Article 77(1) of the Biocidal Products Regulation. 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.

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*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>*