

SUMMARY OF THE DECISION OF 13 AUGUST 2024 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-001-2023

*(Dossier evaluation – Compliance check – Tonnage downgrade –
Right to good administration)*

Background

The appeal concerned a compliance check of the registration for the substance 1,6-dichlorohexane (the '**Substance**')¹.

The Appellant initially registered the Substance at the 100 to 1 000 tonnes per year tonnage band. After having received the Agency's draft decision on the compliance check of its dossier, the Appellant downgraded its tonnage band from 100 to 1 000 tonnes per year to 10 to 100 tonnes per year (the '**tonnage downgrade**'). The Agency acknowledged the tonnage downgrade by adopting a completeness check decision under Articles 22(3) and 20(2) of the REACH Regulation².

By the Contested Decision, the Agency requested information on studies under Annexes VII, VIII and IX.

The Appellant requested the Board of Appeal to annul the Contested Decision insofar as it concerned the information requirements set out in Annex IX. The Appellant also requested the Contested Decision to be amended to the effect that the Appellant was identified as an addressee to which Annex VIII, as the highest annex, is applicable.

In the first place, the Appellant argued that the Agency breached Article 41. According to the Appellant, following the completeness check decision, the Agency could require the Appellant to fulfil only the information requirements under Annexes VII to VIII, and not also those under Annex IX, since the Appellant's ability to legally manufacture or import the Substance had been restricted to a maximum of 100 tonnes per year. The Appellant also argued that the Agency was prevented from assessing the relevance of the tonnage downgrade for the ongoing compliance check process.

In the second place, the Appellant argued that the Agency breached Article 41 of the Charter of Fundamental Rights of the European Union and its duty to examine each case individually. According to the Appellant, the Agency could not presume that a tonnage downgrade made after receiving a draft compliance check decision is used by a registrant to escape its responsibilities. In addition, the Appellant argued that the volume of a substance produced in the calendar year preceding a tonnage downgrade is not a reliable indicator of the industrial or commercial considerations justifying that tonnage downgrade.

Main findings of the Board of Appeal

The Board of Appeal annulled the Contested Decision insofar as the Appellant was identified as a registrant to which Annex IX applies and remitted the case to the Agency for further action.

¹ EC No 218-491-7; CAS No 2163-00-0.

² 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). All references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise.

The Board of Appeal rejected the Appellant's plea regarding the breach of Article 41. In the present case, the Agency was entitled to verify whether the tonnage downgrade was relevant for the ongoing compliance check process. The Board of Appeal also found that the completeness check decision did not deprive the Agency of its power to verify the relevance of the tonnage downgrade during the ongoing compliance check process. Therefore, the Agency did not breach Article 41 by proceeding to that verification in the framework of the compliance check process leading to the Contested Decision.

However, the Board of Appeal upheld the Appellant's plea regarding the breaches of Article 41 of the Charter of Fundamental Rights of the European Union and of the Agency's duty to examine each case individually.

The Board of Appeal held that the REACH Regulation does not prevent the Agency from assessing a tonnage downgrade submitted by a registrant after receiving a draft compliance check decision. Notwithstanding the Agency's discretion to set an administrative cut-off point in a decision-making process, the Agency is required to take into account all relevant factors and circumstances of a particular case until the final decision is adopted. Such an obligation may exceptionally be limited, after an administrative cut-off point, to substantial new information. The Agency must have in place mechanisms to take into account substantial new information coming to light after the cut-off point.

The Agency may disregard a tonnage downgrade made after the receipt of a draft compliance check decision if it is established, following an individual assessment, that such a tonnage downgrade amounts to an abuse of procedure.

In the present case, the Board of Appeal found that, by limiting its assessment to the examination of the volume of the Substance produced by the Appellant in the calendar year preceding the tonnage downgrade and without considering any other factors, the Agency failed to proceed to an individual assessment to determine whether the tonnage downgrade amounted to an abuse of procedure.

First, the Board of Appeal considered that the volume of the Substance produced in the calendar year preceding the tonnage downgrade was only one of the elements that the Agency should consider in its assessment.

Second, the examination of the objective industrial or commercial considerations that led the Appellant to decide and justify the tonnage downgrade could not be limited to the examination of the volume of the Substance produced in the calendar year preceding the tonnage downgrade.

Third, the Agency should have gathered evidence to prove a possible abuse of procedure on the part of the Appellant.

The Board of Appeal consequently concluded that, in the present case, the Agency failed to carry out an individual assessment of the tonnage downgrade and therefore breached the Appellant's right to good administration.

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. 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:
<https://echa.europa.eu/about-us/who-we-are/board-of-appeal>