EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF THE DECISION OF 21 OCTOBER 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case A-001-2019

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Weight-of-evidence – Error of assessment)

Factual background

The Appellant sought the annulment of an ECHA decision taken under Article 42(1) of the REACH Regulation in follow-up to an initial compliance check decision concerning sulphur hexafluoride (EC No 219-854-2, CAS No 2551-62-4; the 'Substance').

In the initial compliance check decision taken under Article 41 of the REACH Regulation, the Agency found that the Appellant's registration dossier was missing information on a pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex IX to the REACH Regulation).

To fill the data-gap identified by the Agency, the Appellant updated its dossier with a weight-of-evidence adaptation. However, in the follow-up compliance check decision taken under Article 42(1) of the REACH Regulation (the 'Contested Decision'), the Agency rejected the adaptation and found that the Appellant's registration dossier still does not comply with Section 8.7.2. of Annex IX to the REACH Regulation.

Main findings of the Board of Appeal

In its Decision of 21 October 2020, the Board of Appeal dismissed the appeal.

The Board of Appeal decided that the Contested Decision was correctly based on Article 42(1) of the REACH Regulation.

The Board of Appeal also rejected the Appellant's claim that the Contested Decision must be annulled because it did not contain '*adequate time limits for the submission of further information*' within the meaning of Article 41(3) of the REACH Regulation.

Article 42(1) of the REACH Regulation provides that follow-up compliance check decisions taken under that provision must be drafted in accordance with Article 41 of the REACH Regulation. However, the Board of Appeal found that the requirement to specify adequate time limits for the submission of further information set out in Article 41(3) of the REACH Regulation is not relevant to the follow-up compliance check procedure. Therefore, the Agency was not required to specify a time limit in the Contested Decision for the Appellant to provide the PNDT study missing from its dossier.

In addition, the Board of Appeal rejected the Appellant's claim that the Contested Decision breached the principle of legal certainty. Contrary to the Appellant's arguments, it was clear from the Contested Decision that the Appellant's registration dossier is non-compliant, that the Appellant is still required to provide information on a PNDT study, and that the competent authorities of the Member States may decide to take enforcement action against the Appellant. It was also clear that the Appellant could still rely on an adaptation to meet the requirement of Section 8.7.2. of Annex IX to the REACH Regulation.

The Appellant's claim that the Agency breached the principle of the protection of legitimate expectations by failing to specify an adequate time limit for the Appellant to provide the PNDT study was also rejected. In particular, it could not be inferred from the Agency's guidance documents, or the case-law of the General Court of the European Union and of the Board of Appeal, that the Agency would specify an additional time limit to provide the PNDT study.

The Board of Appeal also rejected the Appellant's claim that the Agency committed an error of assessment by failing to take into account a relevant study and in concluding that the Appellant's weight-of-evidence adaptation failed to meet the requirements of Section 1.2. of Annex XI to the REACH Regulation. The Board of Appeal found that, from the Appellant's weight-of-evidence adaptation, even when the evidence is taken together, it is not possible to identify and characterise the pre-natal developmental toxicity of the Substance. The Appellant's weight-of-evidence adaptation did not contain sufficient evidence leading to the '*assumption/conclusion*', within the meaning of Section 1.2. of Annex XI, that the Substance is not a pre-natal developmental toxicant.

The Appellant's claim that the Agency breached the Appellant's right to be heard was also rejected. The Appellant had argued that the Agency changed the wording of the draft decision on which it had commented by inserting substantial new information. The Appellant claimed that it should have had the opportunity to make its views known on this change.

The Board of Appeal found however that the Agency had provided the Appellant with the opportunities to be heard foreseen in the REACH Regulation. Since the changes made to the Contested Decision were not decisive to the findings in the Contested Decision, the Agency was not obliged to grant the Appellant further opportunities to be heard.

The Appellant's pleas that the Agency breached Article 25 of the REACH Regulation and the principle of proportionality were also rejected. In the Contested Decision, the Agency rejected the Appellant's adaptation and concluded, without committing an error, that the Appellant's registration dossier still has a data-gap under Section 8.7.2. of Annex IX. Under the REACH Regulation, the Appellant is obliged to submit either information on a PNDT study or, alternatively, an acceptable adaptation. As a consequence, in adopting the Contested Decision, the Agency was neither required nor empowered to consider whether it is proportionate, or consistent with Article 25, for the Appellant to be required to submit this information.

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.

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