EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 9 APRIL 2019 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-001-2018

(Dossier evaluation – Compliance check – Registration dossier update during the decision–making procedure – Cut-off points for considering dossier updates – Legal certainty – Duties of the Agency)

Factual background

The appeal concerns a compliance check decision (the 'Contested Decision') on the Appellant's registration dossier for sodium hydroxymethanesulphinate (EC number 205-739-4, CAS number 149-44-0; 'the Substance').

The appeal focused on the Agency's practice of not taking into account, in its compliance check decisions, dossier updates received after the draft decision is sent to the registrant for comments (the 'cut-off point for updates').

The Agency's practice regarding cut-off points for updates was set out in a news alert of 28 January 2015, a practical guide from July 2015, and in the cover letter to the draft decision sent to the Appellant on 14 December 2015.

On 16 August 2017, the Appellant updated its registration dossier. In its dossier update, the Appellant amended the descriptions of the uses of the Substance.

On 10 November 2017, the Agency adopted the Contested Decision requiring the Appellant to submit the same information as that set out in the draft decision of 14 December 2015, namely:

1. Carcinogenicity study (Section 8.9.1. of Annex X; test method: OECD TG 451), in rats, oral route;
2. Pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex X; test method: EU B.31/OECD TG 414) in a second species (rabbits), oral route; and
3. Extended one-generation reproductive toxicity study ('EOGRTS') (Column 2 of Section 8.7.3. of Annex X; test method: EU B.56/OECD TG 443) in rats, oral route, with certain study-design specifications, including extension of cohort 1B to include the F2 generation.

According to the cover letter to the Contested Decision, the Agency adopted the decision without taking into account the Appellant's dossier update of 16 August 2017 as the Appellant had submitted that update after the cut-off point for updates.

The Appellant challenged the Agency's refusal to take into account the dossier update. The Appellant requested the Board of Appeal to annul the requirements in the Contested Decision to provide information on a carcinogenicity study and a PNDT study. The Appellant also requested the partial annulment of the requirement to provide information on an EOGRTS, insofar as it required the extension of cohort 1B to include the F2 generation.

Main findings of the Board of Appeal

The Board of Appeal decided that the Agency's notification of the cut-off point for updates to the Appellant failed to meet the fundamental requirement of the principle of legal certainty. Under that principle, registrants must be made aware in a timely manner and in a clear and precise way of the applicable rules so that they can plan their actions accordingly.

The Board of Appeal found that the cut-off point for updates was expressed inconsistently and confusingly by the Agency in the news alert, in the practical guide, in the letter accompanying the draft decision, and during the appeal proceedings. The Agency also acted contrary to its own communications regarding the cut-off point for updates. It was therefore unclear to the Appellant whether, and in what circumstances, a dossier update submitted after the draft decision was notified to it would be taken into account.

The Agency also breached the requirement for legal certainty by failing to ensure that the exact cut-off point applicable in the present case was communicated in a timely manner so that the Appellant could know precisely the time at which the measure came into being and began to have legal effects. Since the Appellant was notified of the deadline for dossier updates to be taken into account on the same day as that deadline expired, it was unable to react to this deadline. Furthermore, as the Appellant could not have been aware of the Agency's strict deadline for dossier updates prior to receiving the letter accompanying the draft decision, it was not able to plan for this situation. Even if the Appellant had clearly understood in advance that the cut-off point for updates was the date it received the draft decision, it did not know when it would receive the draft decision. Therefore, the Appellant had no way of knowing in advance the date of the cut-off point for updates.

The form of order sought by the Appellant was therefore upheld in its entirety. The requirements to provide information on a carcinogenicity study and a PNDT study were annulled and the case remitted to the Agency for further action in relation to these two endpoints. The requirement to provide information on an EOGRTS was annulled in so far as it required the extension of cohort 1B to include the F2 generation.

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: http://echa.europa.eu/about-us/who-we-are/board-of-appeal