ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 13 DECEMBER 2017 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-023-2015

(Substance evaluation – Article 42 – Section 8.7.2. of Annex IX – Grounds for concern – Pre-natal developmental toxicity – Mutagenicity – Manifest error of assessment – Article 25 – Right to be heard)

Factual background

The Appellants requested the Board of Appeal to partially annul an ECHA decision on the substance evaluation of tert-butyl perbenzoate (CAS No 614-45-9, EC No 210-382-2) (the 'Substance') in so far as it required them to provide information on a pre-natal developmental toxicity ('PNDT') study in a second species (OECD TG 414) and a Comet assay (OECD TG 489).

During the substance evaluation of the Substance by the Competent Authority of Italy (the eMSCA), the lead registrant (one of the Appellants) updated its registration dossier with the results of a first species PNDT study pursuant to a testing proposal decision. Based on the results of that study the Agency submitted a proposal for amendment to include a request for a second species PNDT study in the substance evaluation decision. The request to perform a Comet assay was added to the Contested Decision following a proposal for amendment from Denmark.

Main findings of the Board of Appeal

1. Arguments regarding the PNDT study in a second species

The Board of Appeal rejected the Appellants' arguments that the Agency had failed to demonstrate a concern related to developmental toxicity to justify the request for a PNDT study in a second species under substance evaluation. The Board of Appeal considered that the results of the first species PNDT study were sufficient to justify the request for a second species PNDT study. In reaching its conclusion the Board of Appeal rejected the Appellants' arguments that the Agency had committed errors in interpreting the results of the first species PNDT study (paragraphs 45 to 97 of the Board of Appeal's decision).

The Board of Appeal also rejected the Appellants' arguments that the Agency had breached the REACH Regulation by requesting the second species PNDT study under substance evaluation rather than dossier evaluation (paragraphs 102 to 134).

In this respect, the Board of Appeal found that the Agency had not breached Article 42 of the REACH Regulation. The Agency had acted according to Article 42(2) by sending a letter to the Member States and the Commission closing the dossier evaluation following the submission of the results of the first species PNDT study (paragraphs 114 to 120).

The Board of Appeal also found that to meet their registration obligations, where a first species PNDT study has been conducted, registrants registering a substance at 100 to 1 000 tonnes per year (such as the Appellants) must:

- conduct a second species PNDT study pursuant to Column 2 of Section 8.7.2. of Annex IX of the REACH Regulation, or

- provide a justification as to why a second species PNDT study is not required at the Annex IX level pursuant to Column 2 of Section 8.7.2. of Annex IX, or
- satisfy the information requirement through the application of Annex XI.

The Board of Appeal rejected the Appellants' claim that the Agency had breached Article 46 of the REACH Regulation. The Agency should usually request a second species PNDT study under dossier evaluation. However, in the present case, the Agency was able to follow the substance evaluation procedure because:

(a) the request to provide the second species PNDT study was not justified by a lack of standard information alone as the Agency had demonstrated a potential risk to human health (paragraphs 98 to 101 and 124 to 125), and

(b) the Appellants' rights were not prejudiced by the Agency's use of the substance evaluation procedure rather than the dossier evaluation procedure (paragraphs 126 to 132).

The Appellants' arguments that the Agency exceeded its competence by submitting proposals for amendment during the substance evaluation process were also rejected (paragraphs 182 to 187).

2. *Arguments regarding the Comet assay*

The Board of Appeal rejected, amongst others, the Appellants' arguments that:

- the Agency committed a manifest error of assessment in interpreting the information contained in the registration dossier as demonstrating that there is a mutagenicity concern (see paragraphs 203 to 226), and
- the Comet assay is not appropriate to address the mutagenic effects of the Substance as it degrades rapidly in the stomach (see paragraphs 251 to 254).

3. Arguments regarding the second species PNDT study and the Comet assay

The Board of Appeal rejected the Appellants' arguments that:

- the Agency breached Article 25 (paragraphs 269 to 282),
- the deadline to provide the requested information should be increased from 15 to 24 months (paragraphs 286 to 290),
- the Agency breached the principle of proportionality (paragraphs 293 to 300), and
- the Agency infringed the Appellants' right to be heard (paragraphs 303 to 324).

The Board of Appeal therefore dismissed the appeal in its entirety. Having regard to the suspensive effect of appeals, the Appellants must provide the information requested in the Contested Decision by 20 March 2019 (paragraphs 328 to 329).

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.
