EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-001-2018
Appellant	BrüggemannChemical, L. Brüggemann GmbH & Co. KG, Germany
Appeal received on	12 February 2018
Subject matter	A decision adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 41(3) of the REACH Regulation, in accordance with the procedure laid down in Articles 50 and 51 of the REACH Regulation
Keywords	*Dossier evaluation – Compliance check – Dossier update – Good governance – Cost-sharing – Proportionality*
Contested Decision	CCH-D-2114373456-42-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to revoke or annul the Contested Decision, or alternatively order the Agency to act to that effect. If the appeal is found to be inadmissible or is dismissed, the Appellant requests the Board of Appeal to amend the deadline set in the Contested Decision to take account of the suspensive effect of appeals.

The Appellant also requests the Board of Appeal to order the Agency to refund the appeal fee.

Pleas in law and main arguments

The Contested Decision was adopted by the Agency on 10 November 2017 following a compliance check of the Appellant's registration for the substance sodium hydroxymethanesulphinate (EC No 205–739–4, CAS No 149-44-0; the 'Substance'). The Contested Decision requires the Appellant to submit information on:

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.

[1] Announcement published in accordance with Article 6(6) of Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, as amended by Commission Implementing Regulation (EU) 2016/823.

In relation to all three information requirements, the Appellant claims that the Agency infringed the principle of good governance, as set out in Article 41 of the Charter of Fundamental Rights of the European Union and Article 10 of the European Union Code of Good Administrative Behaviour, as the Agency did not consider the dossier update submitted by the Appellant prior to adoption of the Contested Decision. The Appellant states that the dossier update in particular revised the '*use scenarios*' for the Substance.

The Appellant also claims that the carcinogenicity study cannot be requested by the Agency as the uses triggering the request for that study have been removed from the registration dossier. In support of this claim the Appellant argues that:

- the conditions set out in Column 2 of Section 8.9.1 of Annex X to the REACH Regulation are not met since there is no widespread dispersive use or evidence of frequent or long-term human exposure;
- as the uses triggering the information requirement have been removed from the registration dossier, by the analogous application of Article 50(3) of the REACH Regulation, the request is deprived of a legal basis and would be disproportionate; and
- the information requirement is contrary to Article 25(1) of the REACH Regulation according to which testing on vertebrate animals should be undertaken only as a last resort.

The Appellant also claims that the requirement to provide a PNDT study is based on Annex X of the REACH Regulation despite the fact that the information requirement is already triggered at Annex IX. The Appellant argues that as a result:

- the Agency infringed the Appellant's rights stemming from the provisions on data and cost sharing, as set out in the REACH Regulation and Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing, as the Appellant is prevented from requesting a share of the costs from members of the joint submission registering the Substance at the Annex IX level;
- the request for the PNDT study discriminates against the Appellant; and
- the request for the PNDT study contradicts Article 1(1) of the REACH Regulation as it does not enhance competitiveness for EU-based manufacturers.

The Appellant argues that the request for the PNDT study also breaches Article 41(2)(c) of the Charter of Fundamental Rights of the European Union and Articles 5(1) and 18(1) of the European Union Code of Good Administrative Behaviour as it does not provide sufficient justification on why the test is requested under Section 8.7.2 of Annex X rather than under Section 8.7.2 of Annex IX to the REACH Regulation.

Further information

The rules for the appeal procedure and other background information are available on the 'Appeals' section of the Agency's website:

http://echa.europa.eu/web/guest/regulations/appeals