

Announcement of appeal¹

Published on	06 June 2022
Joined cases	A-002-2022 and A-003-2022
Appellants	BASF Lampertheim GmbH, Germany (A-002-2022) Metall-Chemie GmbH & Co. KG, Germany (A-003-2022)
Appeals received on	11 April 2022 (A-002-2022) 14 April 2022 (A-003-2022)
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41 of the REACH Regulation ²
Keywords	<i>Dossier evaluation – Compliance check – Section 8.7.3. of Annex IX – Legal basis – Proportionality – Animal welfare</i>
Contested Decision	Decision of 14 January 2022 on the compliance check on O,O,O-triphenyl phosphorothioate (EC No 209-909-9; CAS No 597-82-0, the 'Substance'), notified to the Appellants under the following annotation numbers: CCH-D-2114580865-34-01/F (A-002-2022), and CCH-D-2114580866-32-01/F (A-003-2022)
Language of the cases	English

Background and remedy sought by the Appellants

By the Contested Decision, the Agency required the registrants of the Substance to submit information on an extended one-generation reproductive toxicity study ('EOGRTS'; Column 1 of Section 8.7.3. of Annex IX; test method: OECD TG 443) to be performed on rats, by oral route, with the following specifications:

- Ten weeks pre-mating exposure duration for the parental generation;
- Dose level setting shall aim to induce systemic toxicity at the highest dose level;
- Cohort 1A (Reproductive toxicity);

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.

² All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

- Cohort 1B (Reproductive toxicity) with extension to mate the Cohort 1B animals to produce the F2 generation which shall be followed to weaning;
- Cohorts 2A and 28 (Developmental neurotoxicity);
- investigations on learning and memory function as described in paragraph 37 of the OECD TG 426; and
- Cohort 3 (Developmental immunotoxicity).

The Appellants, which are both registrants of the Substance, request the Board of Appeal to partially annul the Contested Decision insofar as it requires the submission of information related to investigations on learning and memory function as described in paragraph 37 of the OECD TG 426.

The Appellants also request the Board of Appeal to order the refund of the appeal fees. In addition, if the Board of Appeal decides to uphold the Contested Decision, Metall-Chemie GmbH & Co. KG requests a reasonable extension of the deadline set in the Contested Decision for the submission of the requested information.

The Board of Appeal decided to join the two appeal cases on 24 May 2022.

Pleas in law and main arguments

The Appellants argue that the Agency breached Section 8.7.3. of Annex IX by requesting investigations on learning and memory function as described in paragraph 37 of the OECD TG 426. According to the Appellants, the contested information is not necessary to fulfil the standard information requirements under Annex IX and cannot therefore be required by the Agency under Article 41.

In addition, Metall-Chemie GmbH & Co. KG argues that the Agency breached Article 25 and the principle of proportionality by requiring information which is not necessary.

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>