EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	19 May 2022
Case	A-004-2022
Appellant	Symrise AG, Germany
Appeal received on	14 April 2022
Subject matter	A decision taken by the European Chemicals Agency ('the Agency') pursuant to Article 41 of the REACH Regulation[2]
Keywords	*Dossier evaluation – Compliance check – Sections 8.7.2. and 8.7.3. of Annex IX – Error of assessment – Powers of the Agency – Animal welfare – Right to be heard*
Contested Decision	CCH-C-2114591506-41-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 14 January 2022, the Agency adopted the Contested Decision following the compliance check of the registration dossiers for the substance (E)-anethole (EC No 224-052-0; CAS No 4180-23-8, the 'Substance'). In that decision, the Agency requires the Appellant and other registrants of the Substance to submit, by 21 October 2024, information on:

1. Transgenic rodent somatic and germ cell gene mutation assay (Column 2 of Section 8.4. of Annex IX; test method: OECD TG 488 from 2020) in transgenic mice or rats, oral route; or

   In vivo mammalian alkaline comet assay (Column 2 of Section 8.4. of Annex IX; test method: OECD TG 489) in rats, oral route;

2. Pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex IX; test method: OECD TG 414) by oral gavage, in one species (rat or rabbit); and

3. Extended one-generation reproductive toxicity study ('EOGRTS'; Column 1 of Section 8.7.3. of Annex IX; test method: OECD TG 443) by oral gavage, in rats specified as follows:
   - Ten weeks premating exposure duration for the parental (P0) generation;
   - Dose level setting must aim to induce systemic toxicity at the highest dose level;
   - Cohort 1A (Reproductive toxicity);
   - Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

[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.

The Appellant requests the Board of Appeal to partially annul the requirement to provide information on a PNDT study insofar as the Contested Decision requires the Substance to be administered via gavage in that study instead of via feeding.

The Appellant also requests the annulment of the requirement to provide information on an EOGRTS; in the alternative, the Appellant requests the partial annulment of that part of the Contested Decision insofar as it requires (a) the Substance to be administered via gavage instead of via feeding and (b) that the dose level setting must aim to induce systemic toxicity at the highest dose level.

The Appellant also requests the Board of Appeal to annul the Contested Decision in so far as it requires the Appellant to submit the required information by 21 October 2024.

Finally, the Appellant requests the Board of Appeal to order the refund of the appeal fee and take other such measures as justice may require.

Pleas in law and main arguments

In relation to each of the information requirements requested in the Contested Decision, the Appellant raises all or some of the following pleas in law:

- The Agency committed an error of assessment and exceeded its competence;
- The Agency breached Article 25, as well as Sections 8.7., 8.7.2. and 8.7.3. of Annex IX; and
- The Agency breached the Appellant's right to be heard.

The Appellant supports its pleas in law with the following arguments.

In relation to the second and third information requirements, the Appellant argues that gavage is neither necessary nor appropriate since it does not reflect human exposure and is more stressful to animals compared to the feeding mode of administration.

In relation to the third information requirement, the Appellant argues that the conditions triggering the EOGRTS under Annex IX are not fulfilled. The Appellant also argues that the Agency failed to provide it with the opportunity to comment on the potential need for additional information on the Substance before the Contested Decision was adopted. In addition, the Appellant argues that, by imposing a dose level setting based on fertility effects, the Agency disregarded the requirements of OECD TG 443.

In relation to all of the information requirements, the Appellant argues that the imposed timeframe for generating and submitting the requested information (33 months) obliges it to carry out the studies in parallel instead of in sequence. According to the Appellant, the Agency failed to take into account that the information requirements set out in the Annexes VII to X are cumulative and that the results of the first information requirement could indicate that the PNDT study and the EOGRTS are not needed.

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