EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	24 August 2022
Case	A-006-2022
Appellants	Symrise AG, Germany ADEKA Europe GmbH, Germany Evonik Dr. Straetmans GmbH, Germany CBW Chemie GmbH, Germany
Appeal received on	12 July 2022
Subject matter	A decision taken by the European Chemicals Agency ('the Agency') pursuant to Article 41 of the REACH Regulation[2]
Keywords	*Compliance check – Section 8.7.3. of Annex IX – Step-wise approach and timeline – Error of assessment – Legal certainty – Legitimate expectations*
Contested Decision	CCH-D-2114592346-40-01/F
Language of the case	English

Background and remedy sought by the Appellants

On 13 April 2022, the Agency adopted the Contested Decision following the compliance check of the registration dossiers for the substance Octane-1,2-diol (EC No 214-254-7; the 'Substance'). According to the Contested Decision, the Appellants are required to submit, by 19 July 2024, 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 premating exposure duration for the parental ('P0') generation;
- The highest dose level in P0 animals must be determined based on clear evidence of an adverse effect on sexual function and fertility without severe suffering or deaths as specified in Appendix 1 of the Contested Decision, or follow the limit dose concept. The reporting of the study must provide the justification for the setting of the dose levels;
- Cohort 1A (Reproductive toxicity); and
- Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation.

The Appellants request the annulment of the requirement to submit information on an EOGRTS; in the alternative, the Appellants request the Board of Appeal to exercise its powers under Article 93(3) by, for example, allowing for 36 months for the submission of the contested

[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.

information, and removing from Appendix 1 of the Contested Decision the following specification: "*Regarding the highest dose level, it is important to ensure that sufficient severity of toxicity in both female and male animals is achieved to ensure that potential effects on sexual function and fertility in either gender is not overlooked*".

The Appellants also request the Board of Appeal to order the Agency to refund the appeal fee and take such other or further measures as justice may require.

Pleas in law and main arguments

The Appellants argue that by requesting the contested information, the Agency erred in its assessment of the available data, failed to take all relevant information on the Substance into account, exceeded its competence, and breached Articles 13(3) and 25, as well as the principles of legal certainty and legitimate expectations.

The Appellants support their pleas in law with the following main arguments.

The Appellants argue that existing data on the Substance shows that before conducting the EOGRTS it is necessary to investigate the Substance's antimicrobial activity on the P0 animals' gut microbiome in order to (i) adequately assess the intrinsic properties of the Substance, and (ii) deliver a scientifically robust and regulatory compliant EOGRTS. According to the Appellants, a prior 12-month gut microbiome study is needed for selecting the appropriate dose levels and mode of administration for the EOGRTS. The Appellants argue that such a step-wise approach is essential to distinguish between specific/primary effects due to reproductive toxicity and generic/secondary effects due to systemic toxicity, as well as to conclude on a potential classification of the Substance under the CLP Regulation[3].

The Appellants also argue that, by imposing the top dose for the EOGRTS to be set '*as high as possible*' so as to induce '*sufficient severity of toxicity*' and investigate specific (reproductive) toxicity properties of the Substance, the Agency disregarded the requirements of OECD TG 443, which provide instead that '*some systemic toxicity*' is to be achieved to assess a potential non-specific adverse effect on sexual function and fertility.

The Appellants further argue that the specifications set out in the Contested Decision regarding the dose level setting for the EOGRTS, namely the requirement that '*sufficient severity of toxicity*' is to be achieved, have neither legal grounds nor allow the Appellants to ascertain unequivocally how to practically fulfil the contested information request. The Appellants cannot be therefore certain that, if they perform the requested EOGRTS, the Agency will accept it and not require the Appellants to repeat the study at a different dose level.

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

[3] Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.