EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Published on	29 August 2023
Case	A-009-2023
Appellant	Vevy Europe S.p.A., Italy
Appeal received on	18 July 2023
Subject matter	A decision taken by the European Chemicals Agency pursuant to Article 41 of the REACH Regulation[2]
Keywords	*Dossier evaluation – Compliance check – Right to be heard – Error of assessment – Article 25 of the REACH Regulation – Weight-of-evidence*
Contested Decision	CCH-D-2114633934-43-01/F
Language of the case	English

Background and remedy sought by the Appellant

On 18 April 2023, the Agency adopted the Contested Decision following a compliance check of the registration for the substance C10-C16-(linear and branched)-alkyl esters of salicylic acid (the **Substance**)[3].

The Contested Decision requires the Appellant to provide the following information on the Substance by 25 April 2025:

1. Skin sensitisation (Section 8.3. of Annex VII)
   i. *in vitro/in chemico* skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E) (Section 8.3.1. of Annex VII), and
   ii. if the *in vitro/in chemico* test methods specified under point i. above are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, *in vivo* skin sensitisation (Section 8.3.2. of Annex VII; test method: EU B.42./OECD TG 429);
2. *In vitro* gene mutation study in bacteria (Section 8.4.1. of Annex VII; test method: OECD TG 471, 2020);

[1] Announcement published in accordance with Article 6(6) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5).

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1). All references to Articles and Annexes concern the REACH Regulation unless stated otherwise.

[3] EC Number 950-068-9.

3. Long-term toxicity testing on aquatic invertebrates (triggered by Column 2 of Section 9.1.1. of Annex VII; test method: EU C.20./OECD TG 211);
4. Growth inhibition study on aquatic plants (Section 9.1.2. of Annex VII; test method: EU C.3./OECD TG 201);
5. Ready biodegradability (Section 9.2.1.1. of Annex VII; test method: EU C.4.A/B/C/D/E/F/OECD TG 301A/B/C/D/E/F or EU C.29./OECD TG 310).

The Appellant requests that the Board of Appeal:

- annuls the Contested Decision,
- orders the Agency to refund the appeal fee and other procedural costs, and
- takes such other or further measures as justice may require.

In the alternative, the Appellant requests the Board of Appeal to extend the deadline set in Contested Decision so that it is granted three years to provide the requested information.

Pleas in law and main arguments

Deadline to provide comments on the draft decision

The Appellant argues that the Agency breached the Appellant's right to be heard and Article 41 of the Charter of Fundamental Rights of the European Union (the 'Charter') by setting a deadline that was too short for it to provide comments on the draft decision.

Information on skin sensitisation

The Appellant argues that the Agency committed errors of assessment in deciding that the *in vivo* study available in its registration dossier contained irregularities, does not cover the specifications of current test methods and, therefore, does not allow for a conclusion to be reached on whether the Substance causes skin sensitisation. According to the Appellant, the study in its registration dossier was performed in compliance with the scientific methods available at the time the study was carried out.

The Appellant argues that the Agency breached the principle of proportionality and, by requiring the Appellant to repeat testing on vertebrate animals, breached Article 25.

The Appellant argues that the Agency breached Article 18 of the Cosmetics Regulation[4] and Article 16 of the Charter. This is because the Substance is used exclusively in cosmetic products and, as a result, carrying out tests on vertebrate animals could lead to a marketing ban and/or sanctions at the national level.

The Appellant argues that the Agency committed an error as the Contested Decision does not allow it to fulfil this information requirement through a weight-of-evidence approach.

Information on in vitro gene mutation in bacteria

The Appellant's registration dossier for the Substance includes an *in vitro* gene mutation study which was conducted prior to the entry into force of the REACH Regulation. The Appellant argues that the Agency committed an error of assessment in deciding that that study does not fulfil the information requirement as it did not comply with OECD TG 471. According to the Appellant, the study was performed according to the practice and guidelines existing at the time the study was carried out and fulfils the information requirement on *in vitro* gene mutation in bacteria.

[4] Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59).

The Appellant argues that the Agency committed an error as the Contested Decision does not allow it to fulfil this information requirement through a weight-of-evidence approach.

Information on long-term toxicity

The Appellant argues that, having regard to the properties of the Substance, the Agency committed an error of assessment in requiring it to provide information on long term toxicity.

The Appellant argues that the Agency committed an error as the Contested Decision does not allow it to fulfil this information requirement through a weight-of-evidence approach.

Information on growth inhibition on aquatic plants

The Appellant argues that, having regard to the properties of the Substance, the Agency breached Column 2 of Section 9.1.2. of Annex VII and committed an error of assessment in requiring the Appellant to provide information on growth inhibition on aquatic plants.

Information on ready biodegradability

The Appellant argues that the Agency committed an error of assessment and breached the applicable technical rules on biodegradability in requiring the Appellant to test single components of the Substance rather than the Substance as a whole.

Deadline to provide the requested information

The Appellant argues that the Agency committed an error of assessment in setting a deadline that was too short to provide the information requested in the Contested Decision.

Further information

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

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