EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

Announcement of appeal[1]

Case	A-009-2018
Appellant	Symrise AG, Germany
Appeal received on	12 June 2018
Subject matter	A decision taken by the European Chemicals Agency (the 'Agency') pursuant to Article 41 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 – Cosmetic ingredient – Testing on vertebrate animals - Error of assessment*
Contested Decision	CCH-D-2114386909-26-01/F
Language of the case	English

Remedy sought by the Appellant

The Appellant requests the Board of Appeal to annul the Contested Decision insofar as it requires information on:

- a sub-chronic toxicity study (90-day), oral route in rats (Section 8.6.2. of Annex IX to the REACH Regulation),
- a pre-natal developmental toxicity study in a first species (rat or rabbit), oral route (Section 8.7.2. of Annex IX), and
- an extended one-generation reproductive toxicity study ('EOGRTS') in rats, oral route (Section 8.7.3. of Annex IX),

The Appellant also requests the Board of Appeal to annul the Contested Decision insofar as it requires compliance within a timeline of 42 months instead of 54 months, and order the refund of the appeal fee.

Pleas in law and main arguments

The Agency adopted the Contested Decision on 13 March 2018 following a compliance check of the Appellant's registration dossier for the substance homosalate (EC No 204-260-8, CAS No 118-56-9). The Appellant registered homosalate exclusively for use as an ingredient in cosmetic products.

[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.

The Appellant submits that, in adopting the Contested Decision, the Agency committed errors of assessment, failed to consider all relevant information and breached the principle of legal certainty. In essence, according to the Appellant, the Agency cannot require a substance to be tested on vertebrate animals when that substance is exclusively used in cosmetic products, as this would be against the testing ban set out in Regulation (EC) No 1223/2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation') and, therefore, lead to a marketing ban under the same Regulation.

Moreover, according to the Appellant, the fact that workers may be exposed to a substance used as an ingredient in cosmetic products does not suffice to allow the Agency to require that substance to be tested on vertebrate animals under the REACH Regulation, as this would circumvent the testing ban set out in the Cosmetics Regulation.

The Appellant further argues that the requirement to submit information on an EOGRTS and the oral route selected for its conduct are not justified on the basis of the information available on homosalate. This requirement also breaches Article 25 of the REACH Regulation. In particular, the Appellant raises several issues affecting the relevance of the existing information which was used as a basis for the request to conduct the EOGRTS. However, the Agency failed to take that information into account.

Finally, the Appellant argues that the Agency made an error of assessment with regard to the deadline set 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:

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