ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 18 AUGUST 2020 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-009-2018

(Compliance check – Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX to the REACH Regulation – Substance used exclusively as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation)

Factual background

The appeal concerned the compliance check of a registration dossier for the substance homosalate (EC No 204-260-8, CAS No 118-56-9).

Homosalate is included in Annex VI to the Cosmetics Regulation[1] as an ultraviolet radiation filter allowed for use in cosmetic products with a maximum concentration of 10 %. The Appellant and/or its downstream users use homosalate exclusively as an ingredient in cosmetic products.

Following a compliance check under Article 41 of the REACH Regulation, the Agency required the Appellant to carry out the following studies on homosalate or, alternatively, provide acceptable adaptations:

- 90-day sub-chronic toxicity study (Section 8.6.2. of Annex IX),
- pre-natal developmental toxicity study (Section 8.7.2. of Annex IX), and
- extended one-generation reproductive toxicity study (Section 8.7.3. of Annex IX).

The Appellant requested the Board of Appeal to annul these information requirements.

Main findings of the Board of Appeal

The Appellant argued that the Agency could not require studies on vertebrate animals for human health endpoints because homosalate is used exclusively as an ingredient in cosmetic products. By requiring the Appellant to carry out the tests at issue, the Agency disregarded the prohibitions and restrictions on vertebrate animal testing in Article 18 of the Cosmetics Regulation.

The Board of Appeal examined the respective requirements of the Cosmetics Regulation and of the REACH Regulation.

The Board of Appeal found, firstly, that the Cosmetics Regulation prohibits testing on vertebrate animals, and imposes a marketing ban, if such testing is carried out '*in order to*

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

meet the requirements of [the Cosmetics Regulation]'. Testing carried out under the REACH Regulation on a substance used as a cosmetic ingredient is not, therefore, automatically carried out '*in order to meet the requirements of [the Cosmetics Regulation]*'.

Secondly, the REACH Regulation contains an exemption for substances used as cosmetic ingredients from (some) vertebrate animal testing requirements: under Section 3 of Annex XI to the REACH Regulation, a registrant of a substance used as a cosmetic ingredient may be able to waive certain studies if it can show that there is no (or no significant) exposure other than through the use of finished cosmetic products by end users. In effect, if a registrant can show that the risk posed by a substance arises only from the use covered by the Cosmetics Regulation and there is no other potential exposure (for example to workers), it may be able to waive a test by submitting an adaptation under Section 3 of Annex XI. In the case at issue, however, the requirements for an adaptation under Section 3 of Annex XI were not fulfilled.

The Board of Appeal held that ECHA had not made any errors in requiring the Appellant to provide the vertebrate animal tests in question. The appeal was dismissed.

NOTE: The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

Unofficial document, not binding on the Board of Appeal

The full text of the decision is available on the Board of Appeal's section of ECHA's website:
http://echa.europa.eu/about-us/who-we-are/board-of-appeal