

## **SUMMARY OF DECISION OF 12 DECEMBER 2017 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-013-2016**

*(Testing proposal – Testing on vertebrate animals – Substance registered exclusively for use as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation – Duty to state reasons)*

### *Background*

The substance 'reaction mass of sodium hydrogen N-(1-oxooctadecyl)-L-glutamate and stearic acid' (EC No 939-201-1; the 'Substance') is registered exclusively for use as an ingredient in cosmetic products.

The Appellant made a testing proposal for its registration of the Substance. It proposed to perform a pre-natal developmental toxicity study, which is a vertebrate animal study, on another substance and to read-across the results to the Substance.

The Agency rejected the read-across and required the test to be performed on the Substance itself. The Contested Decision did not mention the use of the substance as an ingredient in cosmetic products.

### *Main findings of the Board of Appeal*

The Board of Appeal held that ECHA breached its duty to state reasons.

The Board of Appeal considered that Article 2(4)(b) and Recital 13 of the REACH Regulation must be read as meaning that the REACH Regulation applies without prejudice to the prohibitions and restrictions laid down in the Cosmetics Regulation as regards testing involving animals.

Article 18(1)(b) of the Cosmetics Regulation<sup>1</sup> provides for a marketing ban for cosmetic products containing ingredients which have been tested on animals '*in order to meet the requirements*' of that Regulation.

The Board of Appeal therefore held that the Agency must take a position on the interpretation of the Cosmetics Regulation insofar as this is necessary to interpret and apply the REACH Regulation. As the Substance is used exclusively as an ingredient in cosmetic products and, depending on how one interprets Article 18(1)(b) of the Cosmetics Regulation, testing the Substance on vertebrate animals could or could not lead to a marketing ban.

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<sup>1</sup> 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 Agency should therefore have explained its interpretation of the relationship between the REACH Regulation and Article 18(1)(b) of the Cosmetics Regulation in the Contested Decision.

The Board of Appeal therefore annulled the Contested Decision and remitted the case to the Agency for further action.

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**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.

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*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>*