



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies  
**Health Technology and Cosmetics**

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Ms. Autumn Burke  
Assemblywoman, 62<sup>nd</sup> District  
California Legislature  
State Capitol  
PO Box 942849  
Sacramento, CA 94249-0062

Sent by e-mail to:  
*tish.rylander@asm.ca.gov*

**Subject: Reply to your letter of 16 July 2018 on the animal testing ban for cosmetics**

Dear Ms. Burke,

I would like to thank you for your letter of 16 July 2018 requesting more information about the EU animal testing ban for cosmetics. It was a pleasure talking to you about this topic at the International Symposium on Cosmetics Legislation last week in Tokyo.

In the EU, Article 18(1) of the Cosmetics Regulation (Regulation 1223/2009) prohibits the testing of finished cosmetic products and cosmetic ingredients, or combinations of ingredients, on animals (testing ban) and the marketing of finished cosmetic products and of cosmetic products containing ingredients, or combination of ingredients, tested on animals (marketing ban) to meet the requirements of the Cosmetics Regulation.

Guidance on the application of the testing and marketing bans is provided in the Communication from the Commission to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics of 11 March 2013<sup>1</sup>. I would like to draw your attention to section 3.1. 'Implementing the 2013 marketing ban and monitoring its effects' and in particular to the following paragraph:

*'The Commission considers that animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out 'in order to meet the requirements of this Directive/Regulation'. The resulting animal testing data should not trigger the marketing ban and could*

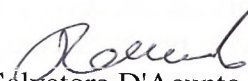
<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0135>

*subsequently be relied on in the cosmetics safety assessment. Reliance on such data is subject to its relevance for the cosmetics safety assessment and its compliance with data quality requirements.'*

Moreover, I would like to draw your attention to a 2016 judgment of the EU Court of Justice which made an important clarification on the interpretation of the marketing ban as regards animal testing carried out in non-EU countries to comply with the cosmetics of a non-EU country legislation. The main question examined by the Court was whether one of the provisions relating to the marketing ban may be interpreted as prohibiting the placing on the EU market of cosmetic products containing ingredients that have been tested on animals outside the EU to comply with the cosmetics legislation of a non-EU country. The Court concluded, in consistence with a statement made by the Commission in its 2013 Communication, that *'[it] must be interpreted as meaning that it may prohibit the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market'* (emphasis added).

Finally, Article 18(2) of the Cosmetics Regulation allows a Member State to request the Commission to grant a derogation from the testing and marketing bans, in exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredients. A derogation shall be granted only where: (a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function; (b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation. No derogation has been granted to date.

Yours sincerely,

  
Salvatore D'Acunto  
Head of Unit