EUROPEAN COMMISSION DIRECTORATE-GENERAL ENVIRONMENT

The Director-General

1 0 JAN. 2019

Brussels, ENV/B.2/KS/ARES(2018)

Dear Petitioner,

Thank you for your letter regarding the animal experimentation on cosmetic ingredients for the purpose of worker safety under the REACH Regulation. Commissioner Vella has asked me to reply on his behalf.

The Commission shares the goal of phasing out animal testing and declared this goal in the horizontal Directive 2010/63/EU (on Protection of Animals used for Scientific Purposes). The principle of avoiding such tests wherever possible and of promoting alternative tests is enshrined in several pieces of relevant sector EU legislation.

While animal testing for purposes of the Cosmetic Regulation is no longer allowed, Article 18(1) of that Regulation does not prohibit animal testing performed on cosmetic ingredients to comply with other EU legislation, such as REACH¹. This kind of testing might still be necessary, as a last resort, to meet the information requirements of the REACH Regulation, e.g. in relation to risks presented to the health of workers through exposure to substances during the manufacture of cosmetics or for environmental endpoints. Unfortunately, we have not yet reached the state of science where we can reliably assess all effects of toxic chemicals with alternative methods only.

REACH actually has a much more modern and far-reaching approach than other legislative frameworks when it comes to minimizing animal testing. It does not only state that animal testing should be used as a last resort only and prescribe the use of validated in vitro test methods, but it also has very flexible and open provisions allowing the use of innovative approaches like computerised methods, modelling or the extrapolation of data from related substances.

In order to limit testing on animals, the Commission actively promotes alternative approaches (the research, validation and regulatory acceptance) at the level of the Organisation for Economic Cooperation and Development (OECD) and their introduction in the EU Test Method Regulation².

¹ OJ L 396, 30.12.2006, p. 1., Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

² Commission Regulation (EC) No 440/2008, OJ L 148, 31.5.2008, p. 1.
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Further information on the Commission's activities dedicated to the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics can be found in the report to the European Parliament³, and more generally in the European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) report⁴.

D. C. STANLEY

Yours sincerely,

Daniel Calleja

³ Report from the Commission to the European Parliament and the Council on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics (2015-2017), https://ec.europa.eu/transparency/regdoc/rep/1/2018/EN/COM-2018-531-F1-EN-MAIN-PART-1.PDF

⁴ EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches, https://ec.europa.eu/jrc/en/science-update/eurl-ecvam-status-report-2017