



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL
MARKET, INDUSTRY, ENTREPRENEURSHIP
AND SMES
Chemicals and Consumer Industries
The Director

DIRECTORATE-GENERAL FOR
ENVIRONMENT

Circular Economy and Green Growth
The Director

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c/o PETA
Cruelty Free Europe
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Sent by e-mail to:
j.moran@eurogroupforanimals.org

Subject: Open letter on animal testing

Dear Sir,

Thank you for the open letter of 2 December 2020 from the coalition of animal welfare stakeholders to the President of the European Commission, Ursula von der Leyen, on whose behalf we are replying. The letter raises concerns about testing of cosmetic ingredients on animals under the REACH Regulation.

The Commission shares the conviction that animal testing should be phased out in Europe and is working towards this goal. A complete ban on animal research in the EU requires time in order to identify alternative approaches, not involving animals.

The Cosmetics Regulation already lays down provisions to prohibit animal testing, however, the evaluation of the risk of cosmetics is not restricted to end-users of cosmetic products only. The ban under the Cosmetics Regulation does not cover safety tests required by the REACH Regulation for environmental endpoints, exposure of workers involved in the production or handling of chemicals on an industrial site or non-cosmetic uses of substances. Moreover, it must be stressed that the promotion of alternative methods to animal testing is one of the objectives of the REACH Regulation and the test on vertebrates is only acceptable as a last resort.

With current scientific knowledge, animals are still needed in basic and applied research, in the development of medicine, and for safety and efficacy regulatory testing of products and substances. It is important to highlight that testing on fish – restricted to the minimum number necessary – allows for the identification of certain hazards for the environment. As

such, subsequent risk management measures will ensure protection of a much larger amount of fish. For example, this is the case for certain tests on endocrine disruptors for the environment that are included in the Chemicals Strategy for Sustainability. Furthermore, this strategy is strongly committed to the promotion of alternative methods, use of digital technologies and advanced methods, and moving away from unnecessary animal testing in both the EU and globally. In addition, a number of actions will allow reducing as much as possible unnecessary animal testing (e.g. effective data sharing, making more use of existing academic data, assessing and regulating as much as possible substances by group, and avoiding the most harmful substances up-front).

The Directive on protection of animals used for scientific purposes already provides a strategy that is legally binding and a step-wise approach for replacing animals as soon as scientifically satisfactory methods become available. The ultimate goal is full replacement of all animal use. The Commission also heavily supports the development of alternatives through its Research & Innovation programmes where over EUR 700 million have been committed to research and innovation in this area over the last two decades; in the future, under Horizon Europe (HE), further development will be supported. We will foster multidisciplinary research and digital innovations for advanced tools, methods and models, and data analysis capacities, which will contribute to the development of alternative solutions moving away from animal testing.

However, pending the lack of alternative methods providing the same level of evidence than non-animal test methods, unfortunately animal testing is the only efficient way of ensuring a high level of protection of human health and the environment which are amongst the main objectives of REACH.

We fully understand your concern about animal testing on cosmetic ingredients. However, out of 23.000 substances registered under the REACH Regulation, only around 150 substances are exclusively used in cosmetics. Until now, there have been very few cases where a test on vertebrate animals was required under REACH for such substances. In fact, the two cases addressed in the decisions by the Board of Appeal (BoA) of the European Chemicals Agency (ECHA) on 18 August 2020 are the first two cases after the 2013 cosmetic animal testing ban, for which the need for such a test (concerning risks to the environment and from exposure to workers) has been confirmed for substances exclusively used in cosmetic products. These decisions are based on the REACH Regulation, and not the Cosmetics Regulation.

The Commission, at this stage, has not identified elements that would be in contradiction with the animal testing bans provided in Article 18 of the Cosmetics Regulation, as further interpreted by the 2013 Commission Communication¹ and the 2014 ECHA-Commission joint statement².

¹ 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 (11 March 2013): <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0135>

² Clarity on interface between REACH and the Cosmetics Regulation (27 October 2014): https://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation

The company that is concerned by the two decisions of the ECHA BoA, as well as an animal protection association, have launched an action for annulment against the two decisions made by ECHA's BoA before the EU General Court³, respectively on 27 and 30 October 2020. We are not in a position to comment on these cases currently pending the judgments from the Court.

Please rest assured that we will continue to foster the spirit of the Cosmetics Regulation by ensuring full compliance with the ban applicable to animal testing in cosmetics products and ingredients across the EU and promoting our regulatory approach internationally.

Yours faithfully,

(e-signed)
Carlo Pettinelli

(e-signed)
Kestutis Sadauskas

c.c.: David Maria Sassoli – President, European Parliament
Charles Michel – President, European Council
S. D'Acunto, M. Flueh, O. Linher, C. Krassnig, R. Mokry, (GROW)
C. De Avila, C. Ceijas Noguera, F. Van Raemdonck (ENV)

³ T-663/20 and T-664/20 – One Voice v ECHA; T-655/20 and T-656/20 – Symrise v ECHA