

## **Request for a reply to the European Chemicals Agency in case 1130/2016/JAS on the allegedly erroneous Joint Statement on the possibility to perform animal tests for substances used in cosmetics**

Correspondence - 03/10/2016

**Case 1130/2016/JAS - Opened on 03/10/2016 - Decision on 21/07/2017 - Institution  
concerned** European Commission ( No maladministration found ) |

Dear Mr Dancet,

I have received a complaint against the European Commission and the European Chemicals Agency (ECHA) from People for the Ethical Treatment of Animals Foundation.

The complaint concerns the allegedly erroneous Joint Statement by the Commission and ECHA on the possibility to perform, under certain conditions, animal tests for substances used in cosmetics [1] .

The complainant alleges that:

- 1. The Commission and ECHA did not have the legal power to issue the Joint Statement.**
- 2. The Commission and ECHA issued a Joint Statement that contains guidance which is contrary to EU law.**
- 3. The Joint Statement will result in certain cosmetics being wrongly labelled as free from animal testing, thus confusing and misleading consumers.**

I have decided to open an inquiry into this complaint and have concluded that it is necessary to ask both ECHA and the Commission for a reply on the **second and third allegation** .

Concerning the **first allegation** , I have concluded that the Joint Statement merely provides guidance for cosmetics manufacturers and Member States charged with monitoring compliance with the Cosmetics Regulation. The Joint Statement thus does not constitute a legally binding interpretation of the Cosmetics and REACH Regulations. The fact that the Commission and ECHA can issue such guidance does not, however, prejudice the issue of whether the guidance given is correct.



**I would appreciate it if you could, in your reply, also set out your views on the specific issues related to the complaint set out below [2] .**

In its letter of 6 July 2016 to the complainant, ECHA stated that it would carefully assess any conclusions to be drawn from the Court of Justice's judgment in case *European Federation for Cosmetic Ingredients* once that judgment was available.

The Court delivered its judgment in that case on 21 September 2016 [3] . The Court ruled that the Cosmetic Regulation's animal testing ban [4] “ *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* ”.

According to the Joint Statement, the Cosmetics Regulation's animal testing ban does not apply to testing required for (i) environmental endpoints, (ii) exposure of workers and (iii) non-cosmetic uses of substances under the REACH Regulation [5] .

Does ECHA consider, in light of the Court's judgment, that results from animal testing carried out to comply with EU legislation such as REACH may be used for the cosmetics safety assessment, taking into account that the risk of circumvention identified by the Court [6] might be equally relevant in these circumstances?

Does ECHA intend to amend the Joint Statement and related documents, taking into account that cosmetics manufacturers risk severe penalties for violations of the Cosmetics Regulation?

Finally, the Cosmetics Regulation allows manufacturers to mention on a product's label that no animal tests were carried out “ *only if the manufacturer [...] [has] not carried [...] any animal tests on the finished cosmetic product [...] or any of the ingredients contained in it [...]*” [7] .

Does ECHA consider that cosmetics manufacturers may label products as free from animal testing if animal tests were carried out on a substance used in these products for any one of the three purposes mentioned in the Joint Statement (environmental endpoints, exposure of workers and non-cosmetic uses of substances)?

Please note that I may decide to send your reply and related enclosures to the complainant for comments. I may also decide to publish ECHA's reply on my website.

If you wish to submit documents or information that you consider to be confidential and which should not be disclosed to the complainant, please contact our case handler, Mr Jan Stadler.

I would be grateful to receive your institution's reply by 2 December 2016.

Should ECHA's and the Commission's position on the complaint and the highlighted specific



issues coincide, I would be happy to accept a single reply containing a statement to this effect.

Yours sincerely,

Emily O'Reilly

European Ombudsman

[1] Available at:

[https://echa.europa.eu/view-article/-/journal\\_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation](https://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation)  
[Link]

[2] In accordance with Article 4.2 of the Ombudsman's Implementing Provisions.

[3] Judgment in *European Federation for Cosmetic Ingredients*, C-592/14, ECLI:EU:C:2016:703.

[4] Article 18 of the Cosmetics Regulation (Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ 2009 L 342, p. 59).

[5] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L 396, p. 1.

[6] Judgment in *European Federation for Cosmetic Ingredients* ECLI:EU:C:2016:703, paragraph 42.

[7] Article 20(3) of the Cosmetics Regulation.