

Highest EU Court Rules on Ban to Market Cosmetics Tested on Animals

September 21, 2016

Cosmetics

On September 21, 2016, the Court of Justice of the EU (CJEU) delivered its judgment in [Case C-592/14 European Federation for Cosmetic Ingredients v UK Secretary of State for Business](#). The Court has ruled that animal tests performed outside the European Union (EU) to comply with non-EU rules should not be used for the product safety assessment to gain access to the EU internal market for cosmetics.

Context

Three companies had carried out animal tests on cosmetic ingredients outside the EU in order to comply with the regulatory requirements in Japan and China. Without these tests, the ingredients could not be used in cosmetics in those countries. In the EU, however, the Cosmetics Regulation prohibits the marketing of products containing ingredients that have been tested on animals “in order to meet the requirements” of the Regulation (article 18(1)(b)). In the UK, companies can incur criminal penalties for violating this marketing ban. Therefore the European Federation for Cosmetic Ingredients initiated a procedure to clarify whether the ban also covers marketing cosmetics on the EU market containing ingredients that have been tested on animals outside the EU, so as to comply with the laws of foreign countries.

Opinion of the Advocate-General

On March 17, 2016 Advocate-General Bobek gave his opinion in this case. The role of the Advocate-General is to provide an independent, reasoned opinion to the Court. In his view, the marketing ban must be understood as preventing the reliance on the results of animal testing for the purposes of meeting the requirements of the Cosmetics Regulation. The European Commission had argued that animal testing that was conducted for compliance with non-cosmetics rules should not be considered to have been carried out “in order to meet” the requirements of the Cosmetics Regulation. In his view, an approach focused on “intent” of animal testing would lead to difficult problems of evidence.

The Advocate-General argued that under the EU Cosmetics Regulation, the ban implies that it is not possible to *rely on* scientific evidence derived from animal testing to demonstrate safety. He said this has a number of implications. First and foremost, ingredients tested on animals can be incorporated in cosmetics on the EU market. Second, the manufacturer cannot rely on tests performed in third countries to prove safety but must, where needed, still include reference to them in the Product Information File (PIF). Third, it is irrelevant to the application of the marketing ban where the testing was conducted, in the EU or outside the EU. Fourth, the subjective intent behind the testing is also irrelevant: it does not matter whether testing was to comply with EU REACH requirements, or with the requirements of foreign legislation (cosmetics or otherwise). Fifth, it is not relevant whether and at what point marketing of the ingredient or cosmetic in the EU was foreseen by the company.

Judgment of the Court of Justice of the EU

The CJEU follows the conclusion of its Advocate-General, but provides less detail on the specific consequences of its reasoning.

First, the Court finds that results of animal tests that are not included in the cosmetic product safety report have not been carried out “in order to comply” with the EU Cosmetics Regulation. The mere inclusion of non-EU animal test results in the product information file, separately from the product safety report, also does not trigger the marketing ban. However, for the Court, relying on animal testing results in the safety report is sufficient to prove that the tests were done to obtain access to the EU market.

Second, the Court is explicit that under article 18(1)(b) it is irrelevant where animal testing has been carried out. Tests carried out outside the EU in order to market cosmetics in non-EU countries cannot be used to support the safety of those products to place them on the EU market.

The Court did not express an opinion on the link with animal testing to comply with REACH or other EU regimes such as the rules on pharmaceuticals. However, since *reliance* on animal tests results is the key trigger for the ban, it should suffice not to rely on these tests to prove safety for human health of the cosmetic product.

In summary, the Court has ruled that animal testing should not be used in order to gain access to the EU internal market for cosmetics.

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