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Practice Group:

*Food, Drugs, Medical
Devices and
Cosmetics (FDA)*

Blanket Ban on Animal Testing on Cosmetics Enters into Force

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The European Union (EU), through a [Commission Communication](#) adopted yesterday, has decided to implement a total marketing ban on cosmetic products and ingredients tested on animals as from March 11, 2013. This ban will be enforced despite the fact that alternative non-animal tests have not yet been developed for repeated-dose toxicity, reproductive toxicity and toxicokinetics tests.

The total marketing ban will impact the marketing in the EU of cosmetics tested on animals in non-EU countries, such as China, as these tests cannot be relied upon in order to prove the safety of the product in the EU.

Consequences

In practice, a cosmetics company wanting to use a new ingredient that cannot be tested via proven alternative methods to animal testing will not be able to rely on animal testing data for the purpose of complying with the safety requirements of [Regulation 1223/2009](#) on cosmetic products.

Companies will be able to rely only on proven alternative methods to animal testing for the purpose of assessing an ingredient's safety. In the absence of such methods, there will be no possibility of using the ingredient. The Commission has acknowledged that this will negatively impact innovation; but believes this decision reflects the EU's political choices with respect to animal testing, which seek to promote animal welfare over other considerations.

Exceptions

Animal testing may be necessary to ensure compliance with certain non-cosmetics related EU legislative frameworks (such as pharmaceuticals, detergents, food or REACH). Testing conducted according to those regulations shall not trigger the marketing ban, and can be relied on in the cosmetics safety assessment.

In contrast, if animal testing has been carried out for the purpose of complying with cosmetics requirements in third countries, this data cannot be relied on in the EU to prove the cosmetic product is safe. This approach seeks to prevent cosmetic providers from conducting animal tests outside the EU, in order to then commercialise their products safely in the EU.

Background

EU laws on cosmetics established a prohibition to test finished cosmetic products and cosmetic ingredients on animals (testing ban), and a prohibition to market in the European Community, finished cosmetic products and ingredients included in cosmetic products which were tested on animals (marketing ban).

A testing ban on finished cosmetic products applies since September 11, 2004. In addition, a testing ban on cosmetic ingredients applies since March 11, 2009.

The marketing ban applies since March 11, 2009 for all tests on animals with the exception of repeated-dose toxicity, reproductive toxicity and toxicokinetics. For these specific tests the Commission could have postponed the ban or provided for derogations, but it has decided that, as

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from March 11, 2013, repeated-dose toxicity, reproductive toxicity and toxicokinetics tests may no longer be performed.

In any case, and regardless of the EU's current position, the ultimate interpretation of the meaning of the marketing ban on animal testing will correspond to the Court of Justice of the European Union.

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