Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 19/09/2016 - Follow-up document

In accordance with Regulation (EC) nº 1223/2009 of the European Parliament and of the Council, the Commission presents its eleventh report on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics.

The report is based on the contributions of Member States received between 2014 and the end of 2015.

Background: it is recalled that the animal testing of finished cosmetic products has been prohibited in the EU since 2004, and the testing of cosmetic ingredients since March 2009 (testing ban).

Since 11 March 2009, the marketing in the EU of cosmetic products and their ingredients that have been tested on animals in order to meet the requirements of Directive 76/768/EEC has also been prohibited. This marketing ban applied to all but the most complex human health effects (endpoints) that needed to be tested, in the absence of alternative non-animal tests (repeated-dose toxicity, reproductive toxicity and toxicokinetics). The European Parliament and the Council decided that the ban would take effect on 11 March 2013 (2013 marketing ban).

Main conclusions of the report

Compliance with the testing and marketing bans and the impact of the bans: virtually **no cases** of non-compliance with the testing and marketing bans have been reported by Member States. The main issue encountered in their market surveillance activities related to the bans is the presence of cases of **incomplete animal testing data in product information files.** In practice, the main way of verifying compliance with the testing and marketing bans is the cosmetic product's product information file. The following gaps in information were remarked:

- the **toxicological data** (including animal testing data) on ingredients was insufficient;
- the product information files did not always contain complete data on compliance with **legislative frameworks** other than the Cosmetics Regulation (e.g. the REACH Regulation);
- the information relating to animal testing was in certain cases limited to a **disclaimer by the person responsible** that no animal testing had been performed on the final product;
- it was found that some **small companies** have an insufficient understanding of the bans or even misinterpret their requirements.

Since the report covers the relatively early stages of the implementation of the 2013 marketing ban, the Commission considers that it will be interesting to **follow future developments in this field**, when economic operators and market surveillance authorities gain more experience regarding the implementation of the full marketing ban. In particular, the competent national authorities should monitor the issue of cases of incomplete animal testing data in the product information file.

Progress made in alternative methods to animal testing: the report notes that significant progress was made in recent years in the development, validation and regulatory acceptance of alternative methods to test for skin irritation/corrosion, serious eye damage/eye irritation and skin sensitisation. However, **considerable scientific challenges remain** for the more complex endpoints for which more research is needed. The current level of alternative methods does not make it possible to fully replace in vivo tests for all toxicological endpoints.

Research and development activities: **major research and development activities** on alternatives to animal testing are ongoing in the EU, particularly through significant research initiatives by public and private actors. **More than EUR 250 million** were dedicated during the Seventh Framework Programme (FP7: 2007-2013), including from the Innovative Medicines Initiative (IMI), to research into alternatives. The five-year SEURAT-1 research initiative, which was completed in 2015, was a unique **EUR 50 million** public-private partnership co-financed by the Commission's FP7 (Health Programme) and the European personal care association.

The Commission is involved in the validation of alternative methods through **EURL ECVAM** (the European Union Reference Laboratory for alternatives to animal testing) and through its support for facilitating the regulatory acceptance of alternative methods by the OECD and international partners.