Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 15/10/2019 - Follow-up document

In accordance with Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, the Commission presented its thirteenth Commission report on the development, validation and legal acceptance of alternative methods to animal testing in the field of cosmetic products.

The report shall also inform the European Parliament and the Council of the compliance with the deadlines for the bans on animal testing laid down in the Regulation and of the technical difficulties they pose.

The main conclusions of the report are as follows:

Problems encountered

Based on inspections carried out by market surveillance authorities, one Member State reported amongst the hundreds cases of control three cases of non-compliance with the marketing ban, following which the companies were asked to remedy the infringement. The very large majority of the Member States who monitored compliance with the testing and marketing bans did not report any difficulties in carrying out compliance checks.

The main issue encountered by a small number of Member States in their market surveillance activities related to the bans is the presence of a limited number of cases of incomplete animal testing information in PIFs. Immediate corrective measures were imposed on economic operators in all reported cases. Most Member States did not report any cases where a manufacturer, in particular an SME, was not able to place a cosmetic product on the market due to an inconclusive safety assessment of the product or ingredient caused by a lack of alternatives to animal testing. However, two Member States reported that SMEs do not have sufficient knowledge about the testing and marketing bans and sufficient financial resources needed for cost-intensive toxicological tests on new ingredients.

Progress made in the development, validation and legal acceptance of alternative methods to animal testing

For more than 25 years the Commission has been fully engaged at all stages of the process to find replacements to animal testing with alternative test methods. Work is increasingly focused on developing defined approaches and integrated approaches to testing and assessment which look at all existing safety data when assessing a chemical ingredient.

Considerable progress was made on several fronts in the development, validation and regulatory acceptance of alternative approaches to animal testing in 2018:

- EU-ToxRisk is a European collaborative project funded by the EU Framework Programme for Research and Innovation, Horizon 2020 (H2020), to advance mechanism-based toxicity testing and risk assessment. With a budget of over EUR 30 million, it was launched in January 2016 and will last for 6 years;

- the European Union Network of Laboratories for the Validation of Alternative Methods (EUNETVAL) has continued to support the EURL ECVAM validation studies. Two EURL ECVAM validation studies deal with methods for the identification of endocrine disruptors and involve the EU-NETVA;

- the European Partnership for Alternative Approaches to Animal Testing (EPAA) is a public-private partnership between the European Commission, eight European trade associations and 36 individual companies from the relevant business sectors. In 2018, the work of EPAA included seven projects to facilitate the promotion, validation, acceptance and implementation of 3R alternatives in European regulatory testing and decision-making, and to promote international harmonisation of regulatory testing.

Acceptance by the international authorities

Despite considerable progress made in the development, validation and legal acceptance of methods alternative to animal testing, alternative test methods have not yet been accepted by the international regulatory community for the safety assessment of ingredients for some of the most complex endpoints, such as repeated dose toxicity, reproductive toxicity or carcinogenicity.

The report stressed that until all toxicological endpoints can be covered by alternatives, the European cosmetics industry remains limited in its ability to introduce new ingredients, apply for new uses of existing ingredients, or respond to new questions regarding the safety of existing ingredients.

The Commission has been and continues to be fully committed to encouraging the regulatory acceptance of alternative methods approved at OECD level and to promoting the EU animal testing ban in cosmetics at international level, through relevant fora and bilateral and multilateral cooperation. These activities aim not only to recognise individual alternative methods, but also to promote animal welfare and to achieve the convergence of safety assessment methods at international level.