

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 11/03/2013 - Follow-up document

The Commission presents a Communication on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics. It has a **twofold purpose**:

- to inform the European Parliament and the Council of the Commission's decision **not to propose any changes in the animal testing related provisions** in Directive 76/768/EEC (Cosmetics Directive) and in Regulation (EC) No 1223/2009 (Cosmetics Regulation), the reasons why and the way forward.
- to present the **annual report** in accordance with the Cosmetics Directive which is the tenth Commission report on the development, validation and legal acceptance of alternative methods to animal tests in the field of cosmetics.

The 2013 marketing ban: the deadline for the 2013 marketing ban in the Cosmetics Directive/Regulation enters into force on 11 March 2013. This completes a 20-year long process on phasing out animal testing for the purpose of cosmetic safety assessment. **Promising progress has been made in advancing alternative methods** to animal testing over the last few years, but **full replacement of this kind of testing will not be possible for some time**.

In light of an impact assessment, the Commission has come to the conclusion that it is most appropriate to **let the 2013 marketing ban enter into force** and not to present a legislative proposal either to postpone the deadline or to provide for individual derogations. The reasons are as follows:

- the Commission considers that a further postponement of the 2013 marketing ban would not reflect the political choices of the European Parliament and the Council when adopting this provision ;
- any change to the 2013 marketing ban could seriously diminish the determination swiftly to develop alternative test methods ;
- a case-by-case derogation allowing the Commission to deviate from the 2013 marketing ban for individual ingredients offering significant benefits for the consumer or the environment would benefit mainly larger manufacturers capable of gathering the necessary evidence.

The way forward: the Commission considers that the most appropriate way forward is to let the marketing ban enter into force and to turn the challenges that the 2013 marketing ban is posing into an opportunity.

1°) Ensure a coherent implementation of the 2013 marketing ban and monitoring its impacts.

Currently, there is no jurisprudence of the Court of Justice of the European Union on the interpretation of the scope of the 2013 marketing ban. The Commission recalls that only the Court can provide a legally binding interpretation. **Under the supervision of the Court, the Commission will oversee the application of the 2013 marketing ban.** It will do so in accordance with its current understanding of the scope of the 2013 marketing ban, which is based on the Cosmetics Regulation/Directive.

The Commission will also monitor the **socio-economic impacts** of the 2013 marketing ban.

2°) Continue the support for research, development and validation of new alternative methods for human safety testing.

The Commission has made about **EUR 238 million** available between the years 2007 and 2011 for research into alternative methods to animal testing alone. It is also important to mention the **SEURAT-1 initiative** ('Safety Evaluation Ultimately Replacing Animal

Testing') which is a jointly funded initiative by the European Commission and the cosmetics industry, each of which contributes EUR 25 million between 2011 and 2015.

The research into alternative methods is by no means near an end. [Horizon 2020](#) is the financial instrument that will ensure the framework for the research activities between 2014 and 2020. **At the same time, strong commitment is required from the sectors that would benefit from the development of new alternative methods, including the cosmetics sector.** The Commission will engage with stakeholders from such sectors to define the research priorities, which, for example, could take the form of a new public-private partnership.

3°) Make alternative methods an integral part of the Union's trade agenda and international cooperation.

A key instrument in agreeing on tools for safety assessment is the development of **OECD Test Guidelines** in the framework of the Existing Chemicals Programme and the Mutual Acceptance of Data. Alternative methods have been included in OECD Test Guidelines and this has been key in leading to their international acceptance. Commission services are actively involved in the OECD work. If significant progress is to be made, the Commission feels it necessary to consider how to reflect Integrated Testing Strategies in OECD Guidelines.

It will endeavour to put these issues on the agenda of all relevant multi and bilateral meetings in the cosmetics field in 2013, notably with the United States and China, but also in contacts with Brazil and India.