Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 10/07/2018 - Follow-up document

In accordance with Regulation (EC) nº 1223/2009 of the European Parliament and of the Council, the Commission presents its twelfth report on the development, validation and legal acceptance of methods alternative to animal testing in the field of cosmetics (2015-2017).

The main points in the report may be summarised as follows:

Court of Justice clarification on scope of the marketing ban: in the *European Federation for Cosmetic Ingredients* case (Case C-592/14), main question examined by the Court was whether Article 18(1)(b) of the Regulation may be interpreted as prohibiting the placing on the EU market of cosmetic products containing ingredients that have been tested on animals outside the EU to comply with the cosmetics legislation of a third country. The Court concluded that the provision must be interpreted as meaning that it may **prohibit** the placing on the European Union market of cosmetic products containing some ingredients that have been **tested on animals outside the European Union**, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.

Compliance with the testing and marketing ban: as in the previous reporting period, Member States reported **practically no cases of non-compliance** with the testing and marketing bans. Based on inspections carried out by market surveillance authorities, one Member State reported two cases of infringement of the bans, following which the companies in question were asked to remedy the breach. The main issue raised by several Member States was the fact that the **product information files (PIFs) were incomplete** with regard to data on animal testing – this information is necessary to verify compliance with the bans. The specific issues with PIFs were the following:

- the information on animal testing or alternatives in the PIF (or declaration thereof) was absent or insufficiently detailed (e.g. it did not reference the ingredients and the finished product, or it did not mention testing under other regulatory frameworks and a justification of the need for this);
- the toxicological data was insufficient for some cosmetic ingredients (for instance the ingredients' suppliers did not provide toxicological data on the ingredients but only a declaration).

The report states that competent authorities appear to be properly addressing these shortcomings.

Progress made in alternative methods to animal testing: the report states that **significant progress** has been made in the development, validation and regulatory acceptance of alternative methods, for skin irritation/corrosion, serious eye damage/eye irritation and skin sensitisation. **Integrated approaches to testing and assessment (IATAs)** have been developed and internationally harmonised in the first two areas and are in the process of being approved for skin sensitisation. In particular, priority work in recent years has focused on developing defined and integrated approaches to testing and assessment that look at all existing safety data when assessing a chemical.

The **more complex human health effects (endpoints) still present challenges** and require more research. This is the case, for example, for **acute and chronic systemic toxicity**, areas in which significant knowledge gaps currently limit the development of IATAs. Significant projects, such as EU-ToxRisk, aim to address these challenges. The latter is a major collaborative project funded by Horizon 2020. With a budget of over EUR 30 million, it was launched in January 2016 and will last for six years.

The project, aims to make progress towards animal-free safety assessments and tackles complex areas of toxicology, such as repeated dose and reproductive toxicity. The first eight case studies have progressed considerably.

The validation of alternative methods at EU level is progressing steadily, through the activities of the **European Union Reference Laboratory for Alternatives to Animal** (EURL ECVAM), which is currently leading the project to develop a guideline based on defined approaches for skin sensitisation testing.

The Commission also remains engaged in encouraging the regulatory acceptance of alternative methods approved at **OECD level** and maintains international cooperation in this field. These activities aim not only to recognise individual alternative methods, but also to achieve the convergence of safety assessment methods at international level. OECD member countries work together to improve and harmonise assessment methodologies for chemicals and collectively gain experience in the development of IATAs, which has become a priority over recent years as an alternative solution to animal testing.