

Cosmetic products. Recast. "Cosmetics Regulation"

2008/0035(COD) - 07/11/2018 - Follow-up document

The Commission presents a review of Regulation (EC) 1223/2009 of the European Parliament and of the Council on cosmetic products (the Cosmetics Regulation) with regard to **substances with endocrine-disrupting properties** pursuant to Article 15(4) of that Regulation.

The Cosmetics Regulation does not have any specific provisions for endocrine disruptors. However, specific rules under Article 15 of the Cosmetics Regulation apply to the use in cosmetic products of substances which have been classified as **carcinogenic, mutagenic or toxic for reproduction** (CMR) under Regulation (EC) No 1272/2008¹⁰ on the classification, labelling and packaging of substances and mixtures. Certain categories of CMR substances are, subject to derogations, prohibited from use in cosmetics based on their CMR classification and inserted in the relevant Annex of the Cosmetics Regulation. For cases where the potential endocrine disrupting substance is not classified as a CMR, its use in cosmetics follows the general provisions of Article 31 of the Cosmetics Regulation, which requires a **scientific opinion** of the Scientific Committee on Consumer Safety (SCCS).

Regulatory approaches to endocrine disruptors: different regulatory approaches exist in different pieces of EU law on endocrine disruptors depending on the specificities of each sector. The report cites, *inter alia*, two Regulations that apply in terms of content for biocides and plant protection products, these being [Commission Delegated Regulation \(EU\) 2017/2100](#) setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012, and Commission Regulation (EU) 2018/605 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. Although the criteria for identifying endocrine disruptors do not have direct legal consequences for other areas of EU law than the areas of plant protection products and biocides, they are taken into account, as far as possible, for the purposes of the review of the Cosmetics Regulation.

Safety assessments of cosmetic ingredients by the SCCS: the SCCS and its predecessors have **already evaluated cosmetic ingredients suspected of having endocrine-disrupting properties**. The report gives examples of ingredients on which the SCCS and its predecessors delivered scientific opinions including several parabens (which are cosmetic preservatives), triclosan (used as a preservative and deodorant), and homosalate (used in sunscreens as UV-filter but also for its skin conditioning properties). In the risk assessment procedure for substances used as cosmetic ingredients, the SCCS also considers the exposure assessment for **specific vulnerable groups**, such as children and pregnant women.

These opinions show that the scientific concerns with regard to the endocrine-disrupting properties of substances can be addressed in the safety assessment of the SCCS. The report notes as an example that the SCCS carried out a case-by-case safety assessment of the different **parabens**. Based on the SCCS safety assessment, the Commission took the appropriate **measures to restrict or ban the use of certain parabens** where there was a potential risk for human health, including the use of some parabens in products designed for application on the nappy area of children under the age of three. The use of other parabens was confirmed as safe.

Consequently, substances identified as endocrine disruptors are currently subject to the general safety assessment of the SCCS. They are treated like substances of concern for human health and are subject to **case-by-case regulatory action** based on the general requirements of the legislation that are aimed at ensuring product safety. The Commission states that, bearing in mind the different approaches taken in

relevant pieces of EU legislation to address endocrine disruptors in different sectors, the experience collected since the entry into application of the Cosmetics Regulation has **not revealed elements which would justify deviating from the regime designed by the legislator** to address the safety concerns related to the use of endocrine disruptors in cosmetics.

Next steps: the Commission will establish by spring of 2019 a **priority list of potential endocrine disruptors** that are not already covered by the bans laid down in the Cosmetics Regulation. It will require data from Member States, stakeholders and academia. Upon receipt of such data, the Commission will **mandate the SCCS to evaluate the substances** in the shortest time-frame. On that basis, the Commission will take the appropriate action to ban or restrict the use of the different substances in cosmetics.

Lastly, as stated in the [Commission Communication](#) Towards a comprehensive European Union framework on endocrine disruptors', the Commission will analyse the efficiency, effectiveness and coherence of the different risk-management approaches to endocrine disruptors laid down in EU law, including the Cosmetics Regulation.