Council of the European Union

Brussels, 13 November 2018
(OR. en)

14249/18

MI 832
ENT 205
CONSOM 314
SAN 389
ECO 96
ENV 757
CHIMIE 71

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	7 November 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2018) 739 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products with regard to substances with endocrine-disrupting properties

Delegations will find attached document COM(2018) 739 final.

Encl.: COM(2018) 739 final

EUROPEAN
COMMISSION

Brussels, 7.11.2018
COM(2018) 739 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Review of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products with regard to substances with endocrine-disrupting properties

1. INTRODUCTION

This report presents the Commission's review of Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[1] (the Cosmetics Regulation) with regard to substances with endocrine-disrupting properties pursuant to Article 15(4) of that Regulation[2].

For the purpose of this review, substances with endocrine-disrupting properties (endocrine disruptors) are chemical substances that alter the functioning of the endocrine system and negatively affect the health of humans and animals[3].

On 15 June 2016 the Commission presented draft Regulations on criteria to identify endocrine disruptors in the field of plant protection products and biocides[4]. The criteria put forward were based on the definition of the World Health Organisation International Programme on Chemical Safety (WHO/ IPCS[5]). The WHO defines an endocrine disruptor as 'an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations'.

These criteria which are in practice equivalent in terms of content for biocides and plant protection products were adopted by the Commission by Regulations of 4 September 2017 and 19 April 2018[6]. Although these criteria do not have direct legal consequences for other areas of EU law than the areas of plant protection products and biocides, they should be taken into account, as far as possible, for the purposes of the present review of the Cosmetics Regulation.

2. RESTRICTION OF SUBSTANCES UNDER THE COSMETICS REGULATION AND IN OTHER SECTORS

[1] OJ L 342, 22.12.2009, p. 59.

[2] *When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties.*

[3] Commission Communication 'towards a comprehensive European Union framework on endocrine disruptors'.

[4] Draft Commission Regulations C(2016) 3751 projet and C(2016) 3752 projet and Communication from the Commission to the European Parliament and the Council on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products (https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/com_2016_350_en.pdf).

[5] World Health Organisation International Program on Chemical Safety, Global assessment of the state-of-the-science of endocrine disruptors, 2002, WHO/PCS/EDC/02.2.

[6] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council, OJ L 301, 17.11.2017, p. 1 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1510927786692&uri=CELEX:32017R2100) and Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, OJ L 101, 20.4.2018, p. 33 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R0605).

In order to ensure a high level of protection of human health, the Cosmetics Regulation lays down a system of restrictions on the use of certain substances in cosmetics[7].

Certain categories of ingredients (i.e. colorants, preservatives and UV-filters) can only be used in cosmetic products if they have been authorised through their inclusion in the respective positive lists of the Cosmetics Regulation (Annexes IV, V and VI to the Cosmetics Regulation). Other ingredients can be used in cosmetics without authorisation. If there are identified risks to human health, ingredients can be prohibited or restricted from use in cosmetics (Annexes II and III to the Cosmetics Regulation).

These Annexes may be amended by the Commission in case of potential risk to human health[8] or for adaptation to technical and scientific progress[9].

The inclusion of substances in these Annexes is preceded by a scientific risk assessment by an independent scientific committee, the Scientific Committee on Consumer Safety (SCCS). More generally, the SCCS provides opinions on health and safety risks (chemical, biological, mechanical and other physical risks) of non-food consumer products (e.g. cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products) and services (e.g. non-permanent tattooing, artificial sun tanning). The SCCS, in the risk assessment procedure for substances used as cosmetic ingredients, considers also the exposure assessment for specific vulnerable groups, such as children and pregnant women. This is critical since cosmetic products are consumer products used by every citizen every day.

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 the reproduction (CMR) under Regulation (EC) No 1272/2008[10] on the Classification, Labelling and Packaging of substances and mixtures. CMR substances of category 1A or 1B[11] and of category 2[12] under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall in principle be prohibited from use in cosmetics based on their CMR classification due to their hazardous properties[13] and inserted in the relevant Annex of the Cosmetics Regulation.

However this general prohibition may be subject to certain derogations (either as authorisation or restriction) if certain conditions are fulfilled, including a favourable opinion by the SCCS.

The Cosmetics Regulation does not have any specific provisions for endocrine disruptors. When a substance identified or considered as a potential endocrine disruptor has been also classified as a CMR, then Article 15 shall apply and the substance shall be banned unless a

[7] Chapter IV of the Cosmetics Regulation.
[8] Article 31(1) of the Cosmetics Regulation.
[9] Article 31(2) of the Cosmetics Regulation.
[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1.
[11] Known or presumed CMR substance.
[12] Suspected CMR / substance of concern.
[13] Article 15 of the Cosmetics Regulation.

derogation to the ban is granted subject to the strict requirements laid down in Articles 15(1) (opinion by the SCCS) and 15(2) (compliance with food safety requirements of the General Food Law, use limited to specific product category, lack of availability of suitable alternative substances, evaluation and positive opinion by the SCCS as regards the safe use in cosmetics products). For cases where the identified or 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 SCCS.

Chemical substances with adverse effects to the environment are taken care of under the REACH Regulation[14] where they can be, for example, subjected to authorisations or restrictions[15]. This includes chemical substances with endocrine-disrupting properties used in cosmetics which can be subject to regulatory measures under REACH if they have adverse effects on the environment[16].

Different regulatory approaches exist in different pieces of EU law on endocrine disruptors depending on the specificities of each sector[17]. For example, in the EU Food Contact Materials Regulation[18], like in the Cosmetics Regulation, no specific provisions for endocrine disruptors are laid down: where necessary, in order to address potential risks for human health, the Commission can adopt measures banning or restricting the use of substances used in food contact materials based on a scientific risk assessment which takes account of the requirements of the sectoral legislation.

In the areas of biocides and plant protection products, the legislator expressly decided that endocrine disruptors, including those that are not classified as CMRs, should not be, in principle, approved with limited possibilities of derogation. Under REACH, substances with endocrine disrupting properties may be identified as substances of very high concern (SVHC); the latter may be identified as SVHC on a case by case basis provided there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to CMRs (categories 1A/1B) or persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvBs). The new Regulation on medical devices[19] aims at ensuring that when used the benefit of the use of endocrine disruptors in the devices is higher than the potential risk of their use. This applies to medical

[14] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), OJ L 396, 30.12.2006, p. 1.
[15] For example, REACH restricts the use of nonylphenol, used as a surfactant, in cosmetic products (point 46(a) of Annex XVII to REACH).
[16] Up to now, 9 substances have been identified under REACH as endocrine disruptors with adverse effects to the environment.
[17] Commission Communication 'towards a comprehensive European Union framework on endocrine disruptors'.
[18] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1539937344962&uri=CELEX:32004R1935).
[19] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0745).

devices that are invasive and come into direct contact with the human body, administer medicines and body liquids and the use of endocrine disruptors in such devices shall be justified.

3. SAFETY ASSESSMENT OF COSMETIC INGREDIENTS BY THE SCCS

a. SCCS' METHODOLOGY FOR SAFETY ASSESSMENT

The SCCS is mandated by the Commission to perform the safety assessment of substances used in cosmetic products, including CMR substances and nanomaterials[20].

Relevant information on the different aspects of testing and safety evaluation of cosmetic substances in Europe is presented in the *SCCS Notes of Guidance for Testing of Cosmetic Ingredients and Their Safety Evaluation* (SCCS Notes of Guidance). They are designed to provide guidance to public authorities and to the cosmetic industry in order to improve harmonised compliance with the Cosmetics Regulation.

The SCCS Notes of Guidance are regularly revised and updated in order to incorporate the progress of scientific knowledge in general, and the experience gained in particular, in the field of testing and safety evaluation of cosmetic ingredients[21].

b. SCCS' APPROACH TO THE SAFETY ASSESSMENT OF ENDOCRINE DISRUPTORS

The SCCS has set out its specific approach to the safety assessment of endocrine disruptors in its *Memorandum on Endocrine Disruptors* (SCCS/1544/14) of 16 December 2014. In that document the SCCS endorsed, in accordance with the European Food Safety Authority (the EFSA)[22] and the 'Endocrine Disruptors Expert Advisory Group' convened by the Commission's Joint Research Centre (JRC)[23], the above-mentioned WHO/IPCS definition of an endocrine disruptor.

In its Memorandum, the SCCS has supported the conclusions of the EFSA that *'[endocrine disruptors] can […] be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment'*. EFSA has also found that *'levels of concern are not determined exclusively by risk assessment but also by protection goals set by the risk management'*.

The SCCS' position to the safety assessment of endocrine disruptors as described in the Memorandum was confirmed in the 9th revision of the SCCS Notes of Guidance[24] of 25 April

[20] Articles 15, 16 and 31 of the Cosmetics Regulation.
[21] Last update: SCCS/1564/15, 9th revision of 25 April 2016.
[22] EFSA (2013), Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment, EFSA Journal 2013;11(3):3132.
[23] Munn S., Goumenou M-P., Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group (ED EAG). JRC-IHCP 2013. [29 pp.]DOI: 10.2788/8659 (online). Retrieved from: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC79981/lbna25919enn.pdf.
[24] SCCS/1564/15, 9th revision of 25 April 2016.

2016. The SCCS pointed out that this approach is in line with its past and present practices with regard to a safety assessment for substances with endocrine-disrupting properties.

The SCCS and its predecessors, the Scientific Committee on Consumer Products (the SCCP) and the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, have indeed already evaluated cosmetic ingredients suspected of having endocrine-disrupting properties. Examples of ingredients on which the SCCS and its predecessors delivered such scientific opinions are several parabens[25] (which are cosmetic preservatives), triclosan[26] (used as a preservative and deodorant), homosalate[27] (used in sunscreens as UV-filter but also for its skin conditioning properties), benzophenones (mainly used to protect cosmetics from the effects of UV-light), the UV-filters 4-methylbenzylidene camphor and 3-benzylidene camphor[28], melatonin[29] (used as an antioxidant), resorcinol[30] (hair dye) and cyclomethicone[31] (which has various functions such as antistatic, softening and smoothing the skin or hair conditioning).

These opinions illustrate the type of data used for ensuring a scientific evaluation of substances suspected to have endocrine disrupting properties[32]. Conclusions are made whether endocrine/hormonal activities are linked to the critical endpoint for assessing the safety of these substances for consumers, including vulnerable groups such as children when applicable. They confirm that the SCCS can perform a risk assessment of these substances for use in cosmetics in accordance with the current SCCS methodology.

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 (subject to the limitations linked to the animal testing ban for cosmetics[33]), as in the case of certain parabens which are used as preservatives in cosmetics. The SCCS carried out a case-by-case safety assessment of the different parabens. While the safety for use in cosmetics of certain types of parabens[34] has been confirmed by the SCCS, the SCCS could not rule out the risk for human health of other categories of parabens[35]. 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

[25] SCCP/1017/06, SCCP/1183/08, SCCS/1348/10, SCCS/1446/11, SCCS/1514/13.
[26] SCCP/1192/08 and SCCS/1414/11.
[27] SCCP/1086/07.
[28] SCCNFP/0483/01 and SCCS/1513/13.
[29] SCCS/1315/10.
[30] SCCS/1270/09.
[31] SCCS/1241/10.
[32] Data from *in vitro* studies suitable to detect different hormonal activities were reviewed together with data from *in vivo* studies relevant for detection of related developmental and reproductive toxicity as well as information on human exposure resulting from the use of these substances.
[33] Article 18(1) of the Cosmetics Regulation.
[34] Methylparaben, ethylparaben, propylparaben and butylparaben
[35] Isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben

designed for application on the nappy area of children under the age of three; while the use of other parabens was confirmed as safe.[36]

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 which are aimed at ensuring product safety.

4. AVAILABLE EVIDENCE FOR THE IDENTIFICATION OF ENDOCRINE DISRUPTORS

To support the impact assessment performed by the Commission in the field of plant protection products and biocides[37], a screening study of available evidence on chemical substances for their potential identification as endocrine disruptors was performed by an external contractor and published on 30 June 2016[38]. The methodology[39] for the screening was developed by the JRC.

The study was carried out to estimate the number and the identity of the chemicals which would be potentially identified as endocrine disruptors under different options for criteria to identify endocrine disrupting properties. The substances screened were overall about 600 chemicals, including almost all approved active substances in the EU for use in plant protection products and biocidal products, plus a subset of chemicals falling under REACH Regulation, the Cosmetics Regulation and the Water Framework Directive.

The results of the screening study do not constitute scientific evaluations of individual substances which need to be specifically carried out under the respective chemical legislations, in particular the Cosmetics Regulation. It would thus be erroneous to consider that the substances listed in the results of this study are considered as endocrine disruptors within the meaning of the EU legislation.

Therefore the results of the screening study cannot be used as such for a regulatory decision and need to be confirmed[40] through a critical review and a re-assessment of the data.

Within the screening exercise performed, the analysis of the 51 substances used as cosmetics ingredients[41] has shown that, according to the methodology applied, the large majority has not been identified as potentially having endocrine-disrupting properties. However this outcome may result from the lack of evidence for endocrine-disrupting properties in the subset of the 51 substances examined rather than negative evidence.

---

[36] Commission Regulation (EU) No 358/2014 of 9 April 2014 amending Annexes II and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 107, 10.4.2014, p. 5 and Commission Regulation (EU) No 1004/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 282, 26.9.2014, p. 5.

[37] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

[38] http://ec.europa.eu/health/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf

[39] http://publications.jrc.ec.europa.eu/repository/bitstream/JRC101950/jrc%20screening%20methodology%20for%20ed%20impact%20assessment%20%28online%29.pdf

[40] See the disclaimer on the front page of the screening methodology and the screening report.

[41] Initially forty-five substances, including the category of parabens of which seven were analysed. (http://ec.europa.eu/health/endocrine_disruptors/docs/impactassessment_chemicalsubstancesselection_en.pdf).

Among the seven cosmetic substances identified as potentially having endocrine-disrupting properties and the three for which the results were inconclusive[42], half is already banned and listed in Annex II to the Cosmetics Regulation ('list of substances prohibited in cosmetic products') or will be prohibited as CMR substances.

The remaining few substances identified as potentially having endocrine-disrupting properties are not covered by an existing or ongoing prohibition. The next steps regarding those substances are presented in Section 5.

In addition to these 51 substances, some substances were not specifically screened for cosmetics in the context of the study but are actually also used in cosmetics and have been identified as potentially having endocrine-disrupting properties.

An example is triclosan, subject to a non-approval decision[43] under the Biocidal Products Regulation[44] for its use in product-type 1 – human hygiene disinfecting product (e.g.: hand disinfectant) due to unacceptable risks for the environment. In 2014, the Commission already implemented a restriction to the use of triclosan as a preservative in cosmetics, following the scientific opinions of the SCCP[45] and of the SCCS[46]. This was a result of the opinions of the SCCP and the SCCS which considered that the continued use of triclosan as a preservative at the previously allowed maximum concentration limit of 0.3 % in all cosmetic products was not safe for the consumer because of the magnitude of the aggregate exposure taking into account the concerns related to endocrine disruption.

The Commission is aware of the ongoing debate on potential endocrine-disrupting properties of triclosan. As soon as new scientific data[47] on possible adverse effects of triclosan on human health become available, the Commission will assess the next steps to be taken based on such data.

5. CONCLUSIONS AND PROPOSED NEXT STEPS

As regards environmental aspects, chemical substances with adverse effects to the environment are taken care of under REACH where they can be, for example, subjected to authorisations or restrictions. Therefore chemical substances with endocrine-disrupting properties impacting on the environment which are used in cosmetics can be subject to regulatory measures under REACH.

---

[42] Limited or no relevant data available.
[43] Commission Implementing Decision (EU) 2016/110 of 27 January 2016 not approving triclosan as an existing active substance for use in biocidal products for product-type 1, OJ L 21, 28.1.2016, p. 86.
[44] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.6.2012, p. 1.
[45] SCCP/1192/08 and SCCS/1414/11.
[46] Commission Regulation (EU) No 358/2014 of 9 April 2014 amending Annexes II and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 107, 10.4.2014, p. 5.
[47] The Member State Committee under REACH, after having carried out a substance evaluation of triclosan, has decided to ask registrants of triclosan to provide further data on endocrine disruption (Decision from 19. September 2014 on Substance Evaluation pursuant to article 46(1) of Regulation (EC) No 1907/2006). (https://echa.europa.eu/documents/10162/c58c17a8-d00f-4327-853e-2b3d66ffad9e)

As regards health aspects, in contrast to CMRs, the Cosmetics Regulation does not specifically lay down any regulatory consequences for endocrine disruptors. However substances identified or considered as potential endocrine disruptors which have been classified as CMRs are to be banned under Article 15 unless a specific derogation is fully justified and scientifically approved by the SCCS. For substances other than CMRs which are identified or considered to be potential endocrine disruptors, the provisions of Article 31 to prohibit or restrict their use would apply following a risk assessment where there is a potential risk to human health identified, as shown in the examples of triclosan and parabens. In the risk assessment procedure for substances used as cosmetic ingredients, the SCCS considers also the exposure assessment for specific vulnerable groups, such as children and pregnant women. This is critical since cosmetic products are consumer products used by every citizen every day.

Therefore, the Cosmetics Regulation provides the adequate tools to regulate the use of cosmetic substances that present a potential risk for human health and to take the appropriate regulatory measures based on a scientific assessment of available data concerning human health.

Mindful of 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.

The cornerstone of the existing legislative framework is the scientific risk assessment of cosmetic ingredients carried out by the SCCS. The SCCS has confirmed that it can assess the safety of cosmetic ingredients with respect to their endocrine-disrupting activity, subject to the restrictions imposed by the animal testing ban for cosmetic products. Substances identified as endocrine disruptors 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 which are aimed at ensuring product safety.

When the SCCS safety assessment concludes to a risk to human health of substances considered as potential endocrine disruptors, the Commission is in a position to take the appropriate measures to ban or restrict the use of such substances in cosmetics on a case by case basis. Such action has already been taken in the past, as shown in the above-mentioned examples and will continue in the future. The Commission will establish by the 1st Quarter 2019 a priority list of potential endocrine disruptors that are not already covered by the bans laid down in the Cosmetics Regulation[48]. In order to prepare the assessment of such substances, the Commission will launch calls for data addressed to Member States, stakeholders and academia. Upon receipt of such data, the Commission will mandate the SCCS to evaluate the substances in the shortest delay. On that basis, the Commission will take the appropriate action to ban or restrict the use of the different substances in cosmetics.

[48] Substances prohibited from use in cosmetic products and specific prohibitions applicable to CMR substances.

The Commission will further analyse the efficiency, effectiveness and coherence between the different risk-management approaches to endocrine disruptors laid down in EU law, including the Cosmetics Regulation, as stated in the Commission Communication 'towards a comprehensive European Union framework on endocrine disruptors' which announces the launch of a cross-sectoral Fitness Check on endocrine disruptors.