Stefanie Merenyi

Consolidated Substances Legislation (CSL)

Band 4

COSMETICS: Regulation (EC) No 1223/2009

Text of the consolidated version (August 2018)

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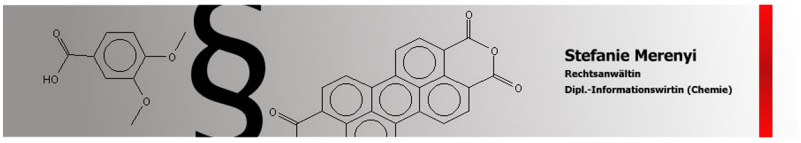

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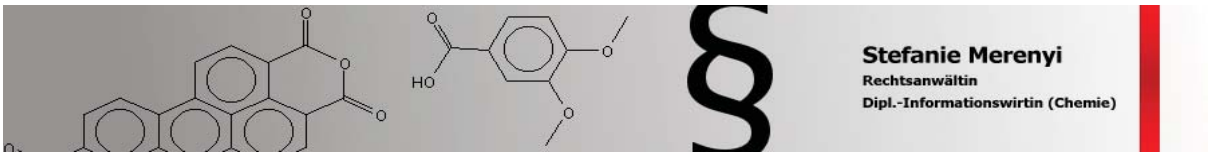

Consolidated Substances Legislation

COSMETICS

Regulation 1223/2009

Consolidated version August 2018

Preface

Chemicals legislation is quite a vivid regulatory arena. As is the case in the science of Chemistry itself there is also no standstill in chemicals legislation. Most of the relevant regulations are subject to chronic revisions.

In order to keep up with the actual legislation beyond the efforts of a loose-leaf-collection

the series

CSL: **C**onsolidated **S**ubstances **L**egislation

has been created.

It offers a firm outline regarding the different fields of substances legislation (besides the general substances legislation like REACH also cosmetics legislation, biocides, etc.) and provides users with the relevant legislative texts in an actual and **consolidated** manner. I.e. starting from the original regulation all modifications can be found at their respective position within the legal text. Therefore, the need for a detailed compilation of each and any corrigendum, amendment and adaptation to the technical progress can be reduced to a minimum.

The area of substances legislation is both a fascinating and demanding legal field that can hardly be compared to any other, as its regulations create direct effects on everyone.

The series **CSL** offers a new access to its origins.

Schoeneck, Germany, September 2018

Attorney-at-Law,
Information Scientist Chemistry

Stefanie Merenyi

Consolidated version of

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 30 November 2009

on cosmetic products

(recast)

last amended by

Commission Regulation (EU) 2018/978

of 9 July 2018

Important Notice:

Consolidation implies the integration of Community legislation,
i.e. their basic instruments, amendments and corrections
in one single, non-official document.

Therefore, this document is **only** be intended as **documentation tool**.

Only European Union legislation printed in
the paper edition of the
Official Journal of the European Union (OJ)
and the electronic edition thereof (e-OJ) accordingly
is deemed authentic.

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of 30 November 2009

on cosmetic products

(recast)

(Text with EEA relevance)

(OJ L 342, 22.12.2009, p. 59)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EU) No 344/2013 of 4 April 2013	L 114	1	25.4.2013
►M2	Commission Regulation (EU) No 483/2013 of 24 May 2013	L 139	8	25.5.2013
►M3	Commission Regulation (EU) No 658/2013 of 10 July 2013	L 190	38	11.7.2013
►M4	Commission Regulation (EU) No 1197/2013 of 25 November 2013	L 315	34	26.11.2013
►M5	Commission Regulation (EU) No 358/2014 of 9 April 2014	L 107	5	10.4.2014
►M6	Commission Regulation (EU) No 866/2014 of 8 August 2014	L 238	3	9.8.2014
►M7	Commission Regulation (EU) No 1003/2014 of 18 September 2014	L 282	1	26.9.2014
►M8	Commission Regulation (EU) No 1004/2014 of 18 September 2014	L 282	5	26.9.2014
►M9	Commission Regulation (EU) 2015/1190 of 20 July 2015	L 193	115	21.7.2015
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►M13	Commission Regulation (EU) 2016/622 of 21 April 2016	L 106	7	22.4.2016
►M14	Commission Regulation (EU) 2016/1120 of 11 July 2016	L 187	1	12.7.2016
►M15	Commission Regulation (EU) 2016/1121 of 11 July 2016	L 187	4	12.7.2016
►M16	Commission Regulation (EU) 2016/1143 of 13 July 2016	L 189	40	14.7.2016
►M17	Commission Regulation (EU) 2016/1198 of 22 July 2016	L 198	10	23.7.2016
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►**M24**	Commission Regulation (EU) 2018/885 of 20 June 2018	L 158	1	21.6.2018
►**M25**	Commission Regulation (EU) 2018/978 of 9 July 2018	L 176	3	12.7.2018

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►**C1** Corrigendum, OJ L 142, 29.5.2013, p. 10 (344/2013)
►**C2** Corrigendum, OJ L 254, 28.8.2014, p. 39 (866/2014)
►**C3** Corrigendum, OJ L 17, 21.1.2017, p. 52 (2016/314)
►**C4** Corrigendum, OJ L 326, 9.12.2017, p. 55 (2017/2228)
►**C5** Corrigendum, OJ L 183, 19.7.2018, p. 27 (2018/978)

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REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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on cosmetic products

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(Text with EEA relevance)

CHAPTER I

SCOPE, DEFINITIONS

Article 1

Scope and objective

This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) ‘cosmetic product’ means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;

(b) ‘substance’ means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(c) ‘mixture’ means a mixture or solution composed of two or more substances;

(d) ‘manufacturer’ means any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

(e) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market;

(f) ‘end user’ means either a consumer or professional using the cosmetic product;

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(g) ‘making available on the market’ means any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

(h) ‘placing on the market’ means the first making available of a cosmetic product on the Community market;

(i) ‘importer’ means any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market;

(j) ‘harmonised standard’ means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services [1] on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

(k) ‘nanomaterial’ means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;

(l) ‘preservatives’ means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;

(m) ‘colorants’ means substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants;

(n) ‘UV-filters’ means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation;

(o) ‘undesirable effect’ means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;

(p) ‘serious undesirable effect’ means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death;

(q) ‘withdrawal’ means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;

(r) ‘recall’ means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;

[1] OJ L 204, 21.7.1998, p. 37.

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(s) ‘frame formulation’ means a formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formulation. The Commission shall provide indications for the establishment of the frame formulation and adapt them regularly to technical and scientific progress.

2. For the purposes of point (a) of paragraph 1, a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.

3. In view of the various definitions of nanomaterials published by different bodies and the constant technical and scientific developments in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level. That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

CHAPTER II

SAFETY, RESPONSIBILITY, FREE MOVEMENT

Article 3

Safety

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

(a) presentation including conformity with Directive 87/357/EEC;

(b) labelling;

(c) instructions for use and disposal;

(d) any other indication or information provided by the responsible person defined in Article 4.

The provision of warnings shall not exempt persons defined in Articles 2 and 4 from compliance with the other requirements laid down in this Regulation.

Article 4

Responsible person

1. Only cosmetic products for which a legal or natural person is designated within the Community as ‘responsible person’ shall be placed on the market.

2. For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation.

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3. For a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person.

The manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

4. Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

5. For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market.

The importer may, by written mandate, designate a person established within the Community as the responsible person who shall accept in writing.

6. The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

Article 5

Obligations of responsible persons

1. Responsible persons shall ensure compliance with Articles 3, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2) and (5), as well as Articles 20, 21, 23 and 24.

2. Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate.

Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authorities of the Member States in which they made the product available and of the Member State in which the product information file is readily accessible, giving details, in particular, of the non-compliance and of the corrective measures taken.

3. Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

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Article 6

Obligations of distributors

1. In the context of their activities, when making a cosmetic product available on the market, distributors shall act with due care in relation to applicable requirements.

2. Before making a cosmetic product available on the market distributors shall verify that:

— the labelling information provided for in Article 19(1)(a), (e) and (g) and Article 19(3) and (4) is present,

— the language requirements provided for in Article 19(5) are fulfilled,

— the date of minimum durability specified, where applicable under Article 19(1), has not passed.

3. Where distributors consider or have reason to believe that:

— a cosmetic product is not in conformity with the requirements laid down in this Regulation, they shall not make the product available on the market until it has been brought into conformity with the applicable requirements,

— a cosmetic product which they have made available on the market is not in conformity with this Regulation, they shall make sure that the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate, are taken.

Furthermore, where the cosmetic product presents a risk to human health, distributors shall immediately inform the responsible person and the competent national authorities of the Member States in which they made the product available, giving details, in particular, of the non-compliance and of the corrective measures taken.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation.

5. Distributors shall cooperate with competent authorities, at the request of the latter, on any action to eliminate the risks posed by products which they have made available on the market. In particular, distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2, in a language which can be easily understood by that authority.

Article 7

Identification within the supply chain

At the request of a competent authority:

— responsible persons shall identify the distributors to whom they supply the cosmetic product,

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— the distributor shall identify the distributor or the responsible person from whom, and the distributors to whom, the cosmetic product was supplied.

This obligation shall apply for a period of three years following the date on which the batch of the cosmetic product was made available to the distributor.

Article 8

Good manufacturing practice

1. The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1.

2. Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

Article 9

Free movement

Member States shall not, for reasons related to the requirements laid down in this Regulation, refuse, prohibit or restrict the making available on the market of cosmetic products which comply with the requirements of this Regulation.

CHAPTER III

SAFETY ASSESSMENT, PRODUCT INFORMATION FILE, NOTIFICATION

Article 10

Safety assessment

1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

The responsible person shall ensure that:

(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;

(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;

(c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

The first subparagraph shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

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The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. Those guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).

2. The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State.

3. Non-clinical safety studies referred to in the safety assessment according to paragraph 1 and carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product shall comply with Community legislation on the principles of good laboratory practice, as applicable at the time of performance of the study, or with other international standards recognised as being equivalent by the Commission or the ECHA.

Article 11

Product information file

1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

2. The product information file shall contain the following information and data which shall be updated as necessary:

(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;

(b) the cosmetic product safety report referred to in Article 10(1);

(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;

(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;

(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.

3. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.

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The information contained in the product information file shall be available in a language which can be easily understood by the competent authorities of the Member State.

4. The requirements provided in paragraphs 1 to 3 of this Article shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

Article 12

Sampling and analysis

1. Sampling and analysis of cosmetic products shall be performed in a reliable and reproducible manner.

2. In the absence of any applicable Community legislation, reliability and reproducibility shall be presumed if the method used is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*.

Article 13

Notification

1. Prior to placing the cosmetic product on the market the responsible person shall submit, by electronic means, the following information to the Commission:

(a) the category of cosmetic product and its name or names, enabling its specific identification;

(b) the name and address of the responsible person where the product information file is made readily accessible;

(c) the country of origin in the case of import;

(d) the Member State in which the cosmetic product is to be placed on the market;

(e) the contact details of a physical person to contact in the case of necessity;

(f) the presence of substances in the form of nanomaterials and:

(i) their identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;

(ii) the reasonably foreseeable exposure conditions;

(g) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;

(h) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

The first subparagraph shall also apply to cosmetic products notified under Directive 76/768/EEC.

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2. When the cosmetic product is placed on the market, the responsible person shall notify to the Commission the original labelling, and, where reasonably legible, a photograph of the corresponding packaging.

3. As from 11 July 2013, a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall submit, by electronic means, the following information to the Commission:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address;

(d) the name and address of the responsible person where the product information file is made readily accessible.

4. Where a cosmetic product has been placed on the market before 11 July 2013 but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address.

On the basis of that communication, the responsible person shall submit to the Commission, by electronic means, the information referred to in paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a (4) of Directive 76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.

5. The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1, and in paragraphs 2 and 3 available electronically to all competent authorities.

That information may be used by competent authorities only for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

6. The Commission shall, without delay, make the information referred to in paragraphs 1, 2 and 3 available electronically to poison centres or similar bodies, where such centres or bodies have been established by Member States.

That information may be used by those bodies only for the purposes of medical treatment.

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7. Where any of the information set out in paragraphs 1, 3 and 4 changes, the responsible person or the distributor shall provide an update without delay.

8. The Commission may, taking into account technical and scientific progress and specific needs related to market surveillance, amend paragraphs 1 to 7 by adding requirements.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

CHAPTER IV

RESTRICTIONS FOR CERTAIN SUBSTANCES

Article 14

Restrictions for substances listed in the Annexes

1. Without prejudice to Article 3, cosmetic products shall not contain any of the following:

(a) prohibited substances

— prohibited substances listed in Annex II;

(b) restricted substances

— restricted substances which are not used in accordance with the restrictions laid down in Annex III;

(c) colorants

(i) colorants other than those listed in Annex IV and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2;

(ii) without prejudice to points (b), (d)(i) and (e)(i), substances which are listed in Annex IV but which are not intended to be used as colorants, and which are not used in accordance with the conditions laid down in that Annex;

(d) preservatives

(i) preservatives other than those listed in Annex V and preservatives which are listed there but not used in accordance with the conditions laid down in that Annex;

(ii) without prejudice to points (b), (c)(i) and (e)(i), substances listed in Annex V but which are not intended to be used as preservatives, and which are not used in accordance with the conditions laid down in that Annex;

(e) UV-filters

(i) UV-filters other than those listed in Annex VI and UV-filters which are listed there but not used in accordance with the conditions laid down in that Annex;

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(ii) without prejudice to points (b), (c)(i) and (d)(i), substances listed in Annex VI but which are not intended to be used as UV-filters and which are not used in accordance with the conditions laid down in that Annex.

2. Subject to a decision of the Commission to extend the scope of Annex IV to hair colouring products, such products shall not contain colorants intended to colour the hair, other than those listed in Annex IV and colorants intended to colour the hair which are listed there but not used in accordance with the conditions laid down in that Annex.

The decision of the Commission referred to in the first subparagraph, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

Article 15

Substances classified as CMR substances

1. The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation.

2. The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

However, such substances may be used in cosmetic products by way of exception where, subsequent to their classification as CMR substances of category 1A or 1B under Part 3 of Annex VI to Regulation (EC) No 1272/2008, all of the following conditions are fulfilled:

(a) they comply with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [1];

(b) there are no suitable alternative substances available, as documented in an analysis of alternatives;

(c) the application is made for a particular use of the product category with a known exposure; and

(d) they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.

[1] OJ L 31, 1.2.2002, p. 1.

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Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure.

In order to implement this paragraph, the Commission shall amend the Annexes to this Regulation in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 32(4) of this Regulation.

The Commission shall mandate the SCCS to re-evaluate those substances as soon as safety concerns arise, and at the latest five years after their inclusion in Annexes III to VI to this Regulation, and at least every subsequent five years.

3. By 11 January 2012, the Commission shall ensure that appropriate guidance is developed with the aim of enabling a harmonised approach to the development and use of overall exposure estimates in assessing the safe use of CMR substances. This guidance shall be developed in consultation with the SCCS, the ECHA, the EFSA and other relevant stakeholders, drawing, as appropriate, on relevant best practice.

4. 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.

Article 16

Nanomaterials

1. For every cosmetic product that contains nanomaterials, a high level of protection of human health shall be ensured.

2. The provisions of this Article do not apply to nanomaterials used as colorants, UV-filters or preservatives regulated under Article 14, unless expressly specified.

3. In addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the responsible person by electronic means six months prior to being placed on the market, except where they have already been placed on the market by the same responsible person before 11 January 2013.

In the latter case, cosmetic products containing nanomaterials placed on the market shall be notified to the Commission by the responsible person between 11 January 2013 and 11 July 2013 by electronic means, in addition to the notification in Article 13.

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The first and the second subparagraphs shall not apply to cosmetic products containing nanomaterials that are in conformity with the requirements set out in Annex III.

The information notified to the Commission shall contain at least the following:

(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI;

(b) the specification of the nanomaterial including size of particles, physical and chemical properties;

(c) an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year;

(d) the toxicological profile of the nanomaterial;

(e) the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products;

(f) the reasonably foreseeable exposure conditions.

The responsible person may designate another legal or natural person by written mandate for the notification of nanomaterials and shall inform the Commission thereof.

The Commission shall provide a reference number for the submission of the toxicological profile, which may substitute the information to be notified under point (d).

4. In the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions. The Commission shall make this information public. The SCCS shall deliver its opinion within six months of the Commission's request. Where the SCCS finds that any necessary data is lacking, the Commission shall request the responsible person to provide such data within an explicitly stated reasonable time, which shall not be extended. The SCCS shall deliver its final opinion within six months of submission of additional data. The opinion of the SCCS shall be made publicly available.

5. The Commission may, at any time, invoke the procedure in paragraph 4 where it has any safety concerns, for example due to new information supplied by a third party.

6. Taking into account the opinion of the SCCS, and where there is a potential risk to human health, including when there is insufficient data, the Commission may amend Annexes II and III.

7. The Commission may, taking into account technical and scientific progress, amend paragraph 3 by adding requirements.

8. The measures, referred to in paragraphs 6 and 7, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

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9. On imperative grounds of urgency the Commission may use the procedure referred to in Article 32(4).

10. The following information shall be made available by the Commission:

(a) By 11 January 2014, the Commission shall make available a catalogue of all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions. This catalogue shall be regularly updated thereafter and be made publicly available.

(b) The Commission shall submit to the European Parliament and the Council an annual status report, which will give information on developments in the use of nanomaterials in cosmetic products within the Community, including those used as colorants, UV-filters and preservatives in a separate section. The first report shall be presented by 11 July 2014 The report update shall summarise, in particular, the new nanomaterials in new categories of cosmetic products, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international cooperation programmes.

11. The Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions.

The first review shall be undertaken by 11 July 2018.

Article 17

Traces of prohibited substances

The non-intended presence of a small quantity of a prohibited substance, stemming from impurities of natural or synthetic ingredients, the manufacturing process, storage, migration from packaging, which is technically unavoidable in good manufacturing practice, shall be permitted provided that such presence is in conformity with Article 3.

CHAPTER V

ANIMAL TESTING

Article 18

Animal testing

1. Without prejudice to the general obligations deriving from Article 3, the following shall be prohibited:

(a) the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Regulation, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;