Schedule 34 of the Product Safety & Metrology etc (Amendment etc) (EU Exit) Regulations 2019
UK Cosmetics Regulation (CTPA Consolidated Version)

According to the Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 SI, the UK Cosmetics Regulation only applies to the GB market (England, Wales and Scotland). Northern Ireland follows the EU Cosmetics Regulation, in accordance with Annex II of the Northern Ireland Protocol to the EU/UK Withdrawal Agreement.

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 of Great Britain, in order to ensure the functioning of the 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 person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under their name or trademark;

(e) 'distributor' means any person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the market of Great Britain;

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

(g) 'making available on the market' means any supply of a cosmetic product for distribution, consumption or use on the market of Great Britain in the course of a commercial activity, whether in return for payment or free of charge and related expressions are to be construed accordingly

(h) 'placing on the market' means the first making available of a cosmetic product on the market of great Britain on or after IP completion day and related expressions are to be construed accordingly;

(i) 'importer' means any person who –

(aa) is established in the United Kingdom and places a cosmetic product from a country outside of the United Kingdom on the market; or

(bb) is established in Northern Ireland and places a cosmetic product on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge, from an EEA state;

(j) omitted;

(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;

(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.

(t) 'Regulation (EC) No 1272/2008' means Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classifications, labelling and packaging of substances

and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) 1907/2006;

(u) 'EU Regulation (pre-exit)' means Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (recast) (a), as it has effect immediately before IP completion day;

(v) 'Enforcement Regulations' means the Cosmetic Products Enforcement Regulations 2013(b);

(va) 'CMR' means carcinogenic, mutagenic or toxic for reproduction;

(w) 'competent authority' has the meaning given to it in regulation 4 of the Enforcement Regulations;

(x) 'enforcement authority' has the meaning given to it in regulation 2(1) of the Enforcement Regulations;

(y) 'finished cosmetic product' means the cosmetic product in its final formulation, as placed on the market and made available to the end user, or its prototype;

(ya) 'historic animal testing data' means data from any animal testing that was carried out before the date on which such testing was prohibited in accordance with Article 18 of the EU Cosmetics Regulation (pre-exit);

(z) 'prototype' means a first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed;

(za) "the transitory period" means the period of 90 days beginning on the day after the day on which IP completion day falls.

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.—(1) Subject to subparagraphs (6) and (7), in this Regulation a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of subparagraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a cosmetic product, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—
(a) the European Committee for Standardisation (CEN);
(b) the European Committee for Electrotechnical Standardisation (Cenelec);
(c) the European Telecommunications Standards Institute (ETSI);
(d) the British Standards Institution (BSI).

4. When considering whether the manner of publication of a reference is appropriate in accordance with subparagraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

5. Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

6. The Secretary of State may remove from publication the reference to a standard which has been published in accordance with subparagraph (1)(b).

7. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

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 'the Food Imitations (Safety) Regulations 1989(a)';

(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. A cosmetic product may not be placed on the market unless there is a responsible person established in the United Kingdom in respect of the cosmetic product.

2. Subject to paragraphs 6 and 7, a manufacturer of a cosmetic product is the responsible person in respect of that product where—

(a) the manufacturer is established in the United Kingdom or subject to Article 5A; and
(b) the cosmetic product—
(i) is manufactured in the United Kingdom; and
(ii) after manufacture but prior to placing on the market is not exported and imported back into the United Kingdom.

3. Where paragraph 4 applies the manufacturer must ensure that—

(a) there is a person established in the United Kingdom designated by written mandate as the responsible person in respect of the cosmetic product; and
(b) that person has agreed in writing to be the responsible person in respect of that cosmetic product.

4. This paragraph applies where—

(a) a manufacturer of a cosmetic product is established in a country outside the United Kingdom; and
(b) the cosmetic product—
(i) is manufactured in the United Kingdom; and
(ii) after manufacture but prior to placing on the market is not exported and imported back into the United Kingdom.

5. Subject to paragraphs 6 and 7, any importer placing a cosmetic product on the market is the responsible person in respect of that cosmetic product.

6. An importer or a manufacturer established in the United Kingdom may by written mandate designate a person established in the United Kingdom as the responsible person.

7. Where the person designated by the importer or the manufacturer under paragraph 6 accepts the designation in writing, that person is the responsible person.

8. A distributor is the responsible person in respect of a cosmetic product where that distributor—
(a) places a product on the market under the distributor's name or trademark; or
(b) modifies a product already placed on the market in such a way that compliance with the applicable requirements 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 authorities 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 authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product.

4. The information and documentation referred to in paragraph 3 must be in English.

Article 5A

Obligations of responsible persons established in Northern Ireland

1. Where paragraph 3 applies, a responsible person is to be treated as complying with Articles 3, 8, 10 to 12, 14 to 18, 19(1), (2) and (5) and 20 to 24.

2. Where paragraph 4 applies, a responsible person is to be treated as complying with Articles 8, 10 to 12, 14 to 18, 19(1), (2) and (5) and 20 to 24.

3. This paragraph applies where—
(a) the responsible person—
(i) is established in Northern Ireland;
(ii) is a responsible person for the purposes of EU Regulation (Northern Ireland);
(iii) has complied with the obligations of a responsible person under Article 5 of EU Regulation (Northern Ireland); and
(iv) when submitting information under Article 13 the responsible person at the same time gives notice to the Secretary of State confirming the matters in points (i) to (iii); and
(b) the cosmetic product is qualifying Northern Ireland goods.

4. This paragraph applies where—
(a) the responsible person is a person—
(i) to which Article 2(i)(bb) applies; and
(ii) who gives notice to the Secretary of State when submitting information under Article 13 that a responsible person for the purposes of EU Regulation (Northern Ireland) has complied with the obligations of a responsible person under Article 5 of EU Regulation (Northern Ireland); and
(b) the cosmetic product is qualifying Northern Ireland goods.

5. In this Article— "EU Regulation (Northern Ireland)" means Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30th December 2008 on cosmetic products (recast), as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the withdrawal agreement. "qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018."".

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 authorities, 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 authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product with the requirements listed under paragraph 2.

6. The information and documentation referred to in paragraph 3 must be in English.

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,
- 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 designated standards.

Article 9 - omitted

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.

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 the Secretary of 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 must comply with the Good Laboratory Practice Regulations 1999" (a), or with international standards recognised as being equivalent by the Secretary of State.

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, their 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 must make the product information file readily accessible to a competent authority in an electronic or other format at the address notified in accordance with Article 13 as the address at which the product information file is kept.

4. The information contained in the product information file must be in English.

Article 12

Sampling and analysis

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

2. Reliability and reproducibility shall be presumed if the method used is in accordance with the relevant designated standards.

Article 13

Notification

1. Before placing a cosmetic product on the market, the responsible person must submit by electronic means the following information to the Secretary of State—

(a) the category of cosmetic product and its name or names, enabling its specific identification;
(b) the name of the responsible person;
(c) the address at which the product information file in respect of the cosmetic product is kept;
(d) the contact details of a natural person to contact in the case of urgency;
(e) where applicable, the following information—
    (i) presence of substances in the form of nanomaterials;
    (ii) the identification including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation; and
    (iii) the reasonably foreseeable exposure conditions;

(f) the name and the Chemicals Abstracts Service (CAS) or EC number of substances classified as CMR substances of category 1A or 1B under Regulation (EC) No 1272/2008;
(g) the frame formulation allowing for prompt and appropriate medical treatment in the event of difficulties.

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

3. Paragraph 4 applies in relation to a cosmetic product where prior to IP completion day —
(a) the cosmetic product has been supplied on the market of the United Kingdom or the market of any EEA state for distribution, consumption or use in the course of a commercial activity (whether in return for payment or free of charge); and
(b) a responsible person designated under Article 4 of the EU Regulation (pre-exit) has complied with Article 13 of that Regulation in relation to that product.

4. Where this paragraph applies—
(a) if the cosmetic product is placed on the market at any time before the expiry of the transitory period, subject to subparagraph (b), paragraphs 1 and 2 are to have effect as if they required the information specified in those paragraphs before the end of the transitory period;
(b) paragraph 1 is to be treated as being satisfied in respect of the cosmetic product and paragraph 2 does not apply in respect of that product where—
(i) before the expiry of the transitory period, the responsible person for the cosmetic product submits to the Secretary of State by electronic means the information set out in points (a) to (d) and (g) of paragraph 1; and
(ii) when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 3 in relation to the cosmetic product;
(c) if at any time a request is made to the responsible person by the Secretary of State in accordance with paragraphs 5 and 5, the responsible person must comply with the request within the period specified in the request.

5. Where the Secretary of State considers it necessary for the purposes of reducing a risk to human health, the Secretary of State may request that a responsible person submits the information referred to in paragraph 1(e) to (f) in relation to a cosmetic product to which paragraph 4 applies.

6. When making a request under paragraph 6 the Secretary of State must specify a period—
(a) within which the responsible person must respond; and
(b) which is reasonable and commensurate with the nature of the risk presented by the product.

7. The Secretary of State must make the following information available in relation to a cosmetic product to all other competent authorities—
(a) the information referred to in paragraph 1(a) to (f); and
(b) the information referred to in paragraph 2.

8. Competent authorities may only use the information referred to in paragraph 8 for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25 to 27.

9. The Secretary of State must without delay make the following information available to poison centres or similar bodies established in the United Kingdom—
(a) the information referred to in paragraph 1; and

(b) the information referred to in paragraph 2

10. Those poison centres and similar bodies may only use that information for the purposes of medical treatment.

11. Where any information provided under this Article in relation to a cosmetic product changes, the responsible person must provide an update by electronic means to the Secretary of State without delay.

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) subject to point (iii) 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;
(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;
(iii) point c(i) does not apply to hair colouring products;

(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;
(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.

Article 15

Substances classified as CMR substances

1. A cosmetic products must not contain a substance classified as a CMR substance of category 1A, 1B or 2 under Regulation (EC) No 1272/2008, unless the substance is included in any of Annexes 3-6.

2. Where a CMR substance of category 1A or 1B is permitted for use in cosmetic products, specific labelling in order to avoid misuse of the cosmetic product must 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.

Article 16

Nanomaterials

1. The provisions of this Article do not apply to nanomaterials used as colourants, UV filters or preservatives that are regulated under Article 14.

2. A cosmetic product containing nanomaterials must be notified in accordance with paragraph 3.

3. To meet the requirements of paragraph 2, the information set out in paragraph 4 must be submitted by electronic means—

(a) to the Secretary of State;
(b) by the responsible person; and
(c) at least six months prior to the cosmetic product being placed on the market.

4. The information referred to in paragraph 3 must contain—

(a) the identification of the nanomaterial including its chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes 2 to 6 to this Regulation;
(b) the specification of the nanomaterial including size of particles and chemical properties;
(c) an estimate of the quantity of nanomaterials contained in cosmetic products intended to be placed on the market per year;
(d) except where paragraph 13 applies, 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.

5. Paragraph 6 applies in relation to a cosmetic product containing nanomaterials where prior to IP completion day —

(a) the cosmetic product has been supplied on the market of the United Kingdom or the market of any EEA state for distribution, consumption or use in the course of a commercial activity (whether in return for payment or free of charge); and

(b) a responsible person designated under Article 4 of the EU Regulation (pre-exit) has complied with Article 16 of that Regulation in relation to that product.

6. Where this paragraph applies—

(a) if the cosmetic product containing nanomaterials is placed on the market at any time before the expiry of the transitory period, subject to subparagraph (b) paragraphs 2 and 3 are to have effect as if they required the information specified in paragraph 4 before the end of the transitory period; and
(b) paragraphs 2 and 3 are to be treated as being satisfied in respect of the cosmetic product where—

(i) before the end of the transitory period, the responsible person for the cosmetic product submits to the Secretary of State by electronic means the information set out in paragraph 4; and

(ii) when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 5 in relation to the cosmetic product;

(c) if at any time a request is made to the responsible person by a competent authority in accordance with paragraphs 9 and 10, the responsible person must comply with the request within the period specified in the request.

7. Paragraph 8 applies in relation to a cosmetic product containing nanomaterials where—

(a) prior to IP completion day a responsible person designated under Article 4 of the EU Regulation (pre-exit) has complied with the requirements of Article 16 of that Regulation in relation to that product; and

(b) the period between the day on which IP completion day falls and the day on which the person designated under Article 4 of the EU Regulation (pre-exit) complied with Article 16 of that Regulation is less than six months.

8. Where this paragraph applies—

(a) paragraphs 2 and 3 are to be treated as being satisfied where—

(i) a period of 7 months has elapsed between the day on which the responsible person designated under Article 4 of the EU Regulation (pre-exit) complied with Article 16 of that Regulation and the day on which the responsible person places the cosmetic product on the market;

(ii) before the expiry of the transitory period, the responsible person for that cosmetic product submits to the Secretary of State the information set out in paragraph 4; and

(iii) when submitting that information, the responsible person at the same time gives notice confirming the matters set out in paragraph 7; and

(b) if at any time a request is made to the responsible person by a competent authority in accordance with paragraphs 9 and 10, the responsible person must comply with the request within the period specified in the request.

9. Where a competent authority has concerns regarding the safety of a nanomaterial, the competent authority may request that a responsible person submits the following information to the competent authority—

(a) which nanomaterials are used in a cosmetic product; and

(b) the reasonably foreseeable exposure conditions.

10. When a competent authority makes a request under paragraph 9, the competent authority must specify a period—

(a) within which the responsible person must respond; and

(b) which is reasonable and commensurate with the nature of the concerns held by the competent authority.

11. Where paragraph 12 applies, the information set out in paragraph 4 may be provided by the person designated in accordance with that paragraph on behalf of the responsible person.

12. This paragraph applies where—

(a) the responsible person designates another person by written mandate to meet the notification requirements under this Article in respect of a cosmetic product on that responsible person's behalf ("the designated person");

(b) the designated person accepts the designation in writing; and

(c) the responsible person informs the Secretary of State of the name and address of that designated person.

13. The Secretary of State may provide a reference for the toxicological profile and that reference may be provided in the place of the information referred to in paragraph 4(d).

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. Except as provided in paragraph 1A, no cosmetic product may be placed on the market—

(a) where the final formulation of the product has been the subject of animal testing in order to meet the requirements of this Regulation;

(b) where the ingredients or combinations of ingredients of the product have been the subject of animal testing in order to meet the requirements of this Regulation.

1A. Paragraph (1) does not prevent the use of historic animal testing data in order to meet the requirements of this Regulation;

2. No animal testing of finished cosmetic products may take place in the United Kingdom in order to meet the requirements of this Regulation.

3. No animal testing of ingredients or combinations of ingredients may take place in the United Kingdom in order to meet the requirements of this Regulation.

CHAPTER VI

CONSUMER INFORMATION

Article 19

Labelling

1. Without prejudice to other provisions in this Article, cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering:

(a) the name or registered name and the address of the responsible person. Such information may be abbreviated in so far as the abbreviation makes it possible to identify that person and their address. If several addresses are indicated, the one where the responsible person makes readily

available the product information file shall be highlighted. The country of origin shall be specified for imported cosmetic products;
(ab) for a period of two years beginning on the day after the day on which IP completion day falls, point (a) is to be treated as satisfied where the requirements of Article 19(1)(a) of the EU Regulation (pre-exit) are complied with;
(b) the nominal content at the time of packaging, given by weight or by volume, except in the case of packaging containing less than five grams or five millilitres, free samples and single-application packs; for pre-packages normally sold as a number of items, for which details of weight or volume are not significant, the content need not be given provided the number of items appears on the packaging. This information need not be given if the number of items is easy to see from the outside or if the product is normally only sold individually;
(c) the date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3 ('date of minimum durability').
The date itself or details of where it appears on the packaging shall be preceded by the symbol shown in point 3 of Annex VII or the words: 'best used before the end of'.

The date of minimum durability shall be clearly expressed and shall consist of either the month and year or the day, month and year, in that order. If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the date of minimum durability shall not be mandatory for cosmetic products with a minimum durability of more than 30 months. For such products, there shall be an indication of the period of time after opening for which the product is safe and can be used without any harm to the consumer. This information shall be indicated, except where the concept of durability after opening is not relevant, by the symbol shown in point 2 of Annex VII followed by the period (in months and/or years);
(d) particular precautions to be observed in use, and at least those listed in Annexes III to VI and any special precautionary information on cosmetic products for professional use;
(e) the batch number of manufacture or the reference for identifying the cosmetic product. Where this is impossible for practical reasons because the cosmetic products are too small, such information need appear only on the packaging;
(f) the function of the cosmetic product, unless it is clear from its presentation;
(g) a list of ingredients. This information may be indicated on the packaging alone. The list shall be preceded by the term 'ingredients'.

For the purpose of this Article, an ingredient means any substance or mixture intentionally used in the cosmetic product during the process of manufacturing. The following shall not, however, be regarded as ingredients:

(i) impurities in the raw materials used;
(ii) subsidiary technical materials used in the mixture but not present in the final product.

Perfume and aromatic compositions and their raw materials shall be referred to by the terms 'parfum' or 'aroma'. Moreover, the presence of substances, the mention of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients in addition to the terms parfum or aroma.

The list of ingredients shall be established in descending order of weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %.

All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.

Colorants other than colorants intended to colour the hair may be listed in any order after the other cosmetic ingredients. For decorative cosmetic products marketed in several colour shades, all colorants other than colorants intended to colour the hair used in the range may be listed, provided that the words 'may contain' or the symbol '+/-' are added. The CI (Colour Index) nomenclature shall be used, where applicable.

2. Where it is impossible for practical reasons to label the information mentioned in points (d) and (g) of paragraph 1 as provided, the following applies:

— the information shall be mentioned on an enclosed or attached leaflet, label, tape, tag or card;
— unless impracticable, this information shall be referred to by abbreviated information or the symbol given in point 1 of Annex VII, which must appear on the container or packaging for the information referred in point (d) of paragraph 1 and on packaging for the information referred in point (g) of paragraph 1.

3. In the case of soap, bath balls and other small products where it is impossible for practical reasons for the information referred to in point (g) of paragraph 1 to appear on a label, tag, tape or card or in an enclosed leaflet, this information shall appear on a notice in immediate proximity to the container in which the cosmetic product is exposed for sale.

4. For cosmetic products that are not pre-packaged, are packaged at the point of sale at the purchaser's request, or are pre-packaged for immediate sale, the requirements of regulation 5(1) and (2) of the Enforcement Regulations apply for indication of the information referred to in paragraph 1.

5. The language of the information mentioned in points (b), (c), (d) and (f) of paragraph 1 and in paragraphs (2), (3) and (4) must meet the requirements of regulation 5(3) of the Enforcement Regulations.

6. The information mentioned in point (g) of paragraph 1 shall be expressed by using the common ingredient name set out in the glossary referred to in Article 33. In the absence of a common ingredient name, a term as contained in a generally accepted nomenclature shall be used.

Article 20

Product claims

1. In the labelling, making available on the market and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.

2. A responsible person must ensure that the wording of any claim in relation to a cosmetic product is in compliance with the common criteria set out in the Annex to Commission Regulation (EU) No 655/2013 of 10th July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

3. The responsible person may refer, on the product packaging or in any document, notice, label, ring or collar accompanying or referring to the cosmetic product, to the fact that no animal tests have been carried out only if the manufacturer and the manufacturer's suppliers have not carried out or commissioned any animal tests on the finished cosmetic product, or its prototype, or any of the ingredients contained in it, or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products.

Article 21

Access to information for the public

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume and aromatic compositions, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product are made easily accessible to the public by any appropriate means.

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.

CHAPTER VII

MARKET SURVEILLANCE

Article 22

In-market control

Enforcement authorities must monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall enforcement authorities must perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file and, where appropriate, physical and laboratory checks on the basis of adequate samples.

Enforcement authorities must also monitor compliance with the principles of good manufacturing practices.

The Secretary of State must entrust other enforcement authorities with the resources and knowledge necessary for the proper performance of their duties.

Article 23

Communication of serious undesirable effects

1. In the event of serious undesirable effects, the responsible person and distributors shall without delay notify the following to the competent authority Secretary of State:

(a) all serious undesirable effects which are known to the responsible person or the distributor or which may reasonably be expected to be known to that responsible person or distributor;

(b) the name of the cosmetic product concerned, enabling its specific identification;
(c) the corrective measures taken by responsible person or distributor, if any.

2. The Secretary of State must immediately inform all other competent authorities of any information notified to the Secretary of State under paragraph 1.

3. Where a distributor reports serious undesirable effects of a cosmetic product to the Secretary of State, the Secretary of State must immediately inform the responsible person.

4. Where end users or health professionals report serious undesirable effects of a cosmetic product to any competent authority that is not the Secretary of State, that competent authority must immediately inform the Secretary of State who must then immediately inform the responsible person.

Where end users or health professionals report serious undesirable effects of a cosmetic product to the Secretary of State, the Secretary of State must immediately inform all other competent authorities and the responsible person.

5. Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

Article 24

Information on substances

In the event of serious doubt regarding the safety of any substance contained in cosmetic products, a competent authority may by reasoned request require the responsible person to submit a list of all cosmetic products for which the responsible person is responsible and which contain this substance. The list shall indicate the concentration of this substance in the cosmetic products.

Competent authorities may use the information referred to in this Article for the purposes of in-market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

CHAPTER VIII

NON-COMPLIANCE, SAFEGUARD CLAUSE

Article 25

Non-compliance by the responsible person

1. Competent authorities shall require the responsible person to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within an expressly mentioned time limit, commensurate with the nature of the risk, where there is non-compliance with any of the following:
(a) the good manufacturing practice referred to in Article 8;
(b) the safety assessment referred to in Article 10;
(c) the requirements for the product information file referred to in Article 11;
(d) the provisions on sampling and analysis referred to in Article 12;
(e) the notification requirements referred to in Articles 13 and 16;
(f) the restrictions for substances referred to in Articles 14, 15 and 17;
(g) the animal testing requirements referred to in Article 18;

(h) the labelling requirements referred to in Article 19(1), (2), (5) and (6);
(i) the requirements related to product claims set out in Article 20;
(j) the access to information for the public referred to in Article 21;
(k) the communication of serious undesirable effects referred to in Article 23;
(l) the information requirements on substances referred to in Article 24.

2. Omitted

3. The responsible person shall ensure that the measures referred to in paragraph 1 are taken in respect of all the products concerned which are made available on the market.

4. Omitted

5. The competent authority shall take all appropriate measures to prohibit or restrict the making available on the market of the cosmetic product or to withdraw the product from the market or to recall it in the following cases:
(a) where an immediate action is necessary in the event of serious risk to human health; or
(b) where the responsible person does not take all appropriate measures within the time limit referred to in paragraph 1.

6. In the event of serious risks to human health, a competent authority which has taken measures under paragraph 5 must inform all other competent authorities of the measures taken.

7. For the purposes of paragraph 6 the database provided for in regulation 33(A1) of the General Product Safety Regulations 2005 (S.I. 2005/1803) must be used.

Article 26

Non-compliance by distributors

Competent authorities shall require distributors to take all appropriate measures, including corrective actions bringing the cosmetic product into conformity, the withdrawal of the product from the market or its recall, within a given reasonable time limit, commensurate with the nature of the risk, where there is non-compliance with obligations laid down in Article 6.

Article 27

Safeguard clause

1. In the case of products meeting the requirements listed in Article 25(1), where an enforcement authority ascertains, or has reasonable grounds for concern, that a cosmetic product or products made available on the market present or could present a serious risk to human health, it shall take all appropriate provisional measures in order to ensure that the product or products concerned are withdrawn, recalled or their availability is otherwise restricted.

2. An enforcement authority which is not the Secretary of State must obtain authorisation from the Secretary of State after requesting the authorisation in accordance with regulation 11 of the Enforcement Regulations prior to taking provisional measures under this Article.

3. The Secretary of State must determine, as soon as possible, whether the provisional measures referred to in paragraph 1 are justified or not. For that purpose the Secretary of State must, whenever possible, consult any person the Secretary of State considers has an interest in the measure".

4. Where the provisional measures are justified the Secretary of State must give authorisation to the enforcement authority to take those measures.

Article 28

Good administrative practices

1. Any decision taken pursuant to Articles 25 and 27 shall state the exact grounds on which it is based. It shall be notified by the competent authority without delay to the responsible person, who shall at the same time be informed of the remedies available to the responsible person under the law and of the time limits to which remedies are subject.

2. Except in the case where immediate action is necessary for reasons of serious risk to human health, the responsible person shall have the opportunity to put forward their viewpoint before any decision is taken.

3. Where applicable, the provisions mentioned in paragraphs 1 and 2 shall apply with regard to the distributor for any decisions taken pursuant to Articles 26 and 27.

CHAPTER IX

ADMINISTRATIVE COOPERATION

Article 29 - Omitted

Cooperation between competent authorities

Article 30 - Omitted

Cooperation regarding verification of product information files

CHAPTER X

POWERS AND FURTHER DUTIES OF THE SECRETARY OF STATE

Article 30

Power to amend Articles

1. Where the Secretary of State considers it necessary to do so to take technical progress into account, the Secretary of State may by regulations amend—

(a) point (k) of Article 2(1) (nanomaterials);
(b) paragraphs 1, 2 and 6 to 12 of Article 13 (notification) to add requirements; or
(c) paragraphs 3, 4 and 11 to 13 of Article 16 (nanomaterials) to add requirements.

2. The Secretary of State may by regulations amend paragraph 3 of Article 2(2) to reflect any changes in the name or structure of the recognised standardisation bodies.

3. Where the conditions in paragraph (4) are met, the Secretary of State may by regulations amend Article 16(1) to extend the provisions of Article 16 to nanomaterials used as colorants, UV-filters or preservatives that are regulated under Article 14.

4. The conditions referred to in paragraph (3) are that the Secretary of State considers that it is necessary to do so in view of-

(a) safety concerns raised by a competent authority; or

(b) scientific or technical evidence that there are safety concerns relating to colorants, UV-filters or preservatives regulated under Article 14.

5. The Secretary of State may amend Article 14(1)(c) to extend its scope to hair colouring products.

Article 31

Power to amend the annexes

1. The Secretary of State may by regulations amend—

(a) Annex 1 where the Secretary of State considers there is sufficient scientific evidence that it is necessary to do so to ensure the safety of cosmetic products;

(b) Annexes 2 to 6 where the Secretary of State considers that there is sufficient scientific evidence that there is a potential risk to human health arising from the use of a substance in a cosmetic product;

(c) Annexes 2 or 3 where the Secretary of State considers that there is insufficient data to be able to determine whether there is a potential risk to human health;

(d) Annexes 3 to 6 and 8 where the Secretary of State considers that there is sufficient scientific evidence that it is necessary to do so to take technical progress into account;

(e) Annex 4 to extend its scope to hair colouring products.

(f) Annex 2 to add a substance classified as a CMR substance of category 1A, 1B or 2 under Regulation (EU) No 1272/2008;

(g) Annexes 3 to 6 –

(i) to allow a substance classified as a CMR substance of category 2 under Regulation (EU) No 1272/2008 to be used in cosmetic products where the Secretary of State considers that there is sufficient evidence that the substance is safe for use in cosmetic products;

(ii) to allow a substance classified as a CMR substance of category 1A or 1B under Regulation (EC) no 1272/2008 to be used in cosmetic products where the conditions in point (h) are met;

(iii) to make provisions as to labelling in order to implement Article 15(2);

(h) the conditions referred to in point (g)(ii) are that –

(i) the CMR substance complies with the food safety requirements as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 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;

(ii) an analysis of alternative substances has been undertaken and concluded that there are no suitable alternative substances available;

(iii) an application to the Secretary of State is made for a particular use of the product category with a known exposure;

(iv) the Secretary of State considers that there is sufficient scientific evidence that the CMR substance has been evaluated and found safe for use in cosmetic products; and

(v) the evaluation referred to in point (iv) took into account exposure to the product and overall exposure to the CMR substance from other sources, particularly for vulnerable population groups.

Article 32

Procedure for making regulations

1. Regulations made under Articles 30 or 31 may—
    (a) make different provisions for different cases; and
    (b) make such supplementary, transitional, transitory, consequential or saving provision as the Secretary of State considers appropriate.
3. Regulations made under Articles 30 or 31 are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

Article 33

Further duties of the Secretary of State

1. The Secretary of State must establish and operate a database containing information relating to cosmetic products which have been made available on the market.

2. The Secretary of State must publish guidance to enable undertakings to comply with the requirements in Annex 1.

3. Before publishing guidance referred to in paragraph 1, the Secretary of State must—
    (a) consult such persons as the Secretary of State considers have an interest in the guidance;
    (b) consider how the guidance can be made accessible to business with fewer than 250 members of staff.

4. The Secretary of State must publish the reference to a glossary of common ingredient names and the glossary must be easily accessible and free to use(a).