SCHEDULE 34

Regulation 37

Amendment of Regulation (EC) No 1223/2009 and related amendments

Introduction

1. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November on cosmetic products (recast) is amended in accordance with paragraphs 2 to 28.

Amendment of Article 1

2. In Article 1 (scope and objective) omit "internal".

Amendment of Article 2

3. In Article 2 (definitions), in paragraph 1—

(a) in point (d) (manufacturer)—

(i) omit "natural or legal";

(ii) for "his" substitute "their";

(b) in point (e) (distributor)—

(i) omit "natural or legal";

(ii) omit "Community";

(c) in point (g) (making available on the market)—

(i) for "Community" substitute "United Kingdom";

(ii) at the end insert "and related expressions are to be construed accordingly";

(d) for point (h) (placing on the market) substitute—

"(h) placing on the market' means the first making available of a cosmetic product on the United Kingdom market on or after exit day and related expressions are to be construed accordingly;";

(e) for point (i) (importer) substitute—

"(i) 'importer' means any person established in the United Kingdom who places a cosmetic product from a country outside the United Kingdom on the market;";

(f) omit point (j) (harmonised standard);

(g) in point (s) omit the last sentence;

(h) after point (s) insert—

"(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)(**1**), as it has effect immediately before exit day;

(**1**) OJ L 342, 22.12.2009, p.59.

(v) 'Enforcement Regulations' means the Cosmetic Products Enforcement Regulations 2013(**2**);

(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;

(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 exit day falls.";

(i) for paragraph (3) substitute—

"**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.

(**2**) S.I. 2013/1478; regulation 7(1)(a) was amended and Schedule 2 was revoked by S.I. 2015/1630.

(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.".

Amendment of Article 3

4. In Article 3 (safety), in point (a) for "Directive 87/357/EEC" substitute "the Food Imitations (Safety) Regulations 1989(**3**)".

Substitution of Article 4

5. For Article 4 (responsible person) substitute—

"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; 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.

(**3**) S.I. 1989/1291.

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.".

Amendment of Article 5

6. In Article 5 (obligations of responsible persons)—

(a) in paragraphs 2 and 3 omit "national";

(b) in paragraph 2 omit the words from "of the Member States" (in the first place in which it occurs) to "accessible";

(c) in paragraph 3 omit ", in a language which can be easily understood by that authority";

(d) after paragraph 3 insert—

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

Amendment of Article 6

7. In Article 6 (obligations of distributors)—

(a) in paragraph 3—

(i) omit "national";

(ii) omit "of the Member States in which they made the product available";

(b) in paragraph 5—

(i) omit "national";

(ii) omit ", in a language which can be easily understood by that authority";

(c) after paragraph 5 insert—

"**6.** The information and documentation referred to in paragraph 5 must be in English".

Amendment of Article 8

8. In Article 8 (good manufacturing practice), in paragraph 2—

(a) for "harmonised" substitute "designated";

(b) omit ", the references of which have been published in the Official Journal of the European Union".

Omission of Article 9

9. Omit Article 9 (free movement).

Amendment of Article 10

10. In Article 10 (safety assessment)—

(a) in paragraph 1 omit the words from "The first subparagraph shall" to "referred to in Article 32(2).";

(b) in paragraph 2 for "a Member State" substitute "the Secretary of State";

(c) in paragraph 3—

(i) for the words from "shall comply with" to "study" substitute "must comply with the Good Laboratory Practice Regulations 1999"(**4**);

(ii) before "international standards" omit "other";

(iii) for "Commission or the ECHA" substitute "Secretary of State".

Amendment of Article 11

11. In Article 11 (product information file)—

(a) in point (e) for "his" substitute "their";

(b) for paragraph 3 substitute—

"**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.";

(c) for paragraph 4 substitute—

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

Amendment of Article 12

12. In Article12, in paragraph 2—

(a) omit "In the absence of any applicable Community legislation,";

(b) for "harmonised" substitute "designated";

(c) omit ", the references of which have been published in the Official Journal of the European Union".

Substitution of Article 13

13. For Article 13 (notification) substitute—

"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—

(**4**) S.I. 1999/3106; regulation 2(1) was amended by S.I. 2004/994; there are some other amendments not relevant to these Regulations.

(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 carcinogenic, mutagenic or toxic for reproduction (CMR) 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 exit 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 6, 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 5 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 7 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.".

Amendment of Article 14

14. In Article 14 (restrictions for substances)—

(a) in paragraph 1(c)(i)—

(i) at the beginning insert "Subject to point (iii);

(ii) omit "except for hair colouring products referred to in paragraph 2";

(b) after point (c)(ii) insert—

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

(c) omit paragraph 2.

Substitution of Article 15

15. For Article 15 (substances classified as CMR substances) substitute—

"Article 15

Substances classified as CMR substances

1. Cosmetic products must not contain substances classified as category 2 CMR substances under Regulation (EC) No 1272/2008.

2. Cosmetic products must not contain substances classified as category 1A or 1B CMR substances under Regulation (EC) No 1272/2008".

Substitution of Article 16

16. For Article 16 (nanomaterials) substitute—

"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 exit 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 exit 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 exit 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)".

Substitution of Article 18

17. For Article 18 (animal testing) substitute—

"Article 18

Animal testing

1. 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.

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.".

Amendment of Article 19

18. In Article 19 (labelling)—

(a) in paragraph 1 point (a) for "his" substitute "their";

(b) after point (a) of paragraph 1 insert—

"(ab) for a period of two years beginning on the day after the day on which exit 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;";

(c) in paragraph 4 for the words from "Member" to "rules" substitute "the requirements of regulation 5(1) and (2) of the Enforcement Regulations apply";

(d) in paragraph 5 for the words from "shall be" to "user" substitute "must meet the requirements of regulation 5(3) of the Enforcement Regulations";

(e) in paragraph 6 for "provided for" substitute "referred to".

Amendment of Article 20

19. In Article 20 (product claims)—

(a) for paragraph 2 substitute—

"**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.";

(b) in paragraph 3 for "his" substitute "the manufacturer's".

Amendment of Article 22

20. In Article 22 (in-market control)—

(a) in the first and second paragraphs for "Member States shall" substitute "enforcement authorities must";

(b) for "They shall" substitute "Enforcement authorities must";

(c) for the third paragraph substitute—

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

(d) omit the fourth paragraph.

Amendment of Article 23

21. In Article 23 (communication of serious undesirable effects)—

(a) in paragraph 1—

(i) for "competent authority" substitute "Secretary of State";

(ii) omit the words from "of the Member State" to "occurred";

(b) in point (a) for "him"—

(i) in the first place in which it occurs substitute "the responsible person or the distributor";

(ii) in the second place in which it occurs substitute "that responsible person or distributor"'

(c) in point (c) for "him" substitute "that responsible person or distributor";

(d) for paragraph 2 substitute—

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

(e) for paragraph 3 substitute—

"**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.";

(f) for paragraph 4 substitute—

"**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.".

Amendment of Article 24

22. In Article 24 (information on substances)—

(a) for "the competent" substitute "a competent";

(b) omit the words from "of a Member" to "market";

(c) for "he" substitute "the responsible person".

Amendment of Article 25

23. In regulation 25 (non-compliance by responsible person)—

(a) in paragraph 1 omit "Without prejudice to paragraph 4,"

(b) omit paragraph 2;

(c) in paragraph 3 omit "throughout the Community";

(d) omit paragraph 4;

(e) in paragraph 5 omit the subparagraph after point (b);

(f) for paragraph 6 substitute—

"**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.";

(g) for paragraph 7 substitute—

"**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".

Amendment to Article 27

24. In Article 27 (safeguard clause)—

(a) in paragraph 1 for "a competent authority" substitute "an enforcement authority"

(b) for paragraph 2 substitute—

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

(c) in paragraph 3—

(i) for "Commission shall" substitute "Secretary of State must";

(ii) for "it shall" substitute "the Secretary of State must";

(iii) for the words from "the interested" to "SCCS" substitute "any person the Secretary of State considers has an interest in the measure";

(d) for paragraph 4 substitute—

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

(e) omit paragraph 5.

Amendment of Article 28

25. In Article 28 (good administrative practice)—

(a) in paragraph 1—

(i) for "him" substitute "that responsible person";

(ii) omit "of the Member State concerned";

(b) in paragraph 2 for "his" substitute "their".

Omission of Chapter 9

26. Omit Chapter 9.

Substitution of Chapter 10

27. For Chapter 10, substitute—

"CHAPTER 10

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. The Secretary of State may by regulations amend—

(a) paragraph 1 of Article 15 (category 2 CMR substances) to allow category 2 CMR substances to be used in cosmetic products where the Secretary of State considers that there is sufficient scientific evidence that the substance is safe for use in cosmetic products; and

(b) where the conditions referred to in paragraph 4 are met, paragraph 2 of Article 15 (category 1A or 1B CMR substances)—

(i) to allow a cosmetic product to contain CMR substances classified as category 1A or 1B CMR substances under Regulation (EC) No 1272/2008; and

(ii) to set out specific labelling requirements to avoid the misuse of the cosmetic product, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure.

4. The conditions referred to in paragraph 3(b) are—

(a) that the CMR substances 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 matters of food safety;

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

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

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

(e) that the evaluation referred to in point (d) took into account exposure to these cosmetic products and overall exposure to the CMR substances from other sources, particularly for vulnerable population groups.

5. Where the conditions in paragraph 6 are met, the Secretary of State may by regulations amend Article 16(1) to extend the provisions of Article 16 to nanomaterials used as colourants, UV-filters or preservatives that are regulated under Article 14.

6. The conditions referred to in paragraph 5 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 colourants, UV filters or preservatives regulated under Article 14.

7. 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.

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(**5**).".

Amendment to the Preamble to Annexes 2 to 6

28. In paragraph 2, after "1907/2006" insert "of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restrictions of Chemicals establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC".

PART 3

Amendment of the Cosmetic Products Enforcement Regulations 2013

29. The Cosmetic Products Enforcement Regulations 2013(**6**) are amended in accordance with paragraphs 30 to 40.

Amendment to regulation 2

30. In regulation 2 (interpretation)—

(a) in the definition of "the EU Cosmetics Regulation" omit "EU";

(b) in the definition of "officer" omit "EU";

(c) omit paragraph (2);

(d) in paragraph (3) omit "EU" in both places in which it occurs.

Amendment to regulation 3

31. In regulation 3 (revocation and savings)—

(a) in paragraph (2)(a) after "apply" insert "subject to the modification in paragraph 3,";

(b) in paragraph (2)(b) omit "EU";

(c) after paragraph (2)(b) insert—

"(c) enforcement authorities must keep information received under regulations 17 or 19 of the 2008 Regulations until 11th July 2020;

(d) a responsible person under those Regulations must keep the information collected under regulation 16 of those Regulations until 11th July 2020.";

(d) after paragraph (2) insert—

(**5**) Copies of the glossary of common ingredients is available from the Office of Product Safety and Standards, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H OET.

(**6**) S.I. 2013/1478; regulation 7(1)(a) was amended and Schedule 2 was revoked by S.I. 2015/1630.

"(3) The modification referred to in paragraph (2)(a) is that any reference to "EEA" is to be read as including the United Kingdom.".

Insertion of regulation 3A

32. After regulation 3, insert—

"**Transitional provisions in relation to EU Exit**

3A.—(1) In this regulation—

"pre-exit period" means the period beginning with 11 July 2013 and ending immediately before exit day;

"product" means a cosmetic product to which these Regulations apply.

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 34 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**7**)—

(a) any obligation to which a person was subject and was enforced under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product; and

(b) enforcement authorities continue to be under an obligation to enforce the obligations referred to in paragraph (a).

(3) Paragraph (2) does not apply to—

(a) any obligation of any competent authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the United Kingdom in respect of that product.".

Amendment to regulation 4

33. In regulation 4 (competent authority)—

(a) in paragraph (1)—

(i) omit "Subject to paragraph (2)"; and

(ii) omit "EU";

(b) omit paragraph (2);

(c) in paragraph (3) omit "Notwithstanding paragraph (2),".

Amendment to regulations 5 to 8 and 10

34. In regulations 5 to 8 and 10 each place in which it occurs and in the heading to regulation 8 omit "EU".

Omission of regulation 9

35. Omit regulation 9.

(**7**) S.I. 2019/696.

Amendment to regulation 10

36. In regulation 10 (notification to the Secretary of State) omit the words from ",which is required" to "member States".

Amendment to regulation 11

37. In regulation 11 for "regulation 9" substitute "Article 27(2) of the Cosmetics Regulation".

Amendment to regulations 12 to 15, 17, 19 to 21

38. In regulations 12 to 15, 17 and 19 to 21 in each place in which it occurs omit "EU".

Amendment to regulation 26

39. In regulation 26 in paragraphs (1) and (3) after "these Regulations" insert "and the Cosmetic Regulation".

Amendment to Schedule 3

40. In Schedule 3 (sampling and testing) omit "EU" in each place in which it occurs.

PART 4

Amendment to EU tertiary legislation

Amendment to Commission Regulation (EU) No 655/2013

41. Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products is amended in accordance with paragraphs 42 and 43.

Amendment to Article 2

42. In Article 2—

(a) in the first place in which it occurs, after "1223/2009" insert "of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast);

(b) in the second place in which it occurs for "Regulation (EC) No 1223/2009" substitute "that Regulation".

Amendment to the Annex

43. In the Annex—

(a) in paragraph 1(1) for "within the Union" substitute "within the meaning of regulation 4 of the Cosmetic Products Enforcement Regulations 2013 or under Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast)**(8)** (as it has effect in EU law)";

(b) in paragraph 6(3) for "relevant Member States" substitute "the United Kingdom or relevant parts of the United Kingdom".

(**8**) OJ L 342, 22.12.2009 p. 59.