Draft Legislation: This is a draft item of legislation and has not yet been made as a UK Statutory Instrument. This draft has been replaced by a new draft, The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 ISBN 978-0-11-118040-2

SCHEDULE 34

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

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.** Where the conditions referred to in paragraph 4 are met 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) 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 the UK mandatory classification and labelling list; 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 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;

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- (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.

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.

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- **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(1).".

⁽¹⁾ 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.