EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS REGULATION (EC) NO 1223/2009 (RESTRICTION OF CHEMICAL SUBSTANCES) (AMENDMENT AND TRANSITIONAL PROVISIONS) (NO. 2) REGULATIONS 2026

2026 No. 109

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for Business and Trade and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Kate Dearden MP, Parliamentary Under-Secretary of State (Minister for Employment Rights, and Consumer Protection) at the Department for Business and Trade confirms that this Explanatory Memorandum meets the required standard.

2.2 Sophie George, Deputy Director for Product Sectors and Metrology Policy, Office for Product Safety and Standards at the Department for Business and Trade confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Will Burrows at the Department for Business and Trade, Telephone: 0121 345 1201 or email: OPSS.enquiries@businessandtrade.gov.uk, can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument amends Regulation (EC) No 1223/2009 on cosmetic products ("the Cosmetic Regulation") to restrict the use of hexyl 2-hydroxybenzoate (known as "hexyl salicylate") in cosmetic products. This instrument also prohibits a set of substances classified carcinogenic, mutagenic and reprotoxic substances ("CMR substances") from use in cosmetic products.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales and Scotland.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales and Scotland.

5. Policy Context

What is being done and why?

5.1 Article 15 of the Cosmetic Regulation prohibits the use of CMR substances in cosmetic products, unless the substance is listed in Annexes 3 to 6. This instrument amends Annex 2 (list of substances prohibited in cosmetic products) to the Cosmetic Regulation to include a set of substances classified as category 1B or 2 CMR

substances under Regulation (EC) No 1272/2008 on classification, labelling and packaging ("the CLP Regulation"). The CMR substances are set out in Schedule 1 to these Regulations.

5.2 This instrument also restricts the use of hexyl salicylate in cosmetic products. Hexyl salicylate is classified as a category 2 CMR substance under the CLP Regulation. Following the submission of an exemption application by industry, the use of hexyl salicylate in cosmetic products was subject to scientific assessment by the Scientific Advisory Group on Chemical Safety ("SAG-CS"). SAG-CS provides the Secretary of State with scientific advice regarding the use of chemicals in consumer products and assesses their safety to human health. SAG-CS concluded that hexyl salicylate is safe for use in cosmetic products subject to certain restrictions[1]. This instrument amends Annex 3 (list of substances which cosmetic products must not contain except subject to the restrictions laid down) to include hexyl salicylate and restrict its use to specific concentrations in a number of cosmetic products. The concentrations vary depending on the cosmetic product type and age of the intended user. The restrictions are set out in Schedule 2 to these Regulations.

5.3 This instrument includes transitional arrangements to support industry. A cosmetic product containing hexyl salicylate that is placed on the market before 15 August 2026, may continue to be made available on the market until the end of 14 February 2027. In addition, a cosmetic product containing any of the specified CMR substances, that is placed on the market before 23 March 2027, may continue to be made available on the market until the end of 22 September 2027. These staggered timelines give industry time to adapt to comply with the updated legislative requirements.

5.4 The same restrictions on the use of hexyl salicylate and CMR substances in cosmetic products are in place in the EU and apply to Northern Ireland under the Windsor Framework. This instrument will bring GB policy in line with that of Northern Ireland.

What was the previous policy, how is this different?

5.5 There is no change of policy. The Government is responsible for ensuring only safe cosmetic products are placed on the market in GB. This instrument makes technical amendments to the Cosmetic Regulation to reflect the most up-to-date scientific evidence on the safe use of certain substances in cosmetic products.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument amends the Cosmetic Regulation to prohibit or restrict the use of certain substances in cosmetic products.

6.2 Prior to the United Kingdom's exit from the EU, the Cosmetic Regulation was directly applicable EU Law. Under the European Union (Withdrawal) Act 2018, it became retained EU law. Deficiencies were corrected by the Product Safety and. Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. No. 2019/696), and other related instruments, to provide powers for the Secretary of State to update the Cosmetic Regulation, in the same way that the European Commission can with respect to the relevant EU legislation, where there are technical or scientific

[1] https://assets.publishing.service.gov.uk/media/6915d847493305b49ce6e764/sag-cs-opinion-19-hexyl-salicylate-in-cosmetic-products.pdf

developments or evidence affecting the assessment of safety of substances in cosmetic products.

6.3 Article 15(1) of the Cosmetic Regulation provides that a cosmetic product must not contain a substance classified as a CMR substance of category 1A, 1B or 2 under the CLP Regulation, unless the substance is included in any of Annexes 3 to 6. Article 31(1)(f) of the Cosmetic Regulation provides the Secretary of State with a power to amend Annex 2 to add a substance classified as a category 1A, 1B or 2 CMR substance under the CLP Regulation. Following the classification of a set of certain substances as category 1B or 2 CMR substances under the CLP Regulation, this instrument amends Annex 2 to insert these substances into the list of substances prohibited in cosmetic products.

6.4 Article 31(1)(g)(i) of the Cosmetic Regulation provides the Secretary of State with a power to amend Annexes 3 to 6 to allow a substance classified as a CMR substance of category 2 under the CLP Regulation to be used in cosmetic products where the Secretary of State considers there is sufficient scientific evidence that the substance is safe for use in cosmetic products.

6.5 Hexyl salicylate received a mandatory category 2 CMR classification under the CLP Regulation. Following scientific assessment by SAG-CS, the Secretary of State considers there is sufficient scientific evidence that hexyl salicylate is safe for use in cosmetic products subject to certain restrictions. This instrument amends Annex 3 to the Cosmetic Regulation to restrict the use of hexyl salicylate in cosmetic products to ensure that different types of cosmetic products contain safe levels of hexyl salicylate in accordance with advice from SAG-CS.

Why was this approach taken to change the law?

6.6 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 A formal consultation was not undertaken given the instrument is limited to making technical amendments to the Cosmetic Regulation in order to reflect scientific assessment of the potential risks to human health of a substance in cosmetic products.

7.2 The Department for Business and Trade has, however, undertaken engagement with stakeholders, including trade associations and key members of the cosmetic industry. Additionally, hexyl salicylate was assessed by SAG-CS following an exemption application submitted directly by industry.

8. Applicable Guidance

8.1 The Office for Product Safety and Standards has published, and regularly updates, a guide on the Cosmetic Regulation on gov.uk to support businesses, enforcement agencies and consumers[2].

[2] https://www.gov.uk/government/publications/cosmetic-products-enforcement-regulations-2013

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the impacts are expected to be de minimis with minor administrative costs for business anticipated.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies because the impact of this instrument is limited to reformulation, labelling and familiarisation costs for businesses associated with adapting to the updated legislation.

9.3 The legislation does not disproportionally impact small or micro businesses.

9.4 No specific action is proposed to minimise the regulatory burdens on small businesses. The legal requirements on the cosmetics industry do not differentiate between businesses in terms of their size and are dependent on the type and nature of products being manufactured and placed on the market. Therefore, we are unable to take any mitigating actions to reduce burdens on small businesses.

9.5 The is no, or no significant, impact on the public sector because the impact of this instrument is limited to businesses in the cosmetic industry.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 This instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Kate Dearden MP has made the following statement: "A review would not be appropriate, given the technical nature of the amendments. However, to ensure that cosmetic products placed on the market in Great Britain are safe, the government keeps the regulatory framework under constant review, including the use of specific chemicals in particular products."

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").