EXPLANATORY MEMORANDUM TO

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

2026 No. 23

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: 07442 998687 or email: will.burrows@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 prohibit the use of 3-(4'-methylbenzylidene)-camphor (commonly known as "4-MBC") in cosmetic products and to reduce the threshold for labelling formaldehyde releasing preservatives used in cosmetic products following scientific assessment. The instrument also prohibits a set of substances classified as carcinogenic, mutagenic or toxic for reproduction ("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 4-MBC is currently permitted as a UV filter in cosmetic products up to a concentration of 4% and is listed in Annex 6 to the Cosmetic Regulation (list of UV filters allowed in cosmetic products) at reference number 18.

5.2 The Scientific Advisory Group on Chemical Safety of Non-Food and non-Medicinal Consumer Products ("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.

5.3 Following the publication of a SAG-CS opinion on 4-MBC[1], to ensure consumer safety, this instrument omits its entry in Annex 6, and amends Annex 2 (list of substances prohibited in cosmetic products) to include 4-MBC, to prohibit its use in cosmetic products.

5.4 Following the publication of a SAG-CS opinion on formaldehyde releasing substances[2], this instrument amends the Preamble to Annex 5 (list of preservatives allowed in cosmetic products) to reduce the threshold for labelling formaldehyde releasing preservatives used in cosmetic products from "0.05%" to "0.001%".

5.5 In addition, this instrument further amends Annex 2 to prohibit the use, in cosmetic products, of 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"). Carcinogenic chemicals can cause or promote cancers, mutagenic chemicals can cause genetic mutations and reprotoxic chemicals can damage the reproductive process.

5.6 The instrument also includes transitional arrangements to support industry. A cosmetic product placed on the market before 15 July 2026 that contains 4-MBC, or formaldehyde releasing preservatives that comply with the labelling requirements set out in the Cosmetic Regulation as it has effect before 15 July 2026, may continue to be made available on the market until the end of 14 January 2027. In addition, a cosmetic product containing any of the CMR substances set out in the Schedule to these Regulations 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. These staggered timelines give industry time to adapt to comply with the updated legislative requirements.

5.7 The same restrictions on the use of these substances in cosmetic products are in place in the European Union ("EU") and apply to Northern Ireland under the Windsor Framework. This instrument will bring Great Britain policy in line with that of Northern Ireland.

What was the previous policy, how is this different?

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

[1] https://assets.publishing.service.gov.uk/media/682ddebab33f68eaba95390b/sag-cs-opinion-18-4-mbc-as-a-uv-filter-in-cosmetic-products.pdf

[2] https://assets.publishing.service.gov.uk/media/682dde5ca599d03a16bff3b2/sag-cs-opinion-16-formaldehyde-releasing-substances.pdf

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument amends the Cosmetic Regulation to prohibit the use of certain substances in cosmetic products and amends the threshold for warning labelling requirements for formaldehyde releasing preservatives used 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 developments or evidence affecting the assessment of safety of substances in cosmetic products.

6.3 4-MBC is currently listed in Annex 6 to the Cosmetic Regulation (list of UV filters allowed in cosmetic products) at reference number 18. Article 31(1)(b) of the Cosmetic Regulation provides the Secretary of State with powers to amend Annexes 2 to 6 where the Secretary of State considers 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.

6.4 Following assessment of 4-MBC by SAG-CS, the Secretary of State considers there is sufficient scientific evidence that there is a potential risk to human health arising from the use of this substance in a cosmetic product. Accordingly, this instrument amends Annex 6 to remove 4-MBC from the list of UV filters allowed in cosmetic products, and amends Annex 2 to insert 4-MBC into the list of substances prohibited in cosmetic products.

6.5 In addition, based on advice from SAG-CS, the Secretary of State considers that there is sufficient scientific evidence that there is a potential risk to human health from the current threshold for warning labelling requirements for formaldehyde releasing preservatives listed in Annex 5 to the Cosmetic Regulation. This instrument amends paragraph 2 of the Preamble to Annex 5 to reduce the threshold for warning labelling requirements for formaldehyde releasing preservatives used in cosmetic products in accordance with recommendations from SAG-CS.

6.6 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 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 further amends Annex 2 to the Cosmetic Regulation to insert these substances into the list of substances prohibited in cosmetic products.

Why was this approach taken to change the law?

6.7 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 to reflect scientific assessment of the potential risks to human health of specific substances 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, before 4-MBC and formaldehyde releasing preservatives were assessed by SAG-CS, the Department published a call for data allowing any interested parties to submit any scientific information relevant to the safety assessment of these substances.

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[3].

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. To ensure that businesses have sufficient time to adapt to any reformulation and labelling costs, the instrument contains transitional provisions set out in paragraph 5.6.

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 There 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 The 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:

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

"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").