EXPLANATORY MEMORANDUM TO

THE COSMETIC PRODUCTS (RESTRICTION OF CHEMICAL SUBSTANCES) (NO. 2) REGULATIONS 2024

2024 No. 1334

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 Justin Madders MP, Parliamentary Under-Secretary of State (Minister for Employment Rights, Competition and Markets) 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: 07442998687 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 The purpose of this instrument is to restrict or prohibit the use of certain substances in cosmetic products. It amends assimilated Regulation (EC) No 1223/2009 on cosmetic products ("the Cosmetics Regulation") to:

- Regulate the use of kojic acid in cosmetic products in line with the uses found to be safe for human health following scientific assessment, and
- Prohibit a set of substances classified as carcinogenic, mutagenic or toxic for reproduction ("CMR substances") 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, Wales, and Scotland.

5. Policy Context

What is being done and why?

5.1 The Government is responsible for ensuring only safe cosmetic products are placed on the market in Great Britain. As such, the Government is responsible for keeping the

Cosmetics Regulation up to date and making amendments if scientific evidence suggests substances being used in cosmetic products may be unsafe for human health.

5.2 The Scientific Advisory Group on Chemical Safety in Consumer Products (SAG-CS) provide the Secretary of State with scientific advice and risk assessment in the areas of public health and safety. Following the publication of a SAG-CS opinion on kojic acid, this instrument amends the Cosmetics Regulation to restrict the use of kojic acid at a maximum concentration of up to 1% in face and hand products. In addition, the instrument prohibits the use, in cosmetic products, of a set of substances classified as category 1A, 1B or 2 CMR substances under assimilated Regulation (EC) No 1272/2008 on classification, labelling and packaging ("the CLP Regulation").

5.3 Without these amendments to the Cosmetics Regulation, there would be continued manufacture of cosmetic products containing ingredients that could have public health and safety implications due to the risks these substances pose to human health.

5.4 The instrument provides transitional arrangements for cosmetic products containing specified CMR substances. These substances were the subject of mandatory classification requirement decisions on different dates. The staggered timeline reflects that and gives industry time to adapt to ensure that products made available on the market comply with legislative requirements. Transitional arrangements also apply to cosmetic products containing kojic acid.

5.5 The same restrictions on the use of kojic acid in cosmetic products, and bans on the CMRs covered in this instrument, are in place in the 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?

5.6 This instrument is being introduced to ensure that only safe cosmetic products can be placed on the market in Great Britain. There is no change to policy intentions or regulatory regimes. The technical amendments to the Cosmetics Regulation are being made 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 Cosmetics Regulation to regulate the use of certain substances in cosmetic products.

6.2 Prior to the United Kingdom (UK)'s exit from the European Union (EU), the Cosmetics Regulation was directly applicable EU Law. Under the European Union (Withdrawal) Act 2018, this became retained EU law, amended by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), and other related instruments, to provide powers for the Secretary of State to update the Cosmetics 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 Article 31(1)(b) of the Cosmetics Regulation provides the Secretary of State with powers to amend Annexes 2-6 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 scientific assessment 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 kojic acid in cosmetic products when its concentration exceeds certain levels. This instrument amends Annex 3 to the Cosmetics Regulation to restrict the use of kojic acid at a maximum concentration of up to 1% in face and hand products.

6.5 Article 31(1)(f) of the Cosmetics Regulation provides the Secretary of State with power to amend Annex 2 to the Cosmetics Regulation to add substances classified as category 1A, 1B or 2 CMR substances under the CLP Regulation. This instrument amends Annex 2 to the Cosmetics Regulation to prohibit the use, in cosmetic products, of a set of substances which have received a mandatory category 1A, 1B or 2 CMR classification requirement under Article 37 of the CLP Regulation.

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 Cosmetics Regulation in order to reflect scientific assessment of the potential risks to human health of certain substances in cosmetic products.

7.2 The Department for Business and Trade has, however, undertaken extensive engagement with a variety of stakeholders, including trade associations and key members of the cosmetic industry.

8. Applicable Guidance

8.1 The Office for Product Safety and Standards has published, and regularly updates, a guide on the Cosmetics Regulation on gov.uk to support business, enforcement agencies and consumers.[1]

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 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

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

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 cosmetics industry.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach is not to monitor this legislation.

10.2 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Justin Madders 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 The Parliamentary Under-Secretary of State (Minister for Employment Rights, Competition and Markets) at the Department for Business and Trade has made the following statement regarding Human Rights:

"In my view the provisions of the Cosmetic Products (Restriction of Chemical Substances) (No. 2) Regulations 2024 are compatible with the Convention rights."

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").