

EXPLANATORY MEMORANDUM TO
THE COSMETIC PRODUCTS (RESTRICTION OF CHEMICAL SUBSTANCES)
REGULATIONS 2024

2024 No. 455

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 Kevin Hollinrake MP, Minister of State in the Department for Business and Trade can confirm that this Explanatory Memorandum meets the required standard.

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

3. Contact

3.1 Will Burrows at Office for Product Safety and Standards, 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 objective of the instrument is to regulate the use of butylated hydroxytoluene (BHT) in cosmetic products in line with the uses to be safe for human health following scientific assessment. It does this by amending the retained EU legislation, Regulation (EC) No 1223/2009 (“the Cosmetics Regulations”).

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 products are placed on the market. In the area of cosmetics, decisions in this space are based on an assessment of the available scientific evidence. As such the government is responsible for keeping the cosmetics schedules and annexes up to date and making amendments if evidence suggests that chemicals being used in the manufacture of cosmetics may be unsafe.

This instrument amends the permitted levels of certain chemicals in the Cosmetic Regulations to permit the use of BHT up to a level of:

- Toothpaste-0.1%
- Mouthwash-0.001%
- Leave-on oral care products-0.001%
- Other leave-on and rinse-off products-0.8%

5.2 Without these amendments, there will be continued manufacture of cosmetics containing ingredients that that could have public health and safety implications due to the risks these chemicals pose to human health.

What was the previous policy, how is this different?

5.3 The legislative framework for product safety operates via regulations covering specific product sectors including cosmetics. These regulations function to ensure that only products that are considered safe can be placed on the market. They also make provisions to correct or remove unsafe or inaccurate products from the market so that consumers and other end users have reassurance about the safety of products available on the market.

5.4 The provisions of this instrument are being introduced to ensure that only safe products can be placed on the market. There is no change to policy intentions or regulatory regimes. The technical amendments to the cosmetics annexes are being proposed to reflect the most up to date scientific opinion represented by the advice offered by the Scientific Advisory Group on Chemical Safety (SAG-CS). SAG-CS provides the Secretary of State with scientific advice and risk assessment in the areas of public health and consumer safety.

5.5 Additionally, technical amendments being made to the underlying regulations will provide the necessary clarity and certainty for business with regards to the specific chemicals that can no longer be used or the new levels that they are permitted to be used at.

5.6 The instrument includes staggered transitional provisions with all amendments coming into force by 24th June 2025.

5.7 Similar restrictions on BHT are in place in Northern Ireland and this instrument will bring GB policy more in line with that of Northern Ireland.

6. Legislative and Legal Context

How has the law changed?

6.1 This Instrument amends the Cosmetic Regulations to regulate the use of certain chemical substances in cosmetic products.

6.2 The European Union (Withdrawal) Act 2018 retained the Cosmetic Regulations. The Cosmetic Regulations were amended by S.I. No. 2019/696 (and other related instruments) to provide powers for the Secretary of State to update the Regulations, 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.

6.3 Article 31(1)(b) of the Cosmetic Regulations provides the Secretary of State with powers to amend Annexes 2-6 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.

- 6.4 This instrument amends the Cosmetic Regulations to:
- Permit the use of butylated hydroxytoluene (BHT) up to levels between 0.001% 0.8%, depending on its uses in specific cosmetics (e.g. mouthwashes or topical leave-on oral care products).

- 6.5 The Secretary of State considers that there is sufficient scientific evidence that butylated hydroxytoluene is safe for use in the cosmetics products listed at the concentration levels detailed above.

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 has not been completed for this instrument. The Department chose not to undertake a public consultation given that its provisions are limited to making only necessary technical amendments to the Cosmetic Regulations in order to reflect scientific assessment regarding potential risks to human health.
- 7.2 The Department 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 There is guidance on the UK's regulation for cosmetics, provided to support business, enforcement agencies and consumers, which can be found on the Office for Product Safety and Standards section of GOV.UK¹

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 of Cosmetic Products (Restriction of Chemical Substances) Regulations 2024 are expected to be de-minimis. The impact of this instrument is limited to businesses familiarising themselves with the updated regulations as well as changes to the chemical levels used within the cosmetics products.

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 businesses familiarising themselves with the updated regulations as well as changes to the chemical levels used within the cosmetics products.
- 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 industry do not differentiate between business in terms of their size and they 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 business.

- 9.5 There is no, or no significant, impact on the public sector because the impact of this instrument is limited to businesses familiarising themselves with the updated regulations as well as changes to the chemical levels used within the cosmetics products.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

- 10.1 The Department does not intent to monitor this instrument.
- 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, Kevin Hollinrake MP, Minister of State in the Department for Business and Trade, has made the following statement:
- “A review would not be appropriate, given the technical nature of the amendments. However, to ensure that products placed on the GB market 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 Kevin Hollinrake MP, Minister of State in 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) 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”).