

**EXPLANATORY MEMORANDUM TO**  
**THE COSMETIC PRODUCTS (RESTRICTION OF CHEMICAL SUBSTANCES)**  
**(NO. 2) REGULATIONS 2023**

**2023 No. 836**

**1. Introduction**

- 1.1 This explanatory memorandum has been prepared by the Department for Business and Trade (the Department) and is laid before Parliament by command of His Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

**2. Purpose of the instrument**

- 2.1 This Instrument revokes and replaces the Cosmetic Products (Restriction of Chemical Substances) Regulations 2023 (S.I. 2023/764) before any of its provisions come into force. Some of the provisions of that Instrument are due to come into force on 27<sup>th</sup> July 2023.
- 2.2 The objective of this Instrument is to regulate the use of certain chemical substances in cosmetic products, in line with the uses found 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 Regulation").

**3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 Regulation 2 of this Instrument comes into force on 26<sup>th</sup> July, which is less than 21 days after the day on which it is made. This is because it needs to revoke the Cosmetic Products (Restriction of Chemical Substances) Regulations 2023 (S.I. 2023/764) before it comes into force. That Instrument did not contain an intended provision placing a restriction on one of the chemical substances, to prohibit the substance being used in applications that may lead to exposure of the end user's lungs by inhalation.
- 3.2 Since it revokes and replaces Cosmetic Products (Restriction of Chemical Substances) Regulations 2023, the procedure for free issue has been applied.

**4. Extent and Territorial Application**

- 4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England, Wales and Scotland.
- 4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England, Wales and Scotland.

**5. European Convention on Human Rights**

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

## **6. Legislative Context**

- 6.1 This Instrument revokes and replaces the Cosmetic Products (Restriction of Chemical Substances) Regulations 2023 because that Instrument omitted a restriction on the use of one of the substances regulated by the Instrument. In all other respects this current Instrument is the same as the Instrument it revokes. It amends the Cosmetics Regulation to regulate the use of certain chemical substances in cosmetic products.
- 6.2 The European Union (Withdrawal) Act 2018 retained the Cosmetics Regulation. The Cosmetics Regulation was amended by S.I. No. 2019/696 (and other related instruments) to provide powers for the Secretary of State to update the 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.
- 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 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. Article 31(1)(d) of the Cosmetics Regulation provides the Secretary of State with powers to amend Annexes 3-6 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.
- 6.4 This instrument amends the Cosmetics Regulation to:
- Restrict the use of Methyl-N-Methylantranilate for use up to 0.1% for leave-on products not marketed for exposure to natural or artificial UV light, and 0.2% for rinse-off cosmetic products.
  - Permit the use of HAA299 and HAA299 (nano) as a UV filter up to a level of 10%, excluding use in applications that may lead to exposure of the end user's lungs by inhalation (eg: spray and aerosol products).
- 6.5 The Secretary of State considers that there is sufficient scientific evidence that Methyl-N-Methylantranilate and HAA299 and HAA299 (nano) are safe for use in the cosmetics products listed at the concentration levels detailed above.

## **7. Policy background**

### *What is being done and why?*

- 7.1 The UK makes its own decisions regarding products that can be placed on the GB market. The process for making these decisions is based on an assessment of the available scientific evidence. As such the government is responsible for keeping the cosmetics 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 Cosmetics Regulation:
- To restrict the use of Methyl-N-Methylantranilate for use up to 0.1% for leave-on products not marketed for exposure to natural or artificial UV light and 0.2% for rinse-off cosmetic products.
  - To permit the use of HAA299 and HAA299 (nano) up to a level of 10%, excluding use in applications that may lead to exposure of the end user's lungs by inhalation (e.g.: spray and aerosol products).

- 7.2 Without these amendments, there will be continued manufacture of cosmetics for the GB market containing ingredients that could have public health and safety implications due to the risks these chemicals pose to human health. Additionally, regarding HAA299, without the amendment to Annex 6, businesses will not be able to place products on the market containing HAA299 at a level we believe to be safe.

### *Explanations*

#### What did any law do before the changes to be made by this instrument?

- 7.3 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 products from the market so that consumers and other end users have reassurance about the safety of products available on the market.

#### Why is it being changed?

- 7.4 The provisions of this Instrument are being introduced to ensure that only safe products can be placed on the GB 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.
- 7.5 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.

#### What will it now do?

- 7.6 The Instrument will:
- Amend Annex 3 to the Cosmetics Regulation to restrict the use of Methyl-N-Methylantranilate for use up to 0.1% for leave-on products not marketed for exposure to natural or artificial UV light and 0.2% for rinse-off cosmetic products; and
  - Amend Annex 6 to permit the use of HAA299 and HAA299 (nano) up to a level of 10%, excluding use in spray and/or aerosol products.
- 7.7 The instrument includes staggered timing provisions with all amendments coming in to force by 6th July 2024. There are also transitional provisions which allow cosmetic products that are on the market before certain requirements come into force, to continue to be able to be supplied until 6th July 2026.

## **8. European Union Withdrawal and Future Relationship**

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

## **9. Consolidation**

- 9.1 There are no plans to consolidate the legislation amended by this instrument.

## **10. Consultation outcome**

- 10.1 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 Cosmetics Regulation in order to reflect scientific assessment regarding potential risks to human health.
- 10.2 The Department has, however, undertaken extensive engagement with a variety of stakeholders, including trade associations and key members of the cosmetic industry.

## **11. Guidance**

- 11.1 There is guidance on the UK's regulations for cosmetics, provided to support businesses, enforcement agencies and consumers, which can be found on the Office for Product Safety and Standards section of GOV.UK (<https://www.gov.uk/government/publications/cosmetic-products-enforcement-regulations-2013>).
- 11.2 We will continue to update this guidance when needed and provide specific advice when required to ensure both industry and the public continue to be informed of changes to regulations.

## **12. Impact**

- 12.1 There is no, or no significant, impact on business, charities, or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment (IA) has not been prepared for this instrument because the impacts of Cosmetic Products (Restriction of Chemical Substances) Regulations 2023 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.

## **13. Regulating small business**

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise the regulatory burdens on small businesses.
- 13.3 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 products being manufactured and placed on the market. Therefore, we are unable to take any mitigating actions to reduce burdens on small business.

## **14. Monitoring & review**

- 14.1 The Department does not intend to monitor this instrument.
- 14.2 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, Parliamentary Under Secretary of State (Minister for Enterprise, Markets and Small Business) at 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.”

## **15. Contact**

- 15.1 Will Burrows at Office for Product Safety and Standards, Department for Business and Trade, Telephone: 07442998687 or Email: will.burrows@beis.gov.uk can be contacted with any queries regarding this instrument.
- 15.2 Tony Thomas, Deputy Director Product Safety Policy, at Office for Product Safety and Standards, Department for Business and Trade can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Kevin Hollinrake MP, Parliamentary Under Secretary of State (Minister for Enterprise, Markets and Small Business) at the Department for Business and Trade can confirm that this Explanatory Memorandum meets the required standard.