

## **EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL**

### **Commission Regulation (EU) .../.. of 31.1.2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Methyl-N-methylantranilate in cosmetic products**

Submitted by the Department for Business, Energy and Industrial Strategy on 10 March 2021.

#### **SUBJECT MATTER**

1. The Regulation will amend Annex III, to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ('EU Cosmetic Products Regulation') which apply to products placed on the EU market. The Annexes to the Regulation set restrictions on the ingredients that can be used in cosmetic products. As the EU Cosmetics Products Regulation is included in Annex 2 of the Northern Ireland Protocol, this update to the technical annexes will also apply to cosmetic products placed on the market in Northern Ireland.
2. The amendments and correction concern one chemical and its use in cosmetic products, Methyl-N-methylantranilate (M-N-MA). It is currently not subject to any prohibitions or restrictions and is allowed for use in cosmetic products including fine fragrances, shampoos, soaps and other toiletries.
3. Following an assessment of M-N-MA by the EU Scientific Committee on Consumer Safety (SCCS), the EU has added M-N-MA to the Annex of restricted substances for use in cosmetics, meaning that it cannot be used in sunscreen products, and products marketed for exposure to natural light or artificial UV and in other cosmetic products where the concentration of the substance is more than 0.1% for leave-on products and 0.2 % for rinse-off products. This will apply to cosmetic products placed on the EU market six months after the Regulation enters into force and the same will apply to cosmetics placed on the market in Northern Ireland.
4. This Regulation amending the annexes of the EU Cosmetics Products Regulation enters into force on the twentieth day following its publication in the Official Journal of the European Union. The Regulation was published on 31 January and entered into force on 20 February 2022.

## **SCRUTINY HISTORY**

5. The Regulation has been adopted in accordance with relevant regulatory and scrutiny procedures.

## **MINISTERIAL RESPONSIBILITY**

6. The Secretary of State for the Department for Business, Energy and Industrial Strategy has responsibility for cosmetic products safety policy.

## **INTEREST OF THE DEVOLVED ADMINISTRATIONS**

7. Product safety is a reserved matter for Scotland and Wales and consumer safety in relation to goods is reserved in respect of Northern Ireland. As the EU Cosmetic Products Regulation is included in Annex 2 of the Northern Ireland Protocol, Northern Ireland has an interest as it will apply in Northern Ireland. The Devolved Administrations have been consulted on this Explanatory Memorandum. The NI Executive, and Scottish and Welsh Governments, did not express any concerns about this Regulation.
8. These changes will apply to goods placed on the Northern Ireland market from the date set out in the Regulation, that is six months from 20 February 2022 (with a longer period of nine months for further sales of goods that have been placed on the market (, products that have been lawfully placed on the market until 20 August 2022 can be further sold until 20 November 2022. The Secretary of State has powers to amend the annexes of the GB Cosmetic Regulations and may choose to lay a Statutory Instrument to make equivalent changes for cosmetic products placed on the GB market, based on an assessment of scientific evidence.

## **LEGAL AND PROCEDURAL ISSUES**

9. This Regulation applies to Northern Ireland, as per the Northern Ireland Protocol, where it comes into force automatically under the EU Cosmetics Regulation, and its substantive provisions will apply from six months after the Regulation enters into force 20 February 2022, for cosmetic products placed on the market, and nine months for further distribution for goods lawfully on the market.

## **POLICY IMPLICATIONS**

10. These changes will apply to cosmetics placed on the Northern Ireland market six months after the Regulation entered into force on 20 February. This phased timeline allows business time to adjust their processes and supply chains. Under the terms of the Protocol relevant products placed on the Northern Ireland market would need to be compliant with the Regulation as it applies in Northern Ireland regardless of where they were manufactured. Under the Government's commitments to Northern Ireland's unfettered access to the rest of the UK market, cosmetics that meet the technical requirements to be placed on the market in Northern Ireland will be able to be placed on the GB market as long as the Secretary of State is informed of essential safety data (through the cosmetics notification database) before the product is placed on the GB market.
11. The matters on which the Secretary of State needs to be informed is the same regulatory information required before a cosmetic product is placed on the market in the EU/Northern Ireland. This information is necessary to assure the Secretary of State that the product has undergone the necessary regulatory checks and to provide regulators and poison centres with the information they need to fulfil their market surveillance, safety and public health responsibilities.
12. The EU Regulation does not apply to products placed directly onto the GB market. Cosmetics that exceed permitted levels of M-N-MA in Northern Ireland (once the changes made in the Regulation take effect), but that meet the current levels permitted in GB, can still legally be placed on the GB market. That is, this Regulation has no effect on the GB market. This will remain the case unless equivalent changes are made to GB legislation via a Statutory Instrument that reduces the permitted levels of M-N-MA in cosmetics.
13. The UK will make its own decision for products placed on the GB market. That decision will be informed by an assessment performed by the UK Scientific Advisory Group on Chemical Safety (SAG-CS) on the available safety data and other scientific evidence on these chemicals when used in cosmetics in addition to wider consideration of the impacts on the UK internal market. The SAG-CS' review is underway; we are working with them to expedite this, but are unable to give a timeframe for completion at present.
14. No data is currently available on the number or proportion of products, or manufacturers that use M-N-MA in their products in either in the EU or UK. No data is currently available on the financial impact expected from these changes in either in the EU or UK.

## **CONSULTATION**

15. There has been no consultation on this change. In accordance with the Northern Ireland Protocol, the changes made by this Regulation will be automatically applicable in NI.

## **FINANCIAL IMPLICATIONS**

16. There is no data available on the financial implications of these changes



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