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

Commission Regulation (EU) 2022/1176 of 7 July 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council regards the use of certain UV filters in cosmetic products.<sup>1</sup>

Submitted by the Department for Business, Energy and Industrial Strategy on 1 August 2022.

#### **SUBJECT MATTER**

- The Regulation (EU Commission reference number C(2022)4647) will amend Annex VI, 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.
- 2. 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 under current terms of the Protocol.
- 3. The amendments concern two chemicals benzophenone-3 and octocrylene and their use as ultra violet (UV) filters in cosmetic products. Both chemicals are currently allowed as UV filters in cosmetics while being subject to specific restrictions within Annex VI of Regulation (EC) No 1223/2009.
- 4. Following an assessment of both benzophenone-3 and octocrylene by the EU Scientific Committee on Consumer Safety (SCCS), the EU has concluded that there is potential risk to human health from the use of these chemicals as UV filters in cosmetic products. As such, the EU has decided that further restrictions should be put in place regarding the maximum concentrations of these chemicals permitted in specified cosmetic products.
- 5. The amendment results in the current maximum concentration of benzophenone-3 (up to 6%) being reduced to a maximum of 2.2% when used in cosmetic products, including body creams, propellant sprays and in pump sprays. With regards to octocrylene, its use will be reduced to a concentration of up to 9% in propellant sprays, and in other cosmetic products the limit will be set at a maximum of 10%.
- 6. This Regulation amending the annexes of the EU Cosmetics Products Regulation had legal effect on 28 July 2022 to all EU members states (and in

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<sup>&</sup>lt;sup>1 1</sup> OJ L 183 8.7.22 p51

Northern Ireland, as set out in paragraph 2 above). There is a transition period allowing products which do not comply with the requirements of this Regulation to be placed on the market before 28 January 2023. Products placed on the market before 28 January 2023 can continue to be made available on the market until 28 July 2023.

#### **SCRUTINY HISTORY**

- 7. Since the UK's exit from the EU the EU Scrutiny Committees have considered several EU regulations amending EU Regulation 1223/2009 relating to the use of cosmetic products; those documents were C(2022)455, 10796/21, an EM on Commission Regulation 2021/850 and 6871/21.
- 8. The Regulation has been adopted in accordance with relevant regulatory and scrutiny procedures.

#### MINISTERIAL RESPONSIBILITY

9. 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

- 10. 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 currently 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.
- 11. The Secretary of State has powers to amend the annexes of the GB Cosmetic Regulation and may (if required) 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**

12. This Regulation applies to Northern Ireland, as per the current terms of the Northern Ireland Protocol, where it comes into force automatically under the EU Cosmetics Regulation. The changes will have legal effect in relation to goods placed on the Northern Ireland market from 28 July 2022. There is a transition period allowing products which do not comply with the requirements of this Regulation to be placed on the market before 28 January 2023. Products placed on the market before 28 January 2023 can continue to be made available on the market until 28 July 2023.

#### **POLICY IMPLICATIONS**

- 13. These changes will apply to cosmetics placed on the Northern Ireland market six months after the Regulation entered into force on 28 July 2022. 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.
- 14. 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 and 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.
- 15. The EU Cosmetic Products Regulation does not apply to products placed directly onto the GB market. Cosmetics that exceed permitted levels of benzophenone-3 and octocrylene in Northern Ireland (once the changes made in the Regulation take effect), but 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.
- 16. 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 the scientific advice, the Government also examines wider consideration of the impacts on the UK internal market before making changes to the GB Cosmetic Regulation.
- 17.On 5 April 2022, the Office for Product Safety and Standards (OPSS) issued a call for data on the safety of five cosmetic ingredients with suspected endocrine disrupting properties including benzophenone-3 and octocrylene. The SAG-CS is due to further review the risks to human health associated with these two compounds, considering the new data, in due course. The Government will take a decision on whether or not to legislate based on this assessment of the available scientific evidence and any wider considerations including impacts on the UK internal market.

## **CONSULTATION**

18. 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**

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

## MINISTERIAL NAME AND SIGNATURE

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01.08.2022