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

C(2022) 7942 final

Commission Regulation (EU) 2022/2195 of 10 November 2022 amending Regulation (EC) NO 1223/2009 of the European Parliament and of the Council with regards to the use of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate, HAA299 and Resorcinol in cosmetic products.

Submitted by the Department for Business, Energy and Industrial Strategy on 2 December 2022.

SUBJECT MATTER

1. The Regulation amends Annexes III and 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 the current terms of the Protocol.

3. The amendments concern the use of five chemicals in cosmetic products. These are Butylated Hydroxytoluene, Acid Yellow 3, Homosalate, HAA299 and Resorcinol. Homosalate and Acid Yellow 3 are currently contained within the Annexes of Regulation (EC) No 1223/2009. Acid Yellow 3 is listed in Annex IV and can currently be used as a colourant in cosmetics products without any maximum concentration, while Homosalate is permitted as a UV filter in cosmetics, although is subject to specific restrictions listed within Annex VI. Butylated Hydroxytoluene and HAA299 are currently not regulated under Regulation (EC) No 1223/2009 and thus do not appear on any of the Annexes. In addition to changing the permitted usage on a set of chemicals, the Regulation also makes a technical change with regards to the labelling requirements for oxidative hair dye products that contain Resorcinol.

4. Following an assessment and publication of scientific advice on Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 by the EU Scientific Committee on Consumer Safety (SCCS), the EU has decided to amend (or in the case of HAA299, introduce) maximum concentrations of these chemicals permitted in specified cosmetic products.

5. The amendment results in the concentration of Butylated Hydroxytoluene being set as a maximum of 0.001 % in mouthwash, 0.1% in toothpaste and

0.8% in other leave-on and rinse-off products. With regards to Acid Yellow 3, its use will be restricted to a concentration of up to 0.5% in non-oxidative hair colouring products. In addition, the amendment reduces the permitted level and use of Homosalate as a UV filter in cosmetics from 10% (as currently permitted) to 7.34% for use in face products only (non-spray and pump spray products). The use of HAA299 (both nano and non-nano forms) as a UV-filter in cosmetics with a maximum concentration of 10% is also permitted.

6. This Regulation, amending the annexes of the EU Cosmetics Products Regulation, will have legal effect on 1 December 2022 in all EU members states (and in Northern Ireland, as set out in paragraph 2 above).

SCRUTINY HISTORY

7. Since the UK's exit from the EU, the EU Scrutiny Committees have considered several EU regulations that amend EU Regulation 1223/2009 relating to the use of cosmetic products. A full list of these Regulations has been outlined in Annex A.

MINISTERIAL RESPONSIBILITY

8. 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

9. 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 there under the current terms of the Protocol. 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.

10. 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

11. 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 1 December 2022. Depending on the chemical, there are transition periods in place ranging between 6 and 24 months to allow products which do not comply with the requirements of this Regulation to be placed on the market.

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

POLICY IMPLICATIONS

13. These changes will apply to cosmetics placed on the Northern Ireland market after the Regulation enters into force on 1 December 2022 with transition periods in place to allow for compliance. This phased timeline allows business time to adjust their processes and supply chains. Under the current terms of the Protocol, relevant products placed on the Northern Ireland market would need to be compliant with the Regulation 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 contains 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 required 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 any of the relevant chemicals 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. This will remain the case unless or until equivalent changes are made to GB legislation via a Statutory Instrument.

16. The UK will make its own decisions for products placed on the GB market. Those decisions will be informed by independent scientific assessment of 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 Butylated Hydroxytoluene and Homosalate, which closed on 31 May 2022. OPSS has also received safety data on HAA299. In all cases, as outlined above, decisions regarding the use of these substances in cosmetics will be informed by independent scientific assessment of the data received to understand any risks to human health associated with these compounds. Assessment is underway for these three

substances, led by the UK Scientific Advisory Group on Chemical Safety (SAG-CS). OPSS issued a further call for data on 22 July 2022, which sought data on six further suspected endocrine disrupters, including Resorcinol. The Government will take a decision on whether to legislate based on these assessments of the available scientific evidence and any wider considerations including impacts on the UK internal market.

18. The proposed Regulation would interact with the introduction of a dual regulatory regime in Northern Ireland, as proposed in the Northern Ireland Protocol Bill. Under a dual regulatory regime, manufacturers will have a choice to meet either UK or EU regulations. In principle, this would allow for products sold in NI to meet either UK or EU rules.

CONSULTATION

19. 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

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

MINISTERIAL NAME AND SIGNATURE

Kevin Hollinrake
Parliamentary Under Secretary of State
Department for Business, Energy and Industrial Strategy 02/12/2022

Annex A – Scrutiny History

COMMISSION REGULATION (EU) 2022/1176 of 7.7.2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products was deposited for scrutiny (C(22)4647). BEIS submitted an EM dated 1 August 2022. The House of Commons European Scrutiny Committee completed scrutiny on 9 October 2022 without substantive follow up (Report 9, 22/23). Scrutiny by the House of Lords European Affairs Committee was completed at the Chair's Sift 23 on 11 October.

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-methylanthranilate in cosmetic products was deposited for scrutiny (C(22)455). BEIS submitted an EM dated 10 March 2022. The House of Commons European Scrutiny Committee completed scrutiny on 28 April 2022 without substantive follow up (Report 21, 21/22). The Regulation has been retained under scrutiny by the House of Lords European Affairs Committee's Sub-Committee on Ireland/Northern Ireland.

COMMISSION REGULATION (EU) …/… of XXX amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction was deposited for scrutiny (10706/21). BEIS submitted an EM dfated 24 August 2021. The House of Commons European Scrutiny Committee completed scrutiny on 8 September 2021 without substantive follow up (Report 7, 21/22). Scrutiny by the House of Lords European Affairs Committee was completed at the Chair's Sift 7 on 16 September 2021.

COMMISSION REGULATION (EU) 2021/850 of 26 May 2021 amending and correcting Annex II and amending Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products was deposited for scrutiny. BEIS submitted an EM dated 9 July 2021. The House of Commons European Scrutiny Committee completed scrutiny on 19 July 2021 without substantive follow up (Report 6, 21/22). The Regulation has been retained under scrutiny by the House of Lords European Affairs Committee's Sub-Committee on Ireland/Northern Ireland.

COMMISSION REGULATION (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products was deposited for scrutiny (6871/21). BEIS submitted an EM dated 15 April 2021. The House of Commons European Scrutiny Committee completed scrutiny on 12 May 2021 without substantive follow up (Report 1, 21/22). The Regulation has been retained under scrutiny by the House of Lords European Affairs Committee's Sub-Committee on Ireland/Northern Ireland.