

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

2021/850 Cosmetic Products

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.

Submitted by the Department for Business, Energy and Industrial Strategy on 9 July 2021

SUBJECT MATTER

1. This Regulation (2021/850) amends and corrects Annex II and amends Annexes III, IV and VI contained in Regulation (EC) No 1223/2009 ('EU Cosmetic Products Regulation') which will 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 Ireland/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, Titanium Dioxide (TiO₂). It is currently allowed for use in cosmetic products in wider conditions as a colourant or UV filter. Following the classification of TiO₂ as a CMR (carcinogenic, mutagenic or reprotoxic) chemical, the EU has added TiO₂ to the Annex of restricted substances for cosmetics for use in face products in powder form and hair aerosol spray products and other products, further restricting it for use under specific limited conditions, for products placed on the EU market and the same will apply to cosmetics placed on the market in Northern Ireland.
3. A number of other chemicals that are not currently used in cosmetics, which have also been classified as CMRs, have also been added to the annex of substances prohibited for future use in cosmetics. A duplicate entry made in error in another Annex has also been removed.
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 28 May and will apply from 1 October 2021.

SCRUTINY HISTORY

5. This is the second draft regulation amending the technical annexes, (to add or remove substances from those listed in the relevant annex), of the EU Cosmetics Regulation for which an Explanatory Memorandum has been produced. However, this the first time these specific chemicals have been the subject matter.

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. A nil response was received from all of the Devolved Administration Governments.
8. These changes will apply to goods placed on the Northern Ireland market on the date that the Regulation applies on 1 October 2021. The UK may 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 EU Regulation 1223/2009, and its substantive provisions will apply from 1 October 2021.

POLICY IMPLICATIONS

10. These changes will apply to cosmetics placed on the Northern Ireland market on and after the date that the Regulation enters into force on 1 October. 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 TiO₂ in Northern Ireland, but that meet the current levels permitted in GB, can still legally be placed on the GB market. This will remain the case unless equivalent changes are made to GB legislation via a Statutory Instrument that reduce the permitted levels of TiO₂ in cosmetics.
13. The UK will make its own decision for products placed on the GB market. That decision will be based on an assessment of the available scientific evidence on permitted levels these chemicals when used in cosmetics and any wider consideration of the impacts on the UK internal market. The UK's Scientific Advisory Group (SAG), established by the Office for Product Safety and Standards (OPSS), has been commissioned to provide a recommendation to Government on the merit of the TiO₂ changes with regards to human health and are due to consider this specific issue in September 2021.
14. The Government has begun the process of assessing its approach to the use of TiO₂ in cosmetic products on the GB market and therefore has not made an assessment of the effect of a temporary period of regulatory divergence between GB and NI. However, as stated above, should a manufacturer meet the requirements of the legislation in NI they will also be able to demonstrate compliance with the current restrictions on the use of these chemicals in products on the GB market.
15. The SAG will consider this issue and advise the BEIS Secretary of State accordingly. It would be premature to make an assessment until that advice has been sought and considered. However, should the UK SAG recommend that we make the same changes as the EU Regulation then the government will seek to change UK law, via an amending Statutory Instrument, with a view to it coming into force as close as possible to the date the changes in NI take effect.
16. No data is currently available on the number or proportion of products, or manufacturers that use TiO₂ 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

17. 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

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

MINISTERIAL NAME AND SIGNATURE

A handwritten signature in blue ink, appearing to be 'Paul Scully', written in a cursive style.

Paul Scully

Parliamentary Under Secretary of State

Department for Business, Energy and Industrial Strategy