

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

10706/21 Cosmetic Products

DRAFT COMMISSION REGULATION (EU) 10706/21 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.

Submitted by the Department for Business, Energy and Industrial Strategy on 24 August 2021

SUBJECT MATTER

1. The draft Regulation seeks to amend Annexes II, III and V contained in Regulation (EC) No 1223/2009 ('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, (T-4)- bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S] zinc (Zinc Pyrithione). It is currently allowed for use in cosmetic products under restricted conditions. Following the classification of Zinc Pyrithione as a CMR (carcinogenic, mutagenic or reprotoxic) chemical, the EU has added it to the Annex of prohibited substances, and removed it from the list substances permitted under restricted 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.
4. This Regulation amends the Annexes of the EU Cosmetics Products Regulation and enters into force on the twentieth day following its publication in the Official Journal of the European Union and will apply from 1 March 2022.
5. It should be noted that the Government is seeking to find a new balance in the Protocol to place it on a more sustainable footing. This includes proposals to establish a dual regulatory regime, to ensure that consumers in Northern Ireland do not face barriers in accessing goods from Great Britain, which would enable goods made to UK rules to circulate and be placed on the market in Northern Ireland. In such a scenario, the rules above would apply only where

goods were to be made to EU rules to access both the NI market and the EU market.

SCRUTINY HISTORY

6. This is the third proposed regulation that seeks to amend 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 is the first time these specific chemicals have been the subject matter.

MINISTERIAL RESPONSIBILITY

7. 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

8. 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 did not raise any issues or concerns about this Regulation.
9. These changes will apply to cosmetic products placed on the Northern Ireland market on and after the date that the Regulation applies on 1 March 2022. A decision is yet to be made on whether the UK will lay a Statutory Instrument to make equivalent changes for cosmetic products placed on the GB market and any such decision will be based on an assessment of scientific evidence as set out below.

LEGAL AND PROCEDURAL ISSUES

10. Cosmetic Regulation is directly applicable in Northern Ireland and any amendments made to it such as those being made through this Commission Regulation, will also be automatically directly applicable from the date the amendment takes effect, in this case 1 March 2022.

POLICY IMPLICATIONS

11. Under the terms of the Protocol cosmetic 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.

12. 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 centers with the information they need to fulfil their market surveillance, safety and public health responsibilities.
13. The EU Regulation does not apply to products placed directly onto the GB market. However, cosmetics that have the levels of Zinc Pyrithione allowed on the GB market will not be allowed in Northern Ireland from the date the Regulation takes effect.
14. 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. 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 Zinc Pyrithione changes with regards to human health.
15. The SAG will consider this issue and advise the BEIS Secretary of State accordingly. It would be premature to make any comment on whether the UK make changes to its laws until that advice has been sought and considered. However, should the UK SAG recommend the same changes as the EU Regulation then the Government will seek to change to the 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. The outcome of SAG considerations will be made publicly available.
16. The Government has not made an assessment of the effect of any period of regulatory divergence between GB and NI. As stated above, any impact from a period of divergence should not be significant as 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.
17. No data is currently available on the number or proportion of products, or manufacturers that use Zinc Pyrithione 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 the EU or UK.
18. As noted above, the Government is seeking to find a new balance in operating the Protocol in order to place it on a more sustainable footing. These proposals, set out in the Government's July 2021 Command Paper (Northern Ireland Protocol: the way forward), include the arrangements covering trade in goods and the institutional framework. This includes a dual regulatory regime in Northern Ireland that would allow goods made to either UK or EU rules to circulate within Northern Ireland, reducing burdens on businesses trying to put goods from Great Britain on the market. This would mean that the rules covered in here would apply only if manufacturers wished to make goods to EU rules to

access the EU as well as the NI market. These proposals would also remove the potential UK internal market consequences should there be a period of regulatory divergence between GB and NI on the rules regarding the use of Zinc Pyrithione.

CONSULTATION

19. There has been no consultation by the EU with the UK 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



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