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

C (2022) 3493

Commission Delegated Regulation (EU) 2022/860 of 01.06.2022 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards monacolins from red yeast rice. "Regulation 2022/860"

Submitted by the Department of Health and Social Care ("DHSC") on the 22 July 2022

SUBJECT MATTER

1. EU Regulation 2022/860 amends Annex III of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (Regulation 1925/2006). The amendments restrict the use of a substance (monacolins from red yeast rice[1]) in foods and food supplements placed on the EU market. (Background on Regulation 1925/2006 is provided in Appendix 1 of this document).

2. The regulation sets provisions to ensure an individual portion of a food product or food supplement which is intended for daily consumption and is placed on the EU market shall provide less than 3mg of monacolins from red yeast rice. For products which contain monacolins from red yeast rice the legislation sets a number of additional labelling requirements including a number of mandatory statements and warnings regarding consumption for vulnerable sub-groups of the population which must be included on the product label.

3. Following concerns regarding potential harmful effects to health, the restriction placed on this substance accounts for the 2018 European Food Safety Authority (EFSA) scientific opinion on the safety of monacolins in red yeast rice.

4. This will have no direct impact on Great Britain's domestic nutrition legislation, however, under the Protocol on Ireland/Northern Ireland (NIP), the amending legislation Regulation 2022/860 will apply in the UK in respect of Northern Ireland. This is because Regulation 1925/2006, is included in Annex 2 to the NIP.

5. Regulation 2022/860 was adopted by the EU Commission on 01.06.2022 and came into force in the EU on 22.06.2022, 20 days after the date of its publication in the Official Journal of the European Union (02.06.2022).

SCRUTINY HISTORY

[1] Red yeast rice is made by fermentation of rice with yeasts, resulting in the production of monacolins, the most abundant of which is monacolin K. Monacolin K is traditionally used in China as a food colouring and as a traditional remedy to promote digestion and blood circulation. In the EU, it is not authorised for use as a food colour as it is not included in the Union list of retained Regulation (EC) No 1333/2008 on food additives. Food supplements containing red yeast rice preparations have been marketed and consumed to a significant degree before 15 May 1997 and therefore monacolins from red yeast rice are not considered novel foods.

6. We are not aware of any previous parliamentary scrutiny or requests of EU regulations specifically to monacolins from red yeast rice in foods and food supplements.

MINISTERIAL RESPONSIBILTY

7. The Secretary of State for Health and Social Care is responsible for the nutrition related labelling, composition, and standards (NLCS) of food law in England, as set out in the NLCS provisional common framework[2]. Scottish Government Ministers, Welsh Government Ministers and Northern Ireland Executive Ministers have responsibility for NLCS in their respective nations.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

8. The subject matter of this EM relates to food law which is a devolved matter in the UK.

9. Through the UK-wide Nutrition labelling composition and standards (NLCS) provisional common framework, which has been developed to maintain a consistent and co-ordinated policy approach across the UK, Scottish Government Ministers, Welsh Government Ministers and Northern Ireland Executive Ministers will have an interest in the implications of this Regulation on the UK internal market (UKIM). Devolved government officials were informed during the preparation of this EM and the EM has been shared with them for their information and the EM incorporates comments which were received.

10. The NLCS framework sets out arrangements for co-operation between officials in the DHSC, Food Standards Scotland, Welsh Government and the Food Standards Agency in Northern Ireland regarding NLCS policy and legislation.

11. The provisional NLCS framework is implemented and operates in a similar way to the proposed enduring framework but is agreed without prejudice to any future joint decisions that the Governments may take. The agreements as set out within the NLCS framework provide for close collaboration with consistency of approach across all four nations always being sought in the first instance. It reflects the obligations in the Protocol on Ireland/ Northern Ireland and re-iterates the commitment to a four-nation approach in terms of policy consideration, governance, and dispute resolution. In particular, it stresses Northern Ireland's continued participation in risk management considerations.

12. Following the processes set out in the NLCS framework, policy decisions made by GB authorities will, where appropriate, result in amendments to Annex III of Regulation 1925/2006.

LEGAL AND PROCEDURAL ISSUES

13. There are no legal or procedural issues arising.

14. The subject of this proposal is relevant to retained EU law.

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1. The framework was provisionally agreed by the JMC(EN) on 03 September 2020, good progress on the framework continues to be made and we expect the final framework to be approved in Spring 2022
ES1019747_CCS207_CCS0920279110-001_NLCS Framework v02_PRINT.pdf (publishing.service.gov.uk)

15. The NIP provides that limited areas of EU law will continue to apply to and in the UK in respect of Northern Ireland, this includes Regulation 1925/2006 as amended by this EU Regulation 2022/860 to restrict the use of monacolins from red yeast rice in foods and food supplements as detailed above.

POLICY IMPLICATIONS

16. Under the provisions of the Protocol on Ireland/Northern Ireland (NIP), this proposal has policy implications for the UK in respect of Northern Ireland.

17. The EU's amendment to Annex III of Regulation 1925/2006 is a mandatory change to the compositional requirements for foods or food supplements which contain monacolins from red yeast rice. The amending Regulation mandates that individual portion of foods or food supplements intended for daily consumption which are placed on the EU market, and therefore the Northern Ireland market, provide less than 3mg of monacolins from red yeast rice and are appropriately labelled.

18. Although Regulation 1925/2006 creates mandatory obligations when adding vitamins, minerals and other substances to foods, the addition itself is voluntary. Therefore Regulation 2022/860 will only be relevant to industry stakeholders who produce products which contain monacolins from red yeast rice.

19. Through the principles of mutual recognition and non-discrimination, the UK Internal Market (UKIM) Act 2020 delivers unfettered access for goods moving from Northern Ireland to GB. Where there is divergence in the regulatory approach between GB and Northern Ireland regarding the use of monacolins from red yeast rice in foods, UKIM allows qualifying Northern Ireland goods to continue to be able to be placed on the market in GB. However, in the presence of conflicting regulations for GB and Northern Ireland, the movement of goods from GB to Northern Ireland which do not comply with EU regulations would not be permitted.

20. As there is no restriction on food products or food supplements which provide daily consumption levels above 3mg of monacolins from red yeast rice in GB, products which contain monacolins from red yeast rice at any level which are compliant with all other aspects of food law can be freely placed on the GB market. Due to the amending Regulation applying in Northern Ireland unrestricted products, which provide daily consumption levels above 3mg of monacolins from red yeast rice, would not be able to be placed on the Northern Ireland market.

21. The EU Commission power to amend the Annexes of Regulation 1925/2006 was transferred to the 'appropriate authorities' for GB by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 in respect of the retained legislation.

22. The practical implication of deciding whether to amend Annex III of retained Regulation 1925/2006 in GB would be considered as part of the NLCS framework, following the risk assessment and risk management process (which includes seeking a scientific assessment) decisions made by the appropriate GB authorities may result in Regulation 1925/2006 being updated – following the fulfilment of any statutory duties – to reflect the prohibition, restriction, or scrutiny of this substance.

23. Following the process set out in the NLCS provisional common framework, officials from DHSC and the Devolved Administrations[3] from the NLCS policy group have sought advice from the Food Standards Agency (FSA) and have requested a scientific assessment on the safety of monacolins from red yeast rice. Following the FSA scientific assessment, the next steps for GB are still under consideration. The NLCS policy group are following the risk assessment and risk management process set out in the NLCS framework to consider the scientific opinion provided by the FSA, alongside the 2018 EFSA scientific opinion.

24. Each GB nation will need to seek ministerial agreement on the proposed next steps which are agreed by the NLCS policy group.

25. Subject to agreement by the NLCS policy group on proceeding with amending legislation GB wide, consent from Scottish and Welsh Ministers would be sought to agree for the amending legislation to have a GB-wide territorial extent and application. If Scotland or Wales do not grant consent to legislation being applied GB wide, England will be able to proceed on an England only basis and Scotland and Wales have the power to similarly lay their own legislation.

26. There is a statutory duty to consult on changes to food legislation and therefore subject to the ministerial decision made there will be an opportunity for stakeholders to feed into any legislative amends which are proposed via a UK consultation process.

CONSULTATION

27. No consultation has happened in the UK as the EU Commission's actions to amend Annex III of Regulation 1925/2006 will have no direct impact on GB domestic legislation

28. Consultation with EU Member States on the amendment of Regulation 1925/2006 in the EU has already been undertaken by the EU Commission. The consultation on the draft Regulation to restrict the use of monacolins from red yeast rice to ensure this substance was used safely in foods and food supplements was held between 20 May -17 June 2021. The feedback is available on the EU Commission website Food safety – restrictions on the use of monacolins from red yeast rice in foods (europa.eu). The UK in respect of Northern Ireland was not involved in this. The FSA in Northern Ireland has communicated with stakeholders to ensure that they are aware of relevant EU changes.

FINANCIAL IMPLICATIONS

29. There are no known financial implications for products placed on the GB market, as manufacturers who place products on the GB market will be able to continue to use monacolins from red yeast rice in an unrestricted form. However, as the new stricter requirements of Regulation 2022/860 will be directly applicable in Northern Ireland products which provide daily consumption levels above 3mg of monacolins from red yeast rice would not be able to be placed on the Northern Ireland market. As the addition of this substance to foods and food supplements is voluntary, Regulation 2022/860 will only be relevant to manufacturers or importers of products which contain monacolins from red yeast rice. There may be some financial implication if UK manufacturers or importers who place products on the Northern Ireland market have to amend their products in line with the new requirements

[3] Information is shared with the three GB authorities (England, Wales and Scotland) as well as Northern Ireland as all nutrition issues continue to be considered on a 4-nation basis. Northern Ireland's full participation in risk assessment and risk management processes ensure that any decisions taken in GB account for the potential impacts across the UK.

of the legislation. However, we do not routinely capture market data on products containing this substance including the level if any at which it is present and therefore, we are unable to estimate the financial impact of the amending Regulations on UK manufacturers.

MINISTERIAL NAME AND SIGNATURE

Maria Caulfield MP

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Appendix 1

30. The addition of vitamins, minerals, and other substances to foods (fortification) is voluntary. If manufacturers choose to fortify the provisions of Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods should be followed. The regulation outlines the compositional and labelling requirements for foods that have substances added to them, stipulates which vitamins and minerals maybe added to foods and sets out the safety assessment on the use of other substances. Annex I of the Regulation is a list of vitamins and minerals which may be added in fortified foods. Annex II is a list of the sources of vitamins and minerals which may be used. Annex III is a list of substances whose use in foods is prohibited, restricted or under Community scrutiny. There is no positive list of “other substances” which may be added.

31. The Regulation 1925/2006 are enforced in the UK by The Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 and equivalent legislation in Scotland, Wales, and Northern Ireland.

32. Following the end of the EU-Exit transition period, Regulation 1925/2006 was retained and amended as GB law. The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 amongst other things transferred responsibilities and functions to legislate, in respect of nutrition legislation from EU entities to authorities in GB; and amended retained Regulation 1925/2006, to remedy the inoperability that would otherwise have arisen.

33. Article 8 of Regulation 1925/2006 provides the power to put under scrutiny, to restrict and, if necessary, to prohibit the use of substances added to foods or used in the manufacture of foods, other than a vitamin or mineral, under conditions that would result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.