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

C(2022)8592

Commission Regulation (EU) 2022/2340 of 30.11.2022 amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards green tea extracts containing (-)-epigallocatechin-3-gallate "Regulation 2022/2340"

Submitted by the Department of Health and Social Care 7 February 2023

SUBJECT MATTER

1. Regulation 2022/2340 restricts the use of green tea extracts containing (-)-epigallocatechin-3-gallate (EGCG) in foods and places the substance under scrutiny for the next 4 years.

2. Teas are classified into four different subtypes: green tea, black tea, white tea, and oolong tea according to the processing. Production of green tea extracts (without the process of fermentation) results in the presence of flavanols, commonly known as catechins, of which the most abundant is EGCG.

3. Green tea catechins can be consumed as traditional green tea infusions, reconstituted tea drinks or as a food supplement containing concentrated green tea extracts, all with potentially differing levels of EGCG. Green tea as an infusion has been extensively consumed as a beverage in Asian countries for centuries.

4. Following concerns regarding potential harmful effects to health, the restriction placed on this substance takes into consideration the 2018 European Food Safety Authority (EFSA) scientific opinion on the safety of green tea catechins (Appendix 1 provides further details of the scientific assessment).

5. The Regulation 2022/2340 amends Annex III of EU Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and certain other substances to foods "Regulation 1925/2006". Further detail on this Regulation is provided in Appendix 2[1]. The Regulation 2022/2340 sets restrictions for an individual portion of a food to contain less than 800mg of EGCG. In addition, the labels of all foods including food supplements containing EGCG at any level must include information on maximum number of portions of the food for daily consumption, the content of EGCG per portion and warnings for consumers on appropriate use including a warning not to consume a daily amount of 800mg EGCG or more.

6. Regulation 2022/2340 will have no direct impact on Great Britain's (GB) domestic nutrition legislation. However, under the Protocol on Ireland/Northern Ireland (NIP), the amending legislation will apply in the UK in respect of Northern Ireland. This is because Regulation 1925/2006, is included in Annex 2 to the NIP. Regulation 2022/2340 will amend Annex III in EU Regulation 1925/2006. Retained Regulation 1925/2006 is in scope of the "Retained EU Law (Revocation and Reform) Bill 2022". Under the Bill the Government is currently considering whether retained EU law should be repealed,

[1] EUR-Lex - 32006R1925 - EN - EUR-Lex (europa.eu)

reformed or preserved. Any changes to retained EU law will uphold international commitments, including the NIP.

7. Regulation 2022/2340 was adopted by the EU Commission on 30 November 2022 and came into force in the EU on the 21 December 2022.

SCRUTINY HISTORY

8. We are not aware of any previous parliamentary scrutiny or requests of EU regulations specifically related to green tea extracts in foods and food supplements.

9. Commission Regulation (EU) 2022/860 of 1 June 2022 which also amended Annex III of Regulation 1925/2006 was subject to parliamentary scrutiny as EU document C(2022)3493. Commission Regulation (EU) 2022/860 restricted the use of a substance (monacolins from red yeast rice) in foods and food supplements placed on the EU market. The Department of Health and Social Care (DHSC) submitted an explanatory memorandum dated 22 July 2022. The House of Commons European Scrutiny Committee completed scrutiny on 23 November 2022 without a substantive report to the House (Report 10, 22/23). The Commission Regulation (EU) 2022/860 was considered at the Chair's sift 23 on 11 October and was drawn to the attention of the House of Lords European Affairs Committee's Sub-Committee on the Protocol on Ireland/Northern Ireland without substantive follow up from the committee. European Parliament and Council Regulation 1925/2006 was subject to scrutiny as EU document 14823/03 on which the Government submitted EMs dated 4 December 2003 and 1 July 2004.

MINISTERIAL RESPONSIBILITY

10. 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

11. The subject matter of this explanatory memorandum (EM) relates to food law which is a devolved matter in the UK.

12. Through the UK-wide NLCS provisional common framework, which has been developed to maintain a consistent and co-ordinated policy approach across the UK, the implications of Regulation 2022/2340 on the UK internal market (UKIM) will be of interest to all four UK nations.

13. The NLCS framework sets out arrangements for co-operation between officials in the DHSC, Food Standards Scotland, Welsh Government and the Food Standards Agency (FSA) in Northern Ireland regarding NLCS policy and legislation. Officials with responsibility for this policy in the Devolved Governments were consulted on the preparation of this EM and the EM incorporates comments which were received.

14. 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

[2] ES1019747_CCS207_CCS0920279110-001_NLCS Framework v02_PRINT.pdf (publishing.service.gov.uk)

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 (NIP) 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.

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

LEGAL AND PROCEDURAL ISSUES

16. There are no legal or procedural issues arising.

17. The subject of this proposal is relevant to retained EU law in that the retained Regulation 1925/2006 does not contain the equivalent provision.

18. Under the terms of the NIP, EU food and feed law continues to be directly applicable in the UK in respect of Northern Ireland. This includes EU Regulation 1925/2006 as amended by EU Regulation 2022/2340 to restrict the use of EGCG in foods including food supplements.

POLICY IMPLICATIONS

In Northern Ireland

19. Under the provisions of the NIP, this proposal has policy implications for the UK in respect of Northern Ireland.

20. Regulation 2022/2340 amends Annex III of EU Regulation 1925/2006 to:

- restrict the use of, and set conditions on the use of green tea extracts containing EGCG in foods and food supplements by placing them in Part B of Annex III.
- Additionally place green tea extracts containing EGCG under community scrutiny by adding them to Part C of Annex III.

21. Under the process set out in EU Regulation 1925/2006, whilst substances remain under community scrutiny relevant parties are able to submit data to the Commission to demonstrate the safety of the substance. Within four years from the entry into force of Regulation 2022/2340, the Commission must decide whether to list green tea extracts containing EGCG in Part A or Part B of Annex III or to generally allow the use of the substance, as appropriate, taking into account the opinion of EFSA on any submitted data.

22. Although EU Regulation 1925/2006 creates mandatory obligations when adding vitamins, minerals and other substances to foods, the addition itself is voluntary. Therefore Regulation 2022/2340 will only be relevant to industry stakeholders who produce products which contain EGCG.

23. Foods including food supplements containing green tea extracts containing EGCG which do not comply with the requirements of Regulation 2022/2340 and were lawfully placed on the market before the entry into force of the Regulation may remain on the market until 21 June 2023.

24. Regulation 2022/2340 does not affect the use of EGCG in fortified foods and food supplements which use a highly purified extract from the leaves of green tea with a minimum of 90% EGCG. This is considered safe and authorised for use as a novel food under Regulation (EU) 2015/2283[3].

25. 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 and across England, Wales, and Scotland. The UKIM Act allows qualifying Northern Ireland goods that comply with the amended EU requirements to continue to be able to be placed on the market in GB. However, in the presence of divergence between the requirements that apply in GB and Northern Ireland, the movement of goods from GB to Northern Ireland which do not comply with amended EU requirements, would not be permitted. In the presence of conflicting regulations in GB, the UKIM Act also allows for mutual recognition and access for goods moving across England, Wales, and Scotland.

26. Manufacturers placing products on the Northern Ireland market that contain these green tea extracts will need to ensure individual portions of food intended for daily consumption contain less than 800 mg of EGCG and are appropriately labelled. The FSA in Northern Ireland has communicated with stakeholders to ensure they are aware of this EU change, and will continue to engage with industry and enforcement authorities to aid familiarisation and preparedness in relation to the new requirements

27. It should be noted that the Government introduced the Northern Ireland Protocol Bill on 13 June 2022. The overriding priority for the Bill is preserving political stability in Northern Ireland. The situation as it stands with the NIP is undermining the balance established by the Belfast (Good Friday) Agreement and power sharing, and with it, political stability in Northern Ireland. It is the Government's preference to resolve this through talks and the Government is engaging in constructive dialogue with the EU to find solutions to these problems. However, the Northern Ireland Protocol Bill aims to fix the practical problems the NIP has created in Northern Ireland if a solution cannot be found with the EU.

In GB

28. The EU Commission power to amend the Annexes of retained 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.

29. The practical implication of deciding whether to amend Annex III of retained Regulation 1925/2006 in GB would be considered as part of the UK wide NLCS framework, following the risk assessment and risk management process (which includes seeking a

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[3] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance) (legislation.gov.uk)

scientific assessment). Decisions made by the appropriate GB authorities may result in retained Regulation 1925/2006 being updated – following the fulfilment of any statutory duties – to reflect the prohibition, restriction, or scrutiny of this substance.

30. Following the risk assessment and risk management process set out in the NLCS framework, officials from DHSC and the Devolved Governments[4] have sought the advice of the Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment "Committee on Toxicity (COT)". The NLCS policy group has requested a domestic scientific assessment on the safety of green tea catechins to evaluate whether the conclusions of the 2018 EFSA opinion are still applicable considering any new data that has become available since its adoption. The domestic scientific assessment by COT is due to be completed by the end of 2023.

31. Following the conclusion of the scientific opinion each GB nation will need to seek ministerial agreement on the proposed next steps which are agreed by the NLCS policy group. This will include whether any restrictions are needed in relation to the use of this substance in foods placed on the GB market.

32. 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.

33. 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

34. 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.

35. Consultation with EU Member States on the amendment of Regulation 1925/2006 in the EU has already been undertaken by the EU Commission. The public consultation on the draft Regulation to restrict the use of foods containing EGCG and to ensure this substance was used safely in foods was held between 06-October – 03 November 2021. The feedback is available on the EU Commission website Food safety - restricting the use of green-tea catechins in foods (europa.eu). The Government did not hold any discussions with the EU on these regulations, either informally or within the dialogue structures established under the EU Withdrawal Agreement, 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

[4] 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.

36. There may be some financial implications if UK manufacturers or importers who place products on the Northern Ireland market have to amend their products in line with the new requirements of the legislation. All products containing EGCG sold in Northern Ireland (except for those specifically excluded) will have to change their product labels to include the appropriate information and warning statements. The requirements apply from the coming into force of the regulation on 21 December 2022, however foodstuffs which do not comply with the requirements of this Regulation and were lawfully placed on the market before the entry into force of this Regulation may remain on the market until 21 June 2023. As food supplements can have a shelf life of 2 to 3 years there is likely to be financial loss attributed to food and packaging waste. We have made enquiries with a relevant food supplements trade body regarding the impact of the regulation on the UK market. They were unable to provide specific data on the size of the UK market and noted although individual businesses will have their own records, most organisations that gather market data do not capture specific data on all substances used in foods and food supplements. However, the trade body highlighted that they understand most products on the UK market provide less than 800 mg of EGCG per recommended daily portion and therefore would not be impacted by the restriction placed on the level of this substance present.

MINISTERIAL NAME AND SIGNATURE

Neil O'Brien [Add Minister's name] 

[Add Minister's Tile] Min for Primary Care & Public Health

[Add Department] DHSC

Appendix 1

1. In 2015, the EFSA Panel Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety of green tea catechins from dietary sources from all sources in foods including preparations such as food supplements and infusions.

2. The EFSA 2018 scientific opinion on the safety of green tea catechins concluded:
   - according to reported intakes of EU member states, catechins from green tea infusions prepared in a traditional way, and reconstituted drinks with an equivalent composition to traditional green tea infusions, are generally considered safe. The mean daily intake of EGCG resulting from the consumption of green tea infusions ranges from 90 - 300 mg/day.
   - based on the available data on the potential adverse effects of green tea catechins on the liver, there was evidence from interventional clinical trials that showed intake of doses of EGCG equal to or above 800 mg/day are indicative of liver injury[5].
   - there were a number of uncertainties regarding exposure to green tea catechins and their biological and toxicological effects.
   - the chemical composition of green tea catechins, including the content of EGCG, varies widely depending on the plant variety, the growing environment, the season, the age of leaves and the manufacturing conditions, and there are uncertainties on how the composition of extracted catechins and other substances used to prepare green tea extracts is influenced by manufacturing procedures.
   - they were unable to provide advice on a dietary intake of green tea catechins that does not give rise to concerns about harmful effects to health for the general population and, as appropriate, for vulnerable subgroups of the population.
   - more data was needed for an assessment of a dose–response relationships between doses of EGCG and abnormal liver parameters.
   - there were also uncertainties as to whether more serious liver effects may develop after long-term use of green tea extracts, as well as regarding the mechanisms leading to dose-dependent hepatotoxicity (damage to liver cells which affect functioning of the liver) of EGCG.

Appendix 2

1. 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.

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[5] These trials were based on case subjects (individuals consuming equal to or above 800mg/day of EGCG in the form of a food supplements) versus control subjects (individuals who did not consume EGCG) having statistically significant levels (levels which occurred not through chance) of certain enzymes (serum transaminases) which are indicative of liver injury.

2. Regulation 1925/2006 is 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.

3. 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.

4. 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.