EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

C(2022)9048

Commission Delegated Regulation (EU) 2023/439 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of nicotinamide riboside chloride as a source of niacin in food for special medical purposes and total diet replacement for weight control. "Regulation 2023/439"

Submitted by the Department of Health and Social Care 21 March 2023.

SUBJECT MATTER

1. Regulation 2023/439 will amend the Annex (providing the list of permitted substances) of Regulation (EU) No 609/2013[1] (Regulation 609/2013) which establishes the compositional and information requirements for the following categories of food:

    a. infant formula and follow-on formula ("formula")

    b. processed cereal-based food and baby food (baby foods)

    c. food for special medical purposes (FSMPs) which includes specific requirements for FSMPs developed to satisfy the nutritional requirements of infants and young children (iFSMPs)

    d. total diet replacement for weight control (TDR) products

    Background

2. Regulation 609/2013 defines:

    - TDR products as food which is specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet.

    - FSMPs as food which has been specially processed or formulated and intended for the dietary management of patients, including infants whose dietary management cannot be achieved by modification of a normal diet alone. They are to be used under medical supervision.

3. The specific composition and information requirements for TDR products are legislated in the EU under "Commission Delegated Regulation (EU) 2017/1798" (Regulation 2017/1798).

4. The specific composition and information requirements for FSMPs are legislated in the EU under Commission Delegated Regulation (EU) 2016/128 (Regulation 2016/128).

5. The amendments provided by Regulation 2023/439 are to allow an additional form of the vitamin niacin (nicotinamide riboside chloride) to be permitted for use in FSMPs and TDR products and updates the Annex of EU Regulation 609/2013 the "Union list" accordingly.

[1] EUR-Lex - 32013R0609 - EN - EUR-Lex (europa.eu)

The regulation does not extend the authorisation of this form of niacin to be used in baby foods or formula. The amendments do not make it a mandatory requirement for this form of niacin to be added to all FSMPS and TDR products but provides manufacturers with the option to use this alternative form of niacin, in addition to the existing permitted forms (nicotinic acid and nicotinamide).

6. These amendments to the Annex of EU Regulation 609/2013 follow the 2021 European Food Safety Authority (EFSA) scientific opinion on the extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283. In accordance with EU regulation 2015/2283[2] "novel food"[3] means any food that was not used for human consumption within the EU before 15 May 1997.

7. The Commission considered that the 2021 EFSA scientific opinion gave sufficient grounds to establish that nicotinamide riboside chloride is not of safety concern as a source of niacin when used in FSMPs and TDR products (details of the scientific assessment and authorisation of the use of this substance is provided in Appendix 1).

8. Regulation 2023/439 was adopted on 16 December 2022 and, was published in the Official Journal of the European Union on 1 March 2023 and will come into force on 21 March 2023.

9. Regulation 2023/439 will have no direct impact on Great Britain's (GB) domestic nutrition legislation. However, the amending legislation will apply in the UK in respect of Northern Ireland. This is because EU Regulation 609/2013, is included in Annex 2 to the Protocol on Ireland/Northern Ireland (NIP) hereafter referred to as the Windsor Framework[4].

10. Retained Regulation 609/2013 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, reformed, or preserved. Any changes to retained EU law will uphold international commitments, including the Windsor Framework.

SCRUTINY HISTORY

11. As nicotinamide riboside chloride is a novel food, this is a new addition to the Annex of Regulation 609/2013. We are not aware of any previous parliamentary scrutiny of covering the use of niacin in foods. Appendix 2 provides further information on other relevant EU legislation which has been scrutinised.

MINISTERIAL RESPONSIBILITY

12. 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[5]. Scottish Government Ministers, Welsh

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[2] EUR-Lex - 32015R2283 - EN - EUR-Lex (europa.eu)

[3] Novel foods need to be authorised before they can be placed on the market in GB and EU. Examples of novel foods include traditional foods eaten elsewhere in the world, for example, chia seeds, baobab and foods produced from new processes, for example, bread treated with ultraviolet light to increase the level of vitamin D present

[4]The Windsor Framework is a reference to the Protocol, as amended by Joint Committee Decision No XX/2023, expected to be effective in March 2023

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

Government Ministers and Northern Ireland Executive Ministers have responsibility for NLCS in their respective nations.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

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

14. 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 2023/439 on the UK internal market (UKIM) will be of interest to all four UK nations.

15. 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.

16. The NLCS framework provides for close collaboration with consistency of approach across all four nations always being sought in the first instance. It upholds UK governments 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.

17. The EU Commission power to be able to amend the Annex of Regulation 609/2013 was transferred to the 'appropriate authorities' for GB, in respect to retained nutrition legislation by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. Following the processes set out in the NLCS framework[4], policy decisions made by GB authorities will, where appropriate, result in amendments to the Annex of the retained Regulation 609/2013.

LEGAL AND PROCEDURAL ISSUES

18. There are no legal or procedural issues arising.

19. The subject of this proposal is relevant to retained EU law in that the retained Regulation 609/2013 does not contain the equivalent provision for the addition of this new form of niacin to FSMPs and TDR products.

20. The Windsor Framework requires that EU food and feed law will continue to be directly applicable in the UK in respect of Northern Ireland. This includes EU Regulation 609/2013 as amended by Regulation 2023/439 to allow the use of nicotinamide riboside chloride as a source of niacin in FSMPs and TDR products.

POLICY IMPLICATIONS

In Northern Ireland

21. This proposal has policy implications for the UK in respect of Northern Ireland due to the application of the Windsor Framework.

22. Regulation 2023/439 amends the Annex of EU Regulation 609/2013 to allow the use of nicotinamide riboside chloride as a form of niacin which is permitted for use in FSMPs and TDR products.

23. Regulation 2023/439 will only be relevant to industry stakeholders who produce FSMPs and TDR products containing niacin. EU Regulation 2016/128 and EU Regulation 2017/1798 creates mandatory compositional requirements for FSMP and TDR products. However, as long as the form of vitamin or mineral used (in this case, niacin) is one included in the Annex of Regulation 609/2013 (providing the list of permitted forms) industry are able to choose the form used. The amendment does not mandate that nicotinamide riboside chloride must be used, but it amends the Annex of Regulation 609/2013 to permit its use, should industry choose to use it. The FSA in Northern Ireland will engage with stakeholders to ensure they are aware of this EU change.

24. 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. In practice this means only FSMPs and TDR products which use nicotinamide riboside chloride as form of niacin, and which fulfil the criteria of being a "qualifying Northern Ireland good" can be sold in GB. 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.

In GB

25. Article 11 of Regulation 609/2013 sets provisions for the specific compositional and information requirements of the food categories covered by the regulation and, subject to complying with Article 18 of the same regulation, allows for delegated acts to be adopted to set the specific compositional and information requirements for food categories in scope.

26. Commission Delegated Regulation (EU) 2016/128 is an EU delegated regulation made under Regulation (EU) No 609/2013 which sets the provisions for FSMPs. This regulation was retained for use in GB.

27. In the EU, from October 2022 TDR products are legislated for under the delegated act Commission Delegated Regulation (EU) 2017/1798. However, for GB any regulation that did not apply at the end of the UK's transition period ending on 31 December 2020 was not retained and did not become part of GB legislation. Therefore, in GB TDR products are regulated by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (as amended) "1997 TDR regulations".

28. No application has been submitted to GB authorities to request an assessment and or authorisation of nicotinamide riboside chloride as an additional form of niacin which is permitted for use in these foods. However, the NLCS Policy Group has requested a domestic scientific assessment on the safety of nicotinamide riboside chloride for use in FSMPs and TDR products as outlined in the EFSA 2021 scientific opinion. Details of the domestic scientific assessment and the timeline for this opinion is to be confirmed.

29. Following the conclusion of the scientific assessment each GB nation will need to seek ministerial agreement on the proposed next steps in respect of whether to amend GB legislation to permit the use of this substance in FSMPs and TDR products.

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

CONSULTATION

31. No consultation has happened in the UK as the EU Commission's actions to amend the Annex of Regulation 609/2013 will have no direct impact on GB domestic legislation.

32. Consultation with EU Member States experts on the amendment to the Annex of Regulation 609/2013 in the EU has already been undertaken by the EU Commission. EU Member States' experts were consulted on this draft regulation in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control between 22 April 2022 and 13 May 2022[6]. The UK in respect of Northern Ireland was not involved in this. The EU did not hold any discussions with the UK Government on this regulation, either informally or within the dialogue structures established under the EU Withdrawal Agreement. The FSA in Northern Ireland will engage with stakeholders to ensure that they are aware of these upcoming relevant EU changes.

FINANCIAL IMPLICATIONS

33. Regulation 2023/439 will only be relevant to manufacturers or importers of FSMPs or TDR products. There are no financial implications for FSMPs, or TDR products placed on the GB market. For Northern Ireland, the amendments provided by Regulation 2023/439 do not place a new requirement on businesses but offers them further flexibility as it allows them the option to manufacture FSMPs and TDR products with a different form of niacin which is already permitted for use. As this regulation does not impose any additional mandatory requirements, the amendments are not expected to have significant impact on industry stakeholders. There may be some financial implications if UK manufacturers or importers who place products on the Northern Ireland market choose to amend their products in line with the additional form of niacin permitted within the legislation. We do not routinely capture market data on FSMPs or TDR products and therefore, we are unable to estimate the financial impact of Regulation 2023/439 on UK manufacturers. In addition, although individual businesses will have their own records of ingredients used, manufacturers of these products are not required to stipulate the form of niacin which is used and so measuring the impact of the change would be difficult to measure.

Minister Neil O' Brien MP
Parliamentary Under Secretary for State (Minister for Public Health and Primary Care)
Department of Health and Social Care

[6] Reference E02893 in the Register of Commission Expert Groups and other similar entities.

Appendix 1

1. In 2019, the European Food Safety Authority (EFSA) opinion confirmed the safety of nicotinamide riboside chloride as a novel food in accordance with Regulation (EU) 2015/2283 on novel foods[7] and the bioavailability of nicotinamide from this source, in the context of food supplements. Food supplements are defined in Directive 2002/46/EC which sets the provisions of food supplements in the EU.[8]

2. Following the scientific opinion, nicotinamide riboside chloride was authorised as a novel food under Commission Implementing Regulation 2020/16[9]

3. The Commission received an application to extend the use of nicotinamide riboside chloride as a novel food to include its use in FSMPs and TDR products and the Commission requested EFSA to deliver its opinion on the safety and bioavailability of nicotinamide riboside chloride when added to FSMPs and TDR products. EFSA were asked to consider this assessment in the context of both the novel foods regulation (Regulation (EU) 2015/2283) and Regulation 609/2013.

4. In 2021, the EFSA published a further scientific opinion on the extension of use of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283. EFSA concluded that nicotinamide riboside chloride is as safe as pure nicotinamide and can be permitted for use as an alternative form of niacin in FSMPs and TDR products.

5. The Commission considered that the 2021 EFSA scientific opinion gave sufficient grounds to establish that nicotinamide riboside chloride is not of safety concern as a source of niacin when used in FSMPs and TDR products.

6. Commission Implementing Regulation (EU) 2022/1160 authorised the use of nicotinamide riboside chloride in FSMPs and TDR products (among other products) for the adult population, excluding pregnant and lactating women, subject to certain conditions.

Appendix 2

1. Commission Implementing Regulation 2020/16 which set the provisions to authorise nicotinamide riboside as a novel food subject to the requirements of Regulation (EU) 2015/2283 was not deposited for scrutiny.

2. Commission Regulation (EU) 2021/418 which amended Directive 2002/46/EC[10] (which sets the provisions for food supplements) to allow nicotinamide riboside chloride as a permitted form of niacin in the manufacture of food supplements was not deposited for scrutiny.

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[7] EUR-Lex - 32015R2283 - EN - EUR-Lex (europa.eu)

[8] EUR-Lex - 32002L0046 - EN - EUR-Lex (europa.eu)

[9] EUR-Lex - 32020R0016 - EN - EUR-Lex (europa.eu)

[10] EUR-Lex - 32002L0046 - EN - EUR-Lex (europa.eu)

3. Commission Delegated Regulation (EU) 2017/1798 regarding the specific composition and information requirements for TDR products was issued as Council document 10021/17, C(2017)3664, but it was not deposited for parliamentary scrutiny following consultation with the clerks of the EU committees.

4. Commission Delegated Regulation (EU) 2022/2182 which amended Commission Delegated Regulation (EU) 2017/1798 as regards the lipid and magnesium requirements for TDR products was deposited for parliamentary scrutiny as EU document C(2022) 6107 and the Department of Health and Social Care (DHSC) submitted an EM dated 12 October 2022.

5. Commission Delegated Regulation (EU) 2021/1040 which amended Commission Delegated Regulation (EU) No 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children was deposited for parliamentary scrutiny as EU document C(2021) 2527 and DHSC submitted an EM dated 08 June 2021.