EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE WINDSOR FRAMEWORK

C(2024)454

Commission Delegated Regulation (EU) …/... of 29.01.2024 amending the Annex to Regulation (EU) No 609/2013 of the European Parliament and of the Council to allow the use of iron milk caseinate as a source of iron in total diet replacement for weight control and in food for special medical purposes, excluding food for infants and young children

Submitted by the Department of Health and Social Care 26 March 2024.

SUBJECT MATTER

1. The Food for Specific Groups (FSG) Regulation (EU) No 609/2013[1] establishes compositional and information requirements for the following categories of food:
   - infant formula and follow-on formula (IFFOF);
   - processed cereal-based food and baby food;
   - food for special medical purposes (FSMP);
   - total diet replacement (TDR) for weight control.

2. Regulation (EU) No. 609/2013 provides that certain forms of vitamins and minerals can only be used in the food categories in scope of the Regulation if they are included in the Annex to the Regulation which is referred to as the "Union list". The Commission Delegated Regulation updates the "Union List" in the way set out in paragraph 3.

3. The amendment made by Commission Delegated Regulation ("CDR") (EU) C(2024)454 will allow an additional form of the mineral iron (iron milk caseinate) to be permitted for use in TDR for weight control products and in FSMP (excluding foods for infants and young children).

4. The CDR C(2024)454 provides manufacturers with the option to use this alternative form of iron voluntarily, in addition to the existing permitted forms of iron in the Annex of Regulation (EU) No 609/2013 for use in TDR for weight control and in food for special medical purposes, excluding food for infants and young children.

5. The CDR legislation does not extend the authorisation of this form of iron to be used in IFFOF, processed cereal-based food and baby food or FSMPs for infants or children, which are other categories of food in Regulation (EU) No 609/2013.

6. The amendments made by the CDR follow a successful application from a food business operator (Société des Produits Nestlé S.A.) to the EU Commission and

[1] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations(EC) No 41/2009 and (EC) No 953/2009

subsequent positive scientific assessment by the European Food Safety Authority (EFSA) on the safety of iron milk proteinate as a novel food and the bioavailability of iron from this source in the context of EU food supplements legislation.

Background

7. Regulation (EU) No 609/2013 defines:

   - "total diet replacement for weight control" products (TDR) 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.

   - "foods for special medical purposes" (FSMPs) as foods which have been specially processed or formulated 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. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.

8. The specific composition and information requirements for TDR products are legislated for in the EU under Commission Delegated Regulation (EU) 2017/1798 (Regulation 2017/1798)[2].

9. The specific composition and information requirements for FSMPs are legislated for in the EU under Commission Delegated Regulation (EU) 2016/128 (Regulation 2016/128)[3].

10. Iron milk caseinate (with agreed name change from iron milk proteinate in application) was authorised as a Novel Food by the European Commission via Commission Implementing Regulation (EU) 2023/949[4]. It was authorised for use in several food categories including TDR for weight control and FSMP, both as defined under Regulation (EU) 609/2013. This CDR amends Regulation (EU) 609/2013 to update the Union List, permitting the use of iron milk caseinate in those food categories. As with some other novel foods, the approval was for the exclusive use of iron milk caseinate by Société des Produits Nestlé S.A for 5 years from 4 June 2023; thereafter any company will be able to use it.

[2] Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control
[3] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes
[4] Commission Implementing Regulation (EU) 2023/949 of 12 May 2023 authorising the placing on the market of iron milk caseinate as a novel food and amending Implementing Regulation (EU) 2017/2470

11. Now iron milk caseinate has novel food status determined in the EU, this new CDR is to add it to the list of permitted forms of iron in TDR products and in FSMPs in the Annex to Regulation (EU) No 609/2013, while respecting the 5-year exclusive use and relevant conditions of use set out in the Implementing Regulation (EU). The conditions relate to the amount of iron milk caseinate that can be used in some authorised foods and food supplements and a name change to the novel food.

12. The European Commission adopted this Delegated Regulation on 29 January 2024, and it is now being scrutinised by the European Parliament and Council of the EU. It is due to come into force 20 days after its publication in the Official Journal of the European Union.

13. To date, there has been no parallel application to authorities in England, Wales or Scotland (Great Britain (GB) authorities) for the authorisation of the safety and suitability of this form of iron to be used to manufacture TDR for weight control products or FSMP in GB. Therefore, the EU's amendment to the "Union List" is not currently under consideration by GB authorities and the assimilated GB legislation will not be amended to include these changes.

SCRUTINY HISTORY

14. We are not aware of any previous parliamentary scrutiny or requests for an EM relating specifically to the use of iron milk caseinate in foods. However, in March 2023, the Department of Health and Social Care submitted an EM on a similar Delegated EU Regulation ("Regulation 2023/439") for a new form of niacin in FSMP and TDR that was permitted under the same Regulation (Regulation (EU) No 609/2013). That EM completed scrutiny by both committees without any follow up questions.

MINISTERIAL RESPONSIBILITY

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

INTEREST OF THE DEVOLVED ADMINISTRATIONS

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

17. Officials with responsibility for this policy in the devolved Governments have been consulted in the preparation of this EM and the EM incorporates their comments.

[5] https://www.gov.uk/government/publications/nutrition-labelling-composition-and-standards-provisional-common-framework-command-paper

18. The NLCS common framework has been developed to maintain a consistent and co-ordinated policy approach across the UK. It 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.

19. The NLCS framework was provisionally agreed by the Joint Ministerial Committee (EN) on 03 September 2020. Since then, the framework has been operating on a practical basis pending final approval. In the meantime, the provisional 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.

20. 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 Windsor Framework 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.

21. Since the provisionally agreed Common Framework was published all policy proposals have been / are considered on a four-nation basis via the NLCS four-nation policy group established through the framework, with the impact assessed on not just each individual nation, but on the UK internal market as a whole. Regulations which are in scope of the provisional NLCS framework as shown in Appendix II of the framework (excluding nation-specific derogations and directives).

LEGAL AND PROCEDURAL ISSUES

22. This CDR will enter into force 20 days after its publication in the Official Journal of the European Union if no objection is raised by the Council or the Parliament.

23. The CDR (and the updated Regulation (EU) 609/2013) will be directly applicable in Northern Ireland.

24. The subject of this EM is relevant to assimilated EU law in that the assimilated Regulation 609/2013 does not contain the equivalent provision for the addition of this form of iron in TDR for weight control products and FSMP (excluding foods for infants and young children).

POLICY AND LEGAL IMPLICATIONS

25. Under the terms of the Windsor Framework, the CDR and the amendment made by it to the Annexes of Regulation (EU) 609/2013 apply directly to the UK in respect of Northern Ireland. This is because Regulation (EU) 609/2013 is included in Annex 2 to the Windsor Framework. Manufacturers placing TDR for weight control products and FSMP (excluding foods for infants and young children) on the Northern Ireland

market are not mandated to use this form of iron but will be permitted to use it voluntarily in addition to other forms of iron included in the legislation. Use is therefore optional.

26. The amendments to Regulation (EU) 609/2013 do not apply in GB. There are no changes for manufacturers who place products on the market in GB. They will continue to only be able to use those forms of iron already permitted in assimilated Regulation (EU) 609/2013.

27. 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 EU requirements to continue to be able to be placed on the market in GB. Unfettered access for Northern Ireland businesses to the rest of the UK market is longstanding Government policy, strengthened as a result of the package of commitments in our Safeguarding the Union Command Paper. The Windsor Framework (UK Internal Market and Unfettered Access) Regulations 2024 further entrench the legislative protections for unfettered access. Therefore, products that make use of these changes under the amendments to the EU Regulation and are sold in Northern Ireland can be freely moved to and sold in the rest of the UK.

28. In terms of the movement of goods from GB to NI and for sale across the UK, since its introduction on 1 October 2023, the Windsor Framework allows for GB marketing standards to apply to goods moved through the Northern Ireland Relative Movement Scheme (NIRMS) placed on the NI market. Goods moving within the UK internal market via NIRMS are not mandated to meet EU requirements and indeed in this case there are no new EU requirements. Inclusion of this new form of iron, is an additional voluntary manufacturing option, should a manufacturer choose to use it, and is therefore not a mandatory requirement for goods on the Northern Ireland market. Therefore, there is no effect on GB to NI movements of applicable products, and therefore there is no concern about divergence.

29. We do not anticipate any impacts on UK (GB or NI) supply of FSMP and TDR products under these changes. Although the UK has a high dependency on the EU market for supply of EU FSMP products, and Nestlé is a major supplier of EU FSMP products to the UK market, the EU rule does not mandate FSMP suppliers use iron milk caseinate. If Nestlé or other suppliers wish to voluntarily use this form of iron in these products in the GB market, they are able to make a similar application to GB authorities.

CONSULTATION

30. No consultation has happened in the UK as no parallel application for the authorisation of the safety and suitability of this form of iron for use in TDR for weight control products and in FSMP (excluding foods for infants and young children) has been submitted for consideration, and therefore currently, no amendment to GB legislation is required. The assessment for the safety and suitability of this form of iron underwent the usual EU authorisation process, including undergoing scientific assessments by the European Food Safety Authority (EFSA). The EU did not hold any discussions with the UK Government on this regulation, either informally or within the dialogue structure established under the EU Withdrawal Agreement. The FSA in

Northern Ireland will work to ensure that impacted partners and stakeholders are aware of relevant EU changes.

FINANCIAL IMPLICATIONS

31. Regulation C(2024)454 will only be relevant to Nestlé for 5 years, and thereafter other manufacturers or importers of TDR for weight control products or FSMPs (excluding foods for infants and young children). There are no financial implications for TDR products or FSMPs, placed on the GB market. For Northern Ireland, the amendments provided by Regulation C(2024)454 do not place a new requirement on businesses, but offers them further flexibility as it allows businesses the option to manufacture TDR products and FSMP's with a different form of iron in addition to those forms of iron already permitted for use.

32. 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 the products in line with the additional form of iron permitted within the legislation.

33. We do not routinely capture market data on TDR for weight control products and FSMPs and therefore we are unable to estimate the financial impact of this legislation on UK manufacturers.

MINISTERIAL NAME AND SIGNATURE

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