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

C(2024)549

Commission Delegated Regulation (EU) …/... of 2.2.2024 amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysate

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

SUBJECT MATTER

1. The new amending Commission Delegated EU Regulation sets technical provisions to amend the specific compositional requirements for infant formula and follow on formula (IFFOF) as set out in the Annexes to Commission Delegated Regulation (CDR) (EU) 2016/127[1]. The legislation permits, but does not mandate, the addition of a particular type of protein hydrolysate (protein hydrolysed into its component products including amino acids and peptides) for use in the manufacture of IFFOF.

2. This minor and technical amendment to the legislation follows a successful application from a food business operator (FrieslandCampina Nederland B.V.) to the EU Commission and subsequent positive scientific assessment by the European Food Safety Authority (EFSA) on the safety and suitability of a protein hydrolysate used to manufacture their IFFOF made from hydrolysed protein. There has not been an equivalent application in Great Britain (GB).

3. CDR (EU) 2016/127 supplements the Foods for Specific Groups (FSG) parent regulation (EU) 609/2013[2], which establishes compositional and information requirements for processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control in addition to IFFOF.

4. CDR (EU) 2016/127 lays down specific compositional and information requirements for IFFOF. The Regulation was adopted in 2016 and applied from 22 February 2020 except in respect of IFFOF manufactured from protein hydrolysates, which applied from 22 February 2022. From this date, manufacturers of IFFOF which are made from protein hydrolysates, must demonstrate the safety and suitability of specific formula containing protein hydrolysates, established by scientific evaluation. The Regulation provides that IFFOF manufactured from protein hydrolysates are only to be placed on the market if they comply with the requirements as set out in the Annexes of CDR (EU) 2016/127.

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[1] Commission Delegated Regulation (EU) 2016/127 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 infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

[2] 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

5. The recitals (see paragraph 21) to CDR (EU) 2016/127 set out that the compositional requirements can be updated to reflect the approval of IFFOF manufactured from protein hydrolysates with a composition different from those already positively assessed, following a case-by-case evaluation of their safety and suitability.

6. The European Commission adopted this Delegated Act on 2 February 2024 and it is now being scrutinised by the European Parliament and Council of the EU. It will come into force on the day of its publication in the Official Journal of the European Union.

7. The technical amendment to the Annexes of CDR (EU) 2016/127 is not a mandatory requirement for the compositional requirements for all IFFOF to change, but subject to the compositional requirements being followed, this amendment will allow IFFOF manufactured from the newly approved protein hydrolysate to be placed on the EU and Northern Ireland market, and Annexes I, II and III of CDR (EU) 2016/127 will be updated to reflect this.

8. To date, there has been no application to authorities in England, Wales or Scotland (Great Britain (GB) authorities) for the authorisation of the safety and suitability of any new protein hydrolysates used to manufacture IFFOF in GB which does not correspond to the current compositional requirements of assimilated CDR 2016/127. Therefore, the EU's amendment to the compositional requirements set out in the Annexes of CDR (EU) 2016/127 is not currently under consideration by GB authorities and the assimilated CDR 2016/127 will not be amended to include these compositional changes.

SCRUTINY HISTORY

9. In March 2022, the Department of Health and Social Care submitted an Explanatory Memorandum (EM) on a similar Delegated Regulation ("C(2022) 99") that amended CDR (EU) 2016/127 following an earlier application from another food business operator, Danone, and subsequent approval of that form of protein hydrolysate. That EM completed scrutiny by both committees without any follow up questions.

10. In January 2023 an assessment summary was provided to the Scrutiny Committee clerks for another similar Delegated Regulation "C (2023) 21" that amended CDR (EU) 2016/127 following an earlier application from HIPP-Werk Georg Hipp OHG and subsequent approval of that form of protein hydrolysate. On that occasion an EM was not requested.

MINISTERIAL RESPONSIBILITY

11. 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.[3] Scottish Government Ministers,

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

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

INTEREST OF THE DEVOLVED ADMINISTRATIONS

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

13. Officials with responsibility for this policy in the devolved Governments have been consulted in the preparation of this EM and the EM incorporates comments which were received.

14. 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.

15. 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.

16. 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.

17. 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 are shown in Appendix II of the framework (excluding nation-specific derogations and directives).

LEGAL AND PROCEDURAL ISSUES

18. The Commission Delegated Regulation will enter into force on the day of its publication in the Official Journal of the European Union if no objection is raised by the Council or Parliament.

19. The Commission Delegated Regulation will be directly applicable in Northern Ireland.

20. The subject of this EM is relevant to assimilated EU law in that the assimilated Regulation 2016/127 does not contain the equivalent provision for the addition of the new form of protein hydrolysate.

POLICY AND LEGAL IMPLICATIONS

21. Under the terms of the Windsor Framework, the current amendments to the Annexes of CDR (EU) 2016/127, which would be made by this Commission Delegated Regulation apply directly to the UK in respect of Northern Ireland. This is because it is supplementary to Regulation (EU) 609/2013, which is included in Annex 2 to the Windsor Framework. Manufacturers placing IFFOF products on the Northern Ireland market are not mandated to use this type of protein hydrolysate but will be allowed to use this in addition to others whose composition corresponds to the requirements set out in the legislation. Use is therefore optional.

22. The amendments to CDR (EU) 2016/127 do not apply in Great Britain so products containing the protein hydrolysate in scope are not permitted for use 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 existing protein hydrolysates whose composition corresponds to the requirements set out in assimilated CDR (EU) 2016/127.

23. 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 CDR (EU) 2016/127 and are sold in Northern Ireland can be freely moved to and sold in the rest of the UK.

24. 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 protein hydrolysate is an additional voluntary manufacturing option, should a manufacturer choose to use it, and is therefore not a mandatory requirement for goods on the NI market. Therefore, there is no effect on GB to NI movements of applicable products, and therefore there is no concern about divergence.

25. Under the assimilated CDR (EU) 2016/127 as amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (SI 2020/1476) the GB authorities have developed and established a domestic process for the authorisation of the safety and suitability of protein hydrolysates used to manufacture IFFOF. Similar to the process in the EU, businesses may submit applications to GB authorities in support of amending the compositional requirements as set out in the Annexes of CDR (EU) 2016/127. As explained above (Paragraph 8), to date, GB authorities have not received any

applications for the authorisation of the safety and suitability of any new protein hydrolysates used to manufacture IFFOF in GB which does not correspond to the current compositional requirements of assimilated CDR (EU) 2016/127.

26. We do not anticipate any impacts on UK (GB or NI) supply of IFFOF products under these changes. Although the UK has a high dependency on the EU market for supply of IFFOF products, the amendments made by this Commission Delegated Regulation do not mandate IFFOF suppliers to use this form of protein hydrolysate. If FrieslandCampina or other suppliers wish to voluntarily use this form of protein hydrolysate in these products in the GB market, they are able to make a similar application to GB authorities.

CONSULTATION

27. No consultation has happened in the UK as no parallel application for the authorisation of the safety and suitability of protein hydrolysates used to manufacture IFFOF has been submitted for consideration, and therefore no amendment to GB legislation is required. The FSA in Northern Ireland will work to ensure that impacted partners and stakeholders are aware of relevant EU changes.

FINANCIAL IMPLICATIONS

28. There are no financial implications for GB as IFFOF manufactured from protein hydrolysates with a composition different from those already positively assessed as set out in assimilated CDR (EU) 2016/127 are not authorised in GB. For Northern Ireland, this does not place a new mandatory requirement on businesses but allows them to manufacture IFFOF with a newly authorised protein hydrolysate, provided it meets the requirements as set out in this Commission Delegated Regulation, should businesses choose to do so.

29. As this Commission Delegated 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 voluntarily amend the products in line with the additional form of protein hydrolysate permitted within the legislation.

30. We do not routinely capture market data on IFFOF products and therefore we are unable to estimate the financial impact of this legislation 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 protein hydrolysate which is used and so measuring the impact of the change would be difficult.

MINISTERIAL NAME AND SIGNATURE

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