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

5443/22
COM (2022)99

Commission Delegated Regulation (EU) .../... of 14.1.2022 amending Delegated Regulation (EU) 2016/127 as regards the protein requirements for infant and follow-on formula manufactured from protein hydrolysates. (Un-numbered)

Submitted by the Department of Health and Social Care ("DHSC") on 8 March 2022

SUBJECT MATTER

1. This new amending EU Regulation sets technical provisions to amend the specific compositional requirements for infant formula and follow-on formula (IFFOF) as set out in the Annex to Commission Delegated Regulation (EU) 2016/127. (CDR 2016/127). The legislation permits the addition of a particular type of protein hydrolysate to IFFOF. This minor and technical amendment to the legislation follows a successful application from a food business operator (Danone ELN 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 (derived from whey protein concentrate) used to manufacture their IFFOF made from hydrolysed protein. There has not been an equivalent application in Great Britain (GB).
2. The Food for Specific Groups (FSG) legislation "Regulation (EU) No 609/2013[1]", establishes compositional and information requirements for the following categories of food (Article 1 (1)):
    a. infant formula and follow-on formula (IFFOF)
    b. processed cereal-based food and baby food
    c. food for special medical purposes (FSMPs)
    d. total diet replacement for weight control
3. CDR 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 will apply from 22 February 2022. From this date, manufacturers of IFFOF which are made from protein hydrolysates (protein hydrolysed into its component products including amino acids and peptides) must demonstrate the safety and suitability of each specific formula containing protein hydrolysates has been established by scientific evaluation. The Regulation

[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

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.

4. The recitals to CDR 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.

5. The European Commission adopted this Delegated act on 14 January 2022. It is due to come into force on the day of its publication in the Official Journal of the European Union.

6. This technical amendment to the Annexes of CDR 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 market. As set out under Annexes I and II of the amended EU legislation both infant formula and follow-on formula manufactured from protein hydrolysates will therefore comply either with the current protein related requirements provided under point 2.3.1., or with the new protein related requirements provided under point 2.3.2.

7. 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 retained CDR 2016/127. Therefore, the EU's amendment to the compositional requirements set out in the Annexes of CDR 2016/127 is not under consideration by GB authorities and the GB legislation will not be amended to include these compositional changes.

8. Under the current approach to the Protocol on Ireland/Northern Ireland (NIP) the application which has been approved in the EU and the amending Regulation C (2022)99 will apply in respect of Northern Ireland. This is because overarching regulation for CDR 2016/127, Regulation (EU) No 609/2013 is included in Annex 2 to the NIP. Regulation C (2022)99 authorises the use of an additional protein hydrolysate for the EU and Northern Ireland markets, following the positive safety assessment by the EFSA. Although this technical and minor change results in a small divergence in the compositional requirements of IFFOF across GB and Northern Ireland, the use of the new compositional requirements is merely permissive in Northern Ireland with no material impact upon GB industry.

9. The United Kingdom Internal Market Act 2020 (UK IM Act 2020) ensures unfettered access for qualifying Northern Ireland goods to the GB market. In accordance with the mutual recognition principle in the Act, qualifying Northern Ireland goods that comply with the amended compositional requirements of the CDR 2016/127, may be placed on the GB market.

SCRUTINY HISTORY

10. We are not aware of any previous parliamentary scrutiny relating specifically to IFFOF manufactured from protein hydrolysates. However, Commission Delegated Regulation (EU) 2021/572 of 20 January 2021 amending Delegated Regulation (EU) 2016/127 as

regards the date of application of certain of its provisions "C (2021)155" was waived from requiring an EM following consultation with the Secretariats of the EU Scrutiny Committees.

11. CDR (2016)172 was subject to scrutiny as deposited EU document 12430/15, C(2015)6478 on which the Government submitted an EM dated 10 November 2015. The proposal was examined by the then Lords European Affairs Committee sub-committee D where it completed scrutiny on 3 February 2016 following correspondence with Ministers. The proposal completed scrutiny in the Commons European Scrutiny Committee on 25 November 2015 without requiring a substantive report to the House.

12. C (2021)155 amended the CDR 2016/127 as regards the date of application for provisions relating to IFFOF manufactured from protein hydrolysates from 22 February 2021 to 22 February 2022. For GB the Nutrition (Amendment) and Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment) Regulations 2021 (SI 2021 No. 168) was made and laid on 19 February 2021 to similarly delay the coming into effect date of retained CDR 2016/127 for IFFOF manufactured from protein hydrolysate in GB; aligning the dates in both GB and the EU.

MINISTERIAL RESPONSIBILITY

13. 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

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

15. The devolved governments have been consulted in the preparation of this EM and the EM has been shared with them for their information. No comments were provided.

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

17. 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*

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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)

terms of policy consideration, governance and dispute resolution. In particular, it stresses Northern Ireland's continued participation in risk management considerations.

18. Following the process set out in the NLCS framework, policy decisions made by GB authorities will where appropriate result in amendments to retained CDR 2016/127. As explained above (paragraph 7), no application for the authorisation of the safety and suitability of protein hydrolysates used to manufacture IFFOF in GB, which does not correspond to the current requirements of CDR 2016/127, has been submitted to the GB authorities. As provided for by the provisions of the UK IM Act 2020, IFFOF products that meet the amended compositional requirements of the CDR 2016/127 may be placed on the Northern Ireland market, and if they meet the conditions for mutual recognition as qualifying Northern Ireland goods may be freely moved to the GB market.

LEGAL AND PROCEDURAL ISSUES

19. This legislative amendment to EU law has followed an application to the EU Commission by Danone ELN B.V. The delegated will enter into force into force if no objection is raised by the Council or the Parliament.

20. The updated Regulation will be directly applicable in Northern Ireland.

POLICY IMPLICATIONS

21. There is limited policy implication in GB from the EU authorisation of the safety and suitability of protein hydrolysates used to manufacture IFFOF, which does not correspond to the current requirements of retained CDR 2016/127. There is an implication in Northern Ireland in that the specific protein hydrolysate (as assessed as safe by EFSA) will be authorised for use in IFFOF on the Northern Ireland market, giving manufacturers the option to use it if they meet the compositional requirements.

22. The EU's amendment to the Annexes of CDR 2016/127 is not a mandatory change to the compositional requirements for all IFFOF, and IFFOF can continue to comply with the current compositional requirements which are set out in the Annexes of CDR 2016/127. The significance of the amendment is that in the EU and Northern Ireland it also authorises IFFOF manufactured from protein hydrolysates with a composition different from those already positively assessed.

23. The EU Commission power to amend the compositional requirements for IFFOF as set out in CDR 2016/127, was transferred to the 'appropriate authorities' for GB by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. Applications for the authorisation of the safety and suitability of protein hydrolysates used to manufacture IFFOF may be submitted for authorisation for use GB wide, or alternatively for use in England only, or for use in Scotland only or for use in Wales only. Following positive scientific assessment of the safety and suitability of protein hydrolysates used to manufacture IFFOF, regulations which amend the compositional requirements as set out in CDR 2016/127 in England, may be made by the Secretary of State, for Scotland –by Scottish ministers (the Minister for Public Health, Women's Health and Sport), for Wales by Welsh ministers (the Deputy Minister for Mental Health and Wellbeing). The NLCS Framework outlines that the Northern Ireland Minister of Health will be informed and have the opportunity to raise a dispute.

24. To date, there has been no application to 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 CDR 2016/127. In practice this means that IFFOF manufactured from hydrolysed protein which uses a protein hydrolysate derived from whey protein concentrate with the new compositional requirements positively assessed by EFSA cannot be sold in GB without seeking prior assessment in GB, unless it fulfils the criteria of being a qualifying Northern Ireland good.

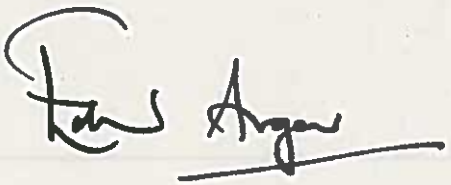
CONSULTATION

25. No consultation has happened in the UK as no 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. Consultation with EU Member States on the amendment of the compositional requirements of CDR 2016/127 in the EU has already been undertaken by the Commission; EU Member States were consulted in writing 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"[3] between 29 March 2021 and 16 April 2021. The UK in respect of Northern Ireland was not involved in this. The FSA in Northern Ireland is working to ensure that impacted partners and stakeholders are aware of relevant EU changes.

FINANCIAL IMPLICATIONS

26. 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 retained CDR 2016/127 are not authorised here. For Northern Ireland, this does not place a new requirement on businesses but allows them to manufacture IFFOF with a newly authorised protein hydrolysate, provided it meets the requirements set out in the Regulation.

MINISTERIAL NAME AND SIGNATURE



7. iii. 2022

Ed Argar

Minister of State for Health

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[3] Register of Commission expert groups and other similar entities (europa.eu)