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

C(2022) 6107

Commission Delegated Regulation (EU) …/... of 30.08.2022 amending Commission Delegated Regulation (EU) 2017/1798 as regards the lipid and magnesium requirements for total diet replacement for weight control.

Submitted by the Department of Health and Social Care ("DHSC") on the 12 October 2022.

SUBJECT MATTER

1. Regulation EU No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control[1] (Regulation 609/2013) defines 'total diet replacement for weight control' (TDR) as '*food 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'*.

2. Commission Delegated Regulation (EU) 2017/1798 regarding the specific composition and information requirements for TDR, (Regulation 2017/1798) is an EU delegated regulation which supplements the overarching Regulation 609/2013 and will apply from 27 October 2022 (further detail provided in Appendix A).

3. Following a scientific statement in April 2021 from the European Food Safety Authority (EFSA), the amending Regulation "C(2022) 6107" updates Annex I of Regulation 2017/1798. This amendment removes the requirement for linoleic acid (a type of fatty acid) to be present, lowers the minimum content required for alpha-linolenic acid (a type of fatty acid), and raises the maximum content of magnesium which is permitted.

SCRUTINY HISTORY

4. Regulation 2017/1798, which is being amended, was issued as Council document 10021/17, C(2017)3664, but it was not deposited for scrutiny following consultation with the clerks of the EU committees.

MINISTERIAL RESPONSIBILITY

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

INTEREST OF THE DEVOLVED ADMINISTRATIONS

[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

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

7. Scottish Government Ministers, Welsh Government Ministers and Northern Ireland Executive Ministers will have an interest in the implications of C(2022) 6107 on the UK internal market (UKIM).

8. The UK-wide NLCS common framework (further detail provided in Appendix B) 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. Devolved government officials were informed during the preparation of this EM and the EM has been shared with them for their information and the EM incorporates comments which were received.

9. At the end of the EU Exit transition period, Regulation 2017/1798 was still in its transition phase (as it is not fully applicable until 27th October 2022), and therefore it was not retained for use in Great Britain (GB). The amendments made to the compositional requirements of Annex I of Regulation 2017/1798 via C(2022) 6107 will therefore not apply in GB.

10. TDR products are regulated in GB by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (the "1997 legislation"). Until 27th October 2022 there is similar legislation in Northern Ireland. These regulations implement Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction.

11. Under the Protocol on Ireland/Northern Ireland (NIP), C(2022) 6107 will apply in the UK in respect of Northern Ireland. This is because Regulation 609/2013 is included in Annex 2 to the NIP. Consequently, NIP applies to any supplementing pieces of Regulation 609/2013 including Regulation 2017/1798.

LEGAL AND PROCEDURAL ISSUES

12. There are no legal or procedural issues arising for GB.

13. The subject of this proposal is relevant to retained EU law. The NIP provides that limited areas of EU law will continue to apply to the UK in respect of Northern Ireland (see paragraph 11).

14. The legal basis of C(2022) 6107 is Article 11(2) of Regulation 609/2013. According to that provision the EU Commission is empowered to adopt delegated acts in order to update the delegated acts adopted pursuant to Article 11(1) of that Regulation, such as Regulation 2017/1798. The power to update delegated acts is subject to the general requirements set out in Articles 6 and 9 of Regulation 609/2013, to the additional requirements of Article 10, and considering relevant technical and scientific progress.

15. The Regulation "C(2022) 6107" shall enter into force in the EU on the twentieth day following that of its publication in the Official Journal of the European Union.

POLICY IMPLICATIONS

16. The EU's amendment to the compositional requirements set out in Annex I of Regulation 2017/1798 will only be relevant to industry stakeholders who produce TDR products.

17. The amendments made via C(2022) 6107 will have no direct impact on GB domestic nutrition legislation. They ease the existing position by removing the requirement for TDR products to contain linoleic acid, lower the minimum content required for alpha-linolenic acid and raise the maximum required level for magnesium. It is the application of EU Regulation 2017/1798 on the 27 October 2022 in Northern Ireland, which will mean there will be divergence between the legislative requirements for EU regulated TDR products placed on the market in Northern Ireland and GB regulated products.

18. 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. Where there is divergence in the regulatory approach between GB and Northern Ireland, UKIM allows qualifying Northern Ireland goods to continue to be able to be placed on the market in GB. However, in the presence of conflicting regulations for GB and Northern Ireland, the movement of goods from GB to Northern Ireland which do not comply with EU Regulations would not be permitted.

19. Due to C(2202) 6107 applying in Northern Ireland, TDR products which do not comply with the amended compositional requirements would not be able to be placed on the Northern Ireland market. The amendments were informed by the 2021 EFSA scientific statement which was requested by TDR industry stakeholders. As C(2022) 6107 removes some of the limitations on the compositional requirements and does not impose any additional restrictions the amendments are not expected to have significant impact on industry stakeholders.

20. It should be noted that the government introduced the Northern Ireland Protocol Bill on 13 June 2022. The Bill seeks to restore the balance of the objectives of the NIP and includes proposals for a dual regulatory regime in Northern Ireland, thereby allowing for the movement of goods from GB to Northern Ireland which comply with GB regulations. The government is currently engaging with stakeholders on the operation of the dual regulatory regime and will provide further information in due course, alongside the Bill passage.

21. As Regulation 2017/1798 is not applicable in GB, products which comply with the GB 1997 legislation and all other aspects of food law can continue to be freely placed on the GB market.

22. However, during the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and 2020 debates, it was indicated that it was the government's intention to make legislation which would set the same standards as EU legislation that the UK was part of making while an EU Member State but were not fully applicable at the time of EU Exit. This would include Regulation 2017/1798 which was adopted in June 2017.

23. Through the risk assessment and risk management processes of the NLCS common framework a UK TDR ad-hoc expert group has been established to conduct a domestic scientific assessment on the compositional changes for TDR products. This scientific

assessment is focused specifically on critically appraising the compositional changes for TDR products which are proposed via the 2021 EFSA statement, and which are being implemented in the EU via C(2022) 6107, and the evidence used to inform the proposed changes. The ad-hoc expert group have also been asked to identify and review any other relevant new scientific evidence available that aligns with the EFSA inclusion criteria from the 2021 statement. This scientific opinion is expected to be published by the end of 2022.

24. Therefore, the precise scope of the future policy on TDR products in GB and any resulting legislative changes are subject to the outcome of the scientific opinion and will require further ministerial agreement.

25. Subject to ministerial agreement to update the legislation on TDR, we would consult. It is both common practice and a statutory duty to consult on changes to food legislation. Although any legislative changes which are implemented in GB will not be applicable to Northern Ireland, their full participation in risk assessment and risk management processes of the NLCS framework ensure that any decisions taken in GB account for the potential impacts across the UK. This is to recognise that supply chains throughout the UK are interlinked and reflects Northern Ireland's role within the UK.

CONSULTATION

26. The EU Commission's actions to amend the compositional requirements for TDR products as set out in Regulation 2017/1798 will have no direct impact on GB domestic legislation and no consultation has happened in the UK.

27. Consultation with EU Member State experts on the amendment to Regulation 2017/1798 in the EU has already been undertaken by the EU Commission. EU Member State experts 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"[2] between 13 July 2021 and 10 September 2021, between 25 November 2021 and 13 December 2021 as well as between 16 February 2022 and 28 February 2022.

28. The UK in respect of Northern Ireland was not involved in this consultation. The FSA in Northern Ireland has engaged with industry representation bodies and is communicating with stakeholders to ensure that they are aware of relevant EU changes.

FINANCIAL IMPLICATIONS

29. There are no known financial implications for products placed on the GB market, as manufacturers who place products on the GB market will be able to continue to manufacture products in line with the 1997 legislation. However, Regulation 2017/1798 will be directly applicable in Northern Ireland from 27th October 2022. The amendments proposed to the compositional requirements as set out in C(2022) 6107 will only be relevant to manufacturers supplying to the EU/Northern Ireland market or importers of TDR products from EU/Northern Ireland. They ease the existing position by removing the

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

requirement for TDR products to contain linoleic acid, lower the minimum content required for alpha-linolenic acid and raise the maximum permitted level for magnesium.

30. There may be some financial implication 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. However, we do not routinely capture market data on TDR products and therefore, we are unable to estimate the financial impact of the amending Regulations on UK manufacturers.

31. We understand the majority of TDR products are manufactured outside the UK and we are not aware of any TDR manufacturers in Northern Ireland. We understand from conversations with industry there is a minimal TDR market in Northern Ireland and therefore the practical implication of divergence is expected to be low. We understand there are UK manufacturers of TDR products who export to EU countries and therefore if they were to continue to export, they would be required to follow the requirements of Regulation 2017/1798.

RT HON ROBERT JENRICK MP
MINISTER OF STATE

Appendix A – background to Regulation 2017/1798

32. The remaining compositional requirements for TDR as set out in Regulation 2017/1798 are based on the 2015 EFSA scientific opinion on the essential composition of total diet replacement for weight control. Regulation 2017/1798 was adopted in the EU in June 2017.

33. Prior to the coming into effect date of Regulation 2017/1798 (27th October 2022) and in response to a request made by a TDR sector trade body to review the scientific evidence, the EU Commission mandated EFSA to consider the compositional requirements of the two fatty acids and magnesium. If necessary EFSA were requested to update the conclusions of its scientific opinion of 2015 as regards the required minimum levels of linoleic acid and alpha-linolenic acid as well as the maximum level of magnesium required for TDR.

34. On the basis of the conclusions of the EFSA 2021 statement, under the powers of Article 11(2) of Regulation 609/2013 the EU Commission made C(2022) 6107 to update the compositional requirements of TDR products.

Appendix B

35. The NLCS provisional common framework has been developed to maintain a consistent and co-ordinated policy approach across the UK. 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. The agreements set out 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 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.