EXPLANATORY MEMORANDUM TO

THE HEALTH CLAIMS (REVOCATION) REGULATIONS 2024

[2024] No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament in accordance with the Retained EU Law (Revocation and Reform) Act 2023.

1.2 This memorandum contains information for the Sifting Committees (the European Statutory Instruments Committee and the Secondary Legislation Scrutiny Committee).

2. Declaration

2.1 Minister Leadsom, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Kevin Dodds, Deputy Director for Healthy Weight, Food and Nutrition, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 For any queries regarding this Instrument contact: Andrew Herd at the Department of Health and Social Care, Telephone: 01132546121/07584265932 or email: Andrew.herd@dhsc.gov.uk.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 These Regulations ("the Revocation Regulations") revoke 60 instruments of secondary assimilated law (as defined in section 21(1) of the Retained EU Law (Revocation and Reform) Act 2023 (c.28)("the REUL Act") for Great Britain.

4.2 Regulation No (EC) 1924/2006 ("Regulation 1924/2006") of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods governs the regulation of the use of health claims on food, and provides that a Register must be kept of both authorised and rejected health claims. The instruments revoked by these Regulations were made, as tertiary legislation under Regulation 1924/2006, by the European Commission prior to the UK's exit from the EU and authorised the use of, or refused authorisation for the use of, specific health claims in respect of food. Where a health claim was approved by the European Commission, it was added to the register in the Annex of Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ("Regulation 432/2012"). Regulation 1924/2006, Regulation 432/2012 and the tertiary legislation revoked by these Revocation Regulations were all incorporated into domestic law by section 3 of the European Union Withdrawal Act ("EUWA"),

amended by the Nutrition (Amendment etc) (EU Exit) Regulations 2019 (SI 2019/651) and became secondary assimilated law under section 5 of the REUL Act.

4.3 The amendments made by SI 2019/651 to Regulation 1924/2006 mean that the Secretary of State is under an obligation to maintain a Register of authorised and rejected health claims for Great Britain (which is called the Great Britain Nutrition and Health Claims Register and is available on the DHSC website). Authorised health claims also continue to be listed in the Annex to assimilated Regulation 432/2012.

4.4 The instruments revoked by these Regulations, therefore, have no ongoing legal purpose, as the health claims which they authorised or rejected are listed in the Register that must be kept under assimilated Regulation 1924/2006, and authorised health claims additionally in the Annex to Regulation 432/2012.

Where does the legislation extend to, and apply?

4.5 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is Great Britain (England, Scotland and Wales).

4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is Great Britain (England, Scotland and Wales).

5. Policy Context

What is being done and why?

5.1 Regulation 1924/2006 (which is now assimilated law) (as amended by the Nutrition (Amendment etc) (EU Exit) Regulations 2019) sets out the legal framework for making claims about the nutrition and health benefits of a food on the labelling, presentation and product specific advertising in a commercial context. Businesses may want to highlight the relationship that exists between the consumption of a food, or one of its constituents, and health. However, it is important that where health claims are used they are accurate, and consumers are not misled.

5.2 A ‘health claim’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. A ‘reduction of disease risk claim’ means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

5.3 To have a health claim approved for use, businesses are required to make an application to the appropriate authority, the Secretary of State for Health and Social Care.

5.4 Approved health claims must be substantiated by evidence. The appropriate authority undertakes an assessment of the application to inform decisions to authorise or reject the claim and update the relevant Annex in the regulations and GB Register.

What was the previous policy, how is this different?

5.5 Revoking the instruments specified in these Regulations has the benefit of significantly reducing the amount of Nutrition-related Labelling, Composition and Standards assimilated EU law on the GB statute book, which is a key aim of the REUL Act. It will simplify the statute book and make it easier to navigate.

6. Legislative and Legal Context

How has the law changed?

6.1 Assimilated Regulation 1924/2006 sets out the legal framework for businesses making nutrition and health claims on foods and provides for a register of authorised and rejected health claims. Claims must comply with the general requirements as specified in Article 3 of those regulations.

6.2 Prior to EU Exit, each decision to authorise or reject health claims resulted in the EU Commission making a regulation. The Commission was obliged to keep a Register of both authorised and rejected health claims, and permitted health claims were added to the Annex of Assimilated Regulation 432/2012 (which provides a list of permitted health claims (other than those referring to the reduction of disease risk and to children's development and health). Post EU Exit, Assimilated Regulation 1924/2006 and 432/2012, as amended by SI 2019/651, provide that the obligation to keep a Register of authorised and rejected health claims for Great Britian now falls upon the Secretary of State, and these are found in the Great Britain nutrition and health claims (NHC) register. Permitted health claims will also still be added to the Annex to assimilated Regulation 432/2012. Therefore, the Commission Regulations which implemented these decisions do not serve any ongoing legal purpose, and they complicate the statute book.

6.3 The REUL Act provides the opportunity to reform retained EU law to ensure it works best for the UK to reduce the regulatory burden on businesses and support growth. The Secretary of State makes these amending Regulations in exercise of powers in the REUL Act.

6.4 During the REUL Act's passage through Parliament, an amendment was tabled because of concerns raised in Parliament and by devolved administrations, including at the Inter-Ministerial Standing Committee, regarding the exercise of delegated powers in devolved areas. The REUL Act confers on UK Government Ministers powers to revoke, and replace, update or restate REUL on a GB-wide basis. UK Government Ministers committed to not normally using the powers under the REUL Act in devolved areas without the agreement of the relevant devolved administration. Where a UK Minister intends to exercise the powers in devolved areas, the Government will seek agreement on an SI-by-SI basis. In compliance with this agreement these draft Regulations have been discussed with the devolved administrations.

Why was this approach taken to change the law?

6.5 We are exercising the powers in the REUL Act to remove the specified redundant assimilated secondary legislation from the statute book, given they serve no ongoing legal purpose. However, future authorisations of health claims will continue to require individual SIs to be made to modify the Annex to Assimilated Regulation 432/2012 (which are reflected in the GB Register), and authorised and rejected health claims will be added to the GB Register.

7. Consultation

Summary of consultation outcome and methodology

7.1 There has been open and transparent public consultation during the preparation and evaluation of these Regulations. A consultation[1] was published on Gov.uk on the 9th August 2023 for a period of 12 weeks, closing on the 31st October 2023. The consultation invited any person or organisation to provide their views and evidence on the reform proposals contained within the consultation.

7.2 The consultation was developed through engagement with officials in the devolved administrations of Scotland, Wales and Northern Ireland and UK Government Ministers engaged DA Ministers. This is in line with the provisional Nutrition-related Labelling, Composition and Standards Common Framework, which has been developed to maintain consistent positions on nutrition-related legislation across the UK. Although the consultation was conducted by the UK Government, the proposals for revocation are being implemented through a GB-wide statutory instrument, with the consent of governments in Scotland and Wales, as the regulations were retained for GB only. Northern Ireland Ministers have been informed.

7.3 Stakeholders including industry trade bodies, organisations (non-governmental organisations and charities) and enforcement authorities were encouraged to respond to the consultation, which sought views on the policy being implemented through this instrument. The consultation received 52 responses including from individuals and organisations and industry trade bodies representing manufacturers and retailers and local authority trading standards. A significant majority (82%) of respondents agreed with the proposal to remove the redundant tertiary legislation relating to the authorisation of certain health claims.

7.4 Following consideration of the consultation responses, the Government published the consultation outcome[2] on Gov.uk on the 6th February 2024.

7.5 UK Ministers wrote to the Ministers in Devolved Administrations (and DHSC Permanent Secretary wrote to the Northern Ireland Permanent Secretary in line with our wider UK dialogue of food legislation) in January 2024, seeking consent in principle to make and lay the SI revoking GB-wide legislation.

8. Applicable Guidance

8.1 Guidance[3] to support businesses and local authorities to implement the requirements of the Revocation Regulations will be published when the legislation is laid. The Regulations will come into force on the 1 October 2024.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full impact assessment has not been prepared for this instrument because there is minimal impact on businesses or enforcement authorities of revoking the legislation specified in the Revocation Regulations as the legal effect of the historical decisions on the health claims are retained in the relevant Register and the Annex to Regulation 432/2012. A Regulatory Triage Assessment has been completed. Our assessment is

[1] Nutrition and health claims on food: proposed legislative reforms - GOV.UK (www.gov.uk)
[2] Nutrition and health claims on food: proposed legislative reforms - GOV.UK (www.gov.uk)
[3] Nutrition legislation information sheet - GOV.UK (www.gov.uk)

that upfront familiarisation costs are the only cost impact of these policy reforms on business and enforcement authorities and total less than £5 million.

Impact on businesses, charities and voluntary bodies

9.2 There is no impact on business, charities or voluntary bodies because the instruments revoked by these Revocation Regulations have no ongoing legal purpose, as the health claims which they authorised are listed in the Annex to Regulation 432/2012 and the authorised and rejected health claims are found in the relevant Register.

9.3 There is no, impact on the public sector because the effect of the legislation being revoked has not changed.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 As this instrument is made under the relevant European Union Acts (as defined at 13.1), no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument is being laid for sifting by the Sifting Committees.

11.2 Parliament is taking special interest in legislation being brought forward under the REUL Act to reform or revoke assimilated EU law.

12. European Convention on Human Rights

12.1 Minister Leadsom, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care. has made the following statement regarding Human Rights:

"In my view the provisions of the Health Claims (Revocation) Regulations 2024 are compatible with the Convention rights.".

12.2 Minister Leadsom, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care. has made the following statement regarding use of legislative powers in the REUL Act:

12.3 "In my view the Health Claims (Revocation) Regulations 2024 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)".

12.4 This is the case because: as highlighted at paragraphs 5.5 and 5.6 revoking the instruments specified in the Revocation Regulations would have the benefit of significantly reducing the amount of nutrition-related labelling, composition and standards assimilated law on the GB statute book, which is a key aim of the REUL Act, but the legal effect of those instruments would be retained in the Annex to Regulation 432/2012 or the relevant Register. It would tidy up the statute book and make it easier to navigate. These reforms are not contentious given that a significant majority (82%) of consultation responses, summarised at paragraph 7.3, agreed with the proposal to remove redundant tertiary legislation relating to the authorisation of health claims.

13. The Relevant European Union Acts

This instrument is made under section 14 (1) of the REUL Act and relates to the reform of assimilated EU law. These amending Regulations revoke 60 instruments of secondary assimilated EU law (as defined in section 21(1) of the REUL Act).