EXPLANATORY MEMORANDUM TO

THE NUTRITION (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

2020 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 by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of this instrument is to:

- First, reflect the Protocol on Ireland/Northern Ireland (NIP) by amending The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and revoking The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019; and
- Secondly, remedy deficiencies in retained European Union (EU) legislation relating to nutrition.

Explanations

What did any relevant UK law do before exit day?

2.2 EU legislation on nutrition related labelling, composition, and standards, covers the following areas: nutrition and health claims made on foods; the addition of vitamins, minerals, and certain other substances to foods; the composition and labelling of food supplements; the composition and labelling of food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ("Foods for Specific Groups"). Prior to exit day domestic legislation created and implemented enforcement regimes for EU legislation.

2.3 The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/651) and The Nutrition (Amendment etc.) (Northern Ireland) (EU Exit) Regulations 2019 (S.I. 2019/650), which come into force immediately following the end of the Implementation Period ("IP"), were made to remedy deficiencies retained EU and existing domestic nutrition legislation arising from the withdrawal of the UK from the EU. In summary they make the following changes:

- Amend or omit EU/EFSA/Member State references; and
- Retain relevant lists and registers; and
- Transfer scientific advisory functions from the European Food Safety Authority (EFSA) to appropriate Committees in the UK; and
- Transfer relevant Commission powers to the Secretary of State, Scottish Ministers, Welsh Ministers and in relation to the Northern Ireland, the Department of Health as applicable; and
- Make provision for the Secretary of State to make regulations on behalf of the Devolved Administrations ("DAs") to cover the whole or part of the UK with consent from the DAs.

What did any relevant EU law do before exit day?

2.4 Commission Decision of 17 December 2009 authorises a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granted the protection of proprietary data under Regulation (EC) No 1924/2006 of the European Parliament and of the Council.

2.5 Commission Delegated Regulation 2016/127, supplementing Regulation (EU) No 609/2013, updates the specific compositional, labelling and marketing rules for infant and follow on formula, taking into account: scientific developments and new legislation on food information to consumers; prohibiting nutrition and health claims on infant formula; and requiring businesses to notify infant formula and some follow-on formula products to the competent authority.

2.6 Commission Regulation (EU) 2019/343 provides derogations from Article 1(3) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on food for the use of certain generic descriptors.

2.7 Commission Regulation (EU) 2019/651, refuses to authorise a health claim made on foods and referring to children's development and health.

Why is it being changed?

2.8 In order to reflect the NIP in law this instrument amends S.I. 2019/651 and revokes S.I. 2019/650, so that: regulatory and advisory functions are transferred from the EU Commission and European Food Safety Authority (EFSA) to appropriate authorities and committees in England, Scotland and Wales but not in Northern Ireland.

2.9 These amendments and revocations are necessary to ensure that the UK's obligations under the NIP are met and that EU nutrition legislation remains directly applicable in Northern Ireland (NI), as required by Annex 2 of NIP, for as long as the protocol remains in force. The rest of the UK will be free to set its own regulatory regime following the end of the IP.

2.10 This instrument also amends in relevant retained EU nutrition legislation a number of references, e.g. to the EU and its institutions, that will no longer be appropriate following the end of the IP.

What will it now do?

2.11 The amendments will mean that references to the EU, which would have become references to the UK under S.I. 2019/651, will now become references to Great Britain. Functions that would have been transferred to the Department of Health in Northern Ireland will not be transferred. S.I. 2019/650, which would have applied in Northern Ireland to amend EU references in Northern Ireland domestic legislation, will be revoked. These amendments will have the effect of ensuring that EU law continues to apply in Northern Ireland and the EU retained law in England, Scotland and Wales is effective. A detailed breakdown of the various types of changes which this instrument will bring is included in Section 7

The amendments and revocations made by this instrument to retained EU nutrition legislation will ensure that there is minimal disruption to nutrition regulation following the end of the IP. A detailed breakdown is included in Section 7. In summary it will amend or omit references to the EU/ EFSA/ Member States.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is being laid for sifting by the Joint Committee on Statutory Instruments.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument varies between provisions.

3.3 The territorial application of regulations 1 and 2 is all of the UK; regulations 3, 5 and 6 and Part 3 apply to England and Wales and Scotland; regulation 4 applies to England only and Part 4 applies to Northern Ireland only.

4. Extent and Territorial Application

4.1 The territorial extent and application of Parts 1 and Regulation 2 apply of this instrument is all of the UK.

4.2 The territorial extent and application of Regulations 3, 5 and 6 and Part 3 is England, Wales, and Scotland only.

4.3 The territorial extent of Regulation 4 of this instrument is England and Wales, the application of Regulation 4 is England only.

4.4 The territorial extent and application of Part 4 is limited to Northern Ireland.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Prevention, Public Health and Primary Care) Jo Churchill MP has made the following statement regarding Human Rights:

5.2 "In my view the provisions of The Nutrition (Amendment etc) EU Exit Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 As set out in Section 2 above existing nutrition legislation is a mixture of directly applicable EU legislation – EU Regulations and EU tertiary legislation (delegated acts made under those Regulations) and domestic legislation which creates and implements enforcement regimes. S.I. 2019/651 was made to remedy deficiencies in retained EU and existing domestic nutrition legislation arising from the withdrawal of the UK from the EU. Part 2 of this instrument amends S.I. 2019/651, for example removing references to UK, so that EU nutrition legislation remains directly applicable in Northern Ireland ensuring the NIP is reflected in law.

6.2 Part 3 of this instrument amends retained EU law relating to nutrition which was not addressed by S.I. 2019/651 or which has come into force since March 2019 to fix deficiencies caused by EU Exit.

6.3 Part 4 of this instrument revokes S.I. 2019/650. S.I. 2019/650 was made to ensure the operability of the Northern Ireland nutrition regulations once the UK has left the EU by: removing references to EU law/obligations, and instead referring to retained EU law/obligations; removing definitions of "EEA Agreement", "EEA State" and "free circulation in member States"; and fixing references to EU directives where necessary.

7. Policy background

What is being done and why?

Background: Protocol on Ireland/Northern Ireland

7.1 The NIP was designed as a practical solution to avoiding a hard border on the island of Ireland, whilst ensuring that the UK, including Northern Ireland, could leave the EU as a whole. It necessarily included, therefore, a number of special provisions which apply only in Northern Ireland, for as long as the NIP is in force.

7.2 Whilst the NIP is in force, both the UK and EU must respect and abide by the legal obligations it contains. This means that EU nutrition legislation, as detailed in Annex 2 of the NIP, will continue to be directly applicable in NI whilst the rest of the UK will be able to set its own regulatory regime following the end of the IP.

Background: Retained EU Nutrition Legislation

7.3 It is appropriate that this instrument makes necessary amendments to EU nutrition legislation which was not addressed by S.I. 2019/651 or which has come into force since March 2019 to ensure the UK's body of law relating to nutrition remains functional.

7.4 Nutrition law is a devolved competency; however, this policy area has been designated by the UK Government for consideration for a common approach. The justifications for a common approach are twofold: firstly, as these laws originally relate to the cohesion of EU's single market it is appropriate that similar consideration is given to the UK's internal market; and secondly, to ensure a smooth and orderly EU Exit that minimises disruption for businesses and consumers.

What is being done and why: Northern Ireland Protocol

7.5 As referred to in Section 6 of this memorandum, this instrument is being made in order to reflect the NIP in law, by ensuring that EU nutrition legislation continues to directly apply in Northern Ireland following the end of the IP.

7.6 Part 2 of the instrument amends the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 as follows:

- disapplies Part 2 and Schedules 1 and 2 in relation to Northern Ireland. This will mean that whilst the Secretary of State, Scottish Ministers, and Welsh Ministers will have the powers of legislation in respect of vitamins and minerals and purity criteria, in Northern Ireland, the Department of Health will not, as existing EU law will continue to apply in Northern Ireland; and
- disapplies Part 4 from application to Northern Ireland, and consequentially, removes references to Northern Ireland and changes UK-specific references to Great Britain. This will mean that EU law relating to nutrition and health claims made on foods; the addition of vitamins and minerals and of certain other substances to foods; and Foods for Specific Groups will continue to apply in Northern Ireland and any amendments made by the 2019 regulations will apply in Great Britain only. Functions previously exercised by the EU Commission will be exercised by the 'appropriate authority' within Great Britain; and

- amends regulations 16(2) and 72(2) to (5), which would have disapplied provisions of Commission Delegated Regulation 2016/128 setting out specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants. Regulations 16(2) and 72(2) to (5) had been necessary in March 2019 to prevent Commission Delegated Regulation 2016/128 apply infants immediately after a potential no deal scenario as these requirements did not come into force until February 2020.
- Omits, in all regulations as necessary, references to "United Kingdom" and replaces with "Great Britain" and omits references to "Northern Ireland".

7.7 Part 4 of the Instrument revokes The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019

What is being done and why: Retained EU Nutrition Legislation

7.8 Part 3 of this instrument amends retained EU nutrition legislation to take account of EU references which will be redundant or inaccurate following the end of the IP. For example, retained law includes references to 'Member States' and EU institutions. These have been amended as they will not be relevant when the UK is no longer an EU Member State.

7.9 Commission Decision of 17 December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation, and granting the protection of proprietary data, was not addressed by S.I. 2019/651. The EU process is that claims with proprietary information protection, such as the water-soluble tomato concentrate, revert to the 'normal' approved Community list at the end of a 5-year protection period. Whilst other claims have moved across, this one has not yet moved across to the Community list. This instrument therefore corrects the anomaly, as the claim is validly authorised, and it is expected that the European Commission will formally transfer it to the Community List at the earliest opportunity.

7.10 The proposed fixes would mean that processes for food businesses and consumer protection remain substantially similar to the existing arrangements following the end of the IP.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in sections 8 and 23 and paragraph 21 of Schedule 7 of the European Union (Withdrawal) Act 2018 to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 A public consultation was conducted between 9th and 30th July 2020. The consultation invited comments from the food manufacturing and nutrition industry,

representative groups, the public and other interested parties in relation to the practical amendments that this instrument makes to retained EU legislation.

10.2 As the provisions within this instrument maintain an effective regulatory regime, by making amendments that are predominantly technical in nature, a relatively short consultation period was deemed appropriate and ministerial approval given

10.3 The majority of the responses were positive with respondents agreeing with proposals across the 3 queried areas: the approach to reflecting the NIP law (64.7% agreed); technical fixes to retained EU nutrition that has come into force since March 2019 (82.3% agreed), and the assessment of impacts (76.4% agreed).

10.4 Requests for detail on the processes underpinning the regulatory framework will be addressed through industry guidance and officials will engage stakeholders in the development of this.

10.5 Scotland, Wales, and Northern Ireland have been engaged throughout development of the consultation and in relation to the amendments included in this instrument.

11. Guidance

11.1 The Department of Health and Social Care is currently developing guidance documents that will explain to industry how proposals will affect them. These documents will be made available in print and online in October 2020

12. Impact

12.1 The impact on business, charities, or voluntary bodies is estimated to be minimal as no significant changes are being proposed, meaning the law, associated processes, and procedures will be highly aligned with those currently in force. We estimate that businesses will only have to spend a short amount of time familiarising themselves with the new procedures. This legislation affects manufacturers and retailers of: pre-packaged foods and food supplements; infant and follow-on formulae; processed cereal based foods and baby foods; food for special medical purposes; total diet replacement for weight control; and food products which assert nutritional or health claims in commercial communications, whether in labelling, presentation, or advertising.

Although the approach aims to minimise impact on businesses, there may be ongoing costs for businesses currently operating in the UK as they may to need deal with additional Great Britain-only regulation. Nutrition and health claims authorised by Great Britain will not be valid on the Northern Ireland or EU market, and vice versa. This would increase administrative burden on companies as they would have to submit claims to both Great Britain and the EU if they wished to make the claim in both areas. We estimate that the application paperwork should take around thirty minutes to complete.

12.2 There is no, or no significant, impact on the public sector

12.3 An Impact Assessment has not been prepared for this instrument because of the estimated low level of impact that proposals will have on businesses. As stated in section 12.2 of this explanatory memorandum, the regulatory regime with which businesses will have to comply will remain predominantly the same as it is the government's intention to minimise disruption to business.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses involved in the production of food as they already have to comply with the EU legislation.

14. Monitoring & review

14.1 As this instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

14.2 One piece of legislation being amended has a review clause, The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016. This review provision will continue to apply following the United Kingdom's withdrawal from the EU, with the amended application as provided for by Schedule 8, paragraph 9 of the European Union (Withdrawal) Act 2018.

15. Contact

15.1 Tracey Eckersley at the Department of Health and Social Care Telephone: 01132545521 or email: tracey.eckersley@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jenny Oldroyd, Deputy Director for Obesity, Food and Nutrition Branch at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Edward Argar, Minister for State for Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2.	Explain what, if any, amendment, repeals or revocations are being made to the Equality Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA 2018 SIs.	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence.	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under s. 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under s. 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister of State for Health Edward Argar MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

1.2 This is the case because they do no more than reflect the NIP in law and amend retained EU nutrition legislation to correct deficiencies arising from the UK's withdrawal from the EU or where it would otherwise fail to operate effectively after the UK leaves the EU. This includes removing redundant provisions, amending references to obligations or reciprocal arrangements that will no longer exist, and transferring Commission functions to the appropriate authorities in the UK. Further details, including examples of all the changes included in the instruments, are detailed in Section 7 of the main body of this explanatory memorandum.

2. Good reasons

2.1 The Minister of State for Health Edward Argar MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 Following Implementation Period Completion Day, without amendments to the relevant legislation, the UK would not meet its obligations under the Withdrawal Agreement, specifically the Protocol on Ireland/Northern Ireland, and policy on nutrition related labelling, composition, and standards would cease to function effectively. This instrument seeks to remove or amend provisions in domestic legislation and EU legislation saved by the European Union (Withdrawal) Act 2018, in order to reflect the Protocol on Ireland/Northern Ireland; ensuring that EU nutrition law continues to apply in Northern Ireland and that nutrition policy in Great Britain will continue to function at the same level as prior to EU Exit. The instrument makes a number of technical amendments so that functions which would have been transferred to the Department of Health in Northern Ireland will not be transferred, and that S.I. 2019/650, which would have applied in Northern Ireland to amend EU references in Northern Ireland domestic legislation, is revoked. Further details, including examples of the amendments made and reasons for making them, are set out in Section 7 of the main body of this explanatory memorandum.

3. Equalities

3.1 The Minister of State Health, Edward Argar MP has made the following statement:

"The Nutrition (Amendment etc) (EU Exit) Regulations 2020 instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."

3.2 The Minister of State for Health Edward Argar MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.3 This instrument will have no, or very limited, impact on equalities.

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.