EXPLANATORY MEMORANDUM TO

THE NUTRITION (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 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 Act.

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 remedy deficiencies in UK legislation relating to nutrition, arising from the withdrawal of the UK from the European Union (EU) in the event that the UK leaves without a deal having been agreed. The subject areas covered by this nutrition legislation are: nutrition and health claims made on foods; the addition of vitamins, minerals and certain other substances to foods; composition and labelling of food supplements; the composition and labelling of food for specific groups; and the sale of products containing Kava-kava.

This Statutory Instrument amends existing domestic, and retained EU, legislation as well as revoking some pieces of related EU tertiary legislation which will no longer have any application to the UK after withdrawal. 'EU tertiary legislation' refers to delegated acts and implementing acts made under powers contained in EU legislation (such as Regulations or Directives). The instrument is made under powers in the European Union (Withdrawal) Act 2018.

Explanations

What did any relevant EU law do before exit day?

2.2 There are four main pieces of EU nutrition legislation that are dealt with by this instrument: Regulation (EC) No 1924/2006 on nutrition and health claims made on foods; Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods; 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 ("Foods for Specific Groups"); and Directive 2002/46/EC on food supplements.

2.3 Regulation (EC) No 1924/2006 sets out the legal framework for businesses that want to highlight the nutritional or health beneficial properties of their products, to ensure that claims made in commercial communications are accurate and consumers are not misled. Nutrition and health claims are required to be based on scientific evidence and may only be used on packaging if they have been approved following scientific assessment.

2.4 There are a number of pieces of EU tertiary legislation made under Regulation (EC) No 1924/2006 that set out decisions, the authorisation and rejections of health claims, made under Regulation (EC) No 1924/2006.

2.5 Regulation (EC) No 1925/2006 stipulates which vitamins, minerals, and certain other substances may be added to foods, sets out how new substances may be assessed and approved, and outlines compositional and labelling requirements for foods that have substances added to them.

2.6 There is EU tertiary legislation made under Regulation (EC) No 1925/2006 that sets out implementing rules for considering substances that should be prohibited or restricted in foods under Article 8 and for the Commission to evaluate implementation of the Regulation under Article 16 (Commission Implementing Regulation (EU) No 307/2012) and Commission Implementing Regulation (EU) No 489/2012).

2.7 Regulation (EU) No 609/2013 sets out general compositional and information requirements for Foods for Specific Groups, provides for the making of EU tertiary legislation to set out specific requirements, and establishes a Union List of substances that may be added to these foods.

2.8 It is important to note that the EU legislation relating to Food for Specific Groups is currently in a transitional phase, and that until 20 July 2016 these foods were regulated as 'Foods for Particular Nutritional Uses' or PARNUTS, under Directive 2009/39/EC. To allow food businesses time to adapt to the new regime set out in Regulation (EU) No 609/2013 there is a transitional period for introduction of the delegated legislation to be made under Regulation (EU) No 609/2013.

2.9 Commission Delegated Regulation (EU) No 2016/128 is the only piece of delegated legislation made under Regulation (EU) No 609/2013 that will be in force on exit day. The Delegated Regulation applies from 22 February 2019 to food for special medical purposes ('FSMP'), other than FSMP for infants.

2.10 All products other than FSMP (except that for infants) will at exit day continue to be regulated under the existing regime: Directive 2009/39/EC, Commission Regulation 953/2009 and associated Directives.

2.11 Finally, Directive 2002/46/EC sets out rules for vitamins and minerals used in food supplements. The Directive contains a list of permitted vitamins and minerals, and a list of the permitted forms of those vitamins and minerals.

What did any relevant UK law do before exit day?

2.12 Existing domestic legislation implements and creates enforcement regimes for the EU legislation. There are nine pieces of domestic nutrition legislation, relevant to this instrument, which relate to nutrition and health claims, composition and labelling, further details of which can be found in Section 7.13.

2.13 There is also legislation relating to the sale of foods containing Kava-kava, which does not stem from EU law but will require technical fixes to retain its operability after exit day.

Why is it being changed?

2.14 As a responsible government, we will continue to proportionately prepare for all scenarios, including the unlikely outcome that we leave the EU without any deal in March 2019. The purpose of this Statutory Instrument is to ensure that, in the unlikely scenario that the UK leaves the EU with no deal, there will continue to be a functioning statute book on exit day which maintains continuity in relation to nutrition policy and legislation.

2.15 The legislation being amended contains a number of references that will no longer be appropriate once the UK withdraws from the EU. The European Commission also has a number of powers (to approve or reject nutrition and health claims) which it will no longer exercise on the UK's behalf following exit. The instrument transfers necessary regulatory and advisory functions, further details of which can be found in Section 7, from the European Commission and European Food Safety Authority (EFSA) to appropriate authorities and committees in the UK.

2.16 The lists of vitamins and minerals that may be used in the manufacture of food supplements are contained as an Annex to Directive 2002/46/EC. The lists are being moved into this instrument to ensure that they continue to have affect in the UK.

2.17 Amendments to Regulation (EC) No 1924/2006, and related tertiary legislation, preserve existing decisions regarding nutrition and health claims; whilst also ensuring that processes for food businesses and consumer protections remain substantially similar to existing arrangements.

What will it now do?

2.18 The amendments and revocations made by this instrument will ensure that there is minimal disruption to nutrition regulation as a result of the UK's withdrawal from the European Union. The detailed breakdown of the various types of changes which this instrument will bring is included in Section 7. In summary it will make the following changes:

- Amend or omit EU/EFSA/Member State references; and
- Retain relevant lists and registers; and
- Transfer the scientific advisory function from EFSA to appropriate Committees in the UK; and
- Transfer relevant Commission powers under Regulation (EC) No 1924/2006, Regulation (EC) No 1925/2006 and Regulation (EU) No 609/2013 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.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Joint Committee on Statutory Instruments (JCSI) 9th report for 2016-2017 identified errors in the drafting of The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (SI 2016/688) ('the 2016 Regulations'). The 2016 Regulations were amended by the Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017/62 to correct the errors. However, the JCSI's 25th report for 2016-2017 reported S.I. 2017/62 for amending the amendments made in the Schedule to the 2016 Regulations, but not directly amending the individual statutory instruments, listed below, amended by the 2016 Regulations.

3.2 The 2016 Regulations amended the following statutory instruments:

- Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations (1997)
- The Medical Food (England) Regulations 2000
- The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003
- The Infant Formula and Follow-on Formula (England) Regulations 2007
- The Food for Particular Nutritional Uses (Addition of Substances of Specific Nutritional Purposes) (England) Regulations 2009

3.3 This instrument amends the 2016 Regulations, and three of the individual statutory instruments amended by those Regulations, but the vires do not exist under European Union (Withdrawal) Act 2018 powers to correct these outstanding errors.

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)

3.4 The territorial application of Parts 3, 4 and 5 is the same as the territorial application of each enactment being amended in these Parts: England only for Part 3 and all of the UK for Parts 4 and 5.

3.5 The territorial application of Parts 1 and 2 of this instrument is all of the UK.

4. Extent and Territorial Application

4.1 The territorial extent of Part 3 of this instrument is England and Wales, the application of Part 3 is England only.

4.2 The territorial extent and application of Parts 1, 2, 4 and 5 is the whole of the United Kingdom.

5. European Convention on Human Rights

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

"In my view the provisions of The Nutrition (Amendment etc) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made to ensure that legislation relating to nutrition that relates to areas of DHSC policy will continue to function effectively in the event that the UK leaves the EU without a deal in place. Responsibility for nutrition policy is shared between DHSC, the Food Standards Agency and DEFRA. Nutrition policy is (apart from some exceptions in relation to advertising) an area of devolved competence.

6.2 As set out in section 2.2 above, existing nutrition legislation is a mixture of domestic legislation to implement Directives (this legislation applies in relation to England only) and EU directly applicable legislation – EU Regulations and EU tertiary legislation (delegated acts made under those Regulations). Parts 2 and 3 of this Instrument deal with the domestic legislation and Directives so that this legislation continues to function effectively after exit day. Section 3 of the European Union (Withdrawal) Act 2018 incorporates EU directly applicable legislation into domestic

law. Parts 4 and 5 of this instrument amend and revoke those items of direct EU law in relation to nutrition which are saved by the European Union (Withdrawal) Act 2018 so that they operate appropriately, or are revoked if not appropriate to have as domestic law after exit day.

7. Policy background

7.1 This statutory instrument ensures that the UK possesses a functioning body of law relating to nutrition and health claims, composition and labelling of foods and of certain categories of food. The Department recognises that under a 'no deal' scenario businesses and citizens would need time to adjust, therefore to minimise disruption the focus is on maintaining continuity in the short-term. This instrument ensures that both business and consumers are provided with certainty and continuity in the event of a 'no deal' scenario.

7.2 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: first, 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 exit that minimises disruption for businesses and consumers.

7.3 The Department of Health and Social Care has legislative responsibility for: the composition of fortified foods, those to which vitamins, minerals, and certain other substances have been added; Foods for Specific Groups; and food supplements. The Department is also responsible for: the nutritional labelling of foods, the mandatory 'back of pack' nutrition declaration; and claims that can be made about the nutritional and health qualities of a product.

7.4 The Department for Environment, Food, and Rural affairs has responsibility for: food composition, the ingredients that are permitted and prohibited for use in foods; authenticity, ensuring foods are what they claim to be on their packaging; and labelling that does not relate to nutrition or food safety.

7.5 The Food Standards Agency is responsible for labelling that is related to food safety.

7.6 EFSA publishes between Dietetic 10 – 30 scientific opinions a year on nutrition and health claims submitted for assessment, as required by Regulation (EC) No 1924/2006. We thus expect the amendments to the process for making nutrition and health claims applications to affect a relatively small number of businesses. The law relating to the use of nutrition and health claims will affect any food business that uses such claims to promote its products. However, this statutory instrument does not change the way these claims may be used.

7.7 All food producers who add vitamins, minerals, and certain other substances to their products will be affected by this legislation.

Public Interest

7.8 Public interest in nutrition is moderately high, however, many members of the public are interested by consumer protection regulations. Those who responded to the consultation were predominantly concerned with the maintenance of high levels of consumer protection currently offered by the EU legislation.

What is being done and why?

7.9 As referred to in Section 6 of this memorandum, this instrument is being made in order to correct deficiencies in the UK and EU legislation, to ensure that nutrition legislation continues to function effectively following the UK's withdrawal from the EU. This instrument amends existing domestic legislation in England only, with devolved administrations (DAs) making equivalent fixes independently

7.10 Directive 2002/46/EC on food supplements is implemented in England by the Food Supplements (England) Regulations 2003. The Annexes to the Directive, listing vitamins and minerals, and vitamin and mineral substances, which may be used in food supplements, are currently` applied UK wide by similar legislation made by each DA. When the UK withdraws from the EU, Directives will not be incorporated as part of UK legislation. In order to enable the Annexes to have effect UK wide, Part 2 of the Instrument replicates the Annexes as Schedules to the Instrument.

7.11 It also makes provision for each of the DAs and the Secretary of State to make regulations to amend the lists in the Schedules, set purity criteria for the listed substances, and maximum or minimum amounts of vitamins or minerals in food supplements. The regulation making powers are exercisable in relation to England by the Secretary of State, for regulations in relation to Scotland by the Scottish ministers, for regulations in relation to Wales by the Welsh Ministers, and for regulations in relation to Northern Ireland the Department of health in Northern Ireland.

7.12 In addition, provision is made so that the Secretary of State may make regulations on behalf of the DAs for the whole, or part, of the United Kingdom if consent is given by the Welsh and Scottish Ministers and the Department of Health in Northern Ireland as appropriate.

7.13 Amendments are being made in Part 3 of the instrument to the following pieces of domestic legislation applying in England:

- Medical Food (England) Regulations 2000
- Kava-kava in Food (England) Regulations 2002
- Food Supplements (England) Regulations 2003
- Addition of Vitamins, Minerals, and Other Substances (England) Regulations 2007
- Nutrition and Health Claims (England) Regulations 2007
- Infant Formula and Follow-on Formula (England) Regulations 2007
- Food for Particular Nutritional Uses (Addition of Specific Nutritional Purposes) (England) Regulations 2009
- Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016.

7.14 The amendments to the Medical Food (England) Regulations 2000 ensure that the requirements of Commission Directive 1999/21/EC continue to apply as requirements in domestic legislation. The amendments to the Food Supplements (England) Regulations 2003 ensure that the lists in the schedule apply rather than the Annexes to Directive 2002/46/EC. The amendments to the other instruments (other than the Kava-Kava in Food (England) Regulations 2002) are to remove or amend references. The amendments to the Foods for Specific Groups (Information and Compositional

Requirements) (England) Regulations 2016 take account of the Food for Specific Groups (Information and Compositional Requirements (Amendment) (England) Regulations 2019 which implement, for England, Commission Delegated Regulation (EU) No 2016/128.

7.15 The amendments to the Kava-Kava in Food (England) Regulations 2002 relate to a prohibition on the sale of foods containing Kava-kava with an exception, as required by EU law, for foods that originate or are in free circulation in EEA States. The Kava-kava regulations are being amended to make this exception apply for any foods originating from a third Country that are in transit through England.

7.16 Amendments are being made in Part 4 of the instrument to the following pieces of EU legislation that will be incorporated into domestic law by the European Union (Withdrawal) Act 2018:

- Regulation (EC) No 1924/2006
- Regulation (EC) No 1925/2006
- Regulation (EU) No 609/2013

7.17 Part 5 amends EU tertiary legislation made under Regulation (EC) No 1924/2006 that set out decisions, the authorisation and rejections of health claims, made under Regulation (EC) No 1924/2006:

- 64 Commission Regulations will be amended; and
- 1 Commission Implementing Regulation will be amended; and
- 1 Commission Implementing Decision will be revoked; and
- 1 Commission Regulation will be revoked.

7.18 The following pieces of EU tertiary legislation that will be incorporated into domestic law by the European Union (Withdrawal) Act 2018, are being revoked in Part 5 of the instrument as they concern guidelines and rules which are inappropriate to retain in their current form, and will be established in future guidance:

- Commission Implementing Regulation (EU) No 489/2012
- Commission Regulation (EU) No 907/2013
- Commission Implementing Decision 2013/63/EU

7.19 Examples of the deficiencies addressed by these amendments and revocations are listed below.

EU references which are redundant or inappropriate

7.20 There are a number of amendments being made by these instruments to take account of EU references which will be redundant or inaccurate post exit. 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.

Transfer of Commission Powers & European Food Safety Authority Functions

European Food Safety Authority: Scientific Assessment and Advice

7.21 Scientific advisory functions conducted by European Food Safety Authority related to nutrition and health claims will be transferred to an appropriate UK expert committee.

7.22 Scientific advice provided by the European Food Safety Authority relative to Foods for Specific Groups and vitamins, minerals, and certain other substances will be sought from other appropriate UK Committees.

Transfer of Commission Powers

7.23 There are a range of powers currently held by the European Commission under the pieces of EU legislation outlined in Section 7, which allow the Commission to do things such as update regulation and relevant lists in line with scientific developments. This instrument transfers these powers as regulation making powers to the Secretary of State, Scottish Ministers, Welsh Ministers and in relation to the Northern Ireland, the Department of Health as applicable (the 'appropriate authorities'). As set out in section 2.2 the Secretary of State may also make regulations which apply in Scotland, Wales or Northern Ireland if consent is given by the Welsh and Scottish Ministers and the Department of Health in Northern Ireland as appropriate.

7.24 With regards to Regulation (EC) No 1924/2006

Regulatory functions will be transferred from the European Commission to the 'appropriate authority' enabling them to make regulations to:

i. Establish and maintain a UK wide register of permitted nutrition and health claims; and

ii. set out the detailed procedure for the authorisation of: new nutrition claims and amend the annex of permitted nutrition claims, taking into account the scientific opinion provided by a UK committee; and

iii. authorise new health claims, taking into account the scientific opinion of a UK committee; issue implementing rules in relation to health claim applications; issue guidance and tools to assist business with applications; issue a draft decision regarding the approval of a new health claim to be added to the UK wide register; and

iv. modify, suspend, or revoke authorised health and nutrition claims; and

v. modify, suspend, or revoke authorised health and nutrition claims without allowing for the 30 day comment period on imperative grounds of urgency; and

vi. establish nutrient profiles and conditions of use for nutrition and health claims; and

vii. adopt a list of specific claims other than those referring to the reduction of disease risk or to children's development and health, and modifying that list; and

viii. adopt and update a list of permitted reduction of disease risk claims and claims referring to children's development and health, and modifying that list; and

ix. apply regulatory provisions to non-pre-packaged food; and

x. enable derogations from rules regarding traditional generic descriptors, and establish rules for food business operators who apply for a traditional generic descriptor; and

xi. enable derogations from rules that state nutrition and health claims may not suggest or imply a balanced and varied diet cannot provide appropriate quantities of nutrients; and

xii. specifying foods or categories of foods for which nutrition or health claims may be restricted; and

xiii. establish guidelines regarding conditions of use for permitted health claims.

7.25 With regards to Regulation (EC) No 1925/2006

Regulatory functions will be transferred from the European Commission to the 'appropriate authority' enabling them to make regulations to:

i. Establish and maintain UK Register of Authorised Vitamins, Minerals, and Certain Other Substances and modify relevant annexes; and

ii. modify the Register, taking into account the opinion of an expert committee; and

iii. regarding which products and/or categories of foods to which vitamins and minerals may not be added; and

iv. prohibiting the addition of a vitamin or mineral to a specific food; and

v. stipulating the purity criteria of vitamins and minerals that are added to foods; and

vi. stipulating the maximum and minimum amounts of vitamins and minerals that may be added to foods; and

vii. on food labelling regarding the vitamin and mineral content of a food and balance diets; and

viii. on the labelling of products to which vitamins and minerals have been added.

7.26 With regards to Regulation (EU) No 609/2013

Regulatory functions will be transferred from the European Commission to the 'appropriate authority' enabling them to:

i. Make regulations on whether a given food falls within the scope of Regulation (EU) No 609/2013 and which specific category food it belongs; and

ii. Adopt and update specific regulations on:

- the compositional requirements of foods for specific groups;
- the use of pesticides in products intended for the production of foods for specific groups;
- the labelling, presentation, and advertising of food for specific groups;
- the notification requirements for placing these products on the market;
- promotional and commercial practices related to infant formula;
- information provided in relation to infant and young child feeding to ensure adequate information on appropriate feeding practices;
- food for special medical purposes satisfying the nutritional requirements of infants; and

iii. Adopt technical guidelines to facilitate compliance by food business operators; and

iv. Establish a list of substances that may be added to foods for specific groups; and

v. Modify the list of permitted substances.

8. European Union (Withdrawal) Act/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 Statutory 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 3rd and 14th December 2018. 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 While responses to the consultation were predominantly supportive, particularly regarding Government's intention to maintain current EU standards, some negative responses (22%) were received in relation to the short duration of the consultation.

10.3 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.

10.4 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 A full consultation report will be published in March 2019.

10.6 Scotland, Wales, and Northern Ireland have been engaged throughout development of the consultation and in relation to the amendments included in this instrument. The instrument has been adapted to incorporate changes and comments that Devolved Administrations have proposed. Scotland, Wales and Northern Ireland have all provided their consent to this instrument being made by the Secretary of State insofar as it makes provisions that could otherwise fall within devolved competence.

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 March 2019.

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.

12.2 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 UK-only regulation. Nutrition and health claims authorised by the UK will not be valid on the EU market, and vice versa. This would increase administrative burden on companies as they would have to submit claims to both the UK 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.

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

12.4 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 12.1 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 EU 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 European Union, 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, email: Tracey.Eckersley@dhsc.gov.uk can be contacted with any queries regarding the instrument.

15.2 Jenny Oldroyd / Harriet Becher Deputy Directors for Obesity and Nutrition at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP 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 Equalities 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 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 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
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 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	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 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	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) Act 2018

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State (Public Health and Primary Care) Steve Brine MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

1.2 "In my view The Nutrition (Amendment etc) (EU Exit) Regulations 2019 do no more than is appropriate".

1.3 This is the case because they do no more than amend or revoke legislation on nutrition and health claims made on, and the composition and labelling of, foods to correct deficiencies arising from the United Kingdom's withdrawal from the European Union 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 Parliamentary Under Secretary of State (Public Health and Primary Care) Steve Brine MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

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

2.3 Following Exit Day, without amendments to the relevant legislation, policy on nutrition and health claims made on, and the composition and labelling of, foods would cease to function effectively. This instrument seeks to remove or amend provisions in UK legislation and EU legislation saved by the European Union (Withdrawal) Act 2018, in order to ensure that policy on nutrition and health claims made on, and the composition and labelling of, foods will continue to function at the same level as prior to exit. The instrument makes a number of technical amendments, providing appropriate authorities with powers previously held by the EU Commission which will allow for the Secretary of State and DAs to update legislation on nutrition and health claims made on, and the composition and labelling of, foods in response to emerging threats, changing safety and quality standards, and technological advances. 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 Parliamentary Under Secretary of State (Public Health and Primary Care) Steve Brine MP has made the following statement "The Nutrition (Amendment etc) (EU Exit) Regulations 2019 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 Parliamentary Under Secretary of State (Public Health and Primary Care), Steve Brine MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

3.3 "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."

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

4. Explanations

4.1 The explanations statement has been made in paragraph 2.2 of the main body of this explanatory memorandum.