Department of Health & Social Care

# The Nutrition (Amendment etc.) (EU Exit) Regulations 2020

## A technical consultation

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# Introduction

This consultation concerns the consequences of our exit from the European Union (EU) and the application of the Withdrawal Agreement on nutrition labelling, composition and standards (NLCS) legislation. We welcome feedback on proposals for the Nutrition (Amendment etc.) (EU Exit) Regulations 2020, which would:

- amend The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 ('the 2019 Regulations') in order to reflect the Protocol on Ireland/Northern Ireland (NIP) in law; revoke 'The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019'; and

- account for changes in EU NLCS legislation since March 2019.

The proposals contained within this consultation are of a technical nature and aim to ensure that certain aspects of the law relating to nutrition continue to operate effectively after the end of the transition period (TP).

# Why we are consulting

To further prepare for the end of the TP, the Department of Health and Social Care is proposing to make the Nutrition (Amendment etc.) (EU Exit) Regulations 2020, to amend the 2019 Regulations to reflect the NIP in law and make minor technical amendments to fix inoperabilities which would otherwise occur.

This approach would ensure that the UK retains a functioning body of nutrition law that maintains the continuity of high standards for businesses and consumers.

Article 9 of Regulation (EC) No 178/2002 places a statutory requirement to consult on changes to food law stating:

> "There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it."

This consultation is being conducted on behalf of the whole of the UK with the agreement of the Devolved Administrations (DAs) and is open until 30/07/2020. We would welcome your views.

The wider policy implications of the NIP are not considered within this consultation. This consultation is focused on the legislative technical fixes of the SI.

# Background

## Legislation

The European Union (Withdrawal) Act 2018 ("the EUWA") converts certain EU legislation into UK law. Converted law is referred to in this consultation as 'retained EU law'. Further to this, the EUWA enables UKG and DA Ministers to make regulations to fix any resulting deficiencies in retained EU law, ensuring that the law relating to nutrition continues to operate effectively after the end of the TP.

In respect to NLCS, currently EU law requires the European Commission (EC) and European Food Safety Authority (EFSA), to regulate NLCS, in relation to:

- nutrition and health claims made on foods;
- the addition of vitamins, minerals, and certain other substances added to foods;
- the composition and labelling of food intended for infants and young children including follow on formula; processed cereal-based and baby foods; foods for special medical purposes; and total diet replacement for weight control (Foods for Specific Groups);
- the composition and labelling of food supplements.

While the UK is subject to EU law, NLCS legislation is located in:

- EU Regulations, which are directly effective without further action by Member States and which contain most of the substantive law;
- EU Directives as implemented by domestic secondary legislation;
- domestic legislation that creates enforcement regimes to give effect to the provisions of EU Regulations and to implement the Directives.

## European Union (Withdrawal Agreement) Act 2020 (EUWA)

In October 2019, in line with the process set out under Article 50 on the Treaty on European Union, the Government published the New Withdrawal Agreement and Political Declaration with a view to ensuring "an orderly withdrawal of the United Kingdom from the Union and Euratom". This Withdrawal Agreement is implemented into domestic law via the EUWA.

On 31 January 2020, the UK left the EU, and entered a TP that will last until 31 December 2020. From a legislative perspective this means that while the EU (Withdrawal) Act 2018 has repealed the European Communities Act (ECA) 1972, the European Union (Withdrawal Agreement) Act 2020 preserves certain effects of the ECA for the duration of the TP to enable continued alignment with EU law.

In practice, this means that under the terms of the Withdrawal Agreement, new pieces of directly applicable EU law that are introduced during the TP, will continue to apply automatically in the UK and will need to be implemented in domestic law.

The legal default at the end of the TP is that the Withdrawal Agreement as brought into force in the EU(WA) Act 2020, which includes in it the NIP, will apply. Retained EU law will therefore apply in GB, whilst EU NLCS legislation, as detailed in Annex 2 of the NIP, will continue to be directly applicable in Northern Ireland.

## Common Four Nation Approaches

Nutrition law is devolved. This means that, whilst EU Regulations are directly applicable in all parts of the UK, the enforcement regimes that give effect to EU Regulations are created by legislation drafted by each of the four UK nations. Similarly, the domestic provisions that implement EU Directives within this policy area are also found in legislation drafted by each of the four UK nations.

As food law is a devolved competence, the European Union (Withdrawal) Act 2018 contains provisions for the DAs to make regulations within their respective administrations by transferring to them powers previously held by the European Commission. However, at the end of the Transition Period, this transfer of powers will not apply in NI, due to the NIP and subsequent obligations.

Officials across the four nations are working closely together to prepare the UK for the end of the TP, by establishing common approaches on a number of policy areas within devolved competence, including NLCS policy, known as Common Frameworks. These frameworks will set out a common UK approach, and provide clarity on the appropriate role of Ministers and the governance of any shared structures in line with the devolution settlement.

## Protocol on Ireland/Northern Ireland (NIP)

The NIP was published in October 2019 as part of the Withdrawal Agreement to address the “unique circumstances on the island of Ireland."

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. That is why the democratic principle at the heart of the NIP is so important.

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 NLCS legislation, as detailed in Annex 2 of the NIP, will continue to be directly applicable in NI whilst the rest of the UK will set its own regulatory regime following the end of the TP.

The NIP is not codified as a permanent solution; it is designed to solve a particular set of problems and it can only do this in practice as long as it has the consent of the people of Northern Ireland. That is why it is for the elected institutions in Northern Ireland to decide what happens to the NIP alignment provisions in a consent vote that can take place every four years, with the first vote taking place in 2024.

With regards to trade going from Northern Ireland to the rest of the UK: this should take place as it does now. There should be no additional process or paperwork and there will be no restrictions on Northern Ireland goods arriving in the rest of the UK - that is, there will be unfettered access, as provided for by the NIP. The wider implications of the NIP are currently under consideration outside the remit of this consultation.

UK Government published a Command Paper on its approach to the Northern Ireland NIP on 20 May 2020 and further information can be found there.

# Proposal

EU NLCS legislation 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 Foods for Specific Groups.

In March 2019, and on behalf of DAs, DHSC made the 2019 Regulations to resolve deficiencies that would otherwise occur in domestic legislation following the withdrawal of the UK from the EU. In summary the amendments and revocations were to:

- Amend or omit EU/European Food Safety Authority (EFSA)/Member State references;
- Retain relevant lists and registers;
- Transfer the scientific advisory function from EFSA to appropriate expert Committees in the UK;
- 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 Northern Ireland, the Department of Health; and
- To provide power to the Secretary of State to make regulations to cover whole or part of the UK, if consent is given by Scottish Ministers, Welsh Ministers, and in Northern Ireland, the Department of Health, for regulations applying to these administrations.

The proposed Nutrition (Amendment etc.) (EU Exit) Regulations 2020 will address the following issues:

- To reflect the NIP in law, by amending the 2019 Regulations, revoke 'The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019'; and
- Accounting for changes in EU NLCS legislation, by amending:
    - 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 under Regulation (EC) No 1924/2006 of the European Parliament and of the Council.
    - Commission Delegated Regulation 2016/127, supplementing Regulation (EU) No 609/2013 with regards to the specific compositional and information requirements

for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

- Regulation 2019/343, providing 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.

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

The proposals outlined in this consultation, henceforth referred to as ‘fixes’ will come into effect at the end of the TP.

Plans outlined in this consultation aim to minimise disruption by ensuring that the regulatory framework for nutrition remains functional following the end of the TP to and provide assurance for business and consumers at the end of the TP.

Although food law is devolved, this policy area has been designated by the UK Government for consideration for a common approach, so this consultation is being carried out on behalf of the whole of the UK. With the consent of DA Ministers, this single set of regulations would, therefore:

- amend the 2019 Regulations in order to reflect the NIP in law; revoke 'The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019'; and

- account for changes in EU NLCS legislation since March 2019.

# Reflecting the NIP in law

The main issue in respect of which substantive changes will be required to reflect the NIP in law. For NI, EU NLCS legislation will continue to be directly applicable. This will require Parts 2, 4, and 5 of the 2019 Regulations to be disapplied in respect of NI.

Under the 2019 Regulations, functions currently exercised by the European Commission (EC) will be transferred from the EC to an “appropriate authority”, which means:

- UKG Ministers, or
- The Scottish Ministers, the Welsh Ministers, and in Northern Ireland, the Department of Health, or
- UKG Ministers and the Scottish Ministers, Welsh Ministers, and in Northern Ireland, the Department of Health, making a joint decision that applies uniformly across the whole of the UK.

The proposed technical fixes to Parts 2, 4 and 5 of the 2019 Regulations in effect remove NI from the scope of the previous amendments relating to retained legislation. This is because the impact of the NIP means that EU legislation will apply directly in NI.

## Part 2 - 2019 Regulations

Part 2 of the 2019 Regulations makes provision in relation to food supplements, transferring functions to legislate in respect of vitamins and minerals and purity criteria from the Commission to the Secretary of State, Scottish Ministers, Welsh Ministers and in Northern Ireland, the Department of Health.

### Proposed Amendments

The proposal is to disapply Part 2 and Schedules 1 and 2 of the 2019 Regulations in relation to NI. 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 NI.

## Part 4 - 2019 Regulations

Part 4 amends retained EU law in the field of NLCS. There are three pieces of primary EU NLCS legislation addressed in this part: 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 Foods for Specific Groups;

- 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.

- 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.

- 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.

The 2019 Regulations made the following amendments and revocations to ensure minimal disruption to nutrition regulation following the UK's withdrawal from the EU:

## Proposed Amendments

The proposal is to disapply Part 4 of the 2019 Regulations from application to NI, and consequentially, remove references to NI and change UK-specific references to GB so that 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; and Regulation (EU) No 609/2013 on Foods for Specific Groups are disapplied for applications to NI.

This will reflect the transfer of functions currently exercised in relation to the legislation noted in Part 4, from the EU to the 'appropriate authority' within GB.

This approach will be reviewed in future, taking into account any changes to the NIP.

The proposal is to also revoke Regulation (EC) No 2019/650. Revocation of this legislation is a direct consequence of the NIP and so the most suitable power to implement revocation is Section 8C(1)(c) of the 2018 EUWA.

# Part 5 - 2019 Regulations

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.

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).

## Required Amendments

Commission Delegated Regulation 2016/128

- Amend regulations 16(2) and 72(2) to (5) of the 2019 Regulations which would prevent it from applying to infant food.
    - Regulation 16(2) omits an ambulatory reference. Regulation 72(2) to (5) amends Com Delegated Regulation 2016/128 to disapply it to infants.

All Other Regulations (as necessary)

- Omit references to the “United Kingdom” and replace with “Great Britain”
- Omit references to “Northern Ireland”

# Accounting for changes in EU NLCS legislation since March 2019

The UK Government previously agreed that EU Exit legislation should provide regulation-making processes that are robust, transparent, evidence-based and proportionate, and ensure that regulatory burdens are kept to a minimum.

Therefore, as additional EU NLCS legislation has come into force since March 2019, it will need to be captured in the proposed SI.

## Proposals

With regards to NLCS legislation, fixes will be technical in nature, updating changes to take account of EU legislation which were not included in the 2019 Regulations or that came into effect since March 2019, and changing EU-specific references so that they reflect that the UK is no longer a Member State.

These technical fixes will be made to the following related pieces of EU legislation:

- 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 under Regulation (EC) No 1924/2006 of the European Parliament and of the Council

- Commission Delegated Regulation 2016/127, supplementing Regulation (EU) No 609/2013 with regards to the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

- Regulation 2019/343, providing 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

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

The proposed fixes would mean that processes for food businesses and consumer protection remain substantially similar to the existing arrangements on day 1.

# Impact

## Industry

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; food products which assert nutritional or health claims in commercial communications, whether in labelling, presentation, or advertising.

We assume that these businesses will have an acute interest in our approach to amending the regulatory frameworks that govern their practices and estimate that businesses will only have to spend a short amount of time familiarising themselves with the new procedures. Guidance documents will be updated and published on GOV.UK to reflect developments in the regulatory framework, and further detailed engagement will take place later this year.

The technical fixes proposed would not create new burdens for businesses. We will produce full guidance on the wider consequences of the NIP for business and third parties before the end of the transition period.

## Public sector equality duty impact assessment

An Equalities Impact Assessment for this policy has been completed. We consider that the legislation to domesticate EU food and nutrition legislation will not have any effect on equality in relation to any of the protected characteristics under the Public Sector Equality Duty (age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, or sexual orientation), or disproportionately impact on any particular group. The policy will also have no effect on family relationships and functions.

## Benefits

There are no incremental benefits associated with the proposed SI as it provides only for technical amendments.

# Questions

## Introduction Section

Q1: What is the name of your organisation?
Q2: Type: [select one] Trade body / Manufacturer/ Wholesale/ Retailer/ Local Authority / Other (if other, please specify)
What is your role in your organisation?
How many employees does your business/organisation have?
Q3: What geographical location does your organisation cover?
England/Scotland/Wales/NI, UK
Q4: Contact number
Q5: Contact e-mail
Q6: Which of the following aspects of nutritional legislation are of relevance to you/the institution you represent:
Vitamins, Minerals, and Certain Other Substances
Compositional and Information Requirements of Foods for Specific Groups
Food Supplements
Other

## Section 1: Northern Ireland Protocol (NIP)

Q7: In general, do you agree or disagree with the approach the proposed SI takes to reflect the NIP in law?

## Section 2: Accounting for changes in EU nutrition labelling composition and standards (NLCS) legislation since March 2019

Q8: In general, do you agree or disagree with the approach the proposed SI takes in making technical fixes?

Q9: Regarding the technical fixes, which areas are you most concerned about, or would you need more clarity on?
Wording and technical details of the process
Timing of the process
Access to information on the process
Ways in which you or your institution can be involved in the process
The actions or changes that would be specifically required of you or your institution
Other

Q10: For each area you selected above, please state your main concerns or needs.

## Section 3: Impact

Q11: Do you agree with the Impact Section as set out on page 14?

Q11a: Please provide any evidence to support your statement

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[Population Health Directorate/Obesity, Food and Nutrition Branch]

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