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  3. Public health (<https://www.gov.uk/health-and-social-care/public-health>)
  4. Nutrition labelling, composition and standards (NLCS) legislation from 1 January 2021 (<https://www.gov.uk/government/consultations/nutrition-labelling-composition-and-standards-nlcs-legislation-from-1-january-2021>)
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Consultation outcome

# The Nutrition (Amendment etc) (EU Exit) Regulations 2020: consultation response

Updated 24 September 2020

## Contents

Background

Proposals

Statistical overview

Summary of responses

Next steps

Conclusion



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## Background

In March 2019, and on behalf of the devolved administrations (DAs), the Department of Health and Social Care (DHSC) made the 2019 Regulations (<http://www.legislation.gov.uk/ukSI/2019/651/introduction/made>) to resolve deficiencies that would otherwise occur in directly applicable EU legislation and EU derived 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
- 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 (NI), the Department of Health, for regulations applying to these administrations

The consultation asked respondents to comment upon the proposals for the Nutrition (Amendment etc) (EU Exit) Regulations 2020. The proposals detailed how the 2020 SI would amend the 2019 Regulations in order to reflect the Northern Ireland Protocol (NIP) in law, revoke 'The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019', and account for changes in EU nutrition labelling, composition and standards (NLCS) legislation since March 2019, to ensure that the legislation that currently regulates the applicable areas of nutrition policy, would be operable and would continue to work effectively at the end of the IP.

This includes legislation that governs the following:

- 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

The consultation was split into two sections including one each for the reflection of NIP in law, and for the technical fixes accounting for changes in EU NLCS legislation since March 2019. For these sections, respondents were asked:

- In general, do you agree or disagree with the approach the proposed SI takes to reflect the NIP in law?
- In general, do you agree or disagree with the approach the proposed SI takes in making technical fixes?

Respondents were also asked about areas which they were most concerned about and where further clarity was needed.

The consultation similarly included a section on 'Impacts', where respondents were asked:

- Do you agree with the Impact Section as set out in the consultation document?

Respondents were given the opportunity to provide any evidence they wished to submit to support their statement.

## Proposals

Overall, the consultation asked respondents for feedback on the 4 nations' proposals to reflect the NIP in law; revoke 'The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019'; and make technical amendments to the 2019 Regulations.

For all policy areas covered, fixes contained within the statutory instrument (SI) are primarily technical in nature, including changing EU-specific references to reflect that the UK is no longer a member state and removing NI from the scope of previous amendments relating to retained legislation as EU legislation will apply directly in NI. These fixes aim to ensure minimal disruption to business and consumers while safeguarding the nation's health.

## Statistical overview

The consultation received 18 responses, of which 1 was null. The null answer is excluded from all following analysis and percentages.

Type of respondent	Number	%
Trade body	10	58.8
Private individual	2	11.7
Local authority	2	11.7
National authority	1	5.8
Civil society/Not for profit organisation	1	5.8
Business	1	5.8

## Summary of responses

### Statutory instrument (SI) overview

In general, respondents were supportive of our proposed approach to reflecting the NIP in law and were very supportive of the technical fixes, and of the impact section of the consultation document.

Regarding the technical fixes, 7 of 18 individuals provided feedback on areas where further clarification would be appreciated. 71% of respondents highlighted that the wording and technical details of the process and access to information on the process required more clarification.

## Wording and technical details of the process

In general, there was a call from respondents for more detail on the wording and technical details of the proposed SI.

Further clarification was sought on the interplay between the continuation of EU law in NI and its Statutory Rules. Respondents also requested clarity on the proposal to revoke Regulation (EC) No 2019/650 as regards Yohimbe; as it was not clear whether this revocation would only apply to NI or the UK.

Some respondents requested clarity as to how infant foods for special medical purposes (FSMPs) would be governed after the end of the TP.

One respondent noted that the technical language of the consultation could be simplified, to encourage wider participation. This feedback is noted and will be considered when drafting future consultations.

## Access to information on the process

There was a call from respondents for improved access to information on the SI and its implications; trade bodies welcomed the quarterly Department of Business Energy and Industrial Strategy's (BEIS) Business Expert Group (BExG) updates that they currently receive, but requested more regular updates now that the end of the transition period is approaching.

One respondent also highlighted that they had requested notification of the consultation launch and had only received this through their professional body. We aim to satisfy all such requests, so we apologise that this request was not fulfilled on this occasion. However, we always invite representative bodies to share consultation notifications and links with their wider membership to ensure we reach as many organisations and individuals as possible.

## Potential impact of the NIP

While some respondents expressed concern regarding the possibility of legislative divergence between Great Britain (GB) and NI, and what this could mean for the UK market, due to the complexity of the NIP in relation to the implementation and enforcement of legislation across the UK devolved administrations, they were unable to estimate exactly how they would be impacted individually.

Some respondents requested continued unrestricted trade flow between NI and GB with no additional paperwork, and further clarity on how unfettered access can continue while GB sets its own regulatory regime at the end of the TP.

While the legislation mainly affects manufacturers and retailers, some respondents also raised concerns for consumer protection, noting that any increased costs to producers could result in higher product costs for NI consumers and a risk of reduced consumer choice.

One respondent raised a question regarding the 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, and asked whether it should become part of retained EU law as proposed, or if this raised the potential for divergence.

## Timing of the process

One respondent requested clarity on EU tertiary legislation that is published after 9 July 2020 (the date of the consultation launch) but before 1 January 2021, and whether this would be included in the Nutrition (Amendment etc) EU Exit Regulations 2020.

## Ways in which respondents can be involved in the process

Respondents requested that any new regulations and guidance documents be subject to consultation where possible and noted that they are willing to be involved in delivering information clearly and concisely to their respective networks and stakeholders.

## Actions or changes that would be specifically required of the respondent

Respondents highlighted a need for clarity on labelling and packaging after the transition period to allow businesses to make adequate and timely preparations.

One respondent also noted that, in line with Regulation (EU) 1169/2011, products marketed in NI will require an EU food business operator (FBO) address, in addition to a GB address as required by UK law. The respondent expressed concern that this could present an issue particularly for smaller UK based companies that may not have an EU branch in order to comply, and that including an EU FBO address would allow products to pass into the EU which could potentially have tariff implications such as both UK and EU taxation.

Government will provide further information to stakeholders on food and drink labelling changes required from 1 January, including an update to the information currently available on GOV.UK.

This S<sub>1</sub> does not address tariffs; however, we would advise that the respondent seeks guidance from the Department for International Trade (DIT).

## General comments

Confirmation was sought on how 'on-hold' claims will be dealt with at the end of the TP. They were interested in whether food business operators would be able to continue to use the list of claims and requested details of the procedure for 'on-hold' claims after the end of the TP.

Some respondents noted their use of EFSA registers and databases for supporting information on nutrition and health claims legislation and requested an equivalent system to keep them informed of changes and procedures.

One respondent requested more information on the addition of nutrients to food, with specific reference to the Bread and Flour Regulations (Northern Ireland) 1998, its interplay with Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, and also its amendment process – taking into account the role of EU law in NI.

The Bread and Flour Regulations (BER) are a matter for the Department for Environment, Food and Rural Affairs (Defra) who has committed to reviewing the BER, as they apply in England, after the TP. Food Standards Scotland (FSS) carries this responsibility for Scotland. The Defra review will take into consideration regulatory concerns raised by industry; and Defra, the Food Standards Agency (FSA), FSS and DHSC have jointly been in discussion with industry on this matter. It is possible for fortified flour produced in GB to comply with both the BER and EU law (Regulation (EC) No 1925/2006 and Regulation (EU) No 231/2012). If Food Business Operators comply with the relevant EU food law (as it currently stands) including food fortification rules, then they should be compliant with GB law.

## The consultation process

11 respondents provided feedback on the consultation process itself, of which 82% were satisfied.

In terms of how the consultation could be improved, respondents highlighted the following elements:

- providing more time for stakeholders to adequately provide a response
- providing more space for free text responses
- matching questions from the consultation document to the online questionnaire format
- including more respondents to the consultation

We acknowledge that this was a relatively short timeframe for consultation, however it was considered sufficient given the technical nature of the proposals set out in the consultation.

While industry stakeholders were specifically invited to respond to the consultation at the point of launch due its technical nature, the consultation was made available to the general public and all other interested parties via GOV.UK at the same time, in order to ensure full transparency and equal opportunity for everyone to respond.

We will ensure that all feedback is used to inform future public consultations.

## Next steps

### Our aim

It continues to be the government's priority to ensure the UK has a fully functioning statute book in relation to nutrition at the end of the IP.

The overarching aim for this statutory instrument is to retain the UK's current high standards for nutrition regulation, while minimising any disruption and burdens to business.

DHSC has carefully analysed the responses given by industry, trade bodies, local authorities and individuals who all contributed to our consultation. Overall, respondents supported our proposals to reflect the NIP in law and to undertake technical fixes to address deficiencies in retained EU legislation that would otherwise occur but requested more detail on how these would work in practice.

This response sets out the next steps government will be taking to ensure that this feedback is fully considered in creating an effective system for nutrition regulation in the UK.

## Wording and technical details of the process

DHSC can confirm that the consultation document contained a typographical error. This error suggested the revocation of Regulation (EC) 2019/650, rather than SJ 2019/650, the Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019. However, the revocation of SJ 2019/650 is reflected correctly in the draft SJ which was attached to the consultation, and while unfortunate, this error would have been apparent to respondents.

In relation to governing legislation for infant FSMPs, Article 72 of the 2019 Regulations outlines the amendment of Commission Delegated Regulation (EU) 2016/128 to remove the provisions that exclude foods for special medical purposes for infants. As a result, FSMPs for infants are now covered by the Commission Delegated Regulation (EU) 2016/128. The provisions did not apply until February 2020, after the 2019 Regulations had been made, so they have now been captured in the Nutrition (Amendment etc) (EU Exit) Regulations 2020.

## Timing of the process

The European Union (Withdrawal) Act 2018 (“the EUWA”) retains certain EU legislation as UK law. Any further EU [NLCS](#) legislation passed after the Nutrition (Amendment etc) EU Exit Regulations 2020 are laid, but before the end of the [TP](#), will also be retained by the EUWA.

In the case that deficiencies arise, further legislation will be brought forward to address them at the earliest opportunity.

## Northern Ireland Protocol (NIP)

While the [NIP](#) is in force, both the UK and EU must respect and abide by the legal obligations it contains. While we recognise the potential for future regulatory divergence between [GB](#) and [NI](#), it must be noted that this would be as a result of any legislative change for either [GB](#) or the EU after the end of the [TP](#), rather than as a result of reflecting the [NIP](#) in law.

In order to deal with the risk of divergence, officials across the 4 UK nations are working closely together to prepare 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 to food law and provide clarity on the appropriate role of ministers and the governance of any shared structures in line with the devolution settlement. We understand that businesses will have an interest in our approach to amending the regulatory frameworks that govern their practices; trade between [NI](#) and [GB](#) should take place as it does now.

The [NI](#) Command Paper (<https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol/the-uks-approach-to-the-northern-ireland-protocol>) sets out how we will reflect the [NIP](#) in law, in a way that protects the economy of [NI](#) and its place within the UK internal market ([UKIM](#)) with a 4-point plan to ensure:

- a) unfettered access for Northern Ireland’s businesses to the rest of the UK
- b) no tariffs on internal UK trade
- c) no new customs infrastructure in Northern Ireland
- d) Northern Ireland benefits from UK trade deals

Furthermore, the UK Internal Market Bill which is currently being debated in Parliament, will make provision for mutual recognition and unfettered access.

We will produce full guidance on the wider implications of the [NIP](#) for business and third parties before the end of the transition period.

## The legislation

The Nutrition (Amendment etc) (EU Exit) Regulations 2020 were shared in draft alongside the consultation. The statutory instrument is largely technical in nature, reflecting the [NIP](#) in law, revoking The Nutrition (Amendment) (Northern Ireland) (EU Exit) Regulations 2019, and amending retained EU legislation to ensure that certain aspects of the law relating to nutrition continue to operate effectively after the end of the transition period.

The [SI](#) draft will contain one further amendment as a result of the consultation response, regarding Commission Decision of 17 December 2009 which authorised a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granted the company protection of its proprietary data for 5 years under Regulation (EC) No 1924/2006 on nutrition and health claims on food. Following discussion with the European Commission, we have determined that claims with the



proprietary information protection provided under Article 13.5 of EC 1924/2006 should revert to the full approved list the end of the 5-year protection period (see Commission Regulation 432/2012 (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0432-20170822&from=EN>)).

The change made to the SI means that the health claim will be included in the full GB list of authorised health claims following the end of TP.

The draft regulations will be debated in Parliament by both the House of Commons and House of Lords and, subject to these debates, will come into force at the end of the TP. The dates of the debates are expected to be confirmed shortly.

## Guidance

We have noted respondents' calls for more detail on how our proposals will work in action.

DHSC acknowledges this call for detail and can advise that this request will be fully addressed by guidance. The guidance currently under development will confirm the process for labelling and packaging for food business operators and on-hold claims; and will clarify the timescales for when changes will come into effect, among other relevant detail.

DHSC recognises the request for more regular updates on guidance will be engaging with industry, stakeholders and representative bodies through the BEIS BExG, throughout its development before the end of the TP. It is our hope that this further informal consultation will alleviate concern and guarantee minimal disruption to industry.

DHSC and our devolved administration colleagues remain open to further communications from industry stakeholders.

Future changes will be communicated to interested parties via departmental update bulletins published on GOV.UK. This is a similar process to that used by the EC to communicate updates and is a method which is recognised and accepted by industry. It is our intention to have this operational and in place ahead of the end of the TP.

## Lists, registers and annexes

DHSC noted the call from respondents for further clarification on EU Lists, Registers and Annexes.

As outlined in the 2019 Regulations, all retained EU lists, registers and annexes will be updated and published on the GOV.UK website, alongside all relevant guidance. After the end of the TP, the appropriate UK authority will consider relevant scientific advice on an issue and where appropriate, specify modifications to these retained lists, registers or annexes.

Recognising the importance of the UK internal market, officials across the 4 UK nations continue to work 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. The NLCS framework sets out the agreement for a common UK approach, and will provide clarity on the appropriate role of ministers including those in NI and the governance of any shared structures in line with the devolution settlements.

## Conclusion

Based on the analysis of the responses to this consultation, we are content that the proposed approach to ensure that the UK retains a functioning body of nutrition law after the end of the TP was supported by those who responded.

Officials in UK government and across the devolved administrations are working together closely to prepare the necessary guidance, and a common framework, to ensure the systems currently in place for nutrition regulation will continue to operate smoothly at the end of the TP.

Additional information on how this will operate in practice will be made available through detailed guidance bulletins. It is our intention that this is communicated via GOV.UK ahead of the end of the TP, and DHSC is satisfied that this material will meet the concerns expressed in this consultation.