Department of Health & Social Care

The Nutrition (Amendment etc) (EU Exit) Regulations 2019

Consultation Response

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1. Introduction

1.1 Currently, the United Kingdom (UK) benefits from world-leading standards for both the safety and quality of its nutrition regulation. Following the UK's exit from the European Union (EU), the Government's priority is that these high standards are maintained across the UK, to ensure minimal disruption to industry, retain consumer confidence and safeguard our public health.

1.2 In the event of a no-deal scenario, it is necessary for the UK Government to introduce legislation to amend retained EU law, and where necessary bring provisions of Directives which will not become retained EU law into domestic legislation.

1.3 When passed, the Nutrition (Amendment etc) (EU Exit) Regulations 2019 will remedy deficiencies in retained EU legislation. This will ensure that nutrition law continues to function effectively in governing nutrition and health claims, the addition of vitamins, minerals and other substances to foods, and the composition and labelling of foods for specific groups and food supplements, following the UK's withdrawal from the EU. The deficiencies in retained EU law will be fixed on a UK-wide basis. The Regulations also amend domestic legislation in England so that it too is effective after exit. Scotland, Wales and Northern Ireland will make legislation to fix deficiencies in their respective domestic legislation.

1.4 On 3rd December 2018, the UK Government's Department of Health and Social Care launched a public consultation inviting comments from the food manufacturing and nutrition industry, representative groups, the public and other interested parties across the UK on our proposed approach to correcting deficiencies in legislation arising from EU exit. The consultation closed on 14th December 2018.

1.5 The consultation received a total of 31 responses. Respondents included trade bodies, manufacturers, members of the public as well as one Local Authority. This document provides a summary of the responses received and the Government's response.

2. Consultation Overview

2.1 The public consultation ran between 3rd and 14th of December 2018. Although this was a relatively short time-frame for consultation, it was considered sufficient given that the proposals set out in the consultation did not substantially change the existing regulatory framework for nutrition. As such, the consultation period was deemed to be appropriate and in line with Cabinet Office Consultation Principles.

2.2 The consultation paper was made available on the GOV.UK website. Responses were submitted via the digital platform 'Citizen Space' or by email.

Background

2.3 The consultation asked respondents to comment on the proposals for the Nutrition EU Exit (Amendment) Regulations 2019. The proposals detailed how the Regulations would utilise powers in the European Union Withdrawal Act 2018 to ensure that in the event of a no-deal scenario, retained EU legislation that currently regulates the applicable areas of nutrition policy would be operable as domestic legislation, and would continue to work effectively. 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 supplements
- the composition and labelling of food for specific groups which includes food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

2.4 The consultation was split into seven discrete sections including one for each policy listed in paragraph 2.3 above, and one section on domestic legislation (England only). For these sections, respondents were asked:

- Do you have any comments on the proposed fixes to retained EU law as set out in this consultation?
- Can you identify any fixes that appear not to have been addressed adequately?

2.5 The consultation also included a section on ‘Impacts’, where respondents were asked:

- Do you agree with the impacts that have been identified?
- Are you aware of any impacts that have not been identified?

2.6 Finally, respondents were given the opportunity to provide general comments on the policy areas covered by the proposals. Specifically, respondents were asked:

- While this consultation addresses what is being done to ensure retained EU law remains functional in the unlikely event of a ‘no deal’ scenario, do you have any general comments regarding nutrition and health claims, composition and labelling regulation that the government should make note of for when the UK leaves the EU?

Proposals

2.7 Overall, the consultation asked respondents for feedback on the UK Government’s proposals to make technical amendments to retained EU nutrition legislation. The proposals aimed to continue the existing regulatory regime closely, ensuring minimal disruption to business and consumers whilst safeguarding the nation’s health.

2.8 Importantly, proposals included retaining all relevant EU lists, registers and annexes upon exit day. In this case, following exit, the appropriate UK authority would be able to assess the scientific advice on an issue and if appropriate, specify modifications to any of these retained lists, registers or annexes.

2.9 For all policy areas covered, fixes contained within the SI are primarily technical in nature, including changing EU-specific references to ensure that they are effective in the UK after we exit the EU, and transferring references to EU-specific functions (such as the European Commission) to the appropriate UK authority.

2.10 The consultation also proposed one necessary change to current procedure: the establishment of the UK Nutrition and Health Claims Committee (UKNHCC). The UKNHCC will be an independent panel of scientists established as an expert committee of Public Health England. The UKNHCC’s role will replace that of the European Food Safety Authority (EFSA) Panel on Nutrition, Novel Foods and Food Allergens (NDA) to provide evidence-based scientific opinion to the four devolved UK administrations on any new nutrition and health claims made within the UK post-exit.

2.11 Further to this, the proposals also provided scope for the appropriate UK authority to seek scientific opinion from the most relevant UK committee on a nutrition related issue and if suitable, for the appropriate authority to specify modifications to any of the retained lists, registers or annexes.

3. Statistical Overview

Table 1: Breakdown of Respondents

Respondents	Number of Respondents
Trade Body	13
Manufacturer	10
Members of the Public	7
Local Authority	1

Total responses: 31. Not all respondents answered every question.

4. Summary of Responses

Nutrition and Health Claims

4.1 In general, respondents were strongly supportive of our proposed approach to adopt the current registers of EU-authorised and rejected claims, including support for retaining the current restrictions and conditions of use currently in place at EU-level.

4.2 Further clarification was sought on the practical management of the Registers, such as where the Registers would be made available and whether they would be modified on a UK wide basis.

The UK Nutrition and Health Claims Committee

4.3 There was a call from respondents for more detail on the risk assessment and management processes that would be in place to ensure the new UK Nutrition and Health Claims Committee would operate in the event of a no-deal scenario, including on appointing panel members, information on the timescales for the new scientific-opinion process and the process of submitting scientific dossiers.

Future Relationship with the European Union

4.4 Businesses queried how companies could apply for new nutrition and health claims in both the UK and EU post-exit, and whether there would be mutual recognition of claims and information-sharing.

4.5 Concern was raised on the future impact for business and trade if there was divergence in either the UK internal market or between the UK and EU. Several respondents commented that failure to remain aligned with the EU lists could have severe complications for product labelling, resulting in issues for integrated supply chains which could incur higher costs for businesses and consumers.

Vitamins, Minerals and Certain Other Substances

4.6 Generally, respondents expressed support for proposals to retain the Annexes that are currently contained in the EU legislation for vitamins, minerals and certain other substances.

4.7 However, more information was requested on how the Annexes will operate, including how modifications would be made and whether this would be UK-wide.

Operational management

4.8 Respondents wanted to know more about the process for managing the approval process for amending the Annexes of Regulation (EC) 1925/2006 on the addition of vitamins, minerals and certain other substances to foods. This included practical questions such as timescales, which committee would be used to provide scientific assessment and how changes to Annexes would be communicated.

Future Relationship with the European Union

4.9 Respondents also used this section to seek further clarification on the nature of the UK's future relationship with the EU. Concern was raised over the possibility of future divergence from EU decisions, how this would be managed, and the burdens divergence could place on industry.

Compositional and Informational Requirements of Foods for Specific Groups

4.10 Support was given to the overall approach and for the intention for the UK to adopt the existing EU annexes.

4.11 Concern was expressed about the absence of specific detail in the proposals and overall, respondents called for more information on the processes that would be in place post EU Exit, as well as what would be contained in the statutory instrument itself.

Scientific Opinion

4.12 Respondents queried which committee would provide scientific opinion for foods for specific groups. They were interested to know how members would be appointed, how scientific assessments would be conducted, and how these changes would be communicated to stakeholders.

4.13 Respondents also queried timescales for when any new processes would come into effect, including transition periods to comply with any changes.

New Delegated EU legislation

4.14 There was a strong call from respondents for the UK government to bring in to effect any future delegated legislation made under Regulation (EU) No 609/2013.

Future Relationship with the European Union

4.15 Further clarification was sought on the nature of the future relationship with the EU and whether the UK Government will seek to harmonise with future EU decisions.

Food Supplements

4.16 Support was given for the proposal to adopt the existing lists contained within the annexes of Directive 2002/46, which set out substances that can be used in food supplements.

Operational Effectiveness

4.17 Respondents wanted to know how the lists would be amended, and queried how changes to the process would be communicated to stakeholders, as well as the timescales for approval processes. They were concerned that we should ensure the robustness of the scientific advice provided to the four UK administrations.

Future Relationship with the European Union

4.18 More detail was requested on the future relationship with the EU and how divergence would be managed. Responses stated a preference for future harmonisation the EU.

Legislation

4.19 Clarification was sought on our approach to the legislation, and how amending regulations for food supplements would be addressed by the statutory instrument. For instance, respondents queried the intention to include schedules of permitted minerals and vitamins into The Nutrition EU (Amendment) (EU Exit) Regulations 2019 and not in to the relevant domestic legislation that implemented Directive 2002/46/EC.

Impacts

4.20 Some respondents agreed with the impacts as set out in the consultation paper.

4.21 However, there was strong concern raised on the potential for a greater negative impact on business should regulatory divergence exist between the UK and the EU in the future.

Financial burdens on industry

4.22 Further clarification was requested on costs to industry.

Divergence

4.23 Concern was expressed by industry on the robustness of the future of the various scientific committees that will take on the EFSA functions, with some respondents suggesting that failure to implement the right level of scientific expertise, risk of divergence with the EU could increase.

Application Process

4.24 Some respondents raised concern that the consultation under-estimated the additional burden caused for submitting a new claim. For instance, respondents drew attention to the complexity of the process of submitting new scientific dossiers and how in practice, this can be both time consuming and costly. Further clarification was sought on this process.

Public Health

4.25 Some respondents argued that public health should be considered as an impact, as ultimately, regulations are in place to protect the population's health.

Guidance

4.26 To ensure that guidance was fit for purpose, it was suggested that guidance be developed in conjunction with industry so avoidable impacts are mitigated and overall burdens to industry reduced.

General Comments

4.27 While overall, responses in this section focussed on the need for future harmonisation with the EU to avoid potential impacts that divergence could incur to business, consumers and public health, some trade bodies indicated a desire to utilise EU exit to strengthen both regulation and consumer protections.

4.28 Respondents reiterated the need for clarification on timescales for guidance being published as well as the timeframe for industry to implement the new system post exit.

5. Next Steps

Our Aim

5.1 It continues to be the Government's priority to secure a deal with the EU before the UK exits on 29 March 2019. However, in the event of a no-deal scenario, the Nutrition (Amendment etc) (EU Exit) Regulations 2019 will come into effect, ensuring the UK has a fully functioning set of nutrition legislation from exit day.

5.2 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.

5.3 DHSC has carefully analysed the responses given by industry, trade bodies, and members of the public who all contributed to our consultation. Overall, respondents strongly supported our proposals to mirror existing EU systems, but requested more detail on how these would work in practice.

5.4 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.

The Future Relationship with the EU

5.5 DHSC acknowledges the concern from respondents regarding the potential implications that any future divergence from the EU could have for business.

5.6 The Nutrition (Amendment) (EU Exit) Regulations 2019 were laid before Parliament on 30th January 2019. The purpose of this instrument is to remedy deficiencies in UK legislation relating to nutrition-related labelling, composition and standards (including nutrition and health claims) that could arise in the event that the UK leaves the EU without a deal having been agreed. The amendments and revocations made through this instrument will ensure that there is minimal disruption, ensuring continuity for both businesses and consumers, while safeguarding our public health.

5.7 The UK has a long tradition of close, scientific collaboration with European Food Safety Authority (EFSA), which we greatly value. It remains our preferred position to continue this relationship into the future, and officials are currently exploring ways in which this can be achieved. Ultimately, the exact nature of the future relationship is subject to negotiation with the EU. However, the proposals that

were consulted on in this exercise ensure that nutrition regulation will continue to function effectively in the UK without this relationship with EFSA in place.

5.8 The UK Government is content that The Nutrition (Amendment etc) (EU Exit) Regulations 2019 maintain regulatory standards in nutrition policy in a no-deal scenario. To mitigate the impact on business, the policy intention is to introduce domestic legislation that is in line with EU law under Regulation (EU) 609/2013, where businesses are already in a transitional period. Beyond March 29th, we will continue to review the situation to seek regulatory alignment with the EU, as deemed appropriate by the government.

Guidance

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

5.10 DHSC maintains that the concerns raised by respondents will be fully addressed by guidance. The guidance is currently being developed, and will confirm the process for making claims and for submitting scientific dossiers. In addition, it will clarify the timescales for when changes will come into effect, amongst other relevant detail.

5.11 DHSC acknowledges the request that any guidance should be developed in conjunction with industry. To ensure the guidance fully considers the concerns raised in this consultation, we will be engaging with industry, stakeholders and representative bodies through the Department of Business Energy and Industrial Strategy's Business Expert Group, during its development. It is our hope that this further informal consultation will alleviate concern and guarantee minimal disruption to industry.

5.12 DHSC also acknowledges the queries on how future changes will be communicated to interested parties. Future changes will be communicated via departmental update bulletins that will be placed on GOV.UK. This is similar to how the EU currently communicates 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 exit.

The UKNHCC

5.13 In the event that the UK can no longer access advice from EFSA, the statutory instrument provides for the establishment of an 'expert committee' to assume that role and thus ensure minimal disruption to industry.

5.14 DHSC acknowledges the concern from respondents regarding the robustness of the future scientific committee which will assume responsibility for the provision of scientific opinion on new nutrition and health claim applications made within the UK.

5.15 For nutrition and health claims, the UK Government is therefore in the process of establishing the UK Nutrition and Health Claims Committee (UKNHCC), which will be a committee of Public Health England (PHE). The function of UKNHCC will be to provide opinion on the scientific evidence supporting applications for use of new nutrition and health claims in the UK post exit. Decisions on whether to accept or reject nutrition and health claims will lie with the four UK administrations, taking into account the scientific opinion. It is envisaged that the UKNHCC would meet up to six times per year. Further detail will be set out in guidance.

5.16 PHE are in the process of recruiting the specialist members, including a Chair, required for the committee. The process of recruitment was open and transparent, and the role was advertised on GOV.UK from 8th November to 31st December.

5.17 To ensure the panel is of the highest standard, applicants are required to have a strong understanding of the public health aspects of their area of expertise as well as a track record of significant achievement and personal effectiveness in one or more of the specialist areas to be considered for interview.

5.18 A high calibre of applications has been received and short-listed candidates were interviewed in mid-February. Panel members will be appointed by the time the committee is required.

5.19 In the event that the UKNHCC is required, it is anticipated that the procedure for submitting applications for new claims for assessment by the UKNHCC will be substantially similar to the procedures for submitting claims to EFSA now. Guidance on this will be published in full at the time that the domestic function is initiated.

Other Appropriate UK Committees

5.20 Outside of nutrition and health claims, DHSC acknowledges the request from respondents for more detail on which UK committee/s will replace the remaining functions of EFSA in a no-deal scenario.

5.21 It is Government’s intention that these will be handled on a case-by-case basis. Depending on the application, officials will determine the appropriate UK scientific committee to conduct the necessary assessment which will enable the appropriate authority to reach a decision.

Lists, Registers and Annexes

5.22 DHSC noted the call from respondents for more clarification of EU Lists, Registers and Annexes, where they would be made available and whether they would be modified on a UK-wide basis.

5.23 Upon exit, the necessary registers will be made available on GOV.UK.

5.24 DHSC notes the concern from respondents on divergence within the UK market as well as between the UK and EU. All four UK administrations are working toward an agreed common framework and Concordat which intend to ensure future co-operation and significantly reduce the risk of internal divergence.

5.25 It is our full intention that lists and annexes will be modified consistently across the UK as far as possible, and the governance systems in place through the Concordat will address disagreements between countries, if they arise.

The Legislation

5.26 The Nutrition (Amendment etc) (EU Exit) Regulations 2019 were laid in draft on the 30th of January 2019 and are now available to view at: https://www.legislation.gov.uk/ukdsi/2019/9780111179864/contents. The statutory instrument is largely technical in nature, amending existing domestic, and retained EU legislation as well as revoking some pieces of related EU tertiary legislation which will no longer apply to the UK after withdrawal.

5.27 The regulations will be debated in Parliament by both the House of Commons and House of Lords, and subject to these will come into force on exit day. The House of Commons debate is currently scheduled to be held on 28 February, the date of the House of Lords debate is expected to be confirmed shortly.

5.28 DHSC also acknowledges the queries on our intention to insert the Annexes of Directive 2002/46 on food supplements as schedules in the Nutrition (Amendment) (EU Exit) Regulations 2019, and not into the existing domestic legislation on food supplements. The reason for this is to ensure that we start with a UK wide list, rather than separate lists for each part of the UK, which would create unnecessary complexity for industry.

Delegated Legislation on Foods for Specific Groups

5.29 DHSC acknowledges the concern from respondents as to whether new delegated EU legislation under Regulation (EU) 609/2013 would apply in the UK post-exit.

This is legislation that has already been made but will not apply in the EU on Exit day, and so will not become retained EU law.

5.30 The first part of Delegated Regulation 2016/128 for Food for Special Medical Purposes other than that developed to satisfy the nutritional needs of infants will already become retained EU law on Exit day as those provisions take effect from 22 February 2019.

5.31 It is DHSC's policy intention to make domestic legislation that is consistent with the other delegated legislation that has been made but will not apply on exit day. This includes requirements for foods for special medical purposes developed to satisfy the nutritional needs of infants, and for infant and follow on formulae. Further advice will be provided on this once the EU Exit position is clarified.

General Comments

5.32 DHSC acknowledges the response from some trade bodies that the new statutory instrument should be used to strengthen regulations and consumer protection.

5.33 Legislation made under the EU Withdrawal Act (2018) can only be made to fix deficiencies in UK legislation arising from our exit from the EU. As such, there is no scope to use this instrument to change policy direction at this time. However, DHSC has noted this response for future policy development.

Conclusion

5.34 Based on the analysis of the responses to this consultation, DHSC is content that the proposed approach to ensure that the UK retains a functioning body of nutrition law in a no-deal scenario was supported by those who responded.

5.35 Officials in DHSC and across the four Devolved Administrations are working together closely to prepare the necessary guidance, common framework and underpinning concordat agreements to ensure the systems currently in place for nutrition regulation will continue to operate smoothly in the event of a no deal scenario.

5.36 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 exit day, and DHSC is satisfied that this material will meet the concerns expressed in this consultation.

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EU Exit & Nutrition, Population Health Directorate, Department of Health and Social Care.

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