



The Nutrition (Amendment) (EU Exit) Regulations 2018

A public consultation

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Introduction

This consultation seeks feedback on proposals for regulations necessary to ensure certain aspects of the law relating to nutrition continue to operate effectively after the UK has left the EU in the unlikely event of a no deal scenario. The consultation covers legislation relating to: nutrition and health claims, the addition of vitamins, minerals, and certain other substances to food; food for particular nutritional uses; food supplements; and the regulation of Kava-Kava, with particular regard to the functions of the European Commission and European Food Safety Authority.

We have now agreed in principle the terms of the UK's smooth and orderly exit from the EU, as set out in the Withdrawal Agreement. We have also agreed the broad terms of our future relationship as set out in the outline Political Declaration. But nothing is agreed until everything is agreed - and as such it is the duty of a responsible government to continue to prepare for all scenarios, including the unlikely event of a no-deal.

Therefore, the proposals outlined in this consultation, henceforth referred to as 'fixes' would only come into effect in the unlikely event that the United Kingdom and the European Union are unable to conclude negotiations satisfactorily.

Plans outlined in this consultation would provide continuity and assurance for business and consumers as we seek to mirror existing European systems domestically as far as is practically possible. Further to this the Government does not envisage that this Statutory Instrument will create 'winners' or 'losers', with no practical adverse effects on individual citizens or adverse regional impact.

Although food law is devolved, this policy area has been designated by the UK Government for consideration for a common approach. This means that one set of regulations would make the necessary fixes to all retained EU law with the consent of Ministers from the devolved administrations. This consultation is therefore being carried out on behalf of the whole of the UK.

In addition, the consultation deals with the proposed fixes to English domestic legislation relating to nutrition that is derived from EU law. Devolved authorities will make equivalent fixes independently and issue consultations in their respective countries accordingly.

The consultation is open until 14th December 2018 and we would welcome your views.

Why we are consulting

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 Ministers to make regulations to fix any resulting deficiencies in retained EU law, ensuring that upon leaving the EU in the unlikely event of a ‘no deal’ scenario the policies and systems that underpin nutrition legislation in the UK continue to function effectively.

Currently EU law requires the European Commission (EC) and European Food Safety Authority (EFSA), to regulate:

- nutrition and health claims made on foods;
- the addition of vitamins, minerals, and certain other substances added to foods;
- foods for specific groups, including: infant and follow on formula; processed cereal-based and baby foods; foods for special medical purposes; and total diet replacement for weight control; and
- food supplements.

To prepare for the unlikely event of 'no deal', the Department of Health and Social Care is proposing to make the Nutrition EU Exit (Amendment) Regulations 2019, using powers provided by the EUWA, to fix inoperabilities in retained EU law. Matters relating to nutrition and health claims, composition, and labelling are devolved, however, this policy area has been designated by the UK government for consideration for a common approach. Proposals put forward in specific parts this consultation therefore extend and apply to the UK including Scotland, Wales, and Northern Ireland. We will continue to work with devolved administrations on areas where common frameworks will need to be maintained in the future. This consultation does not pre-empt those discussions.

The provisions in the regulations which amend retained EU law or otherwise transfer EU law into domestic law (such as creating UK lists of minerals and vitamins which may be used in food supplements) would be UK wide. These would include provisions to transfer regulatory and decision-making functions from EU bodies to appropriate UK authorities.

Other provisions will amend existing domestic legislation derived from EU laws, to ensure that it remains operable after EU Exit, with devolved authorities making equivalent fixes independently. Independent fixes would thus be made in relation to those matters (such as enforcement) which are currently regulated separately in each part of the UK. It should be noted however, that many of the proposed fixes are technical in nature, simply changing

EU-specific references so that they remain relevant when the UK is no longer a member State.

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

Nutrition and Health Claims

The Nutrition and Health Claims Regulation, (EC) 1924/2006, sets out the legal framework for businesses that want to highlight the beneficial properties of their products, to ensure that claims 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.

Currently EU law: defines nutrition and health claims; identifies the context in which the regulations related to nutrition and health claims apply; establishes lists of authorised claims and a register of authorised and rejected claims; describes conditions of use for claims; and sets out a process for the assessment and approval of new claims.

Nutrition and Health Claims are defined as follows:

- A 'nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: the energy (calorific value) it provides/provides at a reduced or increased rate/ or does not provide; and/or the nutrients or other substances it contains/contains in reduced or increased proportions/or does not contain.
- A 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

Regulations on nutrition and health claims only apply to those made in a commercial context.

The EC maintains the EU Register which lists all nutrition and health claims that may be made on foods; and sets out restrictions and conditions for their use. The Register also includes details of rejected health claims and the reasons for their rejection.

Currently new claims must be approved by the EC. Currently applications are submitted, with the requisite supporting evidence, to EFSA's Panel on Nutrition, Novel Foods and Food Allergens (NDA) who assess the claims and, provide a scientific opinion to the EC. The EC then rules on whether to approve or reject new claims following consultation with Member States through the Committee procedure.

Proposals

With regards to nutrition and health claims, it is proposed to make fixes to Regulation (EC) 1924/2006, and the following related additional pieces of EU legislation:

- Regulation (EC) 353/2008 established implementation rules for applications for the authorisation of health claims
- Commission Regulation (EU) 432/2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health Text with EEA relevance
- Commission Implementing Decision 2013/63/EU adopted guidelines for the implementation of specific conditions for health claims laid
- Commission Regulation (EU) 907/2013 set rules for applications concerning the use of generic descriptors

Proposed fixes would mean that processes for food businesses and consumer protection remain substantially similar to the existing arrangements. Fixes will be predominantly technical in nature, simply changing EU-specific references so that they remain relevant and valid when the UK is no longer a Member State, whilst EU functions outlined above will be transferred to an appropriate UK authority.

Scientific advisory functions conducted by EFSA will be transferred to the UK Nutrition and Health Claims Committee (UKNHCC), a new committee to be established under the remit of Public Health England. The UKNHCC will be responsible for the scientific substantiation and providing advice to the 4 UK administrations on any new nutrition and health claims made within the UK post exit.

The UK Nutrition and Health Claims Committee (UKNHCC) will be an expert committee of Public Health England (PHE), an executive agency sponsored by the Department of Health and Social Care. The committee will be administrated and resourced by civil servants from within PHE, but will remain politically and operationally independent.

It is proposed that upon exit, the UK will adopt the existing EU lists of claims, including restrictions and conditions of use. An appropriate UK authority may by regulations, and after consulting the new committee, make amendments to the list.

Vitamins, minerals, and certain other substances

Currently EU law: 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.

The European Commission is responsible for establishing, publishing, and maintaining the Community Register, which lists all the vitamins, minerals, and certain other substances that may be added to foods.

Regulation (EC) 1925/2006 establishes three lists contained within its Annexes. Annex I contains the list of vitamins and minerals which may be added to foods. Annex II sets out the permitted formulations of those vitamins and minerals. Annex III lists substances whose use in foods is prohibited, restricted or 'under scrutiny'.

The European Commission may, taking into account scientific opinion provided by EFSA, modify the lists contained in those Annexes.

Regulation (EC) 1925/2006 also sets out the products to which vitamins and minerals may not be added.

When vitamins, minerals, and other certain substances are added to foods they must comply with compositional and labelling requirements established by the EC:

- Minimum amounts – to ensure that fortification of foods is beneficial to health the regulation stipulates the final food to which vitamins or minerals have been added should contain a significant amount of a vitamin or mineral.
- Maximum amounts - to avoid the over consumption of vitamins or minerals, which might have an adverse effect on health, the Regulation permits maximum amounts to be set. However, no maximum amounts have been established.
- Purity – purity criteria define the chemical characteristics of each the vitamin and mineral substances and the Regulation permits purity criteria to be established for vitamins and minerals or provides that generally acceptable criteria shall apply.
- Labelling – Labelling regulations in relation to vitamins and minerals, including both the amounts added and those naturally present, have with some exemptions placed a legal requirement on products.

Proposals

With regards to vitamins, minerals, and certain other substances, it is proposed to make fixes to Regulation (EC) 1925/2006, and the following related additional pieces of EU legislation:

- Regulation (EC) 307/2012: establishes implementing rules for the application of power to prohibit, restrict, or place a substance under scrutiny
- Commission Implementing Regulation (EU) No 489/2012 establishing implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods Text with EEA relevance

Proposed fixes would mean that processes for food businesses and consumer protection remain substantially similar to the existing arrangements. Fixes will be predominantly technical in nature, simply changing EU-specific references so that they remain relevant when the UK is no longer a member State, whilst EU functions outlined above will be transferred to an appropriate UK authority.

Relevant scientific advice will be sought from a UK Committee designated for this purpose.

The lists of vitamins, minerals, and certain other substances contained in the Annexes will become retained law and will apply across the UK. An appropriate authority may by regulations, after taking into account the opinion of the UK Committee designated to provide the scientific advice on these issues, specify modifications to this list.

Compositional and information requirements of food for specific groups

The law relating to food for specific groups is currently in a transitional phase. Until 20 July 2016 these foods were regulated as 'Foods for Particular Nutritional Uses' or PARNUTs, under Directive 2009/39. The Directive set out the general framework for foods for particular nutritional uses and empowered the EC to make specific Directives setting out requirements on composition and labelling. It also empowered the Commission to make a list of substances with specific nutritional purposes. That list is contained in Commission Regulation 953/2009.

Regulation (EU) 609/2013 repealed Directive 2009/39 and the concept of PARNUTs. The Regulation deals with 4 specific categories of foods: infant and follow-on formulae; processed cereal based foods and baby foods; food for special medical purposes; and total diet replacement for weight control.

Under Regulation 609/2013 the EC was empowered to adopt delegated acts with respect to specific compositional and information requirements for these categories of foods. Commission Regulations have now been made for each category except for processed cereal based foods and baby foods. To allow food businesses time to adapt to the new regime from the old PARNUTs regime, however, a transitional period was introduced and the new specific rules do not yet apply. This meant that Regulation 953/2009 and the old composition and labelling rules continues to apply until the 'date of application' of the new rules. The date of application of the new rules is different for each category of foods. Anything that does not apply on Exit day will not become retained law.

This means that on Exit day foods for specific groups will be regulated by the framework contained in Regulation 609/2013 (but the detailed requirements will continue to be set out in Regulation 953/2009) and in the specific directives that were made under Directive 2009/39. The only exception is foods for special medical purposes other than that designed to meet the nutritional needs of infants, which will be entirely regulated under the new regime (Regulation 609/2013 and Delegated Regulation 2016/128).

The Directives will not become retained law but the requirements will continue to be enforced by the domestic legislation that was introduced to implement them. By cross-referring to the Directives as they stood on Exit day, this will continue to provide an effective regulatory regime.

We understand that food businesses may already be using the transitional period to work towards compliance with the regime under Regulation 609/2013. The UK government was

fully involved and committed to the introduction of the new regime within the EU and it is the intention to make domestic legislation that will mirror that in the EU as closely as possible.

Current EU law stipulates compositional and information requirements of foods for specific groups; outlines how relevant products are placed on the market; establishes guidelines for the labelling and advertising of specific products; and sets out how EU bodies regulate products.

Compositional and information requirements are set out for infant and follow on formulae; processed cereal-based foods and baby foods; foods for special medical purposes; and total diet replacement for weight control. Under the PARNUTs regime foods that were designed to replace meals (as opposed to the whole diet) were included in the regulatory regime. These foods are now regulated entirely by the general laws that apply to all foods, including on nutrition and health claims.

When a food for a specific nutritional use is first placed on the market, EU law requires that the relevant competent authority within that market is notified. Further to this, guidelines for the labelling, presentation, and advertising of these products are set out, with specific requirements for infant and follow on formulae.

Under Regulation 609/2013, the European Commission is conferred responsibility for; deciding if a given food falls within the scope of the regulation; establishing further regulations for food for specific groups; and modifying the lists of substances permitted for use in the manufacture of these products, taking into account the scientific opinion of EFSA.

Proposals

With regards to compositional and information requirements of Foods for Specific Groups, it is proposed to make fixes to Regulation (EC) 609/2013, and the following related additional pieces of EU legislation:

- Commission Regulation (EC) 953/2009: on substances that may be added for specific nutritional purposes in foods for particular nutritional uses
- Commission Delegated Regulation (EU) 2016/128: supplementing Regulation (EU) No 609/2013 with regards to the specific compositional and information requirements for food for special medical purposes

Proposed fixes would mean that processes for food businesses and consumer protection remain substantially similar to the existing arrangements. Fixes will be predominantly technical in nature, simply changing EU-specific references so that they remain relevant

when the UK is no longer a member State, whilst EU functions outlined above will be transferred to an appropriate UK authority in consultation with devolved administrations.

Relevant scientific advice will be sought from a UK Committee designated for this purpose.

Food supplements

Food supplements are currently regulated by Directive 2002/46, which sets out rules for vitamins and minerals used in food supplements. The Directive contains a list of permitted vitamins and minerals in Annex I. The permitted forms of those vitamins and minerals is listed in Annex II. The Directive contains a power for the EC to update the lists in the Annexes, to set purity criteria, and to set maximum and minimum amounts for vitamins and minerals that may be used in food supplements.

Directives will not become retained law when the UK exits the EU. The Directive is implemented by Regulations made in each part of the UK (The Food Supplements (England) Regulations 2003 in England; Food Supplements Regulations (Northern Ireland) 2003; The Food Supplements (Scotland) Regulations 2003; The Food Supplements (Wales) Regulations 2003).

Proposals

Proposals will be predominantly technical in nature, simply changing EU-specific references so that they remain relevant when the UK is no longer a member State, whilst EU functions outlined above will be transferred to an appropriate UK authority.

In order that the UK can amend the lists contained in the Annexes after exiting the EU, it is necessary to transpose the Annexes into domestic law. We propose to do this by copying the Annexes out as a schedule to the Nutrition (EU Exit) (Amendment) Regulations 2019, which will make them part of our domestic law. This is necessary in order to have an effective regulatory regime for food supplements after EU exit.

An appropriate UK authority may, by regulations, amend the lists.

Domestic legislation (England only)

The proposed SI would also be used to amend existing domestic legislation in England only, with devolved administrations making equivalent fixes independently. The main purpose of the domestic legislation is to establish an enforcement regime for obligations arising from EU legislation in this area. In amending these pieces of domestic legislation no new powers are granted to the Secretary of State for Health and Social Care, references to the European Union and its public bodies and institutions are simply omitted or amended to ensure that these regulations remain fully operational in the unlikely event of 'no deal'.

The following pieces of domestic legislation are amended by the proposed Nutrition (EU Exit) (Amendment) Regulations 2019

- Medical Food (England) regulations 2000
- Kava-Kava in Food (England) Regulations 2002
- Food Supplements (England) Regulations 2003
- Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003
- Infant Formula and Follow-on Formula (England) Regulations 2007
- Addition of Vitamins Minerals and other Substances (England) Regulations 2007
- Nutrition and Health Claims (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
- The Food for Specific Groups (Information and Compositional Requirements) (Amendment) (England) Regulations 2019

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. However, as no significant changes are being proposed we 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.

Although the approach aims to minimise impact on businesses, there may be ongoing costs for businesses currently operating in the UK as they will need deal with additional UK-only regulation if they currently sell in the EU/EEA.

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.

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 proposal as it does not impose additional or new burdens on business and enforcement bodies.

Questions

1. Do you have any comments on the proposed fixes to retained EU law as set out in this consultation?
2. Can you identify any fixes to retained EU law that appear not to have been addressed adequately?
3. Do you agree with the impacts that have been identified within this consultation?
4. Are you aware of any impacts that have not been identified in this consultation?
5. 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 European Union?