



Guidance Bulletin

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019: Practical Changes for Industry

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Introduction

Using this Guidance

This bulletin outlines changes to domestic and European Union nutrition legislation that will be made by the European Union (Withdrawal) Act 2018 and the Nutrition (Amendment etc) (EU Exit) Regulations 2019 in the event that the United Kingdom leaves the European Union without a deal having been agreed.

In the event of a no deal exit, the European Union (Withdrawal) Act 2018 will retain EU Regulations and tertiary legislation relating to nutrition from exit day, as UK law and that retained EU legislation will be subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019. This guidance sets out the practical effect of the changes to the legislation for Industry

For clarity, processes and procedures by which food business operators, and other interested parties, must comply have been set out in detail in this update.

It must be noted, that the Nutrition (Amendment etc) (EU Exit) Regulations 2019 make only minor practical changes to: applications; frameworks for the scientific evaluation of applications/dossiers/files; and the factors taken into consideration when a risk management decision is taken.

The only significant change to the regulatory framework made by the Nutrition (Amendment etc. (EU Exit) Regulations 2019 is the transfer of responsibilities from EU organisations involved in the risk assessment and risk management processes for nutrition legislation to UK bodies.

However, food business operators, and other interested parties, seeking to submit applications, scientific dossiers, relevant files, currently governed by nutrition legislation amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 should continue forward them for UK consideration to the Department of Health and Social Care (DHSC). DHSC will ensure that all documents are shared with the appropriate authorities in Scotland, Wales and Northern Ireland and the applicable expert committees once deemed complete and valid.

Appropriate UK Authorities

The European Commission currently carries out functions and has powers to make delegated legislation, such as deciding whether to authorise applications for new health claims. The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 transfers these powers

as regulation making powers which would enable any of the 'appropriate authorities' to make legislation equivalent to that the European Commission would have made.

The appropriate authorities are in relation to:

- England, the Secretary of State;
- Scotland, the Scottish Ministers;
- Wales, the Welsh Ministers;
- Northern Ireland; the Department of Health.

Devolved Administrations can therefore each legislate independently, however, the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 also provides for the UK Secretary of State to make legislation for the whole UK where Devolved Administrations agree.

Lists and Registers

Where legislation amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 requires a list or register to be established each appropriate authority must produce and maintain a list or register.

Food business operators may, as set out in this guidance, submit applications or dossiers in support of these lists being amended for UK consideration to DHSC mailboxes (which will centrally coordinate applications for all four UK countries).

For convenience and clarity UK lists and registers, which consolidate all lists produced and maintained by the appropriate authorities, will be made available on [GOV.UK](https://www.gov.uk) for food business operators and other interested parties.

Nutrition and Health Claims

Background: Nutrition and Health Claims within the European Union

Regulation (EC) No. 1924/2006 sets out the legal framework for businesses wanting to make nutrition and/or health claims on their products. This is to ensure that claims made about a product are accurate and consumers are not misled. Nutrition and health claims are required to be based on scientific evidence and may only be used in commercial communications if they have been authorised following scientific assessment of supporting data.

Currently, all authorised and rejected nutrition and health claims are listed in the [Community Register](#) of nutrition and health claims made on foods, which collates the separate lists of claims set out in EU law:

- Permitted nutrition claims that may be made on foods are listed in the Annex to Regulation (EC) No. 1924/2006, as amended by EU tertiary legislation.
- Authorised health claims that may be made on foods, other than those referring to the reduction of disease risk and to children's development and health are listed in the Annex to Commission Regulation (EU) No. 432/2012, as amended by EU tertiary legislation.
- Permitted reduction of disease risk claims and claims referring to children's development and health are set out in various Commission Regulations.
- Rejected health claims are set out in various Commission Regulations.

An application to use a claim that is not authorised and listed in the Commission Register may be submitted to the European Commission (EC) for consideration. The European Food Safety Authority's (EFSA) Panel on Nutrition, Novel Food, and Food Allergens (NDA) conducts the scientific assessment of applications for new claims. EFSA's scientific opinion is taken into consideration by the EC when deciding whether to authorise or reject an application.

Changes to Nutrition and Health Claims after Exit

In amending Regulation (EC) No. 1924/2006 the Nutrition (Amendment etc) (EU Exit) Regulations 2019 makes a number of practical changes to the regulatory framework. This

bulletin outlines those changes for industry so that they may be accounted for when reading existing guidance.

It is the view of the UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland, that current [UK guidance](#), with exception to any references to the EU therein, remains relevant and useful in complying with retained Regulation (EC) No. 1924/2006, as amended. For clarity we have set out how the UK's system will operate when accounting for practical changes made by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

UK Nutrition and Health Claims Register

All nutrition and health claims that are contained within the Community Register, as of exit day, will be adopted and included in the [United Kingdom Nutrition and Health Claims Register](#) (the UK Register).

Importantly, this means that if the European Commission has not taken a decision on an application related to a nutrition or health claim by exit day, an application must be submitted to the appropriate authorities in the UK for assessment if the applicant wishes for the claim to be authorised for use in the UK.

All authorised and rejected nutrition and health claims will be listed in the UK Register, other than those health claims authorised on the basis of proprietary data which will be recorded in a separate Annex to the UK Register. The UK Register, and the separate Annex, will be available at [GOV.UK](#).

Communication of Changes

Any future amendments to the UK Register will be communicated via regular bulletins published on [GOV.UK](#).

Nutrition claims

Only nutrition claims listed in the UK Register, may be used in the UK after exit day. The only exceptions to this are:

- trademarks or brand names that are also health claims (subject to the conditions of Article 1.3 and Article 28.2 of retained Regulation (EC) No. 1924/2006, as amended);

Products that make a nutrition claim must continue to:

- meet the specific conditions of use as set out in the Annex to retained Regulation (EC) No. 1924/2006, as amended; and
- present nutrition labelling as required by Article 7 of retained Regulation (EC) No. 1924/2006 as amended; and
- comply with general conditions set out in Article 5 of retained Regulation (EC) No. 1924/2006, as amended, and any general requirements outlined in [existing guidance](#) such as those that relate to alcoholic beverages.

New Nutrition Claims

The appropriate authorities may make regulations to, after consulting an expert committee, amend the list of permitted nutrition claims contained within the Annex to Regulation (EC) No. 1924/2006, as amended. Authorised nutrition claims will be added to the UK Register. If you wish to propose that a claim is added to the UK Register please contact the appropriate authorities via the [DHSC mailbox](#) (which will centrally coordinate applications for all four UK countries).

The appropriate UK authority will consult an expert committee, such as United Kingdom Nutrition and Health Claims Committee, when considering a new nutrition claim. If a claim is authorised by the appropriate UK authority and added to the Annex, any specific conditions associated with that claim will apply.

Health Claims

Only health claims listed in the [United Kingdom Nutrition and Health Claims Register](#) can be used in the UK. The only exceptions to this are:

- general, non-specific claims (subject to the conditions of Article 10.3 of retained Regulation (EC) No. 1924/2006, as amended); and
- trademarks or brand names that are also health claims (subject to the conditions of Article 1.3 and Article 28.2 of retained Regulation (EC) No. 1924/2006, as amended).

Products that make a health claim must continue to:

- meet the specific conditions of use as set out in the UK Register; and
- present nutrition labelling (subject to the conditions of Article 7 of retained Regulation (EC) No. 1924/2006, as amended);

- and comply with any general requirements as set out in [existing guidance](#) such as those that relate to alcoholic beverages.

Health Claims Authorised on the Basis of Proprietary Data

Health claims that have been authorised on the basis of proprietary data are listed in a separate Annex to the United Kingdom Nutrition and Health Claims Register. Products that make a health claim authorised on the basis of proprietary data must continue to:

- meet the specific conditions of use as set out in the Annex to the UK Register; and
- present nutrition labelling (subject to the conditions of Article 7 of Regulation (EC) No. 1924/2006, as amended);
- and comply with any general requirements as set out in [existing guidance](#) such as those that relate to alcoholic beverages.

New Claims

From exit day anyone wishing to make a new health claim on a product in the UK that is not included in the UK Register must submit an application for that claim to be assessed and authorised before it can be used.

Application forms, which contain supplementary information on completing an application for a claim are available online at [GOV.UK](#).

An application may be made for:

- claims based on newly developed scientific evidence, or those which include a request for the protection of proprietary data; and
- reduction of disease risk claims and claims referring to children's development and health.

All applications should be submitted to the competent UK authority via the [DHSC mailbox](#) (which will centrally coordinate applications for all four UK countries), and may be made either:

- for authorisation in the United Kingdom; or
- for authorisation in one of the following countries - England, Scotland, Wales or Northern Ireland only.

We recommend that applicants complete a [Medicines Borderline Advice Form](#) to be submitted to the Medicines and Health Products Regulatory Agency (MHRA) prior to submitting a health claim for assessment, to confirm whether or not the claim they wish to make about a nutrient or substance would be considered medicinal. Medicinal claims may not be made on food, and an application for a claim that was considered medicinal would therefore not be permitted.

We recommend that applicants check with the Food Standards Agency whether their food would be considered a novel food in the UK.

Applications for Claims Based on New or Emerging Science or Proprietary Data

Article 13(5) of retained Regulation (EC) No. 1924/2006, as amended, provides for the authorisation of health claims based on newly-developed scientific evidence and/or which include a request for the protection of proprietary data to the UK Register. The process to be used is set out in Article 18 of retained Regulation (EC) No. 1924/2006, as amended.

Regulation (EC) No. 1924/2006, did not define 'newly-developed scientific evidence'. Our understanding therefore remains that, in this context, a claim based on newly-developed scientific evidence may be a claim that:

- has never been made before; or
- is based on evidence that has become available since 31 January 2008

Therefore, the process contained in Article 18 of retained Regulation (EC) No. 1924/2006, as amended, may be used to submit health claims other than those referring to disease risk reduction or to children's development and health; for example, a new application for a claim which received a negative opinion from EFSA after submission under Article 13(2), and for which relevant information has come to light since 31 January 2008, could be submitted by this route. In either case any new, relevant information that the applicant wishes the expert committee to consider, should be highlighted within the application and clearly outlined in the reason for the request.

Health claims based on new or emerging science, or health claims based on proprietary data, are required to be authorised prior to use. Retained Regulation (EC) No. 1924/2006, as amended, specifies the procedure for such authorisations. To have a claim authorised an application with supporting information (which will be kept confidential) may be submitted to the competent authority via the [DHSC mailbox](#) (which will centrally coordinate applications for all four UK countries).

The competent UK authority will acknowledge receipt in writing within 14 days and, working with the applicant where necessary, will ensure the application is valid. The competent UK authority will then send the application to the United Kingdom Nutrition and

Health Claims Committee (UKNHCC) for scientific assessment and to the other relevant authorities for information who will ensure that proprietary data remains confidential.

The dossier submitted in support of a claim must contain the following information:

- the name and address of the applicant; and
- the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics; and
- a description of the claimed effect and whether or not it is based on the essentiality of the nutrient; and
- a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in retained Regulation (EC) No. 1924/2006, as amended; and
- where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification; and
- a copy of other scientific studies which are relevant to that health claim; and
- a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use; and
- a summary of the application.

From the date that the UKNHCC receives a valid application from a competent UK authority it has 5 months to provide its opinion to the relevant UK authorities. The UKNHCC has the option to request further information about the application if necessary. If the UKNHCC requests any further information, the overall time limit will be extended by 1 month, with the applicant required to submit the requested information within 15 days. The UKNHCC will forward its opinion to the relevant UK authorities and the applicant as well as making it public. The applicant and members of the public have 30 days to make comments to competent UK authority via the [DHSC mailbox](#) (which will centrally coordinate comments for all four UK countries).

The appropriate UK authorities have two months from receipt of that opinion to decide whether the claim should be authorised. The appropriate UK authorities will take into account the UKNHCC's opinion; relevant provisions in UK law; any enactments; and other factors relevant to the matter under consideration, and will consult one another in reaching a view. Authorised claims will be added to the UK Register together with any conditions of

use. Similarly, if the claim is rejected it will be added to the UK Register together with the reasons for the rejection.

Once authorised and added to the UK Register the claim will be available for use on any product that meets with the requirements of the Regulation, and any conditions of use specified. If however, any of the supporting scientific data or other information has been granted data protection, it cannot be used by any other applicant for five years. This is reliant on:

- the scientific data or other information being designated as proprietary by the applicant when the application is made; and
- the prior applicant having exclusive right of reference to the proprietary data at the time the prior application was made; and
- the health claim not being able to be authorised without the submission of the proprietary data by the applicant.

This aims to protect proprietary data, but will also, to a certain extent, protect particular claims as the Regulation requires manufacturers to be in a position to scientifically justify any claims they make. It does not stop the same claim being submitted with another scientific justification by another food business operator.

Applications for Reduction of Disease Risk Claims and Claims Referring to Children's Development and Health

Retained Regulation (EC) No. 1924/2006, as amended, requires disease risk reduction claims and claims which refer to children's development and health to be authorised prior to use, and specifies a procedure for such authorisations. Once authorised, a claim will be added to the UK Register and can be used on any product that meets the conditions of the Regulation and the conditions of use specified. To have a claim authorised an application with supporting information should be submitted to the competent UK authority via the [DHSC mailbox](#) (which will centrally coordinate applications for all four UK countries).

The competent UK authority is required to acknowledge receipt in writing within 14 days and, working with the applicant if necessary, to ensure the application is valid i.e. that it includes all the elements referred to in Article 15(3) of the Regulation. The competent authority will then forward the application to the UKNHCC for its assessment and make the application and any supplementary information available to other relevant UK authorities. The UKNHCC will make the summary of the application available to the public.

An application must contain the following information about the claim:

- the name and address of the applicant;

- the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
- whether it is a reduction of disease risk claim or a claim referring to children's development and health, if the former what the proposed risk factor for the disease to which the claim refers is;
- a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in retained Regulation (EC) No. 1924/2006, as amended;
- where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
- a copy of other scientific studies which are relevant to that health claim;
- a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;
- a summary of the application (which UKNHCC will make public).

From the date that the UKNHCC receives a valid application from a competent UK authority it has five months to provide its opinion to the relevant UK authorities. The UKNHCC, or the competent UK authority through the UKNHCC, may request further information about the application if necessary. If any further information is requested the overall time limit will be extended by up to two months. To facilitate a timely response and approval, it is important to submit a well prepared dossier that includes all relevant information.

If the UKNHCC gives a positive opinion on the claim, its opinion will contain:

- details of the applicant, the claim, and the nutrient or other substance referred to; and
- a proposal for the wording of the claim; and
- where necessary, any conditions or restrictions on use, including compulsory warnings.

The opinion, whether negative or positive, together with details about the reasoning for that opinion, will be sent to the appropriate UK authorities and will be made available to the public on GOV.UK until further notice. The applicant and members of the public will have 30 days to make comments to the competent UK authority via the [DHSC mailbox](#) (which will centrally coordinate comments for all four UK countries)

Claims authorised by the appropriate UK authorities will be added to the UK Register together with any conditions of use. Rejected claims will also be added to the UK Register together with the reasons for their rejection.

Modification, Suspension, and Revocation of Authorisations

In accordance with Article 19 of retained Regulation (EC) No. 1924/2006, as amended, an applicant and/or user of a claim, authorised for the purposes of Article 13 or Article 14, may apply for a modification of that health claim to be authorised: following the procedures set out in Articles 15 to 18.

The appropriate UK authorities may also, on their own initiative, request that a claim be reconsidered.

Following a request from an appropriate UK authority, the UKNHCC shall issue an opinion on whether a health claim authorised for the purposes of Article 13 or 14 still meets the conditions laid down in retained Regulation (EC) No. 1924/2006, as amended.

The UKNHCC shall make available its opinion to the appropriate UK authorities, the original applicant of the claim in question, and the public. The applicant, user, or member of the public may then make comments to the appropriate authority within 30 days of the publication of the opinion. The applicant and members of the public have 30 days to make comments to the appropriate authorities via the [DHSC mailbox](#) (which will centrally coordinate comments for all four UK countries).

The appropriate UK authorities, taking into consideration the opinion of the UKNHCC and any comments received, may by regulations modify or revoke the claim in question.

In cases of urgency, the appropriate UK authorities may exercise the power to make regulations to modify or revoke a claim without allowing for the 30 day comment period.

'On hold' Health Claims

As set out in a Department of Health Bulletin (2014) intended for interested parties entitled [Article 13\(1\) 'on hold' Health Claims Spreadsheet](#), on hold claims are those which may be used while they are still under consideration, subject to the transition measures in Article (28)(5) of the Nutrition & Health Claims Regulation (EC) 1924/2006. The full list of 'on hold' claims referenced by the 2014 Bulletin is available at [GOV.UK](#).

'On hold' claims are still under consideration in the EU, however, after exit day the UK will have its own system for authorising claims separate from the EU authorisation system.

In the event of no deal the UK Government and Devolved Administrations will launch a call to evidence, seeking information from stakeholders so that the full scale of the issue may be understood. Current thinking is that following the call for evidence, a policy decision would be made on the UK approach to 'on hold' claims and how these will be dealt with under the UK authorisation system.

As it is the intention of the UK Government and Devolved Administrations to minimise disruption to business in the event that the United Kingdom withdraws from the European Union without a deal, we will provide business reasonable time to plan accordingly. 'On hold' claims may continue to be used in accordance with the [Bulletin](#) until a decision is made following the call for evidence.

Generic Descriptors

Retained Regulation (EC) No. 1924/2006, as amended, continues to allow for appropriate UK authorities to make regulations granting derogations from Article 1.3 following the receipt of an application by food business operators.

The Nutrition (Amendment etc) (EU Exit) Regulations 2019 revoked Commission Regulation (EU) No. 907/2013 that set out the application procedure for generic descriptors, this was because the provisions did not work for UK only applications.

Regulations prescribing the procedure and requirements for applications made by food business operators for generic descriptors will be made in due course. Until such a time, we (the UK Government and Devolved Administrations) advise that applications to the UK should be completed in line with the requirements set out in [Part B of the Annex to Commission Regulation \(EU\) No. 907/2013](#). Applications should be submitted for UK consideration to the [DHSC mailbox](#) (which will centrally co-ordinate applications for all four UK countries).

Commission Regulation (EU) No. 2019/43 will apply by exit day, and therefore becomes part of UK legislation on exit day. We are considering whether this will need amendment.

Applications for generic descriptors other than those addressed by Commission Regulation (EU) No. 2019/43 currently being considered by the EU will not be authorised before exit day, we therefore recommend that any applications currently under consideration in the EU are submitted for UK consideration by the appropriate authorities to the [DHSC mailbox](#) (which will centrally coordinate applications for all four UK countries).

Risk Management

Risk management functions related to nutrition and health claims will be assumed by the appropriate UK authorities in respect of: making regulations; publishing guidelines; authorising applications; and maintaining the UK Nutrition and Health Claims Register.

Wording of Claims

Decisions regarding the final wording of a claim will be taken by the appropriate UK authorities when considering whether to authorise a claim. Comments submitted to the appropriate UK authorities by applicants following the publication of the UKNHCC's opinion, consumer understanding, and the opinion of the UKNHCC will all be taken into consideration when establishing the final wording of a claim.

Risk Assessment

Risk assessment functions related to nutrition and health claims will be assumed by the United Kingdom Nutrition and Health Claims Committee (UKNHCC), namely conducting the scientific assessment of applications for new claims and providing opinion to the appropriate UK authorities on nutrition and health claims post exit.

Panel & Secretariat

The UKNHCC is a new expert committee established under the remit of Public Health England, an executive agency sponsored by the Department of Health and Social Care. The UKNHCC is administered and resourced by civil servants from within PHE.

Appointments to the committee are made on merit and in accordance with the principles of the [Government Office for Science Code of Practice for Scientific Advisory Committees](#) and the [Governance Code on Public Appointments](#) issued by the Minister for the Cabinet Office. The Chair and members are appointed as individuals, on a personal basis, to fulfil the role of the committee, not as representatives of their particular profession, employer or interest group, and have a duty to act in the public interest.

Applications and Scientific Dossiers

Updated nutrition and health claim application forms (containing further information on completing an application), have been produced and are available on [GOV.UK](#). Only minor amendments to the application forms have been made, and there are no changes in respect of the scientific dossiers that applicants are required to submit in support of a nutrition or health claim.

Scientific dossiers may therefore be submitted to the appropriate UK authorities for consideration using the same format as those submitted to the EU until further notice.

Scientific Opinion

In conducting a scientific assessment, the UKNHCC will use agreed frameworks which set out criteria for consideration of different types of evidence, for example the Scientific Advisory Committee on Nutrition (SACN) [Framework for the Evaluation of Evidence](#) and EFSA's [Scientific and Technical Guidance](#).

Opinions will be produced with either a favourable or unfavourable conclusion.

In the event the UKNHCC provides a negative opinion, the opinion will set out reasons for that.

In the event the UKNHCC provides a positive opinion, the opinion shall include the following information:

- the names and address of the applicant; and
- the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics; and
- a summary of the evidence submitted in support of the claims and an assessment of its validity; and
- and a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use; and where applicable, conditions or restriction of use of the food and/or an additional statement or warning that should accompany the health claim on the and in advertising.

Domestic Enforcement Provisions

Legislation which provided for enforcement of Regulation (EC) No. 1924/2006 in each part of the United Kingdom's prior to its withdrawal from the European Union still applies.

Making a Claim in Europe

After exit day the United Kingdom will have its own system for authorising nutrition and health claims separate from the European Union authorisation system. After our exit from the EU, the UK will therefore no longer be a member state competent authority for receiving applications for claims to be authorised in the EU.

Guidance Bulletin

Food business operators wishing to make nutrition and health claims in the EU following the UK withdrawal must also continue to comply with the un-amended requirements of Regulation (EC) No. 1924/2006. We therefore recommend that food business operators wishing to make claims in the EU post exit refer to the extensive [guidance on](#) making nutrition and health claims in the European Union published by EFSA.

Vitamins, Minerals, and Certain Other Substances

Background: Vitamins, Minerals, and Certain Other Substances within the European Union

Regulation (EC) No. 1925/2006 stipulates which vitamins and minerals may be added to foods, sets out the safety assessment processes for certain other substances, and outlines how new substances may be considered for inclusion in the Annexes. It also outlines the compositional and labelling requirements for foods that have substances added to them.

Annex I lists vitamins and minerals that may be added to foods.

Annex II lists vitamin formulations and mineral substances which may be added to foods

Annex III lists:

- in Part A, substances that are prohibited from use in the manufacture of foods as it is deemed to have a harmful effect on health.
- in Part B, substances which may only be used in the manufacture of foods subject to the conditions of use specified as it is deemed to have a harmful effect on health.
- in Part C, substances which may be used in the manufacture of foods but where scientific uncertainty exists over the possibility that they represent a risk to health.

The European Commission is responsible for establishing and maintaining a Community Register on the addition of vitamins, minerals, and certain other substances to foods.

EU tertiary legislation, Commission Implementing Regulation (EU) No. 307/2012, sets out implementing rules for considering substances that should be prohibited or restricted in foods under Article 8 of Regulation (EC) No. 1925/2006.

Changes to Vitamins, Minerals, and Certain Other Substances after Exit

In amending retained Regulation (EC) No 1925/2006 the Nutrition (Amendment etc) (EU Exit) Regulations 2019 makes a number of practical changes to the regulatory framework. This bulletin outlines those changes for industry so that they may be accounted for when reading existing guidance.

It is the view of the UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland that current UK guidance, with exception to any references to the EU therein, remains relevant and useful in complying with retained Regulation (EC) No. 1925/2006, as amended. For clarity we have set out how the UK's system will work when accounting for practical changes made by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

UK Register of Vitamins, Minerals, and Certain Other Substances

In preparation for the UK's withdrawal from the EU we have collectively (the UK Government and Devolved Administrations) adopted the Community Register of Vitamins, Minerals, and Certain Other Substances as it exists on exit day, henceforth it shall be known as the United Kingdom Register of Vitamins, Minerals, and Certain Other Substances.

The United Kingdom Register of Vitamins, Minerals, and Certain Other Substances (the UK VMS Register) lists:

- the vitamins and minerals which may be added to foods as listed in Annex I of retained Regulation (EC) No. 1925/2006, as amended; and
- the vitamin formulations and mineral substances which may be added to foods as listed in Annex II of retained Regulation (EC) No. 1925/2006, as amended; and
- the maximum and minimum amounts of vitamins and minerals which may be added to foods and any associated conditions set in accordance with Article 6 of retained Regulation (EC) No. 1925/2006, as amended; and
- information regarding enactments applicable in any part of the United Kingdom on:
 - the mandatory addition of vitamins and minerals to specified foods or categories of foods; or
 - the prohibition or restriction on the use of certain other substances in the manufacture of specified foods; and
- any restrictions on the addition of vitamins and minerals as set out in Article 4 of retained Regulation (EC) No. 1925/2006, as amended; and

- information about the substances referred to in Annex III of retained Regulation (EC) No. 1925/2006, as amended (Part A: prohibited substances, Part B: restricted substances) and the reasons for their inclusions therein; and
- information about the substances listed in Annex III, Part C, of retained Regulation (EC) No. 1925/2006, as amended whose use is generally allowed as referred to in Article 8(5).

The UK VMS Register will have effect across the whole of the UK.

Communication of Changes

Any amendments to the UK VMS Register will be communicated via regular bulletins published on [GOV.UK](https://www.gov.uk).

Modifying the UK VMS Register

Modifying Annexes I & II

Article 3.3 of retained Regulation (EC) No. 1925/2006, as amended, allows for the appropriate UK authorities to make regulations to specify modifications to Annex I (vitamins and minerals which may be added to foods) and Annex II (the vitamin formulations and mineral substances which may be added to foods) after taking into consideration the opinion of an expert committee. Prior to making any modifications to the Annexes of retained Regulation (EC) No. 1925/2006, as amended, the appropriate UK authorities will consult with interested parties.

Food business operators, or other interested parties, that wish for vitamin and mineral substances to be considered for inclusion in the Annexes may submit a scientific dossier concerning the safety and bioavailability of the individual substance for UK consideration by the appropriate UK authorities to the [DHSC Mailbox](#) (which will centrally coordinate dossiers for all four UK countries).

To minimise disruption to business, we (The UK Government and the Devolved Administrations) recommend that, until further notice, scientific dossiers supporting the addition of a vitamin or mineral to the UK Register continue to be completed in line with [administrative guidance](#) produced by the European Commission.

Modifying Annex III Part C

Annex III Part C of retained Regulation (EC) No. 1925/2006, as amended, includes other substances where scientific uncertainty exists over the possibility that they represent a risk to health. This is a temporary listing to allow for further scientific data to be gathered.

Within four years of a substance being listed in Annex III Part C of retained Regulation (EC) No. 1925/2006, as amended, the appropriate UK authorities will, in consultation with one another and taking into consideration an expert committee on any files submitted for evaluation, decide whether to generally allow the substance in question or add it to the list in Annex III Part A or Part B.

During this period food business operators or any other interested parties that wish to demonstrate the safety of a substance listed in Annex III Part C of retained Regulation (EC) No. 1925/2006, as amended, may submit a file to an expert committee (via the process outlined in the following paragraph); in accordance with the procedures set out in retained Commission Implementing Regulation (EU) No. 307/2012, as amended. The file shall be based on relevant guidance documents that have been adopted or endorsed by an expert committee designated by the appropriate authorities for matters related to vitamins, minerals, and certain other substances.

We therefore recommend that, until further notice, files concerning a substance listed in Annex III Part C of retained Regulation (EC) No. 1925/2006, as amended, are submitted for UK consideration by the appropriate UK authorities to the [DHSC Mailbox](#) (which will centrally coordinate files for all four UK countries). Further to this we recommend that files continue to be completed in line with [administrative guidance](#) produced by the European Commission.

We recommend that submitted dossiers not considered by the EU before exit day, are submitted to the [DHSC mailbox](#) (which will centrally coordinate dossiers for all four UK countries) for UK consideration by the appropriate UK authorities if the applicant wishes for that modification to also be applicable in the UK.

The appropriate UK authorities will identify an appropriate expert committee that the dossier should be sent to for evaluation.

The expert committee will assess whether the file is valid for the purpose of conducting a safety assessment of the substance in question within 30 days from receipt of the file. If the file is not considered valid the committee shall inform the food business operator or interested party that has submitted the file and the appropriate UK authorities, indicating the reasons why the file is not considered valid.

The expert committee shall provide its opinion on any valid files within nine months from the date of receipt of a valid file but may, if necessary, request supplementary information

from the food business operator or interested party. A request for supplementary information must be satisfied within 15 days, and extends the time limit by which the expert committee shall provide its opinion by three months.

The resulting opinion given by the expert committee will be taken into account when the UK authorities decide whether the substance can continue to be allowed to be used in food, or restricted by adding it to Part B of Annex III, or prohibited by adding it to Part A of retained Regulation (EC) No. 1925/2006, as amended. There will be no restrictions on use during this scrutiny period.

Only files submitted for evaluation within 18 months of a substance being added to Part C of Annex III of retained Regulation (EC) No. 1925/2006, as amended, shall be taken into account by an expert committee as being a valid file for the purposes of a decision taken by the appropriate UK authorities.

Risk Management

Risk management functions related to vitamins, minerals, and certain other substances will be assumed by the appropriate authorities.

Risk Assessment

Scientific advice previously provided by the European Food Safety Authority in relation to vitamins, minerals, and certain other substances will be sought from existing expert committees in the UK.

An expert committee will be identified by the appropriate UK authorities as necessary depending on the nature of the scientific advice required.

Domestic Enforcement Provisions

Legislation which provided for enforcement of Regulation (EC) No. 1925/2006 in each part of the United Kingdom's prior to its withdrawal from the European Union still applies.

Foods for Specific Groups

Background: Foods for Specific Groups within the European Union

Regulation (EU) No. 609/2013 sets out general compositional and information requirements of food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (“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.

It is important to note that EU legislation 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 (EC) No. 953/2009.

Regulation (EU) No. 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 (EU) No. 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, however, only delegated regulations for foods for special medical purposes will be in force and apply on exit day.

To allow food businesses time to adapt to the new regime from the old PARNUTs regime, a transitional period was introduced and the new specific rules do not yet apply. This meant that Commission Regulation (EC) No. 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 part of UK legislation.

This means that on exit day Foods for Specific Groups will be regulated by the framework contained in Regulation (EU) No 609/2013 (but the detailed requirements will continue to be set out in Regulation (EC) No 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 (EU) No 609/2013 and Delegated Regulation 2016/128).

Further to this Regulation (EU) No. 609/2013 included an Annex which consolidated lists of substances that may be added to products included within the categorisation of Foods for Specific Groups, this Annex was known as the Union List.

Changes: Foods for Specific Groups After Exit

In amending retained Regulation (EU) No. 609/2013 the Nutrition (Amendment etc) (EU Exit) Regulations 2019 makes a number of practical changes to the regulatory framework. This bulletin outlines those changes for industry so that they may be accounted for when reading existing guidance.

It is the view of the UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland that current [UK guidance](#), with exception to any references to the EU therein, remains relevant and useful in complying with retained Regulation (EU) No 609/2013, as amended. For clarity we have set out how the UK's system will work when accounting for practical changes made by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

UK List

Retained Regulation(EU) No. 609/2013, is amended to rename the Annex to the UK List and provides for the list to be updated by regulations made by any of the appropriate authorities.

Substances belonging to the categories of substances listed below may be added to food for special medical purposes (excluding those developed to satisfy the nutritional needs of infants) provided they are contained within the UK List and comply with any stipulated conditions:

- vitamins; and
- minerals; and
- amino acids; and
- carnitine and taurine; and
- nucleotides; and
- choline and inositol.

The UK List contains the following elements:

- the category of food, outlined above, to which substances belonging to the categories of substances listed above may be added; and
- the name of the substance, and where appropriate the specification of its form; and
- where appropriate, the conditions of use of the substance; and
- where appropriate, the purity criteria applicable to the substance.

The UK list will apply to: infant formula and follow on formula; processed cereal-based food and baby foods; and foods for special medical purposes developed to satisfy the nutritional needs of infants once UK legislation is made to mirror the effects of delegated legislation related to these products made under Regulation (EU) No. 609/2013.

Modifying the UK List

In order to take into account technical progress, scientific developments, or the protection of consumer health the appropriate UK authorities may make regulations to modify UK List.

Food business operators, or other interested parties, that wish for vitamin and mineral substances to be considered for inclusion in the UK List may submit a scientific dossier concerning the safety and bioavailability of the individual substance for UK consideration by the appropriate authorities to the [DHSC Mailbox](#) (which will centrally coordinate dossiers for all four UK countries).

We (the UK Government and Devolved Administrations) therefore recommend that, until further notice, scientific dossiers supporting the addition of a substance to the UK List continue to be completed in line with [administrative guidance](#) produced by the European Commission.

The UK List will only apply to foods for special medical purposes (excluding those developed to satisfy the nutritional needs of infants) until UK legislation is made to mirror the effects of delegated legislation for: infant formula and follow on formula; processed cereal-based food and baby foods; and foods for special medical purposes developed to satisfy the nutritional needs of infants made under Regulation (EU) No. 609/2013.

Communication of Changes

Changes to the UK List will be communicated via regular bulletins published on [GOV.UK](#).

Notification of Foods for Special Medical Purposes (FSMP)

When a FSMP is placed on the market food business operators are required to notify the competent UK authority of each part of the United Kingdom where the product is being marketed. For ease, the notification forms along with a model of the label for the product, and any other information that may be reasonably requested to establish compliance with retained Regulation (EC) 2016/128, as amended, may be sent to a [DHSC mailbox](#) (which will centrally coordinate notification forms for all four UK countries) for the purposes of notifying each of the applicable competent UK authorities.

NOTE: This regulation does not apply to Foods for Special Medical Purposes intended for infants.

Risk Management

Risk management functions, such as making regulations to add substances to the UK List, related to Foods for Specific Groups will be assumed by the appropriate UK.

Risk Assessment

Scientific opinion will be sought by the appropriate UK authorities for matters related to Foods for Specific Groups as they deem appropriate.

Future Delegated Legislation

The UK Government (which represented the interests of all UK Countries) was fully involved and committed to the introduction of the new regime within the EU. The intention is therefore to make UK wide legislation to mirror this as closely as possible.

Further communications on this matter will be issued separately after exit.

Enforcement provisions

In each of the UK countries domestic legislation is in place which designates the "competent authorities" who will enforce the requirements of the legislation, as well as establishing enforcement provisions and penalties.

Legislation which provided for enforcement of regulatory regimes for Foods for Specific Groups in each part of the United Kingdom's prior to its withdrawal from the European Union still applies.

Food Supplements

Background: Foods Supplements within the European Union

Food supplements are currently regulated 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). These Regulations cross refer to the Annex of the Directive 2002/46/EC, 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.

Changes: Food Supplements After Exit

Minor changes are being made to the regulatory framework that governs food supplements by inserting the lists of vitamins and minerals that may be used in the manufacture of food supplements, contained as an Annex to Directive 2002/46/EC, into the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have affect in the UK.

It is the view of the UK Government and the Devolved Administrations in Scotland, Wales and Northern Ireland that current [UK guidance](#), with exception to any references to the EU therein, remains relevant and useful in complying with the regulatory framework for food supplements, as amended. For clarity we have set out how the UK's system will work when accounting for practical changes made by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019.

Schedules of Vitamins and Minerals for use in Food Supplements

Details of vitamins and minerals, and vitamin and mineral substances, that may be used in the manufacture of food supplements were contained as an Annex to Directive 2002/46/EC. These lists have now been inserted in to the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules to ensure that they continue to have affect in the UK.

Schedule 1: vitamins and minerals which may be used in the manufacture of food supplements

Schedule 2: Vitamin and mineral substances which may be used in the manufacture of food supplements

Supplementary Information: Schedule 1

When the Annexes to Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 footnotes will be omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included in this Guidance Bulletin for reference.

Folic acid (µg)

Folic acid is the term included in Annex I of Commission Directive 2008/100/EC of 28 October 2008 amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions for nutrition labelling purposes and covers all forms of folates.

Supplementary Information: Schedule 2

When the Annexes to Directive 2002/46/EC are inserted as schedules into the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 footnotes will be omitted. This is because the footnotes set out recommendations rather than legal requirements, consequently they have been included in this Guidance Bulletin for reference.

Vitamin E: (f) Mixed Tocopherols

alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %.

Vitamin E: (g) Tocotrienol Tocopherol

Typical levels of individual tocopherols and tocotrienols:

- 115 mg/g alpha-tocopherol (101 mg/g minimum),
- 5 mg/g beta-tocopherol (< 1 mg/g minimum),
- 45 mg/g gamma-tocopherol (25 mg/g minimum),
- 12 mg/g delta-tocopherol (3 mg/g minimum),

- 67 mg/g alpha-tocotrienol (30 mg/g minimum),
- < 1 mg/g beta-tocotrienol (< 1 mg/g minimum),
- 82 mg/g gamma-tocotrienol (45 mg/g minimum),
- 5 mg/g delta-tocotrienol (< 1 mg/g minimum).

Vitamin K: (b) Menaquinone

Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

Vitamin C: (c) Calcium-L-ascorbate

May contain up to 2 % of threonate.

Mineral: Selenium Enriched Yeast

Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of the total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

Mineral: Silicic Acid

In the form of gel.

Modifying Schedules

The Nutrition (Amendment etc) (EU Exit) Regulations provides for the appropriate UK authorities to make regulations to amend the schedules, set the purity criteria as well as maximum and minimum amounts of vitamins and minerals that may be added to food supplements.

Food business operators, or other interested parties, that wish for vitamin and mineral substances to be considered for inclusion in the Schedules to the Nutrition (Amendment etc) (EU Exit) Regulations 2019 may submit a scientific dossier concerning the safety and bioavailability of the individual substance for UK consideration by the appropriate authorities to the [DHSC Mailbox](#) (which will centrally coordinate dossiers for all four UK countries).

The UK Government and Devolved Administrations therefore recommend that, until further notice, scientific dossiers supporting the addition of a vitamin or mineral to the Schedules continue to be completed in line with [administrative guidance](#) produced by the European Commission and submitted to the [DHSC mailbox](#) (which will centrally coordinate dossiers for all four UK countries).

Risk Management

Risk management functions related to Food Supplements will be assumed by the appropriate authorities.

Risk Assessment

Scientific advice provided by the European Food Safety Authority in relation to food supplements will be sought from existing expert committees in the UK.

Expert committees will be identified by the appropriate authorities as necessary depending on the nature of the scientific advice required.

Appendix A: Mailboxes and Document Locations

Nutrition Legislation Mailbox

nutritionlegislation@dh.gsi.gov.uk

All dossiers and queries related to: vitamins, minerals, and certain other substances; foods for specific groups; and foods supplements.

Nutrition and Health Claims Mailbox

nutritionandhealthclaims@dhsc.gov.uk

All applications and queries related to nutrition and health claims should be directed to this mailbox.

UK Lists and Registers Locations

<https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector>

All UK Lists and Register: related application forms/guidance; and future communications and updates related to EU Exit Nutrition can be found at this web address. This is the Department of Health and Social Care's document collection for no deal preparations.

Existing UK Nutrition Guidance

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/690269/nutrition-legislation-information-sheet.pdf

All relevant existing guidance related to nutrition can be found via the Nutrition Information Sheet at this web address.

Appendix B: Lists and Registers

EU Register / List	UK Register
Community Register of Nutrition and Health Claims Made on Food	United Kingdom Nutrition and Health Claims Register https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector
Annex to Community Register of health claims for which the protection of proprietary data has been granted	Annex to United Kingdom Nutrition and Health Claims Register of Health Claims Authorised on the basis of Proprietary Data https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector
N/A	List of Article 13.1 'on-hold' Health Claims https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector
Community Register of Vitamins, Minerals, and Certain Other Substances	United Kingdom Register of Vitamins, Minerals, and Certain Other Substances https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector
Union List (Annex to Regulation (EU) No. 609/2013)	United Kingdom List (Annex to retained Regulation (EU) No. 609/2013)

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