GOV.UK

Part of
Brexit transition: new rules for 2021 (https://www.gov.uk/transition)

- Department of Health & Social Care (https://www.gov.uk/government/organisations/department-of-health-and-social-care)

Guidance

Nutrition-related labelling, composition and standards from 1 January 2021

Published 17 November 2020

New rules for January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year.

This page tells you what you'll need to do from 1 January 2021. It will be updated if anything changes.

For current information, read: Nutrition legislation information sources (https://www.gov.uk/government/publications/nutrition-legislation-information-sources)

You can also read about the transition period (https://www.gov.uk/transition).

Contents

Print this page

This publication is available at https://www.gov.uk/government/publications/nutrition-related-labelling-composition-and-standards-from-1-january-2021/nutrition-related-labelling-composition-and-standards-from-1-january-2021

Introduction

Using this guidance

This document outlines changes to domestic and European Union (EU) legislation relating to nutrition-related labelling, composition and standards (NLCS). The subject areas covered by this are:

- nutrition and health claims made on foods
- the addition of vitamins, minerals and certain other substances to foods
- composition and labelling of food supplements
- the composition and labelling of food for specific groups (FSG)

Changes will be made by the European Union (Withdrawal) Act 2018, the Nutrition (Amendment etc) (EU Exit) Regulations 2019, and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 in England, Scotland, and Wales (Great Britain) from 1 January 2021 following the end of the transition period.

The Protocol on Ireland/Northern Ireland (NIP) means that EU legislation relating to nutrition related labelling, composition, and standards, as detailed in Annex 2 to the NIP, will continue to be directly applicable in Northern Ireland.

Following the end of the transition period, EU Regulations and tertiary legislation relating to nutrition will be retained under the powers contained within the European Union (Withdrawal) Act 2018 as UK law. That retained EU legislation is subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020.

This guidance sets out the practical effect of the changes to the legislation for industry, and the processes and procedures which food business operators, and other interested parties, must comply.

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transfer responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB).

They also make practical changes, that result from this transfer, to:

- applications
- frameworks for the scientific evaluation of applications/dossiers/files
- the factors taken into consideration when a risk management decision is required

Businesses seeking to submit applications, scientific dossiers, or files in accordance with the legislation covered by this guidance for consideration in the GB market should prepare those applications and requests in line with the advice in this document and submit them to the Department of Health and Social Care (DHSC). DHSC will ensure that all documents are shared with the appropriate authorities in Scotland, and Wales, and Northern Ireland and, once deemed valid, the applicable expert committees.

Information will be shared with Northern Ireland as all nutrition issues will continue to be considered on a 4 nation basis: and importantly, officials and Ministers in Northern Ireland will continue to play a vital role in policy development under the arrangements agreed in the UK-wide common framework for NLCS. Northern Ireland's full participation in risk assessment and risk management processes will ensure that any decisions taken in GB (England, Scotland and Wales) account for the potential impacts across the UK.

Appropriate authorities

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 transfer functions and powers currently held by the European Commission powers to legislate to give effect to a decision, such as whether to authorise applications for new health claims, to the appropriate authorities.

The appropriate authorities are in:

- England: the Secretary of State
- Scotland: the Scottish Ministers
- Wales: the Welsh Ministers

Each appropriate authority may, therefore: make legislation equivalent to that which the European Commission would have made. However, the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 also provide concurrent powers for the UK Secretary of State to legislate for the whole of GB where Devolved Administrations in Scotland and Wales agree.

Functions and powers currently held by the European Commission will not be transferred to Northern Ireland. However, officials and Ministers in Northern Ireland there will continue to play a vital role in policy development under the arrangements agreed in the UK-wide common framework for NI CS. Therefore, references are included in this guidance to 'appropriate UK authorities' where Northern Ireland officials and Ministers will be involved in risk assessment or risk management. The Food Standards Agency (FSA) remains the designated Competent Authority in Northern Ireland.

Common framework for NI CS

Officials from the UK government (UKG) and the Devolved Administrations in Scotland, Wales, and Northern Ireland have jointly developed a UK-wide Common Framework for NI CS (https://www.gov.uk/government/publications/nutrition-labelling-composition-and-standards-provisional-common-framework-command-paper) in preparation for the end of the transition period.

As a devolved policy area NI CS is one of several that were identified in the UKG Frameworks Analysis (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/792738/20190404-FrameworksAnalysis.pdf) which required more detailed discussion to explore whether a common framework agreement was needed to manage potential divergence within the UK after EU Exit and the governance and decision-making processes required for effective joint working and implementation.

Officials across all 4 nations have worked together to develop the NI CS Common Framework, which was provisionally agreed at the Joint Ministerial Committee (EN) on 3 September 2020.

Risk assessment and risk management (policy development) mechanisms

NI CS risk assessments will consider the impact on a UK-wide basis aiming to deliver a consistent approach and process for businesses and enforcement authorities across the UK (with capacity maintained for nation-specific assessments where appropriate).

Decisions based on both scientific opinion and those wider risk management considerations will be made by the appropriate authority (namely the Secretary of State, Scottish, Welsh, Ministers or as appropriate with consent from the Devolved Administrations) through the establishment of 4-nation working arrangements which build on existing consensus-based policy making.

While Ministers will retain the right to take individual decisions for their nation on areas within the scope of the NI CS Framework, the opportunity for consistency of approach across administrations will be sought in the first instance and where agreed, common policy recommendations will be made.

The ability to diverge where appropriate and proportionate will be retained, while taking account of the impact on consumer safety and confidence, and the functioning of the UK internal market in reaching a final decision.

Dispute prevention and dispute resolution

Every effort will be made at working level to resolve any disagreements in difference of approach. It is anticipated that the need for dispute resolution in areas within scope of the Nutrition Framework is unlikely. However, should it be needed, the dispute resolution established by the NI CS Framework will come into play.

Lists and registers

Where EU 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.

Decisions made by the appropriate authorities as set out above, will result in the GB lists and registers needing to be updated periodically.

For convenience and clarity GB lists and registers, which consolidate all lists produced and maintained by the appropriate authorities (https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector) will be made available on GOV.UK for food business operators and other interested parties.

Businesses may submit applications or dossiers in support of these lists being amended for consideration for use on the GB market to DHSC mailboxes, unless stated otherwise in this guidance. DHSC will centrally coordinate applications.

Northern Ireland

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

The UK government published a Command Paper (https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol/the-uks-approach-to-the-northern-ireland-protocol) on its approach to the NIP on 20 May 2020 and further information can be found there, in addition to business guidance (https://www.gov.uk/transition).

The NIP was designed as a practical solution to avoiding a hard border on the island of Ireland, whilst ensuring that the UK, including Northern Ireland, could leave the EU as a whole. It therefore included, a number of special provisions which apply only in Northern Ireland, for as long as the NIP is in force.

The NIP means that EU legislation relating to nutrition related labelling, composition, and standards, as detailed in Annex 2 to the NIP, will continue to be directly applicable in Northern Ireland.

Existing UK guidance (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet) remains relevant and useful in complying with the compositional and labelling requirements set out in EU law when read alongside the updates in this document relevant in Northern Ireland such as advice on submitting applications and requests in Northern Ireland.

With regards to trade going from Northern Ireland to the rest of the UK: this will take place as it does now. Northern Ireland businesses will continue to be able to place their goods on the market throughout the rest of the United Kingdom without new restrictions. Further information can be found on moving goods into, out of, or through Northern Ireland from 1 January 2021 (https://www.gov.uk/guidance/moving-goods-into-out-of-or-through-northern-ireland-from-1-january-2021).

Businesses should note, however, that under the Protocol, in Northern Ireland, the FSA is not able to submit: applications for new nutrition and health claims, to be added to the EU Register of nutrition and health claims made on foods (http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home), or scientific dossiers concerning the modification of:

- the Community Register on the addition of vitamins and minerals and of certain other substances to foods (https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf)
- substances that can be added to FSG
- the Annex of Directive 2002/46/EC (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1600431719867&uri=CELEX:02002L0046-20170726) to the European Commission for consideration

Businesses seeking to submit any of the aforementioned applications or scientific dossiers in respect to authorisation for the Northern Ireland or EU27 markets should forward them to the European Commission in accordance with the following sections of this guidance:

- Making a nutrition and health claim in the EU or Northern Ireland
- Modifying the community register on the addition of vitamins and minerals and of certain other substances to foods in the EU and Northern Ireland
- Modifying the Union List in the EU and Northern Ireland
- Modifying annex of the Directive 2002/46/EC in the EU and Northern Ireland

Northern Ireland's full participation in risk assessment and risk management processes will ensure that any decisions taken in GB (England, Scotland and Wales) account for the potential impacts across the UK.

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 substantiating evidence.

The Community Register (http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home) of nutrition and health claims made on foods, lists all authorised and rejected claims set out in EU legislation:

- Permitted nutrition claims that may be made on foods as listed in the Annex to Regulation (EC) No. 1924/2006.

- 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 as listed in the Annex to Commission Regulation (EU) No. 432/2012.
- Permitted reduction of disease risk claims and claims referring to children's development and health as set out in various Commission Regulations.
- Rejected health claims as set out in various Commission Regulations.

An application to use a claim that is not authorised and listed in the Commission Register for use in the EU, may be submitted via a Member State 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 in GB from 1 January 2021

In amending Regulation (EC) No. 1924/2006, the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 make a number of practical changes to the regulatory framework. This guidance sets out how GB's nutrition and health claim system will operate when accounting for those changes.

Existing UK guidance on nutrition and health claims made on foods (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) remains relevant and useful, with exception to any references to the EU therein, in helping food businesses to comply with the retained Regulation (EC) No. 1924/2006 (https://www.legislation.gov.uk/eur/2006/1924/contents).

The NIP means that EU legislation relating to nutrition and health claims will continue to be directly applicable in Northern Ireland. Given this, existing UK guidance on nutrition and health claims made on foods (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) remains relevant and useful in helping food businesses to comply with EU nutrition and health claims regulations, when read alongside the updates in this document relevant to Northern Ireland, such as making a claim in the EU or Northern Ireland.

GB Nutrition and Health Claims Register

All nutrition and health claims that are listed in the Community Register, as of 1 January 2021, will be adopted and included in the Great Britain Nutrition and Health Claims Register (GB NHC Register).

This means that if the European Commission has not taken a decision on an application related to a nutrition or health claim by 1 January 2021, a new application must be submitted to the appropriate GB authorities in for assessment if the applicant wishes for the claim to be authorised for use in the GB market. Where a scientific opinion regarding the efficacy of a claim is available, from the European Food Safety Authority or other scientific advisory body, this should be included with an application in accordance with Commission Regulation 353/2008 (paragraph 5 of the Annex) and Part 1.7 of the application form (https://www.gov.uk/government/groups/uk-nutrition-and-health-claims-committee#making-an-application-for-authorisation-of-a-health-claim). The appropriate UK authorities will determine whether any such opinion is sufficient to inform a risk management decision or if further risk assessment is required.

All authorised and rejected nutrition and health claims will be listed in the GB NHC Register, other than those health claims authorised on the basis of proprietary data which will be recorded in a separate Annex to the GB NHC Register.

The GB NHC Register, and the separate Annex, will be available on GOV.UK (see appendix B: lists and registers).

Communication of changes

Any future amendments to the GB NHC Register will be communicated via regular bulletins published on post-transition period information for the health and care sector (https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector).

Nutrition claims

Only nutrition claims listed in the GB NHC Register, may be used in GB from 1 January 2021. The only exceptions to this are:

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

Products that make a nutrition claim must continue to do all of the following:

- meet the specific conditions of use as set out in the Annex to retained Regulation (EC) No. 1924/2006
- present nutrition labelling as required by Article 7 of retained Regulation (EC) No. 1924/2006
- comply with general conditions set out in Article 5 of retained Regulation (EC) No. 1924/2006and any general requirements outlined in existing guidance on nutrition and health claims on foods (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) such as those that relate to alcoholic beverages

New GB nutrition claims

The appropriate UK authorities may, after consulting an expert committee, amend the list of permitted nutrition claims contained within the Annex to Regulation (EC) No. 1924/2006 by making regulations. Authorised and rejected nutrition claims will be added to the GB NHC Register.

If you wish to apply for a claim to be authorised for use in the GB market please contact the appropriate GB authorities via the DHSC mailbox (which will centrally coordinate applications for all GB nations).

If you wish to submit an application for a claim to be authorised for use in:

- England only, please contact the competent authority via the DHSC mailbox
- Scotland only, please contact the competent authority via the Food Standards Scotland mailbox
- Wales only, please contact the competent authority via the Welsh Government mailbox

The appropriate authority will consult the United Kingdom Nutrition and Health Claims Committee (UKNHCC), and any other appropriate scientific advisory committee (SAC) when considering a new nutrition claim. If a claim is authorised by the appropriate UK authorities and added to the Annex, any specific conditions associated with that claim will apply.

Businesses wishing to make new nutrition claims in the EU or Northern Ireland market following the end of the transition period should refer to the section on making a claim in the EU or Northern Ireland.

Health claims

Only authorised health claims listed in the Great Britain Nutrition and Health Claims Register may be used in the GB market from 1 January 2021. 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)
- 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)

Products that make a health claim must continue to do all of the following:

- meet the specific conditions of use as set out in the GB NHC Register
- present nutrition labelling (subject to the conditions of Article 7 of retained Regulation (EC) No. 1924/2006)
- comply with any general requirements as set out in existing guidance on nutrition and health claims on foods (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) 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 GB NHC Register. Products that make a health claim authorised on the basis of proprietary data must continue to do all of the following:

- meet the specific conditions of use as set out in the Annex to the GB Register
- present nutrition labelling (subject to the conditions of Article 7 of Regulation (EC) No. 1924/2006)
- comply with any general requirements as set out in existing guidance on nutrition and health claims on foods (https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods) such as those that relate to alcoholic beverages

New GB health claims

From 1 January 2021 anyone wishing to make a new health claim on a product in GB that is not included in the GB NHC Register must submit an application for that claim to be assessed and authorised before it can be used.

See application forms, which contain supplementary information on completing an application for a claim (https://www.gov.uk/government/groups/uk-nutrition-and-health-claims-committee#making-an-application-for-authorisation-of-a-health-claim).

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
- reduction of disease risk claims and claims referring to children’s development and health

Applications seeking authorisation of a claim for use in the GB market should be submitted to the competent authorities via the DHSC mailbox (which will centrally coordinate applications for all GB nations).

Applications seeking authorisation of a claim for use in:

- England only, please contact the competent authority via the DHSC mailbox
- Scotland only, please contact the competent authority via the Food Standards Scotland mailbox
- Wales only, please contact the competent authority via the Welsh Government mailbox

We recommend that applicants complete a Medicines Borderline Advice Form (https://info.mhra.gov.uk/forms/borderline_advice.aspx) 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 (https://www.food.gov.uk/business-guidance/novel-foods) whether their food would be considered a novel food in GB.

Food business operators wishing to make new health claims in the EU or Northern Ireland market following the end of the transition period should refer to the section on making a claim in the EU or Northern Ireland.

Applications for claims based on new or emerging science or proprietary data: Article 13(5)

Article 13(5) of retained Regulation (EC) No. 1924/2006 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 GB NHC Register. The process to be used is set out in Article 18 of retained Regulation (EC) No. 1924/2006

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 either:

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

Therefore, the process contained in Article 18 of retained Regulation (EC) No. 1924/2006may 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 via this route.

In the event of an application being submitted that has received a previous negative assessment by EFSA (or other assessment outside of the UK/GB), the applicant should state the reason or reasons for submitting the new application, and provide a description of the changes made to the application. 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, require authorisation prior to use. Retained Regulation (EC) No. 1924/2006specifies the procedure for such authorisations. To have a claim authorised an application with supporting information (which will be kept confidential) must be submitted to the relevant competent authority via the appropriate mailbox (see the ‘New Claims’ section above).

Within 14 days of the date of receipt the competent authority will, working with the applicant where necessary, conduct a validity check of the application (to ensure it comes within the scope of the regulation) and acknowledge receipt in writing (the acknowledgement shall state the date of receipt of the application). The competent 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.

An application must contain all the following information about the claim:

- the name and address of the applicant
- a statement confirming whether the application is for authorisation of the claim for use in Great Britain, or either in one of England, Scotland, or Wales only
- 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
- a description of the claimed effect and whether or not it is based on the essentiality of the nutrient
- 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
- 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

From the date that the UKNHCC receives a valid application from a competent GB authority it has 5 months to provide its opinion to the relevant 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 (this is known as the ‘stop the clock’ process’). The UKNHCC will forward its opinion to the relevant authorities and the applicant as well as making it public. The applicant and members of the public have 30 days to make comments to the relevant competent GB authority via the appropriate mailbox (see the ‘New Claims’ section above).

The appropriate UK authorities have 2 months from receipt of that UKNHCC scientific opinion to decide whether the claim should be authorised. The appropriate UK authorities will take into account:

- the UKNHCC’s scientific opinion
- relevant provisions in law
- any enactments
- other factors relevant to the matter under consideration, and will consult one another in reaching a view

Authorised claims will be added to the GB NHC Register together with any conditions of use. Similarly, if the claim is rejected it will be added to the GB NHC Register together with the reasons for the rejection.

Once authorised and added to the GB NHC 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 5 years in accordance with Article 21. This is reliant on all the following:

- the scientific data or other information being designated as proprietary by the applicant when the application is made
- the prior applicant having exclusive right of reference to the proprietary data at the time the prior application was made
- 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: Article 14

Retained Regulation (EC) No. 1924/2006requires 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 GB NHC 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 for use in the GB market an application with supporting information must be submitted to the relevant competent GB authority via appropriate mailbox (see the 'New Claims' section above).

Within 14 days of the date of receipt the competent authority will, working with the applicant where necessary, conduct a validity check of the application (to ensure it comes within scope of the regulation) and acknowledge receipt in writing (the acknowledgement shall state the date of receipt of the application). 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 authorities. The UKNHCC will make the summary of the application available to the public.

An application must contain all the following information about the claim:

- the name and address of the applicant
- a statement confirming whether the application is for authorisation of the claim for use in Great Britain, or either in one of England, Scotland, or Wales only
- 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

- 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 the UKNHCC will make public)

From the date that the UKNHCC receives a valid application from a competent GB authority it has 5 months to provide its opinion to the relevant UK authorities. The UKNHCC, or the competent GB 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 2 months following the date of receipt of the requested information submitted by the applicant (this is known as the 'stop the clock' process'). 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
- a proposal for the wording of the claim
- 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. The applicant and members of the public will have 30 days to make comments to the relevant competent GB authority via appropriate mailbox (see the 'New Claims' section above).

Claims authorised by the appropriate UK authorities for use in the GB market will be added to the GB NHC Register together with any conditions of use. Rejected claims will also be added to the GB NHC 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 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 GB authorities may also, on their own initiative, request that a claim be reconsidered.

Following a request from an appropriate GB authority, the UKNHCC shall issue a scientific 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.

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 have 30 days, the publication of the opinion, to make comments to the appropriate UK authorities via the DHSC mailbox (which will centrally coordinate comments for all GB nations).

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 (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/307453/DH_BULLETIN_-_Searching_Article_13.1_on_hold_health_claims_acc.pdf), (2014 Bulletin) 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. See the full list of ‘on hold’ claims referenced by the 2014 Bulletin (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/307453/DH_BULLETIN_-_Searching_Article_13.1_on_hold_health_claims_acc.pdf).

‘On hold’ claims are still under consideration in the EU, however, from 1 January 2021 GB will have its own system for authorising claims separate from the EU authorisation system.

Following the end of the transition period, the UK government and Devolved Administrations in Scotland, Wales, and Northern Ireland will launch a call to evidence, seeking information from stakeholders so that the full scale of the ‘on hold’ claims issue may be understood. Following the call for evidence, a decision will be made on the approach to ‘on hold’ claims for use in the GB market.

As it is the intention of the UK government and Devolved Administrations in Scotland, Wales to minimise disruption to business following the end of the transition period, we will provide business reasonable time to plan accordingly. ‘On hold’ claims may continue to be used in accordance with the 2014 Bulletin (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/307453/DH_BULLETIN_-_Searching_Article_13.1_on_hold_health_claims_acc.pdf) until a decision is made following the call for evidence.

Generic descriptors

Retained Regulation (EC) No. 1924/2006 continues to allow for appropriate authorities to make regulations granting derogations from Article 1.3 following the receipt of an application for the GB market by business.

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.

The procedure and requirements for applications made by businesses for generic descriptors is set out below. Applications for the GB market should be completed in line with the requirements set out in Appendix C of this guidance. Applications should be submitted for GB consideration to the DHSC mailbox (which will centrally co-ordinate applications for all GB nations).

Retained Commission Regulation (EU) No. 2019/343 which provides for derogations from Article 1(3) of Retained Regulation (EC) No 1924/2006 is now applicable. It will be subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2020. The Annex to retained Regulation (EU) No. 2019/343 will contain all the generic descriptors permitted for use in GB following the end of the transition period.

Applications for generic descriptors other than those addressed by Commission Regulation (EU) No. 2019/343 currently being considered by the EU will not be authorised before the end of the transition period. We therefore recommend that any applications currently under consideration in the EU are

submitted for consideration by the UK appropriate authorities for use the GB market to the DHSC mailbox (which will centrally coordinate applications for all GB nations).

GB generic descriptor application process

An application may be made for the use of a generic descriptor in Great Britain or either in one of England, Scotland, or Wales only.

Applications seeking authorisation of a claim for use in the Great Britain should be submitted to the competent authorities via the DHSC mailbox (which will centrally coordinate applications for all GB nations).

Applications seeking authorisation of a claim for use in:

- England only, please contact the competent authority via the DHSC mailbox
- Scotland only, please contact the competent authority via the Food Standards Scotland mailbox
- Wales only, please contact the competent authority via the Welsh Government Mailbox

The application shall be submitted electronically using the format set out in Appendix C Appropriate GB authorities may request a paper copy if they require it. For the data referred to in points 1.5 and 2 of Appendix C, a list of references alone is not sufficient.

On receipt of an application the appropriate GB authority shall:

- acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application,
- forward the full application to the other appropriate UK authorities for which the application concerning the use of the generic descriptor is made.

The appropriate authority shall verify, without delay, and taking into account information provided by the other appropriate authorities, whether the application contains all required information as listed in Appendix C of this document. Where the application does not contain all the elements required under Appendix C of this document, the appropriate authority shall request the necessary additional information from the applicant and inform the applicant of the period within which that information shall be provided.

An application shall be considered as not valid in cases where an applicant does not provide further information as requested by the appropriate authority. In such a case the appropriate authority shall inform the applicant, and other appropriate authorities, indicating the reasons why the application is considered not valid.

The appropriate authority shall forward the valid application to the other appropriate authorities, without delay and inform the applicant thereof.

The appropriate authorities concerned shall provide their opinion to one another within 6 weeks from the date of transmission of the valid application. The opinion shall state whether the generic descriptor fulfils the conditions for obtaining an exemption pursuant to Article 1(4) of Retained Regulation (EC) No 1924/2006, and whether it is supported by the elements referred to in Appendix C of this document, points 1.3, 1.4, 1.5 and shall give the reasons justifying that opinion. The opinions shall be submitted in writing.

After receiving the valid application from appropriate authority, and the opinion(s) referred to in this process, the appropriate UK authorities may, within a reasonable time, initiate the procedure of approval of the generic descriptor seeking the opinions of an expert committee as appropriate.

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 opinions to the appropriate UK authorities on nutrition and health claims post exit.

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 for the GB market
- maintaining the GB 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 GB authorities by applicants following the publication of the UKNHCC's scientific opinion, consumer understanding, and the opinion of the UKNHCC will all be taken into consideration when establishing the final wording of a claim.

Panel and 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 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/278498/11-1382-code-of-practice-scientific-advisory-committees.pdf) and the Governance Code on Public Appointments (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/578498/governance_code_on_public_appointments_16_12_2016.pdf) 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

See updated nutrition and health claim application forms for use in GB (https://www.gov.uk/government/groups/uk-nutrition-and-health-claims-committee#making-an-application-for-authorisation-of-a-health-claim) (containing further information on completing an application). This is similar the EFSA application form, only minor amendments 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 GB authorities for consideration using the same format as those submitted to the EU until further notice.

Applications will be considered in turn. To facilitate timely evaluation, the appropriate UK authorities recommend that applications are not submitted shortly before any scheduled meeting of the UKNHCC (https://www.gov.uk/government/groups/uk-nutrition-and-health-claims-committee).

If the UKNHCC receives an application that is not suitably completed or provides insufficient evidence to complete an assessment, it may request further information from the applicant in accordance with previous sections of this guidance:

- Applications for Claims Based on New or Emerging Science or Proprietary Data: Article 13(5)
- Applications for Reduction of Disease Risk Claims and Claims Referring to Children's Development and Health: Article 14

Under the stop the clock process, the evaluation of an application will be suspended until the applicant provides the requested information. Applicants must provide requested information in line with any timings set out in this guidance.

The UKNHCC will resume the evaluation of the application once it receives the requested information, producing its opinion within the time remaining of the original 5-month evaluation period on the date of suspension plus any additional time (1 month for Article 13.5 claims and 2 months for Article 14 claims).

An application may be withdrawn by the applicant up to the moment the UKNHCC adopts its opinion. A request for withdrawal of an application must be submitted to the Appropriate Authority to which the application was submitted.

Scientific opinion

In conducting a scientific assessment, the UKNHCC will use a framework similar to the Scientific Advisory Committee on Nutrition (SACN) Framework for the Evaluation of Evidence (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338009/SACN_Framework_for_the_Evaluation_of_Evidence_May_2012.pdf).

Opinions will be produced with either a favourable or unfavourable conclusion, i.e positive or negative.

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 all the following information:

- the names and address of the applicant
- 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
- a summary of the evidence submitted in support of the claims and an assessment of its validity
- a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use
- 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 label 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 the EU or Northern Ireland

Following the end of the transition period, there will be a separate system for authorising nutrition and health claims for the GB market.

Businesses wishing to make new nutrition and health claims in the EU or Northern Ireland market following the end of the transition period must continue to comply with the requirements of Regulation (EC) No. 1924/2006.

We recommend that food business operators wishing to submit applications for new claims in the EU or Northern Ireland from 1 January 2021 refer to the extensive guidance on making nutrition and health claims in the European Union (https://www.efsa.europa.eu/en/applications/nutrition) published by EFSA.

Vitamins, minerals and certain other substances

Background: addition of vitamins, minerals and certain other substances to food within the EU

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 requirements regarding the addition of vitamins, minerals and certain other substances to food in GB from 1 January 2021

In amending retained Regulation (EC) No 1925/2006 the Nutrition (Amendment etc) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc) (EU Exit) Regulations 2020 make a number of practical changes to the regulatory framework. This guidance sets out how GB's system will work when accounting for those practical changes.

Existing UK guidance on the addition of vitamins and minerals and certain other substances to foods (https://www.gov.uk/government/publications/fortified-foods-guidance-to-compliance-with-european-regulation-ec-no-1925-2006-on-the-addition-of-vitamins-and-minerals-and-certain-other-substances-to-food) remains relevant and useful, with exception to any references to the EU therein, in helping food businesses to comply with the retained Regulation (EC) No. 1925/2006 (https://www.legislation.gov.uk/eur/2006/1925/contents).

The NIP means that EU legislation relating to the addition of vitamins, minerals, and certain other substances to food will continue to be directly applicable in Northern Ireland.

Given this, existing UK guidance on the addition of vitamins and minerals and certain other substances to foods (https://www.gov.uk/government/publications/fortified-foods-guidance-to-compliance-with-european-regulation-ec-no-1925-2006-on-the-addition-of-vitamins-and-minerals-and-certain-other-substances-to-food) remains relevant and useful in helping food businesses to comply with EU legislation on the addition of vitamins and minerals added to foods, when read alongside the updates in this document relevant to Northern Ireland, such as modifying the Community Register in the European Union and Northern Ireland.

GB Register of Vitamins, Minerals and Certain Other Substances

In preparation for the UK's withdrawal from the EU, the UK government and Devolved Administrations in Scotland and Wales have adopted the Community Register of Vitamins, Minerals, and Certain Other Substances as it exists 1 January 2021, henceforth it shall be known as the GB VMS Register.

The GB 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
- the vitamin formulations and mineral substances which may be added to foods as listed in Annex II of retained Regulation (EC) No. 1925/2006
- 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
- information regarding enactments applicable in any part of Great Britain on either:
    - the mandatory addition of vitamins and minerals to specified foods or categories of foods
    - the prohibition or restriction on the use of certain other substances in the manufacture of specified foods
- any restrictions on the addition of vitamins and minerals as set out in Article 4 of retained Regulation (EC) No. 1925/2006
- information about the substances referred to in Annex III of retained Regulation (EC) No. 1925/2006 (Part A: prohibited substances, Part B: restricted substances) and the reasons for their inclusions therein
- information about the substances listed in Annex III, Part C, of retained Regulation (EC) No. 1925/2006 whose use is generally allowed as referred to in Article 8(5)

The GB VMS Register will have effect across the whole of GB from 1 January 2021.

Communication of changes

Any amendments to the GB VMS Register will be communicated via regular bulletins published on post-transition period information for the health and care sector (https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector).

Modifying the GB VMS Register

Modifying annexes I and II

Article 3.3 of retained Regulation (EC) No. 1925/2006, allows for the appropriate GB 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, 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 consideration for use in the GB market by the appropriate UK authorities to the DHSC mailbox (which will centrally coordinate dossiers for all 4 GB nations).

To minimise disruption to business, we (the UK government and the Devolved Administrations in Scotland and Wales) recommend that, until further notice, scientific dossiers supporting the addition of a vitamin or mineral to the GB Register continue to be completed in line with administrative guidance (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf) produced by the European Commission.

Modifying Annex III Part C

Annex III Part C of retained Regulation (EC) No. 1925/2006, 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 4 years of a substance being listed in Annex III Part C of retained Regulation (EC) No. 1925/2006, 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, 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. The file shall be based on relevant guidance documents that have been adopted or endorsed by an expert committee designated by the appropriate UK 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, are submitted for GB consideration by the appropriate GB authorities to the DHSC mailbox (which will centrally coordinate files for all GB nations). Further to this we recommend that files continue to be completed in line with administrative guidance (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf) produced by the European Commission.

We recommend that submitted dossiers not considered by the EU before the end of the transition period, are submitted to the DHSC mailbox (which will centrally coordinate dossiers for all GB nations) for consideration by the appropriate UK authorities if the applicant wishes for that modification to also be applicable in the GB market.

The appropriate UK authorities will identify an appropriate scientific advisory 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 9 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 3 months.

The resulting opinion given by the expert committee will be taken into account when the GB 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. 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, 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 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 scientific advisory committee committees in the UK.

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

Risk management

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

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.

Modifying the community register on the addition of vitamins and minerals and of certain other substances to foods in the EU and Northern Ireland

Following the end of the transition period, GB will have its own GB VMS Register and modification.

Food business operators wishing to add vitamins and minerals to food in the EU or Northern Ireland following the end of the transition period must also continue to comply with the requirements currently laid out in of Regulation (EC) No. 1925/2006.

We recommend that food business operators wishing to request the inclusion of vitamins and minerals in the Community Register (https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-vitamins_minerals-comm_reg_en.pdf) in the EU or Northern Ireland from 1 January 2021 refer to the extensive guidance on the addition of vitamins and minerals (https://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals_en) published by the European Commission. This guidance relates specifically to administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

Requests for the inclusion of new nutritional substances should be submitted to the European Commission. Guidance on the procedure that should be followed for the submission of requests for substances to be considered for inclusion in the permitted list is available on the European Commission's website (http://ec.europa.eu/food/food/labellingnutrition/vitamins/index_en.htm).

Foods for specific groups (FSG)

Background: requirements for FSG within the EU

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 FSG 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.

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
- 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 and infant and follow-on formula will be in force from 1 January 2021.

The EU legislation for total diet replacement for weight control comes into force in 2022. This will need to be considered with the 4 UK countries. The UK government was fully involved and committed to the introduction of the new regime within the EU. The intention is therefore to make legislation across GB to mirror this as closely as possible. Further communications on this matter will be issued separately following the end of the transition period.

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 fully apply. The date of application of the new rules is different for each category of foods. Anything that does not apply on 1 January 2021 will not become part of GB legislation, but will apply in NI from the date of application.

This means from 1 January 2021 FSG will be regulated by the framework contained in Regulation (EU) No 609/2013. Foods for special medical purposes, and infant and follow-on formula (except those manufactured from protein hydrolysates until 21 February 2021), will be entirely regulated under the new regime (Regulation (EU) No 609/2013, Delegated Regulation 2016/128, and Delegated Regulation 2016/127). Complementary foods and TDRs will continue to be regulated by the specific directives that were made under Directive 2009/39/EC.

Further to this Regulation (EU) No. 609/2013 includes an Annex which consolidates lists of substances that may be added to products included within the categorisation of FSG. This Annex is known as the Union List.

Changes: FSG from 1 January 2021

In amending retained Regulation (EU) No. 609/2013 the Nutrition (Amendment etc) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc) (EU Exit) Regulations 20 make a number of practical changes to the regulatory framework. This guidance sets out how GB system will work when accounting for those changes.

Existing UK guidance on FSG (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet#food-for-specific-groups-fsg-formerly-known-as-foods-intended-for-particular-nutritional-uses-parnuts) remains relevant and useful, with exception to any references to the EU therein, in helping food businesses to comply with the relevant retained Regulation (EU) No. 609/2013 (https://www.legislation.gov.uk/eur/2013/609/contents).

In practice the NIP means that EU legislation relating to FSG will continue to be directly applicable in Northern Ireland.

Given this, existing UK guidance on FSG (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet#food-for-specific-groups-fsg-formerly-known-as-foods-intended-for-particular-nutritional-uses-parnuts) remains relevant and useful in helping food businesses to comply with EU regulations on FSG, when read alongside the updates in this document relevant to Northern Ireland, such as modifying the Union List in the European Union and Northern Ireland.

GB List

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

The GB List will only apply to foods for special medical purposes and infant and follow on formula. The GB List will apply to processed cereal-based food and baby foods and foods for total diet replacement for weight control once legislation is made across GB to mirror the effects of delegated legislation related to these products made under retained Regulation (EU) No. 609/2013.

Substances belonging to the categories of substances listed below may be added to the categories of FSG provided they are contained within the GB List and comply with any stipulated conditions:

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

The GB 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
- the name of the substance, and where appropriate the specification of its form
- where appropriate, the conditions of use of the substance
- where appropriate, the purity criteria applicable to the substance

Modifying the GB List

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

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

The UK government and Devolved Administrations in Scotland and Wales therefore recommend that, until further notice, scientific dossiers supporting the addition of a substance to the GB List continue to be completed in line with administrative guidance (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf) produced by the European Commission.

Communication of Changes

Changes to the GB List will be communicated via regular bulletins published on post-transition period information for the health and care sector (https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector).

Notification of foods for special medical purposes (FSMP) and infant and follow-on formula (IFFOF)

When a FSMP is placed on the market, food business operators are required to notify the competent UK authority where the product is being marketed. The DHSC will centrally coordinate notification forms for all 3 GB nations for the purposes of notifying each of the applicable competent UK GB authorities.

When an infant formula or a follow-on formula based on protein hydrolysates or containing other substances than those listed in Annex II of retained Regulation (EU) 2016/127 are placed on the market, food business operators are required to notify the competent UK authority where the product is being marketed. . The DHSC will centrally coordinate notification forms for all 3 GB nations for the purposes of notifying each of the applicable competent UK GB authorities.

Great Britain

For FSMPs, 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 (EUC) 2016/128, may be sent to a the DHSC mailbox (which will centrally coordinate notification forms for all 3 GB nations) for the purposes of notifying each of the applicable competent UK GB authorities.

For infant formula and follow-on formula based on protein hydrolysates or containing other substances than those listed in Annex II of 2016/127, 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 (EUC) 2016/127, may be sent to a the DHSC mailbox (which will centrally coordinate notification forms for all 3 GB nations) for the purposes of notifying each of the applicable competent UK GB authorities.

Northern Ireland

The Food Standards Agency will remain the designated Competent Authority in Northern Ireland NI from 1 January 2021. This means that notification forms for FSMPs, along with a model of the label for the product, and any other information that may be reasonably requested to establish compliance with Regulation (EU) 2016/128 must be sent to: nutritionlegislation-ni@food.gov.uk

Notifications forms for infant formula and follow-on formula based on protein hydrolysates or containing other substances than those listed in Annex II of 2016/127, along with a model of the label for the product, and any other information that may be reasonably requested to establish compliance with Regulation (EU) 2016/127 must be sent to: nutritionlegislation-ni@food.gov.uk

Risk assessment

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

Risk management

Risk management functions, such as making regulations to add substances to the GB List, will be assumed by the appropriate UK authorities.

Future delegated legislation

The UK government was fully involved and committed to the introduction of the new regime within the EU. The intention is therefore to make legislation across GB to mirror this as closely as possible.

Further communications on this matter will be issued separately following the end of the transition period.

Domestic enforcement provisions

Domestic legislation is in place which designates the “competent authorities” in each part of the UK 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 FSG in each part of the United Kingdom’s prior to its withdrawal from the European Union still applies.

Modifying the Union List in the EU and Northern Ireland

Following the end of the transition period GB will have its own GB List and modification processes.

Food business operators wishing to add substances to FSGs in the EU or Northern Ireland following the end of the transition period must continue to comply with the requirements of Regulation (EU) No. 609/2013 and other applicable delegated regulations and Directives.

We recommend that food business operators who wish for additional substances to be considered for inclusion in the Union List, which applies to the EU and Northern Ireland, from 1 January 2021 refer to the extensive guidance on the addition of substances for specific nutritional purposes (https://ec.europa.eu/food/safety/labelling_nutrition/special_groups_food/dietetic_en), specifically administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

Food supplements

Background: food supplements within the EU

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 from 1 January 2021

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 GB. This guidance sets out how GB system will work when accounting for those changes.

Existing UK guidance on food supplements (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet#food-for-specific-groups-fsg-formerly-known-as-foods-intended-for-particular-nutritional-uses-parnuts) remains relevant and useful, with exception to any references to the EU therein, in helping food businesses to comply with the relevant regulatory framework for food supplements.

The NIP means that EU legislation relating to food supplements will continue to be directly applicable in Northern Ireland.

Given this, existing UK guidance on food supplements (https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs) remains relevant and useful in helping food businesses to comply with EU regulations on food supplements, when read alongside the updates in this document relevant to Northern Ireland, such as modifying Annex of the Directive 2002/46/EC in the European Union and Northern Ireland.

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 into the Nutrition (Amendment etc) (EU Exit) Regulations 2019 as Schedules

to ensure that they continue to have effect in GB.

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 the footnotes in the Annex 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 the footnotes in the Annex 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 2019 provides for the appropriate GB 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 consideration for use in the GB market by the appropriate UK authorities to the DHSC mailbox (which will centrally coordinate dossiers for all 3 GB nations).

The UK government and Devolved Administrations in Wales and Scotland 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 (https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out100_en.pdf) produced by the European Commission and submitted to the DHSC mailbox (which will centrally co-ordinate dossiers).

Risk assessment

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

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

Risk management

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

Modifying annex of the Directive 2002/46/EC in the EU and Northern Ireland

Following the end of the transition period GB will have its own list of vitamins and minerals for use in food supplements and modification processes.

Food business operators wishing to add vitamins and minerals to food supplements in the EU or Northern Ireland following the end of the transition period must continue to comply with the un-amended requirements of Annex of the Directive 2002/46/EC and/or Food Supplements Regulations (Northern Ireland) 2003.

We recommend that food business operators who wish for additional of vitamins and minerals and their sources to be included in the Annex of the Directive 2002/46/EC, which applies to the EU and Northern Ireland, from 1 January 2021 refer to the extensive Food supplements (https://ec.europa.eu/food/safety/labelling_nutrition/supplements_en), specifically administrative guidance on submissions for safety evaluation of substances added for specific nutritional purposes in the manufacture of foods.

Appendix A: mailboxes and document locations

Nutrition legislation mailbox

nutritionlegislation@dhsc.gov.uk

All dossiers and queries related to:

- vitamins, minerals, and certain other substances
- FSG
- food supplements

Nutrition and health claims mailboxes

Great Britain

nutritionandhealthclaims@dhsc.gov.uk

All applications and queries related to nutrition and health claims in the United Kingdom should be directed to this mailbox.

England

nutritionandhealthclaims@dhsc.gov.uk

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

Scotland

nutritionandhealthclaims@fss.scot

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

Wales

NutritionAndHealthClaims@gov.wales

HoniadauAmFaethiadAcIechyd@llyw.cymru

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

GB lists and registers locations

See Post-transition period information for the health and care sector (https://www.gov.uk/government/collections/planning-for-a-possible-no-deal-eu-exit-information-for-the-health-and-care-sector)

All GB 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 DHSC's document collection for the end of the transition period.

Please note: GB lists and Registers will be uploaded to GOV.UK following the publication of this guidance and prior to the end of the transition period to ensure consistency with EU equivalents.

Existing UK nutrition guidance

All relevant existing guidance related to nutrition can be found in the nutrition legislation information sheet (https://www.gov.uk/government/publications/nutrition-legislation-information-sources/nutrition-legislation-information-sheet).

Appendix B: lists and registers

EU register / list	GB register
Community Register of Nutrition and Health Claims Made on Food	Great Britain Nutrition and Health Claims Register
Annex to Community Register of health claims for which the protection of proprietary data has been granted	Annex to Great Britain Nutrition and Health Claims Register of Health Claims Authorised on the basis of Proprietary Data
N/A	List of Article 13.1 'on-hold' Health Claims
Community Register of Vitamins, Minerals, and Certain Other Substances	GB Register of Vitamins, Minerals, and Certain Other Substances
Union List (Annex to Regulation (EU) No. 609/2013)	Great Britain List (Annex to retained Regulation (EU) No. 609/2013)

Appendix C: generic descriptors application contents

1. Mandatory information

The application shall consist of the following:

1.1. A summary of the application that shall include:

- the name and the address of the applicant
- the generic descriptor subject to the application

- a brief description of the particularity of the class of foods or beverages which the generic descriptor covers
- the nation for which the application concerning the use of the generic descriptor is made by the applicant.

1.2. Applicant:

- name, address and contact details of the food business operator submitting an application and/or of the person authorised to communicate with the appropriate authority on behalf of the applicant
- applications for the authorisation of a generic descriptor may also be submitted by trade associations, acting on behalf of their members and shall include the name, address and contact details of the trade association submitting an application and/or of the person authorised to communicate with the appropriate authority on behalf of the trade association; information about the support of the application by the members of the trade association would be desirable

1.3. The generic descriptor subject to the application:

- the generic descriptor as used in the language(s) where it is traditionally used
- a description of the generic descriptor in English, where appropriate
- the nation where the generic descriptor is used

1.4. The class of foods or beverages which the generic descriptor covers:

- an indication of the class of foods or beverages marketed under the generic descriptor for which the application is made
- a detailed description, highlighting the particularity and the elements that distinguish the class of foods or beverages marketed under the generic descriptor, for which the application is made, from other products falling within the same class of foods or beverages

1.5 Supporting data in relation to the use of the generic descriptor:

- relevant bibliographical or otherwise verifiable evidence demonstrating the presence on the market of the class of foods or beverages with the generic descriptor, over at least a 20-year period, in the nation (s), prior to the date of entry into force of this Regulation

2. Additional information that must be provided if requested on the Appropriate Authority's initiative: supporting data in relation to the understanding/perception of the consumer

Recipient appropriate authority and the appropriate authorities concerned may require the additional data by the applicant on the following types of information, prior to the submission of the application to the appropriate authority, where they consider it necessary for the assessment of the application:

- relevant evidence or information related to consumer understanding and perception of the effects that could be implied by the generic descriptor. Such data shall cover the nations where the generic descriptor is used
- relevant evidence or information demonstrating that the consumer links the generic descriptor with the specific class of foods or beverages mentioned in point 1.4 of this part of the Annex

3. Any additional information (optional)

Print this page