



Nutrition Related Labelling, Composition and Standards Provisional Common Framework

Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

October 2020





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NUTRITION RELATED LABELLING, COMPOSITION, AND STANDARDS COMMON FRAMEWORK

PART A: OUTLINE

1 Introduction

- 1.1 This framework sets out arrangements for co-operation between officials in the Department for Health and Social Care (DHSC), Food Standards Scotland (FSS), Welsh Government (WG) and the Food Standards Agency (FSA) ('the parties') with regard to nutrition related labelling, composition, and standards (NLCS) policy.
- 1.2 The framework respects: devolution settlements; established constitutional conventions and practices; and the overarching [Devolution: Memorandum of Understanding](#) as it stands (currently under review) between the UK Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive.
- 1.3 Officials from Northern Ireland Civil Service (NICS), including the FSA have engaged in the common frameworks process where the policy area intersects with the devolved competence of the Northern Ireland Assembly. However, during the absence of the Northern Ireland Executive, officials' input had been limited to analysis and factual responses only.
- 1.4 References within this framework to the development of future framework arrangements are without prejudice to the views of the NI Executive Ministers as [input has up to now been limited due to previous absence of the Executive](#). Similarly; references to commitments made by the devolved administrations should be taken to mean the Scottish Government and Welsh Government and not the views of the NI Executive.

2 Terms of Agreement: High Level Principles

- 2.1 Ministers in the UK, Scottish and Welsh Governments have agreed at JMC(EN) that their officials should work together to examine, in detail, possible arrangements for common framework for NLCS policy (see Appendix I). Despite the absence of the Northern Ireland Executive, civil servants in Northern Ireland have also been involved.
- 2.2 This framework supports the continuation of good practice among the four administrations and will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU.
- 2.3 In delivering the arrangements set out in this framework, the parties agree to adhere to the following high-level principles:

- 2.3.1 The devolution settlements of all administrations and the democratic accountability of the devolved governments will be respected, including the provisions of the Belfast Agreement, with the inclusion of the North/South dimension highlighted in Strand 2 of that Agreement. Current devolution agreements will be preserved; this agreement will provide for full and continuing involvement of the Welsh/Scottish/NI Ministers and their officials in the processes of policy formulation, negotiation and implementation, for issues which touch on devolved matters in accordance with the [Devolution: Memorandum of Understanding](#) (currently under review).
- 2.3.2 Open communications will be maintained, and information shared, to the extent permitted by law, at the earliest appropriate opportunity. This may include but is not confined to: policy issues; stakeholder views; preparations for, and outcomes of, consultations and research; media interest and lines to take; emerging issues and intelligence; local authority or enforcement issues, and food crime.
- 2.3.3 All parties agree to respect the dispute resolution outlined Part D Section 6, when agreement cannot be reached at policy level).
- 2.3.4 In relation to Scotland and Northern Ireland the boards of Food Standards Scotland and the Food Standards Agency will consider advice and evidence available, as appropriate, to provide recommendations and finalise advice prior to informing respective Ministers/Permanent Secretary.
- 2.3.5 Discussions in relation to the development of this framework are confidential and without prejudice to Ministerial policy positions on particular issues.

PART B: OVERVIEW AND SUMMARY

1 Policy Area

- 1.1 EU legislation on nutrition related labelling, composition, and standards, covers the following areas: nutrition and health claims made on foods; the addition of vitamins, minerals, and certain other substances to foods; the composition and labelling of food supplements; the composition and labelling of food intended for infants and young children, food special medical purposes, and total diet replacement for weight control (“Foods for Specific Groups”); and the mandatory nutrition declaration (food labelling), including additional forms of expression and presentation in which it may be given (see Appendix II).
- 1.2 This framework focuses on replacing mechanisms which support current EU functions, necessary to maintain current standards, such as those related to: the authorisation of new claims; the amendment of lists and registers; or the notification of infant formula and medical foods. Existing policy flexibility should be reflected, but does not impose anything new.

2 Scope

- 2.1 **Legislation:** see Appendix II.
- 2.2 **Powers and Functions of Member States and EU Bodies:** responsibilities, powers, and or functions currently held by Member States or EU bodies will be transferred to Ministers, the most notable of which are listed below:
 - 2.2.1 **Member State:** responsibilities regarding the: examination of notifications provided by food business operators when placing certain products onto the market; sharing of relevant information with the Commission; and suspension or restriction of a product on public health grounds.
 - 2.2.2 **European Commission:** responsibilities regarding the establishment of working groups/expert panels to provide it with advice and expertise, and registers and lists.
 - 2.2.3 **European Food Safety Authority:** responsibilities related to the establishment of Dietary Reference Values, and the publication of guidance documents (including those regarding procedural requirements) which must be adhered to; and, from time to time, updated to reflect technical, scientific, or public health developments.
- 2.3 **Intersection with devolved competency:** NLCS policy is governed by harmonised EU derived legislation (see Part B Section 2.1). The EU Regulations are directly applicable across the whole of the UK. The enforcement of these Regulations is delegated to local authorities and powers for enforcement are provided by domestic legislation in each of the four UK nations. Applicable Directives have been implemented through domestic legislation in each of the four UK nations.

- 2.4 ***Split between reserved and devolved competencies:*** whilst NLCS policy is an area of devolved competence, in accordance with the devolution settlements (Scotland Act 1998, Wales Act 2006 and Northern Ireland Act 1998); negotiation of international trade agreements remains reserved. This creates an area of overlapping interests where the negotiation of trade agreements may intersect with aspects of devolved policy areas.
- 2.5 ***Divergence:*** the framework will enable the functioning of the UK Internal Market, while acknowledging policy divergence. Policy consistency should remain where it is agreed that it is necessary or desirable, however, so too must potential for divergence, in order that administrations may respond to territory-specific needs; such as those which relate to public health. Within the current system of nutrition regulation, based on EU Directives and Regulations, there is limited scope for divergence within the UK.
- 2.6 ***Relevant international obligations and relations:*** there are no international obligations relevant to NLCS.
- 2.7 ***Other Relevant Frameworks:*** There is cross-over with other policy areas designed to protect public health, including: Food and Feed Safety and Hygiene, (FSA); and Food Labelling and Compositional Standards (Department for Environment, Food, and Rural Affairs) both of which are included in the 24 policy areas for common frameworks.
- 2.8 ***Interdependencies:*** there are no other interdependencies relevant to NLCS.
- 2.9 This Framework sets out general provisions in relation to the policy as described above. It is not intended to constitute a legally enforceable contract or create any rights or obligations which are legally enforceable.

3 Out-of-scope

- 3.1 Local enforcement is devolved and therefore an area where divergence is already possible with longstanding separate arrangements in place, which recognise the differing legal systems and arrangements for local government in the constituent nations of the UK. However, all parties agree that a level of commonality is beneficial, particularly for those businesses who operate across UK borders, therefore close collaboration between the administrations will continue.
- 3.2 Furthermore, all parties note that the Department of Environment Food, and Rural Affairs is undertaking work regarding the scrutiny of enforcement arrangements and their delivery, as the EU will audit (the) UK (nations) as a 3rd party. All parties therefore need to ensure they can satisfy any new EU requirements at the end of the transition period (TP).

4 Definitions

- 4.1 ***Foods for Specific Groups:*** includes: food intended for infants and young children; food for special medical purposes; and total diet replacement for weight control.

- 4.2 **Local:** There is no legal definition of "local" in food labelling. But the food law code of practice states that it should mean "sales within the supplying establishment's own county/local authority area plus the greater of either the neighbouring county/local authority area or counties/local authority areas or 30 miles/50 kilometres from the boundary of the supplying establishment's county/local authority". (in Northern Ireland this may also include neighbouring counties of Northern Ireland and the Republic of Ireland). This definition is therefore consistent with that in the Local Authority Approvals Guidance. The definition has been in place for a number of years now and is a definition agreed by NI.
- 4.3 **Risk analysis:** is a process consisting of three interconnected components: risk assessment, risk management, and risk communication.
- 4.4 **Risk assessment:** is a scientifically based process constituting of four steps: hazard identifications, hazard characterisation, exposure assessment and risk characterisation.
- 4.5 **Risk management:** is the process, distinct from risk assessment, of weighing policy, alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and if need be, selecting appropriate prevention and control options.
- 4.6 **Risk communication:** is the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

PART C: SUMMARY OF PROPOSED APPROACH

1 Purpose and General Principles

- 1.1 This framework recognises the shared view of all parties that a common framework is highly desirable across UK, to ensure the functioning the UK internal market, while acknowledging policy divergence; and to ensure any future trade arrangements can be done on a UK basis whilst recognising the common frameworks principles agreed at JMC(EN) in the Committee's communique of 16 October 2017 (see Appendix I)
- 1.2 There is currently good information flow and shared surveillance across the UK. It is agreed that a common approach to ensure effective surveillance and information sharing across all areas is desirable to continue to provide effective health protection. Any amendment to this framework should support the continuation of this. The Knowledge Hub is good example of current good practice.

2 Legislative Approach

- 2.1 The arrangements within this agreement do not require additional legislation.
- 2.2 A concordat between UKG, SG, WG, and NIE provides the basis for managing and maintaining commonality in approach and minimum standards as well as surveillance and sharing of information. The concordat sets out agreements including governance arrangements. The dispute resolution process (see Section D Part 6) is sufficient to cover nutrition legislation including any necessary detail or any other areas that need to be addressed. Working arrangements (both existing and new) are established and formalised for collaboration and coordination between all four administrations.

3 Collaborative Working

- 3.1 There is a need for continued robust policy development with the involvement of, and technical expertise from, all four administration, including the need to fully assess the potential impacts of legislative changes on all affected stakeholders.

4 Seeing the Bigger Picture

- 4.1 It is recognised that the consideration of links with other government departments, such as the FSA and DEFRA, and future governance around decision making related to modifications to retained EU law is necessary. Arrangements in this framework link to/reflect other relevant frameworks relating to general food labelling and composition, for example those which cover: Regulation (EU) No. 1169/2011 on the provision of food information to consumers; Regulation (EC) No. 396/2005; Regulation (EU) No. 2015/228 on maximum residue level of pesticides in or on food and feed of plant and animal origin.

5 Risk Assessment and Management

- 5.1 A consistent approach and process to businesses and enforcement authorities across the UK where appropriate will be delivered to ensure a consistent standard of safety (where relevant) to consumers across the UK. Procedures to manage relevant application, assessment and common recommendation¹ making processes have been developed.
- 5.2 Risk assessment processes agreed between the parties are independent and free from undue influence.
- 5.3 The parties will work together via the newly established NLCS Policy Group (see Part D Section 1) to develop common approaches for changes to NLCS policy within scope of this framework and agree common recommendations.
- 5.4 Common recommendations will take account of the impact on consumer safety and confidence, and the functioning of the UK internal market, while acknowledging policy divergence.
- 5.5 Common recommendations will be based on both scientific opinion and wider risk management considerations.
- 5.6 Where consensus cannot be reached at official level regarding a common recommendation (whether that is agreement to a UK wide approach or to diverge) the dispute resolution process (see Part D Section 6) would be triggered.

6 Divergence

- 6.1 All four administrations have the ability to diverge from generally harmonised rules within their territory, where risk assessment shows this is both necessary and proportionate, to protect consumers. Where one nation wishes to diverge from a four-nation approach, they should first consult the UK NLCS Policy Group (see Part D Section 1) to identify whether a common approach can be achieved that meets the desired outcomes, but which ensures the functioning the UK Internal Market, while acknowledging policy divergence. Where a common approach cannot be agreed, and divergence is not considered either necessary or proportionate by one or more counties in the UK (after consideration), then the dispute resolution process should be engaged.

7 Dispute Resolution

- 7.1 Dispute resolution is anticipated to only be required in a very small number of cases. However, should it be needed the following is proposed: dispute resolution processes (see Part D Section 6) should only be used if resolution through normal working practices (including managing divergence) has not been possible. This recognises that in some areas commonality of approach will not be needed in order to meet the JMC (EN) common frameworks principles and therefore an agreement to diverge would be acceptable. The JMC (EN) common frameworks principles are as set out under purpose and general principles in Appendix I.

- 7.2 Where disputes do arise, they should be handled in accordance with agreed principles e.g. evidence-based decision making, transparency and timely resolution.

8 Detailed Overview of Proposed Agreements: Non-Legislative Arrangements

- 8.1 It is proposed that the NLCS policy area requires (aside from the Nutrition (Amendment etc.) (EU Exit) Regulations 2019) a non-legislative common framework.
- 8.2 The a non-legislative approach applied to this framework allows for maximum flexibility to adapt where change is needed and maintains a degree of trust between the parties which serves to bolster good working relationships.
- 8.3 In relation to general principles as set out in current EU legislation, although divergence in areas where law is currently fully harmonised is unlikely, the ability to discuss and address any possible changes to the overarching principles are covered within these framework arrangements e.g. the substance must be safe, and claims/labelling must not mislead the consumer.
- 8.4 The parties agree that common principles will be applied to any future policy development, and all administrations will have an equal opportunity to influence the outcome. The framework arrangements within this framework will also link into any future arrangements for the UK Internal Market.²

¹ Common recommendations refer to risk management advice agreed by officials within the NLCS Policy Group and submitted to Ministers across the UK to ensure that all administrations receive the same information.

² Scottish Government and Cabinet Office officials continue to discuss this section.

PART D: PROPOSED OPERATIONAL ELEMENTS

1 Decision Making: NLCS Policy Group

- 1.1 A group will be formed of representatives from each of the parties to this agreement.
- 1.2 The group will decide and communicate appropriately its ways of working, addressing frequency of meetings, chairing of meetings, and the secretariat function in the terms of reference (see Appendix III).
- 1.3 The functions of the group will be to discuss and agree, in accordance with the joint decision-making process (see Appendix IV), common recommendations regarding:
 - 1.3.1 applications for new nutrition or health claims (see Appendix V); and
 - 1.3.2 requests to modify registers, lists, and schedules (see Appendix VI); and
 - 1.3.3 policy proposals within scope of this framework.
- 1.4 The group will act as a discussion forum, providing an efficient process to keep pace with development elsewhere e.g. in EU.

2 Evidence and Science

- 2.1 Subject to any future review/revision, all parties will continue to use the Reference Intakes and Dietary Reference Values set by retained EU law.
- 2.2 Equivalent lists to the current union/community lists will be published on GOV.UK (in order to present a consolidated UK list for industry and the public) – but this may also be repeated in other places for DAs with relevant links being provided in each.

3 Risk Assessment and Scrutiny

- 3.1 Measures are in place to ensure that appropriate authorities have continued access to relevant and robust scientific advice.

4 Other

- 4.1 In consulting on, clearing, and communicating policy changes with stakeholders and Ministers, and in providing guidance to businesses and enforcement bodies; both UK wide and territory specific options will be considered by all parties.
- 4.2 In relation to Scotland and Northern Ireland the role of the FSS and FSA Boards in advising Ministers will also need to be respected.
- 4.3 The FSA and FSS will wish to consider on a case by case basis whether the matter is something that their Boards will need to consider. It is expected that many of the issues considered through this process will be routine and technical; therefore, it is unlikely that in those cases the Boards would be involved before advice is provided to Ministers on these issues.

- 4.4 With regard to future EU legislative changes (including technical amendments and authorisations) parties to this agreement cannot assume mutual recognition will be in place and must therefore consider the way forward with regards as to what might best for each individual territory and the UK as a whole.

5 Roles and Responsibilities

- 5.1 All parties are responsible for sharing information with one another in relation to the scope of this agreement. This is in order to: maintain public health and consumer protection; allow for effective collaborative working; and help ensure the functioning of the UK internal market, while acknowledging policy divergence.
- 5.2 Information sharing may include but is not confined to:
- 5.2.1 policy issues;
 - 5.2.2 stakeholder views;
 - 5.2.3 preparations for and outcome of consultations and research;
 - 5.2.4 media interest and lines to take;
 - 5.2.5 emerging issues and intelligence (UK/EU/International);
 - 5.2.6 Local Authority/enforcement issues;
 - 5.2.7 food crime.
- 5.3 Information should be shared on a regular basis through planned meetings of the NLCS Policy Group or as and when required by the most suitable communication mechanisms e.g. e-mail. All parties across the UK should commit to attend regular meetings to discuss the broad and specific policies areas.
- 5.4 Parties will be responsible for actioning applications and/or requests relevant to their territories.
- 5.5 This agreement should support the continuation of existing good practice between the parties such as the sharing of information, and the maintenance of central guidance which provides consistent messaging across stakeholder groups. All parties commit to identifying stakeholders and agreeing common approaches to engagement.
- 5.6 A shared portal will be used by the parties to store applications, requests, and papers relevant to NLCS Policy Group's risk management function.
- 5.7 Relevant UKG and DA committees and other relevant bodies will need to be engaged and kept informed as appropriate.

6 Dispute Resolution

- 6.1 The dispute resolution process, set out in Appendix IV, should be only be utilised if:

- 6.1.1 agreement cannot be reached on a common recommendation regarding an application, request, or policy proposals; or
 - 6.1.2 one or more party considers the terms of reference/parameters agreed for the governance framework have been breached; or
 - 6.1.3 one party considers that a JMC(EN) principle has been broken, or undue weight has been placed on one JMC(EN) principle (or part of a principle) at the expense of another.
- 6.2 The intention is to resolve the majority of issues through the NLCS Policy Group meetings including the views of senior officials where necessary, only escalating to Ministers where official level agreement cannot be reached. The model for dispute resolution therefore takes a pyramid approach, as it is envisaged the number of cases decreasing as each stage progresses.

7 Governance

- 7.1 The NLCS Policy Group will collate quarterly information on meetings relevant to this framework, held between the parties, including supplementary information on: attendance; the nature of discussions and decisions taken; levels of divergence; and whether and to what extent the dispute resolution process has been utilised. An annual report will be submitted to Ministers and may be used to inform any reviews that take place in accordance with Part D Section 8.

8 Review and Amendment

- 8.1 The is framework will be formally reviewed six months, one year, and three years after implementation; and thereafter at three-yearly intervals from the end of the TP.
- 8.2 This framework would also be reviewed upon a NI Executive being established and may be reviewed upon request of any of the parties all of whom must participate.

PART E: PRACTICAL NEXT STEPS AND RELATED ISSUES

1 Implementation

- 1.1 Prior to implementation, all parties must be confident that the arrangements set out above are sufficient to provide assurances to ministers in all four nations facilitating their approval to the arrangements (via signing the concordat).
- 1.2 Until such a time that agreement to this framework is secured a Working Level Agreement will ensure that arrangements are in place by which all parties can work together to deliver common approaches for NLCS policy currently harmonised at EU level.
- 1.3 The enduring framework will only be put in place once there is unanimous agreement and it has thus progressed through Stage 5 of the frameworks programme to achieve full sign off from the JMC(EN). The overarching principles agreed at official level via the deep dive discussions remain in place.
- 1.4 The timetable below sets out the plans for agreeing the framework.
 - 1.4.1 **31st October 2019:** in the event that the UK withdraws from the EU without a deal having been secured, a working level agreement will be in place.
 - 1.4.2 **November 2019:** Peer Review of the framework will have taken place
 - 1.4.3 **December 2019:** FSS/FSA Boards will be sighted on the framework and Departmental ministers/Perm Sec will be asked to agree near final drafts for JMC (EN) provisional approval.
 - 1.4.4 **January 2020:** JMC(EN) provisionally sign off on the framework.
 - 1.4.5 **November 2020:** implementation of the provisional framework.
 - 1.4.6 **November 2020- January 2021:** continued refinement of this framework and underpinning concordat.

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communique - October 2017

JOINT MINISTERIAL COMMITTEE (EU NEGOTIATIONS) COMMUNIQUE

October 2017

The fifth Joint Ministerial Committee (EU Negotiations) met today in 70 Whitehall. The meeting was chaired by the Rt Hon Damian Green MP, First Secretary of State and Minister for the Cabinet Office.

The attending Ministers were:

From the UK Government: the First Secretary of State and Minister for the Cabinet Office, Rt Hon Damian Green MP; the Secretary of State for Exiting the EU, Rt Hon David Davis MP; the Secretary of State for Wales, Rt Hon Alun Cairns MP; the Secretary of State for Scotland, Rt Hon David Mundell MP; and, Parliamentary Under Secretary of State for Northern Ireland, Lord Bourne of Aberystwyth.

From the Welsh Government: Cabinet Secretary for Finance and Local Government, Mark Drakeford AM.

From the Scottish Government: the Minister for UK Negotiations on Scotland's Place in Europe, Michael Russell MSP.

In the absence of Ministers from the Northern Ireland Executive, a senior civil servant from the Northern Ireland Civil Service was in attendance.

The Chair opened the meeting by summarising the bilateral engagement and political developments that had taken place since JMC(EN) last met. The Secretary of State for Exiting the EU provided an update on the previous rounds of negotiations with the EU and the Committee discussed forthcoming priorities and the future relationship with the EU. The Committee discussed the establishment of common frameworks.

Ministers noted the positive progress being made on consideration of common frameworks and agreed the principles that will underpin that work (attached).

Common Frameworks: Definition and Principles

Definition

As the UK leaves the European Union, the Government of the United Kingdom and the devolved administrations agree to work together to establish common approaches in some areas that are currently governed by EU law, but that are otherwise within areas of competence of the devolved administrations or legislatures. A framework will set out a common UK, or GB, approach and how it will be operated and governed. This may consist of common goals,

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communiqué - October 2017

minimum or maximum standards, harmonisation, limits on action, or mutual recognition, depending on the policy area and the objectives being pursued. Frameworks may be implemented by legislation, by executive action, by memorandums of understanding, or by other means depending on the context in which the framework is intended to operate.

Context

The following principles apply to common frameworks in areas where EU law currently intersects with devolved competence. There will also be close working between the UK Government and the devolved administrations on reserved and excepted matters that impact significantly on devolved responsibilities.

Discussions will be either multilateral or bilateral between the UK Government and the devolved administrations. It will be the aim of all parties to agree where there is a need for common frameworks and the content of them.

The outcomes from these discussions on common frameworks will be without prejudice to the UK's negotiations and future relationship with the EU.

Principles

1. Common frameworks will be established where they are necessary in order to:
 - enable the functioning of the UK internal market, while acknowledging policy divergence;
 - ensure compliance with international obligations;
 - ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
 - enable the management of common resources;
 - administer and provide access to justice in cases with a cross-border element;
 - safeguard the security of the UK.
2. Frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:
 - be based on established conventions and practices, including that the competence of the devolved institutions will not normally be adjusted without their consent;
 - maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules;
 - lead to a significant increase in decision-making powers for the devolved administrations.

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communique - October 2017

3. Frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK that shares a land frontier with the EU. They will also adhere to the Belfast Agreement.

APPENDIX II: Legislation in-scope

TABLE I: LEGISLATION IN-SCOPE

Issue	Definition and Scope	Legislation and Dates of Compliance	Nation Specific Derogation
Nutrition and Health Claims	Regulation (EC) No 1924/2006 on nutrition and health claims made on foods sets out what nutrition and health claims are and sets conditions for their use. Only nutrition claims that are listed in the Annex are permitted, and any health claims must be authorised. The Regulation establishes general principles for claims, such as that they must not: be false/misleading, encourage/condone excess consumption of a certain food, or suggest that varied and balanced diets cannot provide insufficient nutritional value. It allows for the setting of nutrient profiles as a condition for the use of nutrition or health claims. The regulation covers the role of the Commission and the European Food Safety Authority (EFSA), in authorising claims, as well as safeguarding measures etc.	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. <i>Compliance date:</i> 1 July 2007.	None
Vitamins, Minerals, and Certain Other Substances	Regulation (EC) No 1925/2006 covers vitamins and minerals that can be added to foods. Only those vitamins and minerals listed in Annex 1 to the Regulation, in the forms listed in Annex 2 to the Regulation may be added. This Regulation allows for the setting of purity criteria for vitamins and minerals, outlines the conditions for the addition of vitamins and minerals including allowing maximum and minimum amounts to be set, labelling and advertising restrictions, allows for the prohibition of or conditions for the addition of substances to food, and establishes a register of the vitamins and minerals that may be added to foods. It also contains safeguard procedures in case of a Member State's concerns about an impact on public health. Please note: This regulation covers minimum standards for fortification where voluntary fortification is introduced, such as in breakfast cereals. Nation-specific derogation also permits mandatory	Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. <i>Compliance date:</i> 1 July 2007.	Article 11 of 1925/2006 states that: Member States must inform the Commission of existing national provisions on the mandatory addition of vitamins and minerals by 19 July 2007. If the Member State deems it necessary to adopt new legislation on the mandatory addition of vitamins and minerals or the prohibition/restriction on the use of certain other substances, it shall notify the Commission and take the measures only six months following the notification (and an affirmative response).

APPENDIX II: Legislation in-scope

	fortification under certain circumstances. In the UK, mandatory fortification is stipulated in the Bread and Flour Regulations 1998 (in Northern Ireland equivalent regulations are the Bread and Flour Regulations (Northern Ireland) 1998), and the Spreadable Fats (Marketing Standards) and the Milk and Milk Products (Protection of Designations) Regulations 2008 1998 (equivalent regulations apply in the DA's), which require those manufacturers to fortify their products to certain standards set by UKG The SI for England was amended in 2013 to remove the need to fortify margarine with Vitamins A & D. This remains in place for the other 3 parts of the UK		
Food Supplements	<p>Directive 2002/46/EC covers: the permitted list of vitamins and minerals used as ingredients of food supplements, their minimum and maximum values, labelling presentation, permitted notification requirements, and safeguarding measures.</p> <p>Please note:</p> <p>Food supplements must also comply with the general food labelling requirements.</p>	<p>Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.</p> <p>Compliance date: 12 July 2002.</p>	<p>Article 4(6) of Directive 2002/46/EC states that: Member States may allow use of vitamins and minerals not listed in Annex I on certain conditions (see article 4 (6)(a) and (6)(b)). This stipulation expired 31 December 2009.</p>
Foods for Specific Groups	<p>Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The regulation covers how relevant products are placed on the market, scientific opinions of the authority, general composition and information requirements and technical guidelines. Labelling must not be misleading to the consumer or attribute to the food the property of preventing, treating or curing a human disease.</p> <p>Infant formula and follow-on formula requires labelling, presentation and advertising to be designed so that it does not discourage breastfeeding, nor include picture or text idealising its usage. See the legislation column (right) for repealed directives and regulations.</p>	<p>Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.</p> <p>This repeals:</p> <p>Council Directive 92/52/EEC Commission Directive 96/8/EC Commission Directive 1999/21/EC Commission Directive 2006/125/EC Commission Directive 2006/141/EC Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No</p>	None

APPENDIX II: Legislation in-scope

	<p>Commission Directive 2006/141 on infant formulae and follow on formulae (in force until 21/02/20).</p> <p>Commission Directive 1996/08 on foods intended for use in energy restricted diets for weight reduction (in force until 27/10/22).</p> <p>Commission Directive 1999/21 on food for special medical purposes (in force until 21/02/19 and partly in force until 21/02/20).</p> <p>Commission Directive 2006/125 on processed cereal based foods and baby foods for infants and young children.</p> <p>Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.</p> <p>Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes.</p>	<p>41/2009 and (EC) No 953/2009.</p> <p>In force from: 20 July 2016, apart from Articles 11, 16, 18, and 19 which were in force from 19 July 2013.</p> <p>Commission Directive 2006/141 came into force on 19 January 2007.</p> <p>Commission Directive 1996/8 came into force on 26 March 1996.</p> <p>Commission Directive came into force on 27 April 1999.</p> <p>Commission Directive 2006/125 came into force on 26 December 2006.</p> <p>Commission Delegated Regulation (EU) 2016/127 will come into force over 2019-2020, replacing the directives named in 2, 3, 4, and 5 in the definition and scope column.</p> <p>Commission Delegated Regulation (EU) 2016/128 will come into force over 2019-2020 in accordance with requirements set out in Regulations (EU) 609/2013, replacing the directives named in 2, 3, 4, and 5 in the definition and scope column.</p>	
Nutrition Declaration	<p>This covers general food labelling rules, essentially as set out in EU 1169/2011 food information to consumers (FIC) Regulations. These include areas mainly relating to the Department for Environment, Food & Rural Affairs (DEFRA) including origin labelling, presentation of ingredients, exemptions, meat content etc and as a result DEFRA has the lead on general food labelling.</p> <p>Nutrition, which is led by the Department of Health and Social Care (DHSC), is covered in EU 1169/2011 Section 3, articles 29-35. These regulations relate to the</p>	<p>Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.</p> <p>Compliance dates: 13 December 2014, except for nutrition declarations which applied from 13 December 2016, following a two-year transition.</p>	None

APPENDIX II: Legislation in-scope

	<p>majority of prepacked food, covering: mandatory back-of-pack labelling and additional forms of expression, calculation and expression of nutritional content, and labelling presentation. It also covers the expression of voluntary nutrition information including repeat nutrition labelling on the front of prepacked foods, nutrition labelling on non-prepacked foods, and nutrition (energy) labelling for alcoholic drinks.</p> <p>Please note: EU 1169/2011 legislation in England belongs to DEFRA but the nutrition aspect is led by DHSC.</p> <p>Food supplements and natural mineral waters are excluded (these are covered by Directive 2002/46/EC and Directive 2009/54/EC respectively).</p> <p>General alcohol labelling is under DEFRA's jurisdiction. Existing mandatory elements will be carried over with replacement mechanisms where appropriate being covered in the Concordat</p>		
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APPENDIX III: NLCS Policy Group Terms of Reference

NLCS POLICY GROUP TERMS OF REFERENCE

Membership

- A lead official from each nation will be nominated participate in meetings of the four-nation nutrition group in accordance with the Framework Agreement and Concordat. This official, or any delegate they nominate, will be suitably informed so that they may participate in proceedings.
- A senior [G5/C3 or equivalent] official from each nation will be nominated to participate in official level dispute resolution meetings

Purpose

- Manage and mitigate risk management considerations / issues that arise in relation to nutrition policy. For clarity the roles, responsibilities and expectations for each stage of the process (areas of interaction between official level processes (both requirements under the framework and policy development processes) and the Ministerial decision-making process) are set out from Appendix IV onwards onward.
- Ensure the functioning of the UK's internal market whilst respecting the devolution settlements and common frameworks principles agreed at JCM (EN) (or parts thereof).
- Designate appropriate committee to provide opinion on applications for new substances to be added to existing lists/Annexes.
- Evaluate nutrition and health claim applications/requests for amendments to lists/annexes taking into account the opinion of the relevant expert committee.
- To agree common recommendations for ministers for decision in all four nations on most suitable approach.

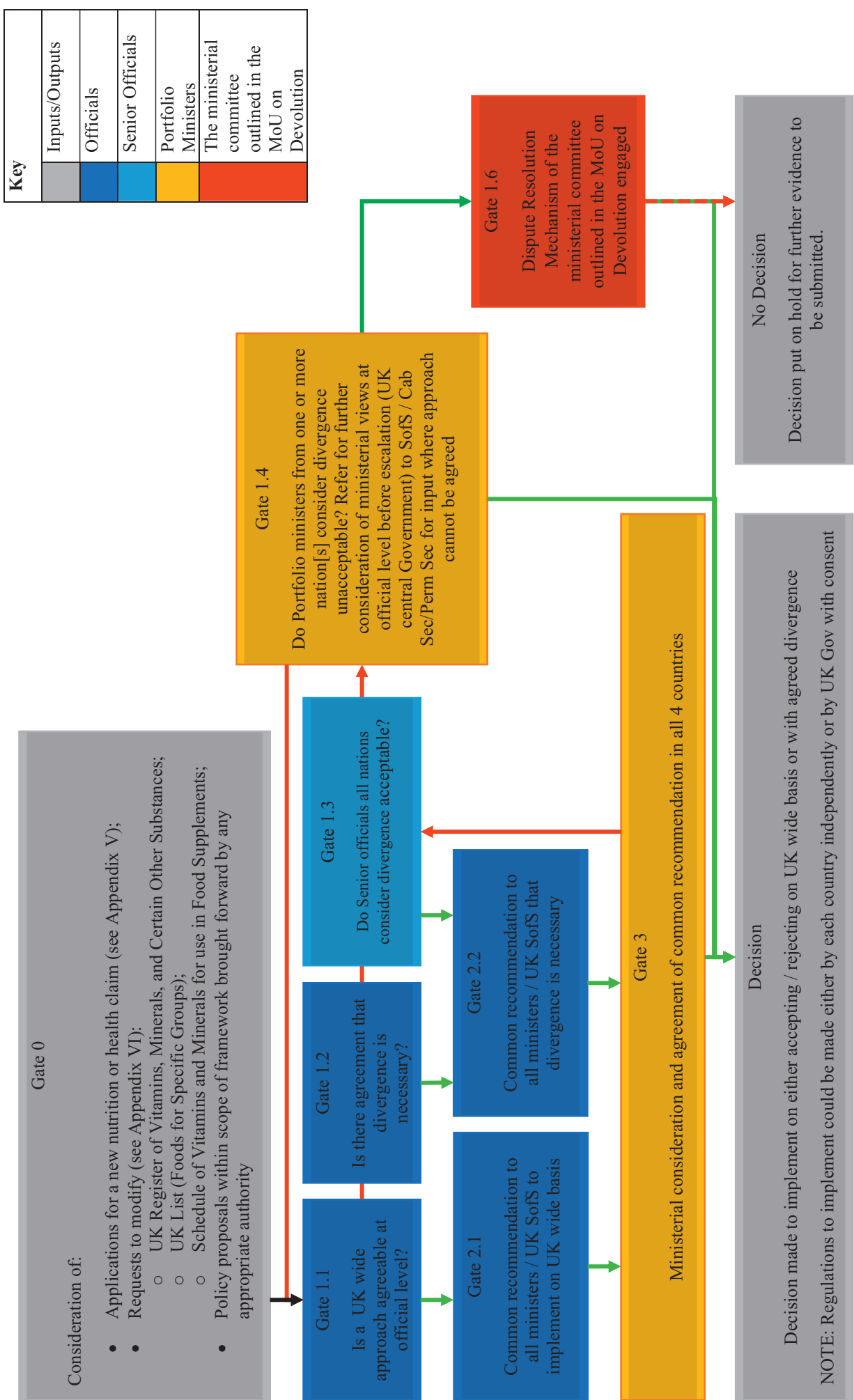
Inputs

- Applications for new nutrition or health claims; requests to modify UK lists or registers; policy proposals within scope of framework.
- Intelligence from four nation Officials based on wider knowledge / meetings with industry which may impact upon UK nutrition policy.

Outcomes

- Achieve consensus on risk management decisions, collectively recommending proposals to respective ministers, supporting joint decision making where appropriate.
- Achieve commonality across the UK in nutrition policy and legislation where appropriate.
- Maintain collaborative working relationships between the four nations of the UK by ensuring proper communication between relevant officials and organisations.

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes



APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

TABLE I: JOINT DECISION-MAKING PROCESS

Gate	Summary	Process	Suggested Framework Requirements	Impact on Policy Development Process
0	<p>In accordance with (SECTION.FRAMEWORK) order to ensure the timely consideration of applications, requests, and policy proposals the NLCS Policy Group will convene at regular intervals, by any appropriate means.</p> <p>The NLCS Policy Group will consider:</p> <ul style="list-style-type: none"> • Applications for new nutrition or health claims*; • Requests to modify: <ul style="list-style-type: none"> ◦ UK Register of Vitamins, Minerals, and Certain Other Substances*; ◦ UK List (Foods for Specific Groups); ◦ Schedule of Vitamins and Minerals for use in Food Supplements; • Policy proposals within scope of framework brought forward by any appropriate authority. • *Legislative and timing obligations for risk management decisions: <ul style="list-style-type: none"> ◦ Risk management decisions must be taken on applications for Article 13.5 health claims, which are based on newly developed scientific evidence or include a request for the protection of proprietary data, within two months of receiving the opinion of the committee. ◦ Within four years of a substance being listed in Annex III Part C of retained Regulation (EC) No. 	<p>For:</p> <ul style="list-style-type: none"> • Applications for new nutrition or health claim see PART C; • Industry requests to modify: <ul style="list-style-type: none"> ◦ UK Register of Vitamins, Minerals, and Certain Other Substances; or ◦ UK List (Foods for Specific Groups); or ◦ Schedule of Vitamins and Minerals for use in Food Supplements see Part D; • Policy proposals within scope of framework brought forward by any appropriate authority see Part E. 	<p>Commitment in Concordat that applications to any of the four nations are submitted via DHSC mailbox.</p> <p>Commitment in Concordat around timings i.e. sharing relevant information, meeting to agree appropriate committee.</p>	N/A

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

	<p>1925/2006, as amended, the appropriate UK authorities must, decide whether to generally allow the substance in question or add it to the list in Annex III Part A or Part B.</p> <ul style="list-style-type: none"> Please note that all request other than those which concern new nutrition or health claims or modifications to Annex III Part C of retained Regulation (EC) No. 1925/2006, as amended, are not legislative requirements. Requests been permitted to submit these applications in order to maintain continuity with current EU procedure. 			
1.1/1.2	<p>Scientific opinion rec'd and any wider risk management issues considered with aim of reaching a consensus for common recommendation to ministers - 4 nation NLCS Policy Group consideration.</p>	<p>Meetings can be face to face, by telephone or video conference</p> <p>In exceptional circumstance e.g. cases of urgency - email exchange.</p>	<p>Commitment in Concordat around timings i.e. meeting to agree way forward – at least bi-monthly to align with UKNHCC outputs.</p>	
2.1/2.2	<p>All four nations submit same common recommendations to Ministers for decision (either for common approaches across the UK or divergent approaches).</p> <p>Where agreement cannot be reached at official level issues is referred to gate 1.3 (Table II) to consider any alternative approach at snr official level.</p>	<p>Officials submit risk management common recommendations, informing Ministers of the approaches being recommended across all four countries.</p> <p>If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge.</p>	<p>Commitment in Concordat that all four nations' common recommendations are communicated to Ministers in all four nations.</p> <p>Commitment in Concordat around timings i.e. ensuring common recommendations go to Ministers at approximately the same time.</p>	<p>Requirement to inform Ministers of the common recommendation being made in all parts of the UK included in framework.</p> <p>If divergence is being proposed, explanation to Ministers in risk management common recommendations of why divergent approaches are being proposed and why the proposed divergence is acceptable provided.</p> <p>Recommendations for the implementation of the decision</p>

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

				(consideration of legislative mechanism, commencement dates etc.) included in common recommendation.
3	Ministers receive risk management common recommendation seeking decision. Officials will be asking Ministers to agree to the recommended approach.	<p>Each Minister considers the common recommendation individually and provides a response to their officials. Ministers can only take a decision for own territory, albeit with the knowledge/context of what is happening in the other 3 nations (or UK SoFS for whole of UK with consent).</p> <p>If the approach being recommended is NOT agreed by ministers revert to Gate 1.3 (Table II) to consider any alternative approach.</p> <p>Where necessary - Officials submit revised risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four nations.</p> <p>If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK, proceed to Decision.</p>	<p>Commitment in Concordat that Ministers' feedback on common recommendations is shared among officials in all four nations.</p> <p>Commitment in Concordat that Ministers provide a response within a specified time / a reasonable time.</p>	<p>Policy officials in all four nations informed by their respective private offices of the decisions taken by Ministers.</p> <p>Policy officials in all four nations share information on Ministers' decisions.</p>
Decision (portfolio Minister level)	Ministers reach agreed decision on common recommendations.	<p>Private offices inform officials in their own respective nations of decision to implement agreed approach.</p> <p>Policy officials in all four nations share information on Ministers' decisions.</p>	Commitment in Concordat to proceed with implementation of decisions at same time.	Policy officials in all four nations (or in appropriate competent authority) take steps to implement decision in a timely way.

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

TABLE II: DISPUTE AVOIDANCE PROCESS

Gate	Summary	Process	Suggested Framework Requirements	Impact on Policy Development Process
1.3 (Senior Official Level)	The issue requires further discussion.	<p>Dispute Avoidance initiated.</p> <p>Pause work progressing implementation of Ministerial decision until differences resolved.</p> <p>Senior officials from all four nations meet to consider ministerial views and determine whether there is any additional information available to support an agreed approach revert to Gate 1.3 (Table II) to consider any alternative approach.</p> <p>Officials submit risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four nations.</p>	<p>Commitment in Concordat for POs to inform policy officials in all four nations that the issue is being escalated to the dispute resolution process.</p> <p>Commitment in Concordat not to proceed with implementation of decisions when dispute avoidance process initiated.</p>	<p>Requirement to inform Ministers of the common recommendation being made in all parts of the UK included in framework.</p> <p>If divergence is being proposed, explanation to Ministers in risk management common recommendations of why divergent approaches are being proposed and why the proposed divergence is acceptable provided.</p> <p>Recommendations for the implementation of the decision (consideration of legislative mechanism, commencement dates etc.) included in common recommendation.</p>
2.2 (official level)	All four nations submit same common recommendations to Ministers (either for common approaches across the UK or divergent approaches).	<p>Officials submit further/revised common recommendations, informing Ministers of the approaches being recommended across all four nations.</p> <p>If recommended approach differs across the UK, officials provide explanation and a summary rationale setting out why it is appropriate to diverge.</p> <p>If the approach being recommended is NOT agreed by ministers revert to Gate</p>	<p>Commitment in Concordat that all four nations' common recommendations are communicated to Ministers in all four nations.</p> <p>Commitment in Concordat around timings i.e. ensuring</p>	<p>Pause work progressing implementation of Ministerial decision until differences resolved.</p> <p>Requirement to inform Ministers of the common recommendation being made in all parts of the UK included in framework.</p>

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

		1c (Table 2) to consider any alternative approach. Where necessary - Officials submit revised risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four nations.	common recommendations go to Ministers at approximately the same time. Commitment in Concordat not to proceed with implementation of decisions when dispute avoidance initiated.	If divergence is proposed, explanation with rationale to Ministers of why divergent approaches are recommended. Recommendations for the implementation of the decision (consideration of legislative mechanism, commencement dates etc.) included in common recommendation.
3 (portfolio minister level)	Ministers receive risk management common recommendation seeking decision.	Each Minister considers the common recommendation individually and provides a response to private offices. If the approach being recommended is NOT agreed across the UK, proceed to Gate 1.3 (Table II). If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK, proceed to Decision.	Commitment in Concordat that Ministers' feedback on common recommendations is shared among officials in all four nations. Commitment in Concordat that Ministers provide a response within a specified time / a reasonable time.	Policy officials in all four nations informed by their respective private offices of the decisions taken by Ministers. Policy officials in all four nations share information on Ministers' decisions.
Decision (portfolio level)	Ministers reach agreed decision on common recommendations.	Private offices inform officials in their own respective nations of decision to implement agreed approach. Policy officials in all four nations share information on Ministers' decisions.	Commitment in Concordat to proceed with implementation of decisions at same time.	Policy officials in all four nations (or in appropriate competent authority) take steps to implement decision in a timely way.

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

TABLE III: DIPPUTE RESOLUTION PROCESS

Gate	Summary	Process	Suggested Framework Requirements	Impact on Policy Development Process
1.4 Portfolio Minister level	The issue requires further discussion.	<p>Dispute Resolution initiated.</p> <p>Pause work progressing implementation of Portfolio ministers/SofS / Cab Sec / Perm Sec level decision until differences resolved.</p> <p>Officials submit further/revised common recommendations, informing Ministers of the approaches being recommended across all four nations.</p> <p>Where consensus cannot be agreed at junior minister level SofS / Cab Sec / Perm Sec level consider common recommendations and ministerial views and determine whether there is any additional information available to support.</p> <p>If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge and why agreement has not been reached to date.</p> <p>SofS / Cab Sec / Perm Sec considers the common recommendation individually and provides a response to private offices.</p> <p>If the approach being recommended is still NOT agreed across the UK, SofS / Cab Sec / Perm Sec consider meeting to discuss/seek resolution, before proceeding to Gate 1.4 (Table IV Escalation to the ministerial committee outlined in the MoU on Devolution)</p>	<p>Commitment in Concordat for POs to inform policy officials in all four nations that the issue is being escalated to the dispute resolution process.</p> <p>Commitment in Concordat not to proceed with implementation of decisions when dispute resolution process initiated.</p> <p>Commitment in Concordat that all four nations' common recommendations are communicated to SofS / Cab Sec / Perm Sec in all four nations.</p> <p>Commitment in Concordat around timings i.e. ensuring Common</p>	<p>Pause work progressing implementation of Ministerial decision until differences resolved.</p> <p>Requirement to inform SofS / Cab Sec / Perm Sec of the recommendation being made in all parts of the UK included in framework.</p> <p>If divergence is proposed, explanation with rationale to SofS / Cab Sec / Perm Sec of why divergent approaches are recommended.</p> <p>Recommendations for the implementation of the decision (consideration of legislative mechanism, commencement dates etc.) included in common recommendation.</p> <p>if SofS / Cab Sec / Perm Sec agreement still NOT reached – continue to pause work progressing implementation of Ministerial decision until differences resolved.</p>

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

		<p>If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK, proceed to Decision.</p>	<p>recommendations go to SofS / Cab Sec / Perm Sec at approximately the same time.</p> <p>Commitment in Concordat that SofS / Cab Sec / Perm Sec 'feedback on common recommendations is shared among officials in all four nations.</p> <p>Commitment in Concordat that SofS / Cab Sec / Perm Sec provide a response within a specified time / a reasonable time.</p>	
Decision	<p>SofS / Cab Sec / Perm Sec reach agreed decision on common recommendation.</p>	<p>Private offices inform officials in their own respective nations of decision.</p> <p>Policy officials in all four nations share information on SofS / Cab Sec / Perm Sec decisions.</p>	<p>Commitment in Concordat to proceed with implementation of decisions at same time.</p>	<p>Policy officials in all four nations (or in appropriate competent authority) take steps to implement decision in a timely way.</p>

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

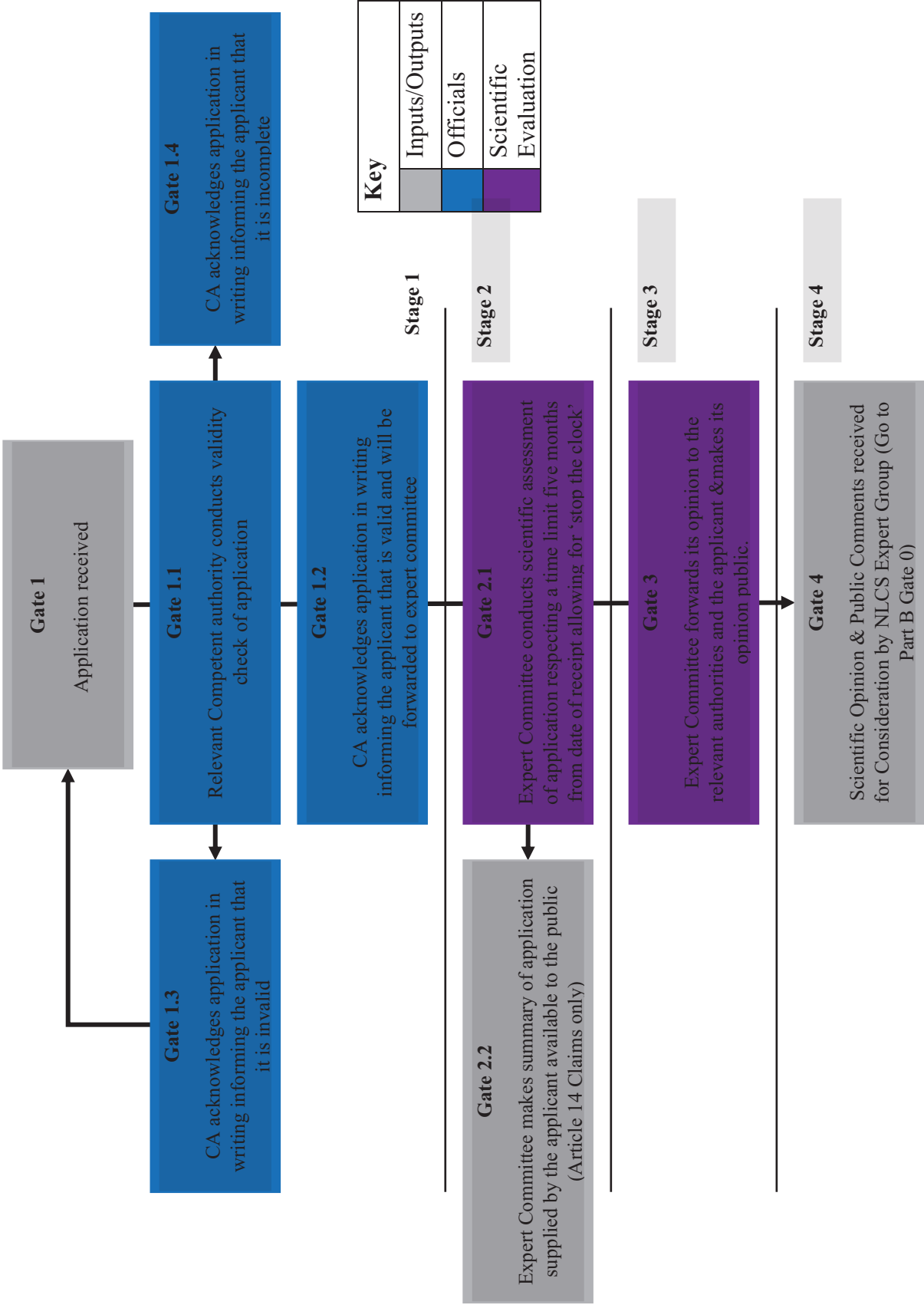
TABLE IV: DISPUTE RESOLUTION PROCESS FOR THE MINISTERIAL COMMITTEE OUTLINED IN THE MoU DEVOLUTION

Gate	Summary	Process	Suggested Framework Requirements	Impact on Policy Development Process
1.5 (THE MINISTERIAL COMMITTEE OUTLINED IN THE MoU level)	The issue requires further discussion.	<p>Escalation to highest level (the ministerial committee outlined in the MoU on Devolution) dispute resolution process initiated.</p> <p>Pause work progressing implementation of SofS / Cab Sec / Perm Sec level decision until differences resolved.</p> <p>Officials submit further/revised common recommendations, informing the ministerial committee outlined in the MoU on Devolution of the approaches being recommended across all four nations.</p> <p>The ministerial committee outlined in the MoU on Devolution consider common recommendations and SofS / Cab Sec / Perm Sec views and consider any additional information available to support decision making.</p> <p>If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge and why agreement has not been reached to date.</p> <p>The ministerial committee outlined in the MoU on Devolution considers the common recommendation individually and provides a response to SofS / Cab Sec / Perm Sec private offices.</p>	<p>Commitment in Concordat for POs to inform policy officials in all four nations that the issue is for escalation to the dispute resolution mechanism of the ministerial committee outlined in the MoU on Devolution.</p> <p>Commitment in Concordat not to proceed with implementation of decisions when dispute resolution process initiated</p> <p>Commitment in Concordat that all four nations' common recommendations are communicated to the ministerial committee outlined.</p>	<p>Pause work progressing implementation of Ministerial decision until differences resolved.</p> <p>Requirement to inform the ministerial committee outlined in the MoU on Devolution of the common recommendation being made in all parts of the UK included in framework.</p> <p>If divergence is proposed, explanation with rationale to the ministerial committee outlined in the MoU on Devolution of why divergent approaches are recommended.</p> <p>Recommendations for the implementation of the decision (consideration of legislative mechanism, commencement dates etc.) included in common recommendation. If the ministerial committee outlined in the MoU on Devolution do NOT reach.</p>

APPENDIX IV: Joint Decision-making, Dispute Avoidance, and Dispute Resolution Processes

		<p>If the approach being recommended is still NOT agreed across the UK, decision put on hold for further evidence to be submitted.</p> <p>If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK, proceed to Decision.</p>	<p>in the MoU on Devolution.</p> <p>Commitment in Concordat that the ministerial committee outlined in the MoU on Devolution feedback on common recommendations is shared among officials in all four nations.</p>	
Decision (the ministerial committee outlined in the MoU on Devolution level)	The ministerial committee outlined in the MoU on Devolution reach agreed decision on common recommendation.	<p>Private offices inform officials in their own respective nations of decision.</p> <p>Policy officials in all four nations share information on decisions of the ministerial committee outlined in the MoU on Devolution.</p>	<p>Commitment in Concordat to proceed with implementation of decisions at same time</p> <p>Policy officials in all four nations (or in appropriate competent authority) take steps to implement decision in a timely way.</p>	
No Decision (the ministerial committee outlined in the MoU on Devolution level)	The ministerial committee outlined in the MoU on Devolution cannot reach agreed decision on common recommendation.	<p>Private offices inform officials in their own respective nations of decision.</p> <p>Policy officials in all four nations share information on decisions of the ministerial committee outlined in the MoU on Devolution.</p>	<p>Commitment in Concordat not to proceed with implementation of decisions - decision put on hold for further evidence to be submitted.</p> <p>Pause work progressing implementation of Ministerial decision until SoftS decision taken on behalf of UK.</p>	

APPENDIX V: Application Process: Nutrition and Health Claims



APPENDIX V: Application Process: Nutrition and Health Claims

TABLE I: OPERATIONAL DETAIL RELEVANT TO THE APPLICATION PROCESSES FOR NUTRITION AND HEALTH CLAIMS

Summary	Stage	Process
<p>Retained Regulation (EC) No. 1924/2006, as amended, permits applications for new nutrition or health claims to be submitted to any of the appropriate authorities. <u>It is agreed that all applications should be sent to a central mailbox, managed by DHSC officials.</u></p> <p><u>It is agreed that DHSC Exchange will be used to file all applications and any supplementary materials, a lead official from each relevant authority will have access.</u></p> <p>The lead Competent Authorities for applications are, in relation to:</p> <ul style="list-style-type: none"> United Kingdom, the Department of Health and Social Care; England, the Department of Health and Social Care; Scotland, Food Standards Scotland; Wales; the Welsh Government; Northern Ireland, the Department of Health. <p>Applications will be assigned ID numbers in the following manner when filed on DHSC Exchange in relation to:</p> <ul style="list-style-type: none"> United Kingdom, UKNHC000 England, ENGNHC000; Scotland, SCOT000; Wales; WA000; Northern Ireland, NI000. 	1	<ul style="list-style-type: none"> Upon receipt of an application the appropriate authority will: <ul style="list-style-type: none"> assign the application an ID Number; promptly upload the application and supporting documentation to DHSC Exchange; and inform without delay the expert committee and relevant authorities of receipt of the application. The Competent Authority designated as lead for the application must, within 14 days from the date of receipt: <ul style="list-style-type: none"> conduct a validity check of the application*; and acknowledge receipt of an application in writing informing the applicant, and relevant authorities, whether the application is valid. The lead Competent Authority will make the application and any supporting supplementary material supplied by the applicant available to the NLCS Policy Committee via DHSC Exchange.
	2	<p>[*the Competent Authority may request that the applicant provide further information during the validity check]</p> <ul style="list-style-type: none"> Upon receipt of a notification that a valid application and supporting supplementary material is available on DHSC Exchange the expert committee will: <ul style="list-style-type: none"> retrieve the valid application and supplementary material from <u>DHSC Exchange</u>; and make a summary of application supplied by the applicant available to the public [Article 14 claims only]. The Expert Committee will conduct a scientific assessment of the application and shall respect a time limit of 5 months from the date of receipt of a valid application. <ul style="list-style-type: none"> With regards to Article 14 claims, whenever the expert committee seeks supplementary information from the applicant the time limit shall be extended by up to two months following the date of receipt of the requested information submitted by the applicant. With regards to Article 13.5 claims, the time limit may be extended by up to one month if the expert committee considers it necessary to seek supplementary information from the applicant and in such a case the applicant shall submit the requested information within 15 days from the date of receipt of the expert committee's request.
	3	<ul style="list-style-type: none"> The expert committee shall forward its opinion to the relevant authorities and the applicant by: <ul style="list-style-type: none"> uploading the report to <u>DHSC Exchange</u> and notifying the relevant authorities; and writing to the applicant. The expert committee shall make its opinion public.

APPENDIX V: Application Process: Nutrition and Health Claims

4	<ul style="list-style-type: none">• The applicant or members of the public may make comments to the competent authority via the DHSC mailbox within 30 days from publication of the opinion of the expert committee.• In order to ensure the timely consideration of applications from industry the NLCS Policy Group will convene at regular intervals, by any appropriate means.• The NLCS Policy Group Secretariat will compile a paper on the application which will include: the opinion of the Expert Committee, relevant enactments, and other relevant factors [such as comments].<ul style="list-style-type: none">• Papers will be considered at earliest opportunity* by the NLCS Policy Group where a risk management decision will be taken [see Appendix IV for further details].	

APPENDIX VI: Application Process: Vitamin, Minerals, and Certain Other Substances; Food Supplements; Foods for Specific Groups

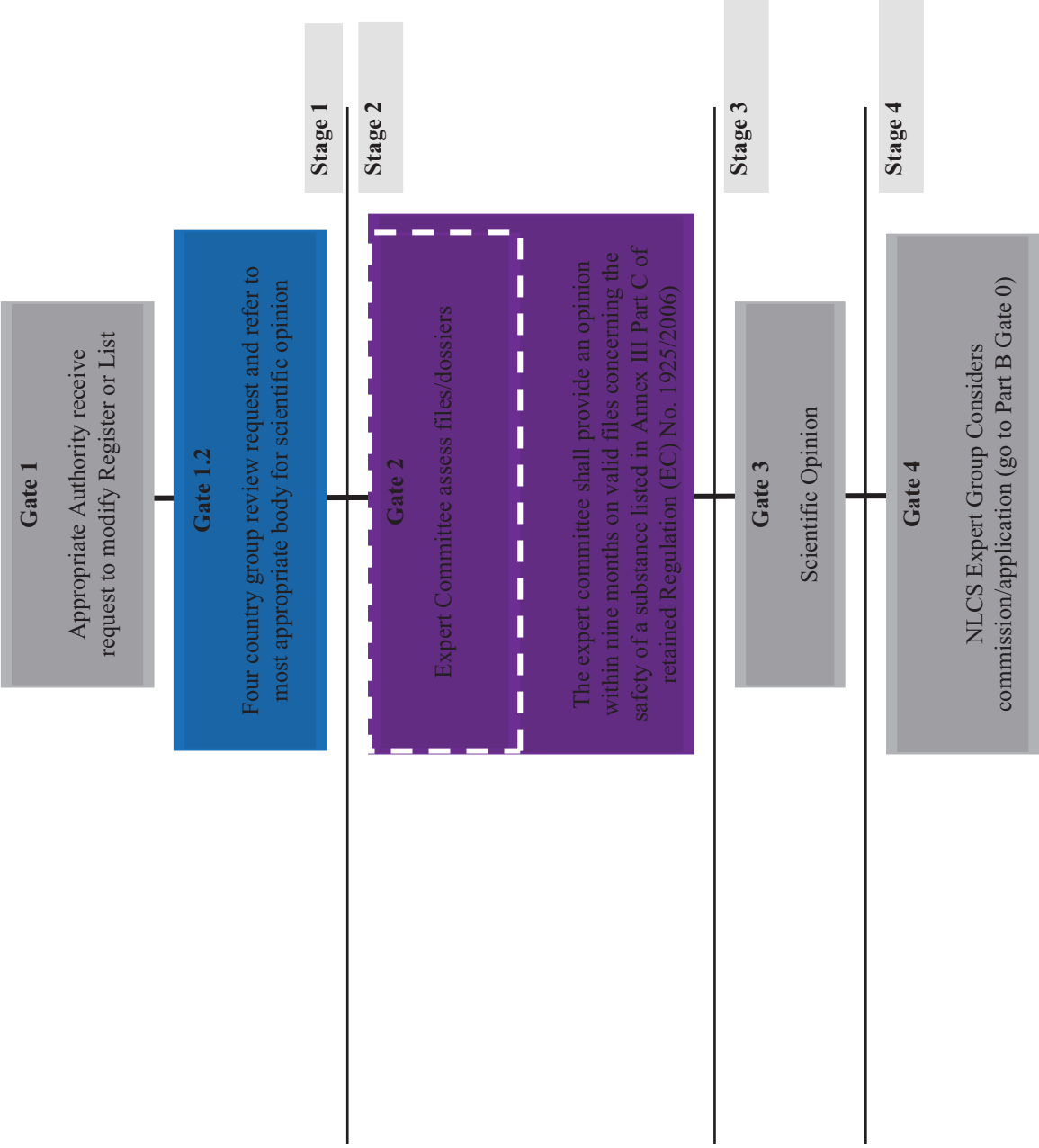


TABLE I: OPERATIONAL DETAIL RELEVANT TO THE APPLICATION PROCESSES FOR: VITAMINS, MINERALS, AND CERTAIN OTHER SUBSTANCES; FOOD SUPPLEMENTS; AND FOODS FOR SPECIFIC GROUPS

Summary	Stage	Process
<p>Retained: Regulation (EC) No.1925/2006, as amended permits food business operators, wishing to demonstrate the safety of a substance listed in Annex III Part C, to submit a file to the appropriate authorities. <u>It is agreed that all files should be sent to a central mailbox, managed by DHSC officials.</u></p> <p>Food business operators, or other interested parties, may request that a vitamin, mineral, or other substance to be included in the:</p> <ul style="list-style-type: none"> • UK Register of Vitamins, Minerals, and Certain Other Substances; or • UK List (FSGs); or • Schedules of Vitamins and Minerals for use in Food Supplements <p>And submit a scientific dossier concerning the safety and bioavailability of an individual substance for UK consideration by the appropriate authorities to the DHSC mailbox. This is not stipulated in the regulations but was an EU process, it was therefore included in guidance published on GOV.UK to provide continuity. <u>It is agreed that all files should be sent to a central mailbox, managed by DHSC officials.</u></p>	1	<ul style="list-style-type: none"> • Upon receipt of all other files/dossiers (request to modify a register, list, or schedule) the <u>appropriate authority</u> will: <ul style="list-style-type: none"> • assign the file/dossier an ID Number; • promptly upload the dossier/file to DHSC Exchange; and • inform without the appropriate authorities of receipt of the application. • The NLCS Policy Group Secretariat will compile a brief paper on the application which will include relevant enactments and other factors to support the NLCS Policy Group's consideration of the file/dossier. • If the file/dossier is concerns the safety of substance in Annex III Part C of retained Regulation (EC) No. 1924/2006 the NLCS Policy Group will identify an expert committee to conduct a scientific assessment at the earliest opportunity. • All other files/dossiers will be consider by the NLCS Policy Group at the earliest opportunity, if the group considers it appropriate it will identify a scientific committee to conduct a scientific assessment. • The <u>appropriate authority</u> file/dossier available to the Expert Committee identified by the NLCS Policy Group.
	2/3	<ul style="list-style-type: none"> • If the file is concerns the safety of substance in Annex III Part C of retained Regulation (EC) No. 1924/2006 the Expert Committee shall assess whether the file is valid for the purpose of conducting a safety assessment of the substance in question within 30 days from the receipt of the file. • If the file is not considered valid it 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. • If the file is considered valid it shall provide its opinion within nine months from the date of receipt 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 expert committee will provide its opinion to the NLCS Policy Group. • An opinion will be provided on all other files/dossiers by an appropriate Expert Committee at the earliest opportunity.

APPENDIX VI: Application Process: Vitamin, Minerals, and Certain Other Substances; Food Supplements; Foods for Specific Groups

<p>It is agreed that DHSC Exchange will be used to file all applications and any supplementary materials, a lead official from each relevant authority will have access.</p> <p>Applications will be assigned ID numbers in the following manner when filed on DHSC Exchange in relation to:</p> <ul style="list-style-type: none">• United Kingdom, UKNHC• England, ENGNHC;• Scotland, SCOT;• Wales; WA;• Northern Ireland, NI.	4	<ul style="list-style-type: none">• The NLCS Policy Group Secretariat will update the paper on the file/dossier so that it includes: the opinion of the Expert Committee and the outcomes of any consultations with interested parties.• Files (request to modify the Annex III Part C Register of Vitamins, Minerals, and Certain Other Substances) which concern the safety of substance in Annex III Part C of retained Regulation (EC) No. 1924/2006 will be considered by the NLCS Policy Group when it decides whether to generally allow the substance in question or add it to the list in Annex III Part A or Part B.• All other dossiers (request to modify a register, list, or schedule) will be considered at earliest opportunity* by the NLCS Policy Group where a risk management decision will be taken.
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Annex

NUTRITION RELATED LABELLING, COMPOSITION, AND STANDARDS CONCORDAT

Concordat between the UK Government, Scottish Government, Welsh Government, and Northern Ireland Executive

1. Introduction

- 1.1 This Concordat is an agreement between the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Executive (NIE), henceforth referred to as “the parties”.
- 1.2 This Concordat provides the non-legislative mechanism to underpin the Nutrition Related Labelling, Composition, and Standards Common Framework and sets out the principles of engagement which all parties will respect and work to.
- 1.3 Responsibility for delivery of arrangements as set out in the NCLS framework agreement is delegated to the Department of Health and Social Care (DHSC) England, Food Standards Scotland (FSS) Scotland, the Welsh Government, and the Food Standards Agency (FSA) Northern Ireland.
- 1.4 Officials from Northern Ireland Civil Service (NICS), and the FSA NI, have engaged in the common frameworks process where the policy area intersects with the devolved competence of the Northern Ireland Assembly. However, during the absence of the Northern Ireland Executive, officials’ input had been limited to analysis and factual responses only. Discussions which have taken place to date are confidential and without prejudice to either: Ministerial policy positions on particular issues; the views of the Executive Minister in Northern Ireland; or the positions of the respective administrations in relation to the European Union (Withdrawal) Act 2018.
- 1.5 Relevant NI contacts:
 - 1.5.1 NI Officials Sharon Gilmore, Nuala Meehan
 - 1.5.2 UKG Cabinet Office - [Nathan](#) Collins nathan.collins1@cabinetoffice.gov.uk
 - 1.5.3 Northern Ireland Office – Deirdre Walsh deirdre.walsh@nio.gov.uk
 - 1.5.4 NICS Executive Office - Stephen Hamilton stephen.hamilton@executiveoffice-ni.gov.uk

1.6 This Concordat establishes an agreed approach for co-operation between the parties. It operates in accordance with the principles outlined in the overarching intergovernmental [Devolution: Memorandum of Understanding](#)¹ and is consistent with, and complemented by, other guidance on common working arrangements, notably the principles described in the Joint Ministerial Committee’s communique of 16 October 2017²: That communique sets out that:

“Common frameworks will be established where they are necessary in order to:

- 1.6.1 enable the functioning of the UK internal market, while acknowledging policy divergence;
- 1.6.2 ensure compliance with international obligations;
- 1.6.3 ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
- 1.6.4 enable the management of common resources;
- 1.6.5 administer and provide access to justice in cases with a cross-border element;
- 1.6.6 safeguard the security of the UK.”

¹ *Memorandum of Understanding and Supplementary Agreements Between the United Kingdom Government, the Scottish Ministers, the Welsh Ministers and the Northern Ireland Executive Committee*, October 2013: <https://www.gov.uk/government/publications/devolution-memorandum-of-understanding-and-supplementary-agreement>

²https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652285/Joint_Ministerial_Committee_communique.pdf

- 1.7 The communiqué also states that “Frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:
- 1.7.1 be based on established conventions and practices, including that the competence of the devolved institutions and will not normally be adjusted without their consent;
 - 1.7.2 maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules;
 - 1.7.3 lead to a significant increase in decision-making powers for the devolved administrations;
- 1.8 Frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK that shares a land frontier with the EU. They will also adhere to the Belfast Agreement³”.
- 1.9 This Concordat will link into any future arrangements to enable the functioning of the UK Internal Market.⁴ [Devolution: Memorandum of Understanding](#) is currently being reviewed, depending on the outcome it may be necessary to revisit this Concordat.
- 1.10 This Concordat remains as a multilateral agreement between all the parties.

2. Scope

- 2.1 The scope of this Concordat relates to all matters for which the parties have equivalent nutrition related labelling, composition and standards or delivery responsibilities within their respective geographical areas of jurisdiction. The scope of this Concordat is confined to those retained EU Regulations within scope of the corresponding NLCS Common Framework (see Appendix II of the NLCS Common Framework). The Nutrition (Amendment etc) (EU Exit) Regulations 2019 corrects deficiencies, on behalf of the whole of the UK, in retained direct EU law relating to nutrition (as set out above) to ensure it remains workable at the end of the TP. Domestic legislation has also been amended within each administration to ensure the enforcement regimes in all UK territories remains workable at the end of the TP.
- 2.2 This Concordat sets out general provisions in relation to the policy as described above. It is not intended to constitute a legally enforceable contract or create any rights or obligations which are legally enforceable.

3. Principles for working together in relation to retained EU nutrition law

- 3.1 The parties affirm their mutual commitment to work together on the application of retained EU law in relation to NLCS policy and their respective responsibilities. This co-operation is intended to give all parties the assurance that working relationships will be conducted in a manner that is both collaborative and helpful aiming, where possible and appropriate, to achieve agreement on policy. In addition, all parties agree that regular contact will continue to discuss ongoing business of mutual interest through close liaison at official and Ministerial level.

- 3.2 This Concordat is intended to provide the basis for the management and maintenance of: common approaches; current standards; surveillance and information sharing (within the relevant legal framework e.g. Data Protection Act) by setting out governance arrangements and a dispute resolution process. All parties to the Concordat agree that a common framework approach is highly desirable across UK to enable the functioning of the UK internal market, while acknowledging policy divergence, and to ensure any future trade arrangements can be agreed on a UK basis, whilst recognising the Devolution settlements and common frameworks principles agreed at JMC(EN) in 2017.
- 3.3 Where common recommendations may be made Ministers will retain the right to take individual decisions for their administration. For those areas within the scope of the NLCS Common Framework the opportunity for consistency of approach across administrations will be sought in the first instance. The ability for divergence must be retained, while taking account of its impact on consumer safety and confidence, and the functioning of the UK internal market. Every effort will be made at working level to resolve any disagreements in difference of approach. Where a consensus cannot be reached by these arrangements (whether that is agreement to a UK wide approach or to accept divergence) the dispute resolution process would come into play.

4. Consent to the Secretary of State Acting as the Appropriate Authority

- 4.1 Where consent is required in legislation for the Secretary of State to be considered as the appropriate authority for regulations, guidelines, or registers in relation to Scotland, Wales, or Northern Ireland, separate clear agreements will be made between the relevant parties.

5. Communications

- 5.1 Principles underpinning good communications between all four administrations are outlined in paragraphs 4 to 6 of the [Devolution: Memorandum of Understanding](#) (currently under review). Open communications will be maintained and information shared, to the extent permitted by law, at the earliest opportunity. This may include but is not confined to: policy issues; stakeholder views; preparations for and outcome of consultations and research; media interest and lines to take; emerging issues and intelligence (UK/EU/International); Local Authority/enforcement issues, and food crime. To this end:

³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/136652/agreement.pdf

⁴ Scottish Government and Cabinet Office officials continue to discuss this section.

- 5.1.1 To ensure that the interests of consumers, stakeholders and others are protected across the UK, all parties agree on the importance of informing the others at the earliest opportunity of any relevant information which would require action by, or have resource consequences for, the other parties.
- 5.1.2 In the interests of good communication and for the avoidance of surprises, the parties shall keep each other fully informed of any new policy proposals before they are made public (at the earliest opportunity) in order to allow full consideration and a common approach to be reached wherever possible. "Policy proposals" include proposals for both primary and secondary legislation and for major non-statutory measures. Each party will also appraise the others of the ongoing development of such proposals. Where pressure of events prevents this, each party will inform the others as soon as possible.
- 5.1.3 The parties shall inform one-another of meetings with industry within their territories which potentially affect the policy areas covered by this Concordat, or where such meetings reveal information that might impact on other frameworks, such as procurement for example. They also agree to report back to each other about such issues, sharing any records as soon as they are available.
- 5.1.4 The parties will notify and consult each other on any proposals to change what is currently UK/GB legislation in good time before they are made public. Where pressure of events prevents this, each party will inform the others as soon as possible.
- 5.1.5 All parties agree to maintain the confidentiality of discussions and of any information shared among parties as far as is possible having regard to any legal duties on any party to disclose (paragraph 12 on confidentiality of the Devolution Memorandum of Understanding refers).
- 5.1.6 Where information is not governed by a legal duty to disclose, all parties must agree before confidential information received by one or more party to this Concordat is disclosed to anyone else.
- 5.1.7 Where there is a legal duty to disclose, each party to this Concordat will advise the others of its intentions and consider any legal argument by the one or more other parties challenging the duty to disclose all or part of the information under consideration;
- 5.1.8 These arrangements will rely for their effectiveness on mutual respect for the confidentiality of discussions and information (including statistics) exchanged.
- 5.1.9 The sharing of information relating to policy formulation will be undertaken with a view to reaching agreement between the parties. Most issues will be capable of being dealt with multilaterally between the parties or through correspondence.

- 5.2 The parties acknowledge that there may be a need for their separate responsibilities to be tackled with uniformity. For example, events could transpire that would require urgent action. Each party shall consider promptly and thoroughly any concerns raised by the others. Where all agree that consistency is needed, consultation on a common approach shall be undertaken.
- 5.3 To avoid causing confusion or attempts by businesses to make individual arrangements with the parties, industry will be made fully aware via stakeholder engagement and relevant policy guidance, of the collective agreement processes set out in this Concordat.

6. Dispute resolution

- 6.1 Following the approach set out in Appendix IV of the NLCS Common Framework and within the spirit of this Concordat the UK administrations will seek every opportunity to resolve differences and reach agreement; either to recommend a UK wide approach or to accept divergence, at official level through discussions at the UK NLCS Expert Group.
- 6.2 Where it has not been possible to resolve any disagreement in approach at official level, this will initially be referred to a panel of senior officials for resolution.
- 6.3 Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the NLCS Common Framework, the making of legislation may need to be postponed until all four administrations are in agreement on how to proceed. The parties may conclude, having considered potential impacts on consumer safety and confidence and the functioning of the UK internal market, that divergence is appropriate.
- 6.4 As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated to the Secretariat of the Joint Ministerial Committee for resolution under the dispute resolution process set out in section A3 of the intergovernmental MoU.

7. Provision of Information and Policy Formulation

- 7.1 All parties will be involved as appropriate in discussions regarding policy positions on all Nutrition related labelling, composition and standards, including nutrition and health claims issues which touch on matters within the scope of the NLCS Common Framework. All parties will also provide information to the other parties on any contacts from other countries which concern their Nutrition related labelling, composition and standards, including nutrition and health claims responsibilities.

8. International Policy and Relations

- 8.1 As foreign policy issues are reserved to the UK government, DHSC retains overall policy responsibility for the formulation of UK policy. DHSC will involve the devolved administrations fully in discussions about the formulation of UK policy in this area as outlined in the current [Devolution: Memorandum of Understanding](#) (currently under review); and will look to agree a stance where possible.⁵

9. International Obligations, Policy, and Relations

- 9.1 International Obligations

- 9.1.1 The devolved administrations are responsible for observing and implementing international obligations that relate to devolved matters as outlined in the Devolution MoU. All parties will consult with and then inform each other of their chosen methods of implementation, for example by exchanging draft copies of administrative rules or legislation. The parties also agree to such mutual exchanges of information, to the extent permitted by law, as are required to assist the good management of schemes and the observance of obligations.
- 9.1.2 Where implementation difficulties arise, the parties will consult with each other in advance of any discussion with the [European Commission or European Court of Auditors. They will similarly consult on any corrective action demanded by the European Commission or European Court of Auditors].

⁵ This final wording for this section is still under discussion.

10. Codex Alimentarius

- 10.1 The Codex Alimentarius is an international body which sets food standards, guidelines and codes of practice in the international trade of food and agricultural products. The Codex Alimentarius Commission, and subsidiary bodies, are responsible for the revision of Codex standards and texts.
- 10.2 After the end of the TP the UK Government will continue to represent the UK at Codex Alimentarius Commission for all policy areas covered by the NLCS Common Framework, including on issues where the EU previously had devolved competence. The UK Government will continue to work with DAs on matters within the remit of the Codex Alimentarius Commission Committee Nutrition and Foods for Special Dietary Use in a co-operative and open manner. DA Officials may attend the committees and task forces alongside UKG representatives as part of the UK contingent, subject to agreement on numbers. Overall co-ordination of Codex Alimentarius Commission remains a DEFRA lead.

11. Exchange of information, statistics and research

- 11.1 The administrations will aim to provide each other with as full and open as possible access to scientific, technical and policy information including statistics and research and, where appropriate, representations from third parties. In order enable each administration to operate effectively in meeting any international obligations, as set out in the proceeding section, and in relation to the policy areas covered by the Common Framework on NLCS; all parties to this concordat will co-operate in line with the [Devolution: Memorandum of Understanding](#) (currently under review).

12. Operation and review

- 12.1 This Concordat will be formally reviewed at six months, one year, three years from the date of its implementation and thereafter at five-year intervals from the end of the transition period (TP).
- 12.2 It will also be reviewed if any of the parties requests it, and all parties will participate in the review.
- 12.3 Any changes made to the Concordat must be agreed by all parties to it.







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