

COMMON FRAMEWORKS: FRAMEWORK OUTLINE – FOOD AND FEED SAFETY AND HYGIENE

Purpose

This document provides a suggested outline for an initial UK wide, or GB, framework agreement in a food/feed safety policy area. It is intended to facilitate multilateral policy development and set out proposed high level commitments for the four UK Administrations. It should be viewed as a tool that helps policy development, rather than a rigid template to be followed. The document may be developed iteratively and amended and added to by policy teams as discussions progress. It should be read alongside the accompanying guidance (UKG and DA Guidance Note for Phase 2 Engagement).

Population of the agreement skeleton should be based on the existing work undertaken and should remain consistent with the underlying Framework Principles agreed by the UK, Scottish and Welsh Governments. The content should inform the drafting of any legislative and non-legislative mechanisms required to implement UK wide frameworks.

Until it is formally agreed this document should not be considered as Government policy for any of the participating administrations and should be treated as confidential. The process for developing and finalising this document will be mutually agreed by all administrations.

The document is made up of four sections:

Outline

1. **Part 1: What We Are Talking About.** This section will set out the area of EU law under consideration, current arrangements, and any elements from the policy that will not be considered. It will also include any relevant legal or technical definitions.
2. **Part 2: Proposed Breakdown of Policy Area and Framework.** This section will break the policy area down into its component parts, explaining where common rules will and will not be required and the rationale for this approach. It will also set out any areas of disagreement.

Operational Detail

3. **Part 3: Proposed Operational Elements of Framework.** This section will explain how the framework will operate in practice by setting out: how decisions will be made; the planned roles and responsibilities for each administration, or a third party; how implementation of the framework will be monitored and, if appropriate enforced; arrangements for reviewing and amending the framework; and proposed arrangements for resolution of a dispute.
4. **Part 4: Practical Next Steps and Related Issues.** This section will set out the next steps that would be required to implement the framework (subject to Ministerial agreement) and key timings.

Draft Framework Outline

Part 1: WHAT WE ARE TALKING ABOUT

1. Policy area

Please use this section to list the name of the overall policy area under consideration, as set out in [the UK Government's provisional policy analysis](#). Please note if this framework only covers a particular element of that policy area and include any additional information necessary to clarify and ensure a shared understanding of what is included in an area.

Food and Feed Safety and Hygiene Law

1.1 Food and feed safety and hygiene (FFSH) law is set out in retained European Union regulations which set out an overarching and coherent framework for the development of food and feed legislation and lay down principles, requirements and procedures that underpin decision-making in matters of food and feed safety. This legislation covers all stages of food and feed production, including risk analysis; food safety labelling, distribution, incident handling, and food and feed law enforcement (official controls).

2. Scope

In this section, policy teams should set out existing arrangements, specifically:

- 2 *the elements of EU law in this area that intersect with devolved competence i.e. the specific regulations, directives, etc.;*
- 3 *the split between reserved and devolved competencies in this area, including highlighting any differences in the devolution settlements, and flagging if there are any disagreements over the division of competencies;*
- 4 *broadly what the EU law currently does, i.e. the rules that all parts of the UK currently have to comply with - the exact areas of EU law will be added as an annex once agreed by lawyers;*
- 5 *briefly how the existing EU framework currently operates, i.e. what the relevant EU or UK bodies are, and the functions and decision-making arrangements of these bodies;*
- 6 *the scope, within these rules, for different parts of the UK to do things differently (i.e. the decision-making powers that the DAs currently are able to exercise, and the extent of existing divergence); and*
- 7 *relevant international obligations.*

Policy teams should also set out:

- 8 *geographic scope of the framework (whether UK wide, or GB only);*
- 9 *any explicit exclusions from their considerations; and*
- 10 *any interdependencies or key variables (including any other frameworks policy areas or elements of policy areas which are inextricably linked).*

Food and Feed Safety and Hygiene Law - intersect with devolved competence and existing arrangements

FFSH is a devolved policy area. This is set out as follows in the devolution settlements for each nation:

- 2.1 Schedule 5 of the Scotland Act 1998 sets out those matters which are reserved to the UK Parliament. Any area not listed in Schedule 5 is devolved to the Scottish Parliament. While 'consumer protection' and 'import and export control' are considered reserved matters, exceptions are included for food and feed safety (see section C5 and C7), meaning FFSH is a fully devolved matter.
- 2.2 Schedule 7A to the Government of Wales Act 2006 sets out those matters which are reserved to the UK Parliament. Any area not listed in Schedule 7A is devolved to the Welsh Parliament. While 'consumer protection' and 'import and export control' are considered reserved matters, exceptions are included for food and feed safety (see section C5 and C6), meaning FFSH is a fully devolved matter.
- 2.3 Schedule Schedule 2 of the Northern Ireland Act 1998 sets out 'excepted matters' (matters of national importance on which the NI Assembly does not have competence to legislate), and Schedule 3 of the Northern Ireland Act sets out which matters fall into the 'reserved' category. Anything that is not explicitly reserved or excepted in Schedules 2 or 3 is deemed to be devolved and the NI Assembly has full legislative competence. While 'technical standards and requirements in relation to products' are reserved under Schedule 3, there is an exception for 'standards and requirements in relation to food, agricultural or horticultural produce, fish or fish products, seeds, animal feeding stuffs, fertilisers or pesticides' meaning FFSH is a fully devolved matter.
- 2.4 While FFSH policy areas are devolved matters, international trade is reserved, creating an area of overlapping interests where UK trade negotiations and implementation may intersect with aspects of devolved policy areas, such as FFSH. Though FFSH is devolved, it remains the responsibility of the UK government to ensure the UK complies with its international trading obligations. For example, the World Trade Organisation Sanitary and Phytosanitary Agreement (WTO SPS Agreement, see Annex 3 for 'Definitions') Article 13 permits Members to devolve the implementation of SPS to non-central government bodies, but explicitly states "Members are fully responsible under this Agreement for the observance of all obligations set forth herein". Thus, UK Government will be held to account on behalf of all devolved nations for this specific function.
- 2.5 The Food Standards Agency (FSA) has responsibility at central government level for the main body of feed and food safety law in England, Wales and Northern Ireland. Food Standards Scotland (FSS) has similar competence in Scotland. The FSA and FSS have an MoU in place which sets out how the organisations work together in detail. Both the FSA and FSS are responsible for developing and implementing policy related to general food and feed hygiene

and traceability. This includes the protection of public health via import controls, labelling related to food safety (such as allergens), biological and chemical safety, and biotechnology.

2.6 In England, Wales and Northern Ireland, the FSA (in conjunction with local authorities which carry out certain functions) is responsible for monitoring, verifying compliance and enforcing the requirements of FFSH law. In Wales and Northern Ireland the FSA also has responsibility for food compositional standards and labelling. In Northern Ireland, the FSA additionally has responsibility for nutrition. The 'food compositional standards and labelling' and 'nutrition labelling, composition and standards framework policy areas are being managed through separate frameworks which are led by Defra and DHSC respectively. FSS undertakes all such controls in Scotland. Unlike the FSA in Wales and Northern Ireland (which are part of the FSA), FSS is a separate and fully devolved body.

2.7 The detailed explanation of the specific scope of the FFSH Framework is set out in section 4.7 - 4.17.

How the EU framework operated

2.8 Until the end of the transition period, the majority of FFSH law was harmonised at European Union level, relying on European Union processes and institutions to carry out most risk assessments, risk management decisions and develop and pass legislation. Much of the FSA's work at the European Union level previously took place through 'comitology' procedures. In policy areas such as FFSH, where uniform conditions for implementation were often needed, the European Commission would adopt 'Implementing Acts' or 'Delegated Acts' to supplement or amend certain parts of European Union regulations. Before doing so, standing ('comitology') committees, in which all Member States would be represented, consulted and voted on proposals. In addition, expert working groups would be consulted carefully before a proposal was put to the standing committee. Commission proposals voted on in standing committees are disclosed to the European Union Parliament and European Union Council (and may or may not be discussed in their committees). Once a decision has been agreed at standing committee, the European Union Parliament and European Union Council have the right of scrutiny and may or may not discuss the matter in their committees). It should be noted that prior to the end of the transition period, a significant number of risk management decisions, such as decisions on enforcement and incident handling, were also taken at national level. Decisions in these areas are considered outside the scope of the FFSH Framework.

2.9 The Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) is the key committee of relevance for FFSH. The FSA represented the UK at 6 sections of the SCoPAFF committee on food and feed safety matters and in technical discussions at 16 working groups that feed into the SCoPAFF standing committees. In representing the UK government on the standing committees, the FSA worked collaboratively with devolved nations and other departments to establish UK positions on proposals, and consulted Ministers and other interested parties as appropriate. Legislative decisions were taken through comitology procedures on a frequent basis: in 2016 there were 76 decisions taken in FFSH policy areas.

2.10 Where changes were proposed to the broader principles of legislation (or new pieces of legislation are put forward), the FSA represented the UK in the European Union's 'Ordinary Legislative Procedure', whereby the Commission would submit a legislative proposal for the European Parliament and European Council to amend and adopt. The FSA fed into Council working parties and Parliament committees (convened to inform the Council/ Parliament) as and when a new law (or amendment to the broad principles of a law) was made that fell within the remit of FFSH policy areas.

2.11 For significant components of European Union food law (particularly in relation to regulated products), the European Union framework relied largely on the European Food Safety Authority (EFSA) for independent scientific advice and risk assessments. Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament and European Union Member States. While some risk assessments were carried out already at UK level, the end of the transition period will require increased capacity for domestic risk assessments, as well as governance processes for how these are carried out across the UK. The UK has expanded its risk assessment capacity accordingly.

Retained European Union rules and what they achieve (See Annex 1 and 2 for further detail)

2.12 FFSH can be broken down into four broad policy areas, all of which fall within devolved competence and were formerly largely harmonised at European Union level, and have been transferred onto the UK statute book as retained European Union law. The exception to this was the limited scope provided for the adoption of national measures to achieve common outcomes where these are in-keeping with the principle of subsidiarity. The four broad policy areas within the scope of European Union FFSH legislation are:

- General Food Law and Hygiene
- Food Safety Standards
- Official Controls for Food and Feed
- Public Health Controls on Imported Food

2.13 The main objectives of food and feed law are to:

- guarantee a high level of protection of human life and health and the protection of consumers' interests.
- ensure free movement of food and feed manufactured and marketed in the European Union, in accordance with the General Food Law Regulation; and
- facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing the European Union legislation, except where this might undermine the high level of consumer protection pursued by the European Union.

International obligations

- 2.14 Codex Alimentarius (Codex) is a series of voluntary food standards and related texts, which aim to provide a high level of consumer protection and fair practice in the international trade of food and agricultural products. The Codex Alimentarius Commission (CAC) is recognised in the relevant WTO agreements as the international body able to provide these guarantees: in the event of a trade dispute, Codex standards would become accepted reference documents for settlement. The CAC is responsible for the development of Codex standards and related texts. Defra acts as the national contact point for the UK in Codex, though the FSA takes the lead in many of the vertical committees dealing with food hygiene, food additives and food contaminants (which draft standards, codes of practice and other guidance). The FSA already undertakes a considerable amount of international engagement beyond the European Union, reflecting the increasingly global nature of food supply systems and of international regulatory standards; plans are also in train to allow for an increase in this activity.
- 2.15 Having left the European Union, the UK has taken up new obligations as an independent WTO member at the WTO SPS committee. The SPS committee was previously attended by European Union experts on behalf of the UK. Cross-departmental processes have been developed by Defra (with participation from the FSA) to ensure we fulfil our new obligations, including consulting stakeholders on SPS measures, notifying the committee of any change in SPS measures, responding to other nations' queries during the consultation period, and actively participating in committee work. The FFSH Framework is designed in a way that ensures the UK can continue to effectively fulfil its international obligations as a WTO member.

Scope for legislative divergence

- 2.16 Under the European Union regime, in a small number of cases where national measures to achieve common outcomes are allowed, different actions and decisions could be taken by individual administrations across the UK. One example of where these differences exist is raw drinking milk: it is an offence to place raw milk or cream on the market for direct consumption in Scotland, but not in the rest of the UK. In addition to this, where the European Union legislation is outcome focused, differences can exist in the means through which administrations achieve the same outcome, for example there are differences in hygiene guidelines for cooking burgers.
- 2.17 European Union legislation also enabled Member States to develop their own enforcement and execution provisions, and the four nations of the UK therefore all have their own national regulations for enforcement and execution of European Union provisions. Similarly, under European Union legislation the operational management of incidents allows Member States to determine their own rules for managing the practicalities of incident response, in line with the general requirements set out in European Union legislation. Protocols for UK incident handling are covered by the FSA-FSS MoU.

Interdependencies/other linked frameworks policy areas

- 2.18 There is cross-over between policy areas under FFSH legislation and other public health policy areas (whose frameworks are being led by Defra or DHSC).

These policy areas include framework areas in which the FSA/FSS are directly involved:

- nutrition labelling, composition and standards (DHSC-led, FSA involved in NI, FSS involved)
- food compositional standards and labelling (Defra-led, FSA involved in NI and Wales, FSS involved) and framework areas in which the FSA/ FSS are not directly involved, but have an interest:
 - animal health and welfare (Defra-led)
 - plant health (Defra-led)
 - pesticides (Defra-led)

2.19 Ongoing work on the UK internal market and international trade obligations will also need to be monitored and factored into the FFSH Framework proposals. It will also be necessary to engage with teams working on the Future Relationship (FR) to ensure the framework takes account of any further requirements that may arise as a result of the UK's future relationship with the European Union, such as how any additional UK governance structures that may be established will work on a four nations basis.

Geographical scope

2.20 It is the intention that the framework should apply in England, Wales, Northern Ireland and Scotland. Officials in all four nations have been closely involved throughout the development of the FFSH Framework proposals.

Northern Ireland considerations

2.21 On 15th June 2020, the Northern Ireland Executive agreed to the principles JMC(EN) had agreed in October 2017 to underpin the development of frameworks. Prior to this, FSA officials in Northern Ireland had provided technical and analytical input to the development of the FFSH Framework.

2.22 The FFSH Framework will be a four nations agreement. However, the specific circumstances of Northern Ireland are respected and reflected throughout the framework outline.

2.23 This includes the provisions of the Belfast Agreement (including the North/South dimension highlighted in Strand 2 of that Agreement). These provisions will be respected.

2.24 Further to this, the framework ensures that Northern Ireland continues to contribute to the formulation of UK policy on food and feed safety and hygiene. Northern Ireland's involvement in policy making will ensure that the economic and social linkages between Northern Ireland and Ireland will be recognised and incorporated into policy outcomes.

2.25 The FSA's role in respect to Northern Ireland within the Framework will also reflect the requirements of the Northern Ireland Protocol. The legislation within the scope of the

Framework is detailed within Annex 2 of the NIP, and therefore European Union legislation will continue to be directly applicable in NI whilst the rest of the UK will set its own regulatory regime at the end of the transition period. While the circumstances in Northern Ireland will be different as a result of the Northern Ireland Protocol, officials and Ministers will continue to be involved in the framework's processes and governance structures. How the specific circumstances in Northern Ireland will be reflected in ways of working is detailed throughout the framework outline.

3. Definitions

In this section, policy teams should include any legal and/or technical definitions required to avoid any misinterpretations and ensure there is a shared understanding of what matters are within the scope of the agreement.

3.1 Key definitions:

A full list of definitions can be found in Annex 3.

Part 2: PROPOSED BREAKDOWN OF POLICY AREA AND FRAMEWORK

4. Summary of proposed approach

In the policy areas where we are exploring legislation, it is likely that the overall framework will have both legislative and non-legislative elements.

Breaking the policy area down into its component parts (where possible) this section should briefly list:

- *The areas where UKG and the DAs will continue to need common rules and/or arrangements for working together, setting out:

 - *where legislation (specifying whether it is primary and/or secondary) is planned; and*
 - *the areas where non-legislative approaches are proposed, including where this will complement legislation.**
- *For each of the areas listed above, whether the common rules/arrangements are necessary according to the JMC(EN) [Frameworks Principles](#), or not necessary, but considered desirable. If there is disagreement about the distinction between necessary and desirable this should be recorded.*
- *The areas where no further action is needed, either because existing arrangements are sufficient, or because UKG and the DAs will not require common rules and/or arrangements for working together.*

Any areas where parties do not agree on the approach, along with an outline of the reason for disagreement.

FFSH Framework analysis

4.1 The FFSH framework proposals have been developed in accordance with the JMC(EN) principles, in line with guidance on frameworks developed jointly by UK Government and the Devolved

Administrations. Officials agreed that in considering the requirements of the FFSH framework, the following JMC(EN) principles would be of key importance¹:

- enabling the functioning of the UK internal market, while acknowledging policy divergence; and
- ensuring the UK can negotiate, enter into and implement new trade agreements and international treaties and comply with international obligations;
- respecting the devolution settlements and the democratic accountability of the devolved legislatures;
- maintaining, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by the current European Union rules.

4.2 In the first UKG-DA deep dive on food safety, officials agreed that common approaches were **at least desirable** for all areas of FFSH within scope of the Framework. It was proposed in a number of areas that it was **necessary** to have a common approach according to the JMC(EN) framework principles. Colleagues from Scottish Government would only accept a common approach was *desirable*, because of a concern that agreeing a common approach was *necessary* would mean that a harmonised approach was required. It has subsequently been discussed and agreed by officials that common approaches for creating FFSH policy should be developed through the framework, noting that such approaches may still result in evidence-based divergence where this is considered appropriate.

4.3 Technical working groups (comprising of representatives from all four nations) collaboratively broke down each broad policy area (see Annex 1) into its component parts. The technical working groups developed initial proposals as to where within each policy area commonality might be needed. Officials from the four nations agreed that commonality is preferred across all areas of food & feed safety and hygiene law which are currently harmonised at a European Union level; the areas in scope of the framework and that common arrangements should be developed to deliver this. Officials from the four nations agreed that existing four nations cooperation mechanisms should be built on where possible.

FFSH Framework implementation

4.4 After the end of the Transition Period, there will be a common body of FFSH law in place across the UK, put in place in GB through the European Union Exit statutory instruments. The FFSH Framework agreement itself will primarily be implemented through non-legislative agreements. It is proposed that the Framework should primarily be implemented through:

- a concordat between the four Governments (signed by Health Ministers); and
- a revised FSA-FSS MoU (setting out the elements of the Framework delivered by the food safety bodies of the UK).

¹ It should be noted that this is not an exhaustive list of principles agreed by JMC, but rather highlights the key principles of relevance to the FFSH framework.

This Framework Outline document will be publicly available once it has been agreed and it will set out the contents of the FFSH Framework.

4.5 These non-legislative elements to the implementation of the UK Framework will need to dovetail with each other, as well as the overarching UKG-DA MoU. The non-legislative elements of the Framework will include the:

- Scope of the Framework;
- High level principles for ways of working;
- Governance and principles for joint ways of working (including management of divergence);
- Framework review and management arrangements; and
- Governance arrangements for dispute avoidance and resolution.

Potential legislative requirements - concurrent powers

4.6 Officials from the four nations will undertake an exercise in 2021 to assess where within FFSH policy areas (within scope of the Framework) it would be beneficial to have concurrent powers² available so that one statutory instrument can be used to implement consistent decisions across the UK. It should be noted that UK wide SIs under FFSH legislation could only be made with the explicit consent of DA Ministers, and if considered appropriate would likely be limited to certain technical areas. The FFSH Framework will be fully functional from the end of the transition period regardless of the outcome of the assessment.

Scope of the food and feed safety and hygiene framework

This section will be reviewed during Phase 4 of the framework development when then the UK Internal Market legislation is in place.

4.7 Officials have agreed to take a principles-based approach to determining whether a proposed change is in scope of the Framework. The following principles should be considered when determining whether a policy change falls:

- a) In scope of the FFSH framework
- b) In scope of the FFSH framework processes and subject to notification procedures but not the full joint risk analysis processes
- c) Outside scope of the FFSH framework

Principles for determining scope

- a) Policy changes should be considered in scope of the FFSH framework if changes are being proposed where:
 - a decision in an area of returning powers would have an effect on any of the JMC principles.

² Concurrent power - the power for a UKG Secretary of State to make changes to retained European Union law in secondary legislation through one UK wide SI with the consent of DA Ministers.

- the requirements (both safety and hygiene) are intended to apply to establishments across the UK (or internationally) or products that are marketed across the UK and are currently harmonised at European Union level.
 - the policy area is the responsibility of food safety bodies in all four nations³.
 - the issue is not explicitly considered outside of scope.
- b) Policy changes should be considered in scope of the FFSH Framework but subject to notification processes and not the joint ways of working where:
- different requirements are proposed for establishments within one territory placing products on the market solely within the territory of that nation (i.e. establishments are based in and supplying the local market only); or
 - different requirements are proposed for products produced in and placed on the market solely within the territory of one nation (i.e. products are produced and consumed exclusively in the local market only).
- c) Policy changes should be considered outside scope of the FFSH Framework where:
- retained European Union legislation provides scope for national measures to achieve common outcomes and so divergence is already possible.
 - existing European Union legislation provides flexibility for the law to be applied in different ways i.e. this flexibility will be maintained.

Areas in scope of FFSH framework

- 4.8 The FFSH Framework applies to retained European Union food & feed safety and hygiene legislation. A detailed breakdown of the legislation is set out in Annex 1: Retained European Union FFSH Legislation. Broadly the FFSH areas currently harmonised at a European Union level where it is agreed by officials that common approaches and arrangements for working together should be developed are (see Annex 1: Retained European Union FFSH Legislation for further details):
- general food and feed law and hygiene
 - food and feed safety standards
 - official controls for food and feed
 - public health controls on imported food and feed
- 4.9 Unless explicitly ruled out of scope (see section 6) changes to the above areas that would be considered in scope of the framework include:

³ The scope of the framework for food and feed safety and hygiene (FFSH) extends only to those policy areas for which responsibility falls to food safety bodies across all four nations (i.e. frameworks / policy areas that fall within other departments' remit at UKG level will be managed by these departments, such as any replacement for Sante F, official controls for animal health and welfare, frameworks for general food labelling, food compositional standards, and nutrition etc.).

- proposals for changes to retained European Union legislation;
- proposals for new legislation in currently harmonised policy areas of retained European Union legislation;

4.10 The scope therefore includes food and feed safety requirements for products which are marketed across the UK and the harmonised rules (both safety and hygiene) under which businesses that operate across the UK produce them. The FFSH Framework will provide for a common approach to developing and making changes to UK FFSH legislation in areas where European Union law is currently harmonised, with a clear approach set out in the framework to manage divergence.

Areas in scope and subject to notification processes within the framework but not the joint ways of working

4.11 The changes identified within scope of this are in principle:

- different requirements proposed for establishments within one territory placing products on the market solely within the territory of that nation (i.e. establishments are based in and supplying the local market only); or
- different requirements proposed for products produced in and placed on the market solely within the territory of one nation (i.e. products are produced and consumed exclusively in the local market only).

4.12 The purpose of ensuring that each nation of the UK has the ability to make changes of this nature without having to engage the full joint risk analysis process is to ensure that where necessary Ministers can make recommendations to protect public health in response to inquests or fatal accident inquiries that have been as a result of specific circumstances within their territory and have primarily occurred only in their territory of the UK. For example, following a public enquiry after an *E. coli* outbreak associated with meat products in Wales (2005), Ministers followed recommendations from a public enquiry to apply additional requirements on establishments, food business operators (FBOs) or local authorities (such as enhanced training for enforcement officers, enhanced hygiene requirements, increased audits etc.) only within Wales.

4.13 In these instances, in the framework there would be requirements to engage as early as reasonably possible with the other nations and notify them of expected changes (i.e. so that other nations in the UK can consider whether they wish to follow the same approach), but these areas would not be subject to the full risk analysis processes outlined in the framework. This would, for example, allow Ministers to respond to serious public health incidents such as the *E. coli* outbreak in Scotland in 1996 where Ministers applied different hygiene requirements for butchers solely in Scotland. As we have seen with the recent allergens review (which is an issue that is out with the scope of the framework) , even where the potential exists for different approaches to be taken now, the four nations can respond in a joint manner to key issues, where appropriate and in line with our ways of working set out in the FSS-FSA MoU.

4.14 Risk management recommendations on products produced within and placed solely on the market within one specific UK nation (i.e. the requirements apply only to producers in one nation of the UK placing the product exclusively on that market), or where structural or hygiene requirements are stipulated for establishments located in one UK nation only, would not be the

subject of the full joint working processes under the UK framework but would still be considered part of the overall framework and subject to a notification procedure. These matters will be subject to policy engagement arrangements as per the FSA-FSS MoU.

Areas outside scope of FFSH framework

- 4.15 Areas outside of scope of the framework will not be included within the formal joint policy-making and joint decision-making protocols set out in the framework. However, for these areas, officials agree that joint notification procedures and working arrangements between food safety bodies under the FSA-FSS MoU should be continued and mechanisms for sharing this information reviewed
- 4.16 Equivalent flexibility for tailoring legislation to the specific needs of each of the four UK nations as is afforded by current European Union rules will be maintained and existing areas of flexibility for different approaches will be maintained. Within food & feed safety and hygiene there are a number of areas where European Union legislation offers flexibility for the law to be applied in different ways, with scope for national measures to achieve common outcomes permitted by the legislation. Within the European Union FFSH legislation, this includes:
- a) Enforcement and execution - European Union legislation provides flexibility for Member States to develop their own enforcement and official control provisions in certain areas.
 - b) Risk management decisions currently taken at national level in areas where European Union legislation permits different approaches.
 - c) Incident management – well developed practical procedures for managing incidents and emergencies are already in place across the UK (while adhering to the broad requirements for incident management outlined in legislation which are in scope of the framework).

Examples of areas outside of scope of framework

- 4.17 Because of the complex and interlinked nature of FFSH legislation both at a European Union level and at a domestic level it is likely that in future there may be uncertainty as to whether a proposed change to food and feed safety rules falls within the scope of the FFSH Framework. To offer additional clarity, the following examples are illustrations of the areas that would be considered outside the scope of the UK framework⁴ (meaning requirements laid out under the framework will not apply to these areas):
- **Enforcement measures:** While European Union legislation sets out the general approaches and principles that must be taken for the monitoring and enforcement of feed and food law requirements (which are in scope of the framework), it also provides considerable scope for national enforcement measures, allowing flexibility for competent authorities in setting enforcement provisions. In addition, each nation in the UK has scope to take different approaches to some enforcement measures. For example, Scotland, Wales and Northern Ireland have extended the scope of where remedial action notices (an enforcement notice) can be used to include all food businesses in comparison to only approved establishments in England.

⁴ The FSA and FSS already have an MoU in place which governs ways of working in these areas.

- Changes in areas where national measures are permitted: Flexibility provisions in the Hygiene Package (commonly understood to consist of: Regulation (EC) No 852/004 concerning the hygiene of foodstuffs; Regulation (EC) No 853/2004 concerning specific hygiene rules for food of animal origin; Regulation (EC) No 625/2019 with regards to requirements for the entry into the European Union of consignments of certain animals and goods intended for human consumption; and Regulation (EC) No 628/2019 concerning model official certificates for certain animals and goods) specifically exclude certain activities from the scope of the regulation, including direct supply by primary producers of small quantities of primary products to consumers (e.g. raw milk) and local retail establishments directly supplying the final consumer (e.g. eggs, honey, fruit, vegetables, wild game). Member States are obliged to adopt national rules for these activities. An example of where different national measures are already adopted in Scotland and the rest of the UK is raw drinking milk: it is an offence to place raw milk or cream on the market for direct consumption in Scotland, as per Scottish national measures, but not in the rest of the UK, where raw milk sales are permitted on a restricted basis to on-farm sales.
- Operational handling of incidents: The general requirements regarding response to food safety incidents harmonised at European Union level (Regulation EC 178/2002) will remain within the scope of the FFSH Framework. However, the operational management of incidents, where Member States currently have scope to determine their own rules for managing the practicalities of incident response, is considered outside the scope of the framework. Protocols for UK incident handling are covered by the MoU between the FSA and FSS, which refers to the FSA's and FSS' incident management plans. As per agreements set out in the MOU and incident management plans, the FSA is responsible for management of incidents with UK-wide implications, while incidents which do not have an impact extending beyond Scotland are managed under the FSS incident management plan (with requirements for information about such incidents to be shared with FSA).

5. Overview of proposed framework

For each of the areas where policy teams know that a Framework is likely to be required, policy teams should set out, with reference to the Frameworks Principles:

- *what the new framework will do/achieve - e.g. establish a common set of rules, or set out required ways of working between the different parties;*
- *to what extent will the Framework enable policy divergence between administrations;*
- *the rationale - why Framework is required, based on the Frameworks Principles; and*
- *the planned vehicle(s) - in thinking about this element, policy teams should consider whether new legislation is required or whether, for example, existing powers could be used to achieve the desired legislative outcome.*

Overview of proposed FFSH framework

- 5.1 This section provides an overview of proposals for the FFSH Framework. Further detail on the proposed operation of the framework can be found in the later sections of this document. The FFSH Framework is intended to put in place shared ways of working between the four nations and their food safety bodies to drive for common approaches to retained European Union law (within scope of the framework), where agreed by all four nations. The intention is not to mandate harmonisation, but to recognise that businesses and consumers in all four nations (as well as international trading partners) often benefit from there being one consistent set of FFSH legislation (where those rules are considered to be in their interests), and agreed approaches for changing FFSH rules. However, the framework also allows for divergence, as there will be instances where it is appropriate for nations in the UK to take different approaches to risk-based consumer protection.
- 5.2 The FFSH Framework commits the parties to UK approaches for:
- policy development, including
 - undertaking FFSH risk assessment
 - developing risk management options and making risk management recommendations to Ministers within FFSH legislation;
 - managing UK pre-market approval and authorisation processes
 - managing divergence;
 - decision-making;
 - implementation of decisions; and
 - dispute avoidance and resolution.
- 5.3 The following principles have been established for the FFSH Framework to underpin shared ways of working while respecting and enhancing the devolution settlements and the democratic accountability of the devolved legislatures:
1. The framework for changing UK FFSH legislation should respect the JMC principles, devolved responsibilities and accountability across the UK.
 2. The four nations should work together to develop evidence based approaches for ensuring protection of public health and wider consumer interests, with the aim being to have common approaches to UK food & feed safety and hygiene policy developed and agreed by all four nations where evidence presented supports that position.
 3. Flexibility should be provided for administrations to act within the framework to meet local needs and circumstances while delivering the same outcomes.
 4. Within the framework, all four administrations should have the ability to diverge within their territory (having followed the principles set out in the framework for managing divergence) where the outputs of risk analysis⁵ undertaken by food safety bodies

⁵ Risk analysis is defined by the World Health Organization as a risk-based approach to the identification and management of public health hazards in food. In the UK, this will follow a structured approach developed and agreed by FSA and FSS comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication).

show that divergence is both necessary and proportionate to the risk to provide appropriate consumer protection in all nations.

5. Governance arrangements should be effective and proportionate whilst keeping administrative complexity and burdens to the minimum.
6. The framework should operate transparently: the framework's governance arrangements should be publicly available, and principles for transparency should be built into the framework where appropriate.

FFSH policy development

- 5.4 The FFSH Framework agreement will set out the commitment of the four nations to deliver joint ways of working. To deliver the framework, new ways of working and governance arrangements will be needed to manage four nations input into the development of risk management advice for Ministers across FFSH policy areas. These new ways of working are being developed to manage the regulatory regime when the UK exits the European Union, building upon existing working arrangements between food safety bodies.
- 5.5 One mechanism through which the framework will be operationalised will be the new risk analysis process (comprising risk assessment, risk management and risk communication) which has been developed as a joint endeavour by the FSA and FSS through the food and feed safety risk analysis project.
- 5.6 Mechanisms will be in place throughout the process to ensure FSA and FSS have opportunity to discuss, and for matters within scope of the framework, agree the prioritisation and triage of issues and risk management proposals (particularly those triaged as "non-routine"), so risk management interventions are effective for the UK as a whole or for individual nations as needed.
- 5.7 To ensure a meaningful four nations approach and allow early and ongoing opportunities for each nation to input into the development of UK policy change it is proposed the framework agreement will include in relation to joint policy development:
 - A commitment from all four nations to engage with the other three nations at the earliest opportunity when considering any potential policy changes (For Northern Ireland, where possible this will include discussion of changes that are being discussed at the Joint Consultative Working Group and other committees established under the Northern Ireland Protocol).
 - A commitment from all four nations to notify and share consistent information in all FFSH policy areas at key stages in the policy development process through the mechanisms of engagement agreed for the risk analysis process.
 - A commitment to provide sufficient resources to joint working arrangements.
- 5.8 To deliver on these commitments, it is proposed that there will need to be:

- A consistent mechanism for policy leads in any of the four nations to identify counter parts and share information.
- Regular engagement between policy leads in all four nations.
- An administrative function to provide oversight of information sharing between the four nations and joint working arrangements.

5.9 In Northern Ireland, European Union risk management decisions will apply for food and feed safety and consequently for any food that comes into the rest of the UK from Northern Ireland. For European Union regulations that will apply only in Northern Ireland under the Protocol, full risk analysis may not be undertaken for some European Union regulations assessed as routine at triage. Those European Union regulations assessed as non-routine at triage would be prioritised for risk analysis as appropriate to the issue.

5.10 Risk assessment is a scientific process which assesses the risk associated with food or feed and consists of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation. Having robust risk assessment principles in place is important for providing assurance to consumers, businesses, stakeholders and trading partners that risk assessments are carried out appropriately for ensuring public health protection across the UK. Although some capacity for FFSH risk assessment already exists in the UK, much of the risk assessment required for FFSH is currently carried out by the European Food Safety Authority (EFSA).

5.11 A set of FFSH Framework principles for governing risk assessment have been developed. These principles should provide assurance that risk assessments are responsive to the four nation's needs. The FFSH Framework principles proposed to govern risk assessment are:

- There is a four nations representation at each appropriate stage of the risk assessment as needed.
- Risk assessments are undertaken on a UK wide basis, but with capacity for non-UK wide risk assessments where particular issues require single nation approaches (risk assessment done on a UK wide basis could also include nation specific outputs, which would allow for comparison of risk across the four nations).
- Risk assessments are independent, free from undue influence and are carried out according to recognised international principles.
- There is a suitable challenge mechanism in the risk assessment process once we have left the European Union.
- There are appropriate governance arrangements in place for recognising devolved matters in the prioritisation, commissioning and quality assurance of risk assessments.

- The FSA will consult the relevant home nation with regard to any issues, evidence or analysis specific to that nation, with the aim of ensuring that risk assessments properly reflect the situation in the different constituent parts of the UK, as far as the evidence allows.
- There is the capacity for a number of different outputs / approaches where required – this could include:
 - RA undertaken on a UK basis with one UK output.
 - RA undertaken on a UK basis with nation specific outputs.
 - RA undertaken on a single nation basis.
 - RA undertaken for more than one nation but not all four.
- Where nation specific outputs are requested / needed risk assessments will capture any different county specific characteristics, nuances and demographics.
- Supplementary information on nation specific issues will be based on robust data sources, for example the National Diet and Nutrition Survey.
- Any difference in risk assessment conclusion for nation specific outputs are clearly set out, explained and justified.

5.12 As part of the risk analysis process, the FSA, in conjunction with FSS, is working to determine how risk assessments will be undertaken, commissioned and prioritised. The principles for risk assessment agreed within the UK framework are reflected in the FSA and FSS risk assessment process. This will ensure that risk assessments are responsive to the four nation's needs.

FFSH risk management

5.13 Within the scope of the UK framework, the risk analysis process will bring together officials from across the UK to consider risk management proposals on issues in scope of the framework.

5.14 Opportunities for four nations discussion will exist at all stages of risk management to ensure that all relevant considerations are taken into account when forming risk management advice and recommendations. Discussion on issues such as terms of reference and potential membership of any joint risk management groups will take place in phase 4 of framework development.

5.15 The risk analysis process will operate transparently, enhancing trust and confidence once the UK is outside of the European Union framework. The process will seek to provide, wherever appropriate, a cohesive UK risk management opinion on matters of food and feed.

UK pre-market approval and authorisation processes

5.16 Where changes are driven by businesses (for example an application for the authorisation of a new feed or food additive), the Framework commits all parties to a

single application process for businesses applying for pre-market approvals and re-authorisations for the GB market. Where applications are made by businesses for the authorisation of a new regulated food or feed product, or for renewals of existing authorisations, these can be submitted via an online portal. All information/data submitted in support of applications will be accessible to the relevant leads in each of the four nations. The operational detail of this has been developed by FSA and FSS officials.

- 5.17 Businesses applying for pre-market approvals and re-authorisations for the Northern Ireland market will submit applications to the relevant body as set out in European Union legislation (ESFA or the European Commission).

Managing divergence

- 5.18 In making changes to retained European Union food & feed safety and hygiene legislation within scope of the framework, the four nations will aim to develop common policy approaches where this is appropriate. Where it is considered that a common approach is not the most suitable for taking forward changes to FFSH legislation, the following principles have been developed to manage divergence:
- Where one or more nation wishes to diverge from a four nations approach to food & feed safety and hygiene, before divergence can happen, nations must first see if they can agree a common approach that accommodates the desired outcomes of individual nations.
 - In line with normal working arrangements, proposals should be discussed on a four nations basis using existing forums in place between FSA and FSS to develop the proposed approaches.
 - Where a common approach cannot be agreed through normal policy routes, and divergence is not considered acceptable by one or more nations in the UK, then the dispute resolution mechanism can be engaged.
 - In Northern Ireland, officials and Ministers will still have the opportunity to fully participate in discussions on how potential divergence will be managed across the UK even when those issues fall within scope of the Northern Ireland Protocol.

Ministerial decision-making

- 5.19 Governance arrangements are needed for how the appropriate authorities (namely UKG and DA Ministers) take decisions based on joint recommendations from food safety bodies. While Ministers will ultimately retain the right to take individual decisions for their nation, as with officials, for areas within scope of the framework a consensus should first be sought, and efforts made to resolve any disputes. Proposals for the governance around Ministerial decision-making are covered in section 7.

Implementation of decisions

- 5.20 The mechanisms for joint working should provide, as part of proposed recommendations to Ministers, a recommendation on the most appropriate means for implementing decisions within scope of the framework, including whether decisions should be implemented in primary or secondary legislation or guidance, when they should come into effect. Shared processes for communicating changes to UK businesses and consumers should be used where appropriate.
- 5.21 UK-wide primary legislation will only be taken forward where consent has been sought of DA Ministers (as is the case at present) as well as Scottish and Welsh parliaments and the Northern Ireland Assembly under respective devolution settlements.
- 5.22 As noted in section 4, work will be undertaken in 2021 to assess the case for including concurrent powers in specific areas. If concurrent powers are put in place in certain areas, further consideration will be needed as to how the parties to the framework will determine the appropriate approach to take in these areas (i.e. whether to implement decisions through UK-wide legislation or separate legislation in one or more nation).

Dispute resolution

- 5.23 The process for resolving disputes at official level is expected to only be needed in a very small number of cases as the majority of the time food safety bodies are likely to agree on the recommendation for Ministers. Dispute resolution processes should only be used if resolution through normal working processes has not been possible. In some areas, commonality of approach will not be needed in order to meet the JMC principles, and in these cases divergent approaches could be recommended to Ministers. Where disputes do arise, they should be handled with adherence to the agreed principles and processes for resolution. The proposed operational detail of dispute resolution within the FFSH Framework is set out in section 12.

Framework implementation

- 5.24 As noted in section 4, the FFSH Framework will primarily be implemented through non-legislative agreements. The Framework will be implemented through:
- a concordat between the four Governments (signed by Health Ministers); and
 - a revised FSA-FSS MoU (setting out the elements of the Framework delivered by the food safety bodies of the UK).

6. Detailed overview of areas where no further action is thought to be needed

Where relevant, in this section policy teams should briefly explain why common rules or further cooperation is not required. This section should also set out where there is disagreement between administrations on whether common rules or further cooperation are required.

- 6.1 There are areas within FFSH where European Union legislation offers flexibility for the law to be applied in different ways, with scope for national measures to achieve common outcomes permitted by the legislation. In these areas, different decisions may be taken by individual administrations across the UK. These areas will be considered explicitly outside the scope of the UK framework. Section 4 of this document provides further detail on the scope of the FFSH Framework and specifies the elements of FFSH that are outside the scope of the framework, where proposals made in this document would not apply (for example, areas such as incidents handling, risk assessment during incidents, specific elements of the hygiene package and local enforcement). It should be noted that working arrangements between the food safety bodies on some of the 'out of scope' areas are already covered in an MoU between FSS and FSA (which will be revised to reflect new ways of working as a result of the framework proposals and European Union exit projects).
- 6.2 There are no areas of retained harmonised European Union FFSH legislation where it has been identified as undesirable to maintain shared ways of working for the development of FFSH policy.

OPERATIONAL DETAIL

Part 3: PROPOSED OPERATIONAL ELEMENTS OF FRAMEWORK

7. Decision making

Policy teams will need to consider the following questions, reflecting on any existing structures, and set out their initial thinking in each area, where appropriate distinguishing between one-off decisions needed to establish and in due course amend/update a framework, and ongoing operational decisions made under a framework:

- a. *What decisions will need to be taken?*
- b. *Which of these decisions will need to be taken at a UK wide level?*
 - i. *How will these joint decisions be made?*
 - ii. *Will specific criteria need to be met before joint decisions can be made?*
 - iii. *Will an evidence base be required, if so how will it be developed?*
- c. *Which decisions will need to be taken by third parties or by individual administrations?*
 - i. *If decisions are taken by individual administrations, will these be taken at an official or Ministerial level?*
- d. *How will decision making be tracked and by whom?*
- e. *How will disagreements be settled? (including any escalation process)*

It will be helpful to consider and work through practical examples to help put these discussions into context.

Any disagreement between administrations on approach should be recorded.

7.1 After European Union Exit, the appropriate authorities (namely UKG and DA Ministers) will need to take decisions on future changes to all areas of retained European Union FFSH law based on recommendations from officials. This will include both technical changes made through secondary legislation (of which there are likely to be many) as well as any changes to or new primary legislation that fall within scope of the framework. Annex 1 provides a detailed breakdown of the areas of European Union FFSH legislation where changes could occur. Annex 2 provides a breakdown of the retained European Union legislation.

7.2 Governance arrangements are needed under the framework for how Ministers will take decisions for their nations based on recommendations from food safety bodies (as jointly agreed by officials across the UK through the risk analysis process) in areas within scope of the framework. While Ministers will ultimately retain the right to take individual decisions for their nation (notwithstanding issues in scope of the Northern Ireland Protocol), as with officials, for areas within scope of the framework a consensus should first be sought on the approaches to take, and efforts made to resolve any disputes. For Ministerial decision making it is proposed that:

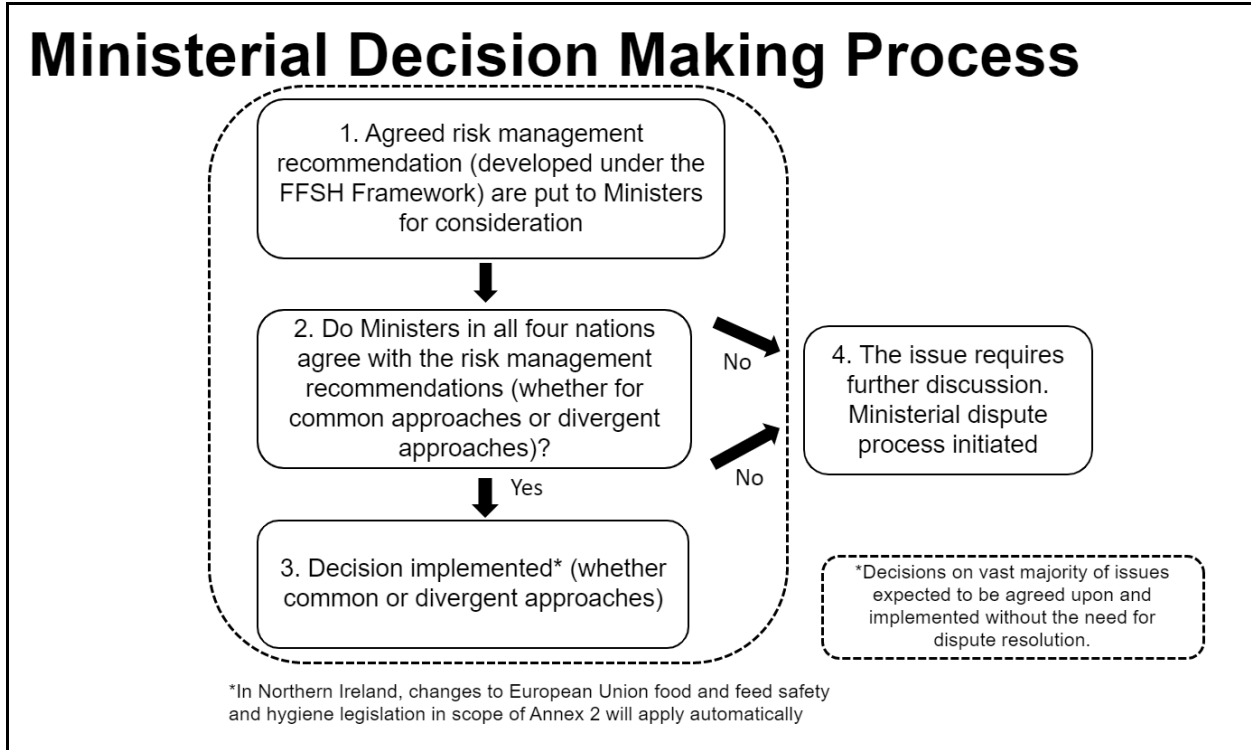
- Where timelines are prescribed in retained European Union law, decision-making processes should operate to these.
- Officials should seek decisions from Ministers at approximately the same time.
- Where Ministers do not agree on the recommendation made by food safety bodies (either for a common approach or divergent approaches across the UK) the Ministerial dispute resolution mechanism can be engaged (see section 12) to see if a consensus can be reached by portfolio Ministers (this is separate to the official level dispute resolution process, which deals with disputes arising at official level).
- Ministers' responses to recommendations should be managed and tracked, and policy officials in each of the four nations should share information on respective Ministers' responses to recommendations.

7.3 When recommendations are made to Ministers by food safety bodies, Ministers will be made aware of the recommendations being made in all four nations (whether for common or divergent approaches). Officials then provide an explanation of the underpinning rationale for the recommendations, including an explanation as to why the specific approaches are considered to be appropriate. The evidence supporting any recommendation (either for common or divergent approaches) would have been generated through a risk analysis process in which all four nations will participate. See section 5 for more information on the risk analysis process.

7.4 It is proposed that the Ministerial decision-making process would follow the process outlined in Diagram 1. Where divergent approaches are recommended to Ministers or one or more Minister is not content to proceed, Ministers have the opportunity to consider whether they are content for respective approaches to be implemented; if not they can decide to escalate the issue and engage the dispute avoidance and resolution mechanism (see section 12 for details).

7.5 There are no areas in scope of the framework where decisions will need to be taken by third parties, or by individual administrations without the issue having been considered through the risk analysis process and Ministerial decision-making process.

Diagram 1:



8. Roles and responsibilities of each party to the framework

The agreement will need to set out clearly the responsibilities of all parties, for example:

- a. commitments on regular meetings;*
- b. information sharing; and*
- c. Parliamentary and stakeholder communication and engagement.*

Policy teams should set out their proposals here, including any areas of disagreement.

See Section 9

9. Roles and responsibilities of existing or new bodies

Policy teams will also need to set out the proposed responsibilities of any third parties, and think about the governance and reporting arrangements for these bodies.

9.1 The FFSH Framework will commit the four nations to participation in ways of working set up as a result of the European Union Exit in part to deliver the framework (such as the risk analysis process) and the formalisation of existing or new working arrangements (such as the FFSH Frameworks Management group). Each of these will have specific roles and responsibilities within the framework.

Four nations working level arrangements

- 9.2 As detailed in the risk analysis process, if one or more nation has a specific issue that they wish to discuss at a working level on a four nations basis in relation to any area within scope of the framework, all four nations are committed to engaging on the issue at a working level. When policy leads from the four nations are engaging to jointly develop risk management recommendations they will do so under agreed ways of working (which will be developed as part of the risk analysis process). These principles will strengthen existing working arrangements between the four nations of the UK.

FFSH Frameworks Management Group

- 9.3 A FFSH Frameworks Management Group will be established to provide oversight of the FFSH Framework. The group would be made up of senior representatives between Grade 6 and Deputy Director level from food safety bodies from all four nations. Key responsibilities would include:

- considering amendments to the framework;
- undertaking reviews of the framework in line with the agreed Terms of Reference (noting that any recommended changes to the framework Concordat would be subject to Ministerial approval);
- reporting on the FFSH Framework to the appropriate authorities (JMC, FSA/FSS Boards, Ministers etc.); and
- resolving working level disputes on disagreements on interpretation or breaches of the agreed framework processes. See Annex 4 for Terms of Reference.

Four Nations Director Group

- 9.4 The Four Nations Director Group would act as the initial stage of escalation within the official level dispute resolution process for policy disputes. This group will meet on an ad-hoc basis as and when required, and membership will comprise of the relevant directors from the food safety bodies as the dispute in hand requires. See Annex 5 for Terms of Reference.

FSA and FSS Boards

- 9.5 The FSA and FSS boards have both made commitments to collaborative working on risk analysis: further information can be found in Board papers published on both organisations' websites. This will commit all four nations to being open and transparent in how risk management recommendations were reached, upholding the public interest in relation to food and protecting public health and consumers' wider interests in food. Both boards have made commitments to publishing the advice they provide and the evidence on which that advice is based, to fulfil both organisations' longstanding principles of openness and transparency.

- 9.6 The FSA and FSS Boards will play a role in assuring that the Framework is operating effectively. This assurance will be provided through the assurance processes for risk analysis (which both Boards have agreed), the annual review of the FSA-FSS MoU and the joint annual framework report carried out by the FSA-FSS Frameworks Management Group.

10. Monitoring and enforcement

Policy teams should consider whether and how any rules set out will be monitored and enforced, and the role of the Ministers from each of the administrations in that process, e.g. whether the framework result in new duties for Ministers or external bodies.

- 10.1 The FFSH Frameworks Management Group (comprising senior officials from all four nations) will monitor the functioning of the framework and assess any new needs of the framework at regular intervals (see section 11). The Frameworks Management Group should oversee the functioning of the framework, and any requests to amend any element of the framework should be raised to this group in the first instance. The group should agree what information it will need and on what frequency to provide assurance as required that the framework is operating effectively.
- 10.2 The dispute avoidance and resolution mechanisms (at both official and Ministerial level) will also be key components in ensuring the framework is adhered to. Any perceived breach of the agreed framework processes would be handled through the dispute avoidance and resolution processes (see section 12).

11. Review and amendment

Policy teams should think about whether there will be a need to review the framework and, if so:

- a. the timeline for this (including any external trigger points);*
- b. whether parties to the framework agreement should be able to call for a review;*
- c. how and by whom the review will be undertaken; and*
- d. how the outcomes of a review will feed into a decision to amend the framework.*

Policy teams should also think about the practical arrangements to amend the framework:

- a. how a decision to change a framework will be made;*
- b. how those changes will then be communicated to stakeholders, especially relevant committees/Parliaments.*

They should set out their proposed approaches here.

- 11.1 There will be a need to review the FFSH Framework after it is put into practice. It is proposed that the FFSH Frameworks Management Group (a senior officials group with representatives from all four nations) should initially meet every quarter to review the delivery and operation of the framework and assess any new needs of the framework. The first full post implementation review should be carried out one year after the framework is implemented; the group will report on the review to those with assurance responsibilities for the framework (likely to include the FSA and FSS Boards, portfolio Ministers and JMC (EN). After that the frequency on framework reviews should be proposed by the Frameworks Management Group to the relevant decision makers (taking account of departmental and wider framework Governance requirements).
- 11.2 Requests to amend any element of the framework should be raised to the Frameworks Management Group. A Terms of Reference has been developed detailing requirements and timescales (see Annex 4).

12. Dispute resolution

Policy teams should outline what they might need from a dispute resolution mechanism. In doing so, policy teams should think about:

- a. the likely causes of a dispute;*
- b. the stages of escalation and timescales for this process;*
- c. the point at which the dispute would be raised in the wider IGR structure; and*
- d. whether third parties would need to be involved;*

- 12.1 The dispute avoidance and resolution processes should only be engaged once all normal avenues to try and resolve the dispute have been exhausted. The Framework governance provides mechanisms for good communication and cooperation, which should reduce the likelihood of disputes arising. Where disputes do occur, consensus should be sought on the approach to take and efforts made to resolve the dispute. Actions under dispute should be paused pending resolution through the dispute resolution mechanism.
- 12.2 Disputes could potentially arise at official level or at Ministerial level. Where disputes arising at official level cannot be resolved through officials' dispute avoidance and resolution process, they should be escalated to Ministerial level.
- 12.3 There is a distinction between a 'difference' and 'dispute'. Differences may arise at any level, even Ministerial, and may be resolved without being elevated to the level of 'dispute' thus avoiding the formal resolution process. For example, a clarification provided by an exchange of emails or letters between senior officials or even Ministers may resolve a concern or potential issue. It should be noted that commonality of approach will not be needed to meet the JMC principles and therefore an "agreement to diverge" would be appropriate on some issues. If an issue cannot be resolved and it is necessary to escalate the issue to ministerial level, Ministers will be informed of the dispute in their advice from the parties and it will be for Ministers to determine whether they raise the dispute with their counterparts.
- 12.4 Where disputes do arise, they should be managed with adherence to the following principles:
- Commitment to evidence-based approaches to resolving disputes
 - Transparency (auditable, open to scrutiny unless legal requirements for non-disclosure)
 - Timely resolution (meeting deadlines for actions/stages, agreement to accelerated timescale in emergencies)
 - Compliance (with process and outcome)

Officials' dispute resolution

- 12.5 At official level, disputes could either arise:

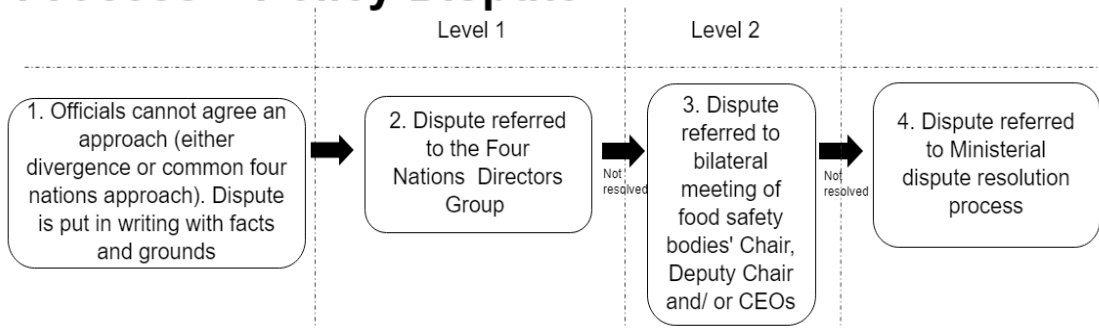
- a) Over disagreement on the approach to a policy issue, where officials cannot agree an approach (either to recommending common approaches, or to recommending that divergence is appropriate); or
- b) Over disagreement on the functioning of the framework, where officials in one or more nation consider officials in another nation/ nations to have breached an element of the agreed framework processes.

12.6 In either type of dispute, for areas within scope of the Framework, the issue should first pass through the officials’ dispute avoidance and resolution processes. In the rare instances where officials cannot resolve a dispute and it is escalated to Ministers, the Ministers’ dispute avoidance and resolution protocol should be engaged (see below).

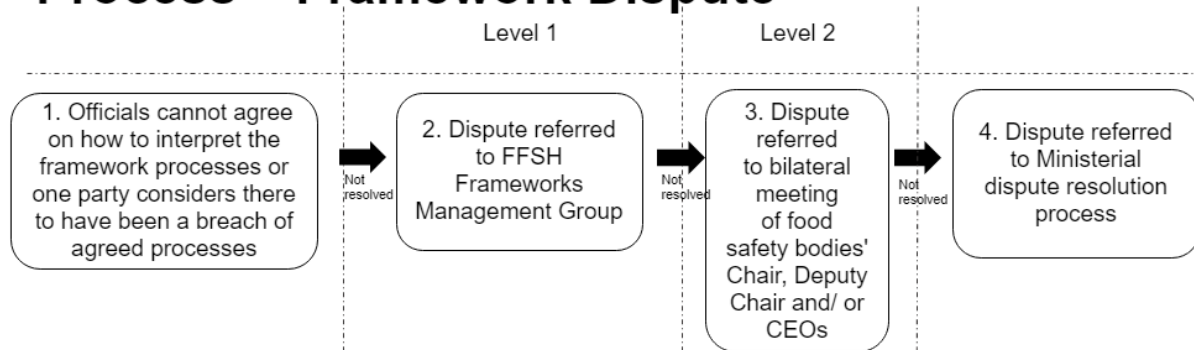
12.7 Diagram 2 sets out the different levels of escalation for different types of disputes arising at official level.

Diagram 2:

Officials' Level Dispute Avoidance & Resolution Process – Policy Dispute



Official Level Dispute Avoidance & Resolution Process – Framework Dispute



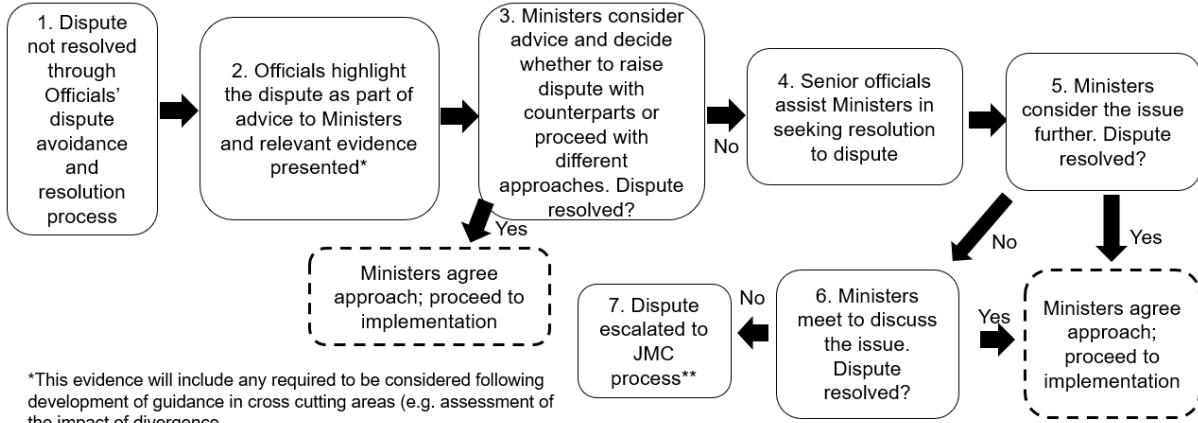
- 12.8 **Level 1:** at level 1 there are two different groups where disputes may be discussed depending on the type of dispute (either a dispute on a policy issue; or a dispute relating to the functioning of the Framework). If the dispute is around the policy recommendation, then the dispute is referred to a four nations Directors group. This group is an ad-hoc group called together only when disputes need to be resolved. The group should consist of the relevant Directors from across the food safety bodies and OGD representatives if required.
- 12.9 If the dispute is around the functioning of the framework itself, then the dispute is referred to the FFSH Frameworks Management Group. This group should consist of senior officials from food safety bodies in all parts of the UK and should have responsibility for overseeing the functioning of the Framework (for example, the annual review of the Framework) as well as seeking to resolve disputes that arise around the functioning of the Framework.
- 12.10 **Level 2:** at level 2, disputes should be handled through the same mechanism regardless of the type of dispute. Bilateral meetings already regularly happen between the FSA Chair/CEO and the FSS Chair/CEO. It is proposed that when a dispute is escalated to level two, the bilateral meeting is used as the forum for discussing the dispute and that the Deputy Chair of each food safety body should also participate in the dispute discussion.

Ministers' dispute resolution

- 12.1 In rare instances where Ministers do not reach unanimous agreement on a joint recommendation from food safety bodies, and in instances where officials cannot agree an approach (having attempted to reach agreement through the officials' dispute avoidance and resolution process), then the Ministers' dispute avoidance and resolution mechanism will be used to resolve the dispute and reach agreement on appropriate approaches.
- 12.2 In either of these situations, disputes should be handled with adherence to the same principles as the officials' dispute avoidance and resolution process. Diagrams 3 and 4 set out the two different ways disputes could be escalated to Ministerial level.

Diagram 3:

Ministerial Dispute Avoidance & Resolution Process – Dispute Arising at Official Level

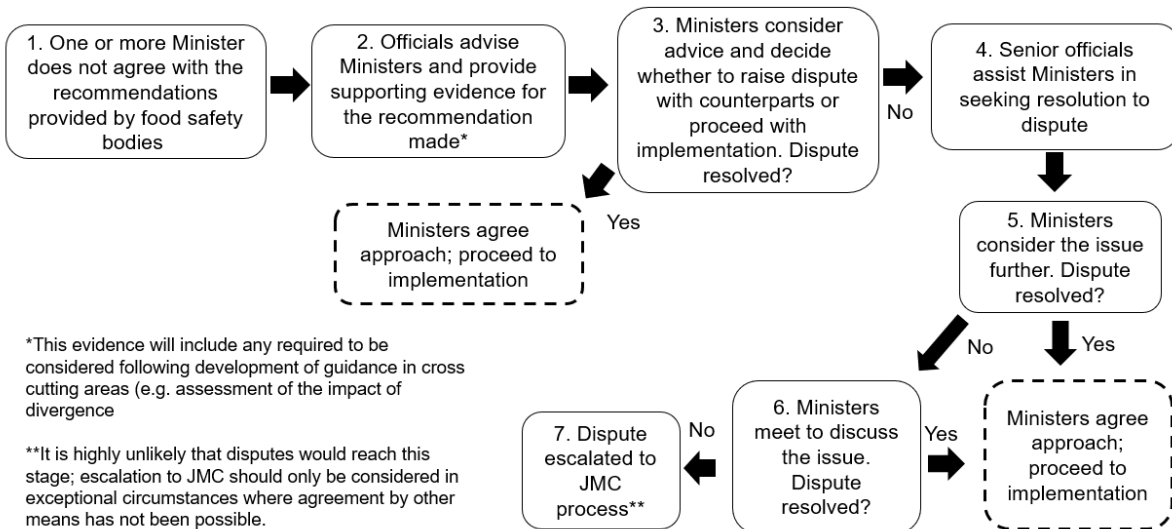


*This evidence will include any required to be considered following development of guidance in cross cutting areas (e.g. assessment of the impact of divergence)

**It is highly unlikely that disputes would reach this stage; escalation to JMC should only be considered in exceptional circumstances where agreement by other means has not been possible.

Diagram 4:

Ministerial Dispute Avoidance & Resolution Process – Dispute Arising at Ministerial Level



*This evidence will include any required to be considered following development of guidance in cross cutting areas (e.g. assessment of the impact of divergence)

**It is highly unlikely that disputes would reach this stage; escalation to JMC should only be considered in exceptional circumstances where agreement by other means has not been possible.

12.11 Disputes could arise at official level if officials cannot agree either to recommending a common approach, or to recommending that divergence is appropriate. Initially, the issue should pass through the officials' dispute avoidance and resolution processes. If it is not possible to resolve the issue through official level processes, the issue would be raised to Ministerial level for a decision on how to proceed.

- 12.12 In this situation, officials would highlight the disagreement at official level alongside respective food safety bodies' advice to Ministers including any relevant evidence (including any required to be considered following development of guidance in cross cutting areas, such as an assessment of the impact of divergence). It would be for Ministers to review the impacts of the proposed approaches before taking a decision on whether to proceed, or to raise a dispute at Ministerial level.
- 12.13 If Ministers could not agree to proceed with the recommended approaches having reviewed the evidence, the issue would continue through the stages of the dispute process: officials would provide assistance to Ministers in seeking resolution as requested, and further consideration of the issue would be given by Ministers.
- 12.14 If the dispute could not be resolved during these stages, portfolio Ministers would meet in person to discuss the issue. If resolution could still not be reached, the issue would be escalated to the JMC process (though it is considered that disputes would very rarely be escalated to this level).
- 12.15 Disputes could also arise at Ministerial level in cases where one or more Minister was not content to proceed with the recommendation from food safety bodies. In these cases, the issue would come back to officials in all four nations to carry out a review of the evidence (including the impacts of decision(s) taken) and provide further advice to Ministers. If the divergence was not considered to be acceptable, a dispute could be raised, following the same stages of escalation.
- 12.16 It will be necessary to continue to discuss the interdependencies of the FFSH Framework dispute avoidance and resolution processes with cross-cutting areas such as internal market considerations and international trade implications to ensure the dispute avoidance and resolution processes of the 'vertical' policy framework joins up appropriately with any 'horizontal' cross-cutting frameworks as these are developed.
- 12.17 In Northern Ireland, for issues in scope of the Northern Ireland Protocol, officials and Ministers will still be a full participant in any four nations correspondence or discussions that take place as part of dispute resolution processes.

Part 4: PRACTICAL NEXT STEPS AND RELATED ISSUES

13. Implementation

Where possible, policy teams should set out the next steps required, following Ministerial agreement, to operationalise their proposals and outline the proposed timetable for delivery. Policy teams should also note any potential resource implications.

Any other relevant issues should be fed into the Frameworks Project Team. Further guidance will be issued as appropriate.

Next Steps

- 13.1 Once Ministers' provisional agreement is given and JMC has agreed to the implementation of the FFSH Framework, preparation to implement the Framework will begin.
- 13.2 The non-legislative agreements that will implement the FFSH Framework will then be signed. These are:
- the Concordat between the four Governments (signed by Health Ministers); and
 - the revised FSA-FSS MoU (setting out the operational detail of the Framework, signed by FSA and FSS CEOs).
- 13.3 Work will also be needed to:
- ensure that the proposals set out in the framework are flexible enough to align with the outcomes of FR negotiations.
 - understand how the governance of the framework might interact with any potential commitments made to the European Union to demonstrate UK wide compliance with FR commitments.

Resource requirements

- 13.4 There will be resource requirements to develop and implement the framework and then ongoing resource requirements to support the effective functioning of the framework. Once implemented, the framework will require continued resourcing from all four nations in the policy groups, supporting Ministerial decision-making and the Frameworks Management Group.

13.5 A significant proportion of this resource would be required anyway to support delivery of FFSH after the European Union Exit and taking a four nations approach under the framework will ensure that expertise is shared and resource requirements are actually lower overall than if the four nations were taking this work forward individually. However, it is likely that ongoing resource and funding requirements will be needed to enable effective functioning of the framework.

ANNEX 1 – DETAILED BREAKDOWN OF EUROPEAN UNION FFSH LEGISLATION

General Food Law & Hygiene

Food and feed safety (as set out in General Food Law)

Regulation (EC) No 178/2002⁶ is often referred to as ‘General Food Law’ and is the key piece of legislation laying down high-level principles underpinning the placing of safe food and feed on the market in the European Union. It establishes and describes institutions and bureaucratic functions concerning food and feed safety. The main objectives of food and feed law are to guarantee a high level of protection of human health and consumers’ interests in relation to food and to ensure free movement of food and feed manufactured and marketed in the European Union. A number of functions are provided by the Commission or other European Union bodies under food and feed law (such as the European Food Safety Authority (EFSA) and tools for sharing of food safety information (such as the Rapid Alert System for Food and Feed (RASFF)).

The main objectives of food and feed law are to:

- guarantee a high level of protection of human life and health and the protection of consumers’ interests;
- ensure free movement of food and feed manufactured and marketed in the European Union, in accordance with the General Food Law Regulation; and
- facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the European Union.

A number of functions are provided by the Commission or other European Union bodies under food and feed law:

- Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) provides expertise to ensure legislation/measures are up to date, practical and effective.
- EFSA undertakes risk assessments for food and feed safety as well as providing scientific advice and support.
- Commission provides tools for sharing of food safety information (such as RASFF).

Food hygiene regulations

Regulation (EC) Nos 852/2004 and 853/2004 set out the requirements for the hygiene of foodstuffs and hygiene rules for food of animal origin. The hygiene package establishes the general principles for food hygiene controls and harmonised approaches. The legislation lays down the food hygiene rules for all food businesses, applying effective and proportionate controls throughout the food chain, from primary production to sale or supply to the final consumer. Commission Regulation (EC) No 2073/2005 provides that food business operators undertake sampling and testing to ensure that foodstuffs comply with the microbiological criteria set out in that Regulation.

⁶ Pursuant to Article 288 of the Treaty of the Functioning of the EU, EU Regulation has general application and is binding in its entirety and directly applicable on all Member States. This applies to all references to EU regulation.

Regulation (EC) No 852/2004 applies general hygiene rules for all food businesses on the hygiene of foodstuffs. Regulation (EC) No 853/2004 provides specific hygiene rules for food products of animal origin.

Commission Regulation (EC) No 2073/2005 lays down the microbiological criteria for certain microorganisms, and in certain food commodities.

Feed hygiene requirements

Regulation (EC) No 183/2005 lays down general rules on feed hygiene; conditions and arrangements ensuring traceability of feed; and conditions and arrangements for registration and approval of establishments to ensure a high level of consumer protection with regard to food and feed safety. Additionally, Regulation (EC) No 767/2009 the objective of which, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to harmonise the conditions for the placing on the market and the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health, as well as to provide adequate information for users and consumers and to strengthen the effective functioning of the internal market.

There are also additional European Union Regulations and Directives relating to feed setting out restrictions on undesirable substances (Directive 2002/32/EC) and feed for particular nutritional uses (Commission Directive 2008/38/EC).

Food Safety Standards

European Union regulations and directives cover requirements for:

Food Improvement Agents, and Feed Additives including:

- Food additives;
- Food enzymes;
- Food flavourings;
- Feed additives; and
- Extraction solvents.

Food improvement agents and feed additives are governed by harmonised rules across the European Union. Food improvements agents and feed additives require authorisation before products can be placed on the market. Proposed authorisations and withdrawals are considered at Working Group level by technical experts from all Member States following a safety assessment by the European Food Safety Authority (EFSA). The final risk management decision on authorisations and withdrawals from the market is taken by the European Commission based on qualified majority voting at Standing Committees (sub-sections of the Standing Committee on Plants, Animals, Food & Feed (SCOPAFF)) with responsibility for food and feed safety, and are brought into effect through legislation.

European Union Regulations provide for: harmonised lists of approved food improvements agents (additives and flavourings), conditions for authorisation and use for food additives, food enzymes, food flavourings; rules on the labelling of certain food improvements agents (including the so called "Southampton colours"); and specifications (purity criteria) for permitted substances. European Union Regulations list those feed additives authorised for use. In some cases, it lays down restrictions / conditions of use.

In relation to feed additives, Regulation (EC) 1831/2003 specifies the information which must appear on additive and premixture labels. It covers zootechnical additives, some categories of which are the responsibility of the Veterinary Medicines Directorate (VMD). In addition, Commission Regulation (EC) No 429/2008 sets out detailed rules for the implementation of Regulation (EC) No 1831/2003 with regard to the preparation and presentation of applications and the assessment and the authorisation of feed additives. Individual Commission Delegated Acts cover the authorisation of feed additives and any particular conditions of use. The process covers first time authorisations and renewal of existing authorisations and is a fast-moving area.

Enforcement is delegated to local authorities and powers for enforcement are provided by the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013; and the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015. Separate, equivalent regulations are in place in the devolved nations, and DAERA is the enforcement authority for feed in NI.

Food Contact materials and contaminants of food and feed, including:

- Food and feed contaminants;
- Food contact materials;
- Radioactive contamination of food and feed; and
- Feed detoxification processes.

Food contact materials and articles such as packaging, containers, cutlery, kitchenware, food handling gloves and plates etc are governed by general safety rules across the European Union and more specific rules for the manufacture, marketing and use of certain materials. In addition, specific European Union measures are in place for plastics, recycled plastics, regenerated cellulose film, lead and cadmium from ceramics and active and intelligent materials and articles. However, in areas where there are no specific European Union measures, Member States may maintain or adopt their own national provisions on other FCMs. For other materials and articles, the European Union deploys the principle of mutual recognition which guarantees that any product lawfully sold in one the European Union Member State can be sold in another, even if the product does not fully comply with the technical rules of the other nation.

European Union Regulations provide detailed requirements to ensure that any migration of chemicals from food contact materials and articles into food is at levels that will not harm human health nor detrimentally affect the nature and quality of the food. The Regulations also require operators to document both good manufacturing practice procedures and legal compliance of goods (including requirements for declarations of compliance).

Enforcement is delegated to local authorities and powers for enforcement are provided by the Materials and Articles in Contact with Food (England) Regulations 2012. Separate, equivalent regulations are in place in the devolved nations.

Contaminants

Contaminants in food and feed are governed by general principles and more specific harmonised rules across the European Union that aim to manage the presence of chemical contaminants in food and feed and ensure that any presence does not compromise public and animal health.

European Union Regulations establish harmonised general principles for food contaminants and provide specific maximum levels for certain foods/contaminants which take account of EFSA

risks assessments on the contaminant in question. In general, where specific maximum levels are provided at European Union level for a contaminant there are no national rules. However, national limits may exist where the European Union has not acted although this can create intracommunity trade problems.

There are some existing examples of relaxation of rules at national level (agreed at the European Union level) where local produce contains higher levels of contamination (e.g. fish from the Baltic sea). Such relaxations allow for local fishing and consumption as long as produce is not marketed outside the nation.

In addition to the European Union legislation, European Union codes of practice are also used such as for the reduction of fusarium and ochratoxin A mycotoxins in cereals which apply in the UK.

Enforcement is delegated to local authorities and powers for enforcement are provided by the Contaminants in Food (England) Regulations 2013. Separate, equivalent regulations are in place in the devolved nations.

Undesirable substances

Directive 2002/32/EC deals with undesirable substances in products intended for animal feed. The aim of this European Union legislation is to ensure that feed is put into circulation only if it is sound, genuine and of merchantable quality and, when correctly used, does not represent any danger to human health, animal health or the environment and does not adversely affect livestock production. This legislation prohibits the dilution of contaminated feed materials and it includes maximum limits for heavy metal presence such as arsenic, lead, mercury and cadmium as well as for arsenic, dioxin, aflatoxin, certain pesticides, and botanical impurities in certain feed materials, feed additives and feeding stuffs.

Enforcement is delegated to local authorities and powers for enforcement are provided by The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015. Separate, equivalent regulations are in place in the devolved nations.

Radioactive contamination of food and feed

Council Directive 2013/59/EURATOM establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical and public exposures against the dangers arising from ionising radiation. These standards set limits and reference levels that take into account total exposure from all sources (ingestion, inhalation and external exposure). The Directive specifically prohibits the deliberate addition of radioactive substances in the production of foodstuffs, animal feeding stuffs, and even cosmetics. It also prohibits the import or export of such products.

Council Regulation (Euratom) 2016/52 sets maximum permitted levels of radioactive contaminants in food and feed following a future nuclear accident or other radiological emergency. Regulations also cover checks and controls on the import of specific foods from nations affected by the Chernobyl nuclear accident (Council Regulation (EC) No 733/2008 and Commission Regulation (EC) No 1635/2006) and from Japan following the Fukushima nuclear accident (Commission Implementing Regulation (EU) 2016/6). Enforcement powers are provided by declarations under the Official Food and Feed Controls (England) Regulations 2009 and the Trade in Animal and Related Products Regulations 2011 in England. Separate, equivalent regulations are in place in the devolved nations.

Feed Detoxification processes

Detoxification processes can be applied to non-compliant animal feed to remove, breakdown into harmless compounds, destroy, or metabolise specific undesirable substances. Once the feed has undergone detoxification it may be placed on the market. To ensure that the detoxified feed does not endanger animal and public health and the environment and that the characteristics of the feed are not adversely altered all processes are safety assessed by EFSA.

European Union Regulations provide acceptability criteria for the authorisation of detoxification processes, whilst the substances that may be removed are listed in the European Union Directive 2002/32/EC. The Directive prohibits the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive. It is down to competent authorities to authorise a company to use the process permitted at European Union level.

GMOs (food and feed); Irradiated Food and Novel Foods, including:

- GMOs food & feed authorisations and labelling;
- GMOs traceability and labelling;
- Irradiated food; and
- Novel foods.

GMOs for use in food and feed are subject to a centralised authorisation procedure with a prior safety assessment before they can be placed on the market. European Union Regulations provide a harmonised procedure for the scientific assessment and authorisation of GMOs and GM food and feed with the European Food Safety Authority (EFSA) responsible for risk assessments.

European Union Regulations are in place for the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs. This provides a harmonised European Union system for identifying GM products throughout the supply chain that covers any products (including food or feed) consisting of or containing GMOs, food produced from GMOs and Feed produced from GMOs which are placed on the market. Responsibility for the safety of GMOs for food and feed use rests with the FSA.

Enforcement is delegated to Local Authorities and powers for enforcement are provided by the Genetically Modified Food (England) Regulations 2004 and the Genetically Modified Organisms (Traceability and Labelling) (England) Regulation 2004. Separate, equivalent regulations are in place in the devolved nations.

Policy on the cultivation of GM crops and environmental release of GMOs in England rests with Defra.

Irradiated Food

European Union Directives 1999/2/EC and 1999/3/EC and related Commission Decisions setting out the foods and food ingredients that may be treated with ionising radiation and the establishments that are permitted to carry out food irradiation. Irradiation treatment can be used to destroy bacteria and other micro-organisms which cause food-borne illness, extend shelf-life by delaying ripening or sprouting and remove insect infestations. These Directives are

implemented in England by the Food Irradiation (England) Regulations 2009. Separate, equivalent regulations are in place in the devolved nations.

These Regulations set out the requirements and procedures for the approval (licensing) of food irradiation facilities in the UK and the restrictions on importation, storage, transport and sale of irradiated foods by other food businesses. There is one licensed facility in the UK however, at present it is not operating in this capacity.

The licensing of food irradiation facilities ensures that food is treated following international (Codex) standards. Properly irradiated food poses no food safety risk but is seen as a consumer choice issue and this legislation ensures traceability of irradiated food so that information can be made available to consumers (ultimately through labelling requirements in the Food Information Regulations 2014).

Enforcement in respect to provisions related to a licensee is the responsibility of the FSA or FSS. Enforcement of provisions other than those of a licensee is delegated to local authorities and powers for enforcement are also provided by The Food Irradiation (England) Regulations 2009. Separate, equivalent regulations are in place in the devolved nations.

Novel Foods

Regulation (EU) 2015/2283 concerning novel foods establishes the concept of a novel food (foods that do not have a significant history of consumption in the European Union before May 1997) and sets out that these foods cannot be marketed within the European Union until they are demonstrated to be safe. The regulation provides for a centralised risk assessment process for both novel foods and a subcategory of these traditional foods from of novel foods. It provides a mechanism by which Member States can share information in order to decide on whether or not foods fall within the scope of the Regulation. Implementing regulation (EU) 2017/2470 establishes the European Union list of novel foods.

Enforcement is delegated to local authorities and powers for enforcement are provided by the Novel Foods (England) Regulations 2018. Separate, equivalent regulations are in place in the devolved nations.

It is noted that labelling requirements are an integral part of the authorisations for some products within scope (e.g. novel foods) and whilst general labelling will be picked up elsewhere, as a legitimate risk management tool specific safety labelling remains directly relevant to food safety common frameworks.

Official Controls for Food and Feed

Regulation (EU) No 2017/625 (the Official Controls Regulation) applied from 14th December 2019. It sets out rules for the performance of official controls by authorities which are required to verify compliance with feed and food law, rules on animal health and welfare, plant health and plant protecting products. It repealed several older Regulations on official controls for food and feed. More detailed rules on areas including import controls and hygiene controls on products of animal origin are set out in several pieces of tertiary legislation.

Official controls legislation is deeply interlinked with the rules it is in place to verify – for example the Food Hygiene Package (Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004) and the Feed Hygiene Regulation (EC) No 183/2005.

European Union legislation in this area sets out what must be achieved by Member State – a comprehensive, risk-based, proportionate, transparent official controls system – as well as detailed rules on how this is to be achieved in certain areas.

Legislation in this area provides a balance of principles and detailed rules, allowing for a reasonable amount of subsidiarity in how controls are performed and organised at MS level. As such the legislation itself spans a number of policy areas, notably:

- General Obligations of MS – this includes operational criteria, rules for the delegation of control tasks, rules on staff training and independence, rules on transparency and confidentiality;
- High-level rules on control methods and activities to be performed, by whom and when;
- Methods of sampling and analysis;
- Rules on laboratories used for the performance of official controls and international networks of reference laboratories;
- Guidelines for crisis management plans;
- Rules on import controls on animals and goods entering from third nations (please see the Imports/Exports return for further detail in this policy area);
- Rules for financing official controls; and
- Rules for cooperation between MS' competent authorities.

Public Health Controls on Imported Food

Specific requirements for imported food entering the European Union are covered by positive lists, standalone SIs and emergency declarations. Positive lists mandate increased levels of controls of feed and food of non-animal origin (FNAO). Where significant or sustained risks are identified, high-risk FNAO products may be subject to more stringent safeguard measures (including documentary checks, percentage of ID and physical checks required, health certificate requirements, sampling and analytical results, imports through designated entry points where appropriate facilities and staff are available to undertake the necessary controls, pre-notification requirements, specified time frames official controls must be completed within, onward transportation requirements and temporary suspension of a specific food or feed from a specific nation where a significant or sustained high risk has been identified). Importers are required to ensure that all listed products comply with the import requirements before they can be legally placed on the market. Standalone SIs cover specific import requirements for high-risk food (such as curry leaves and okra from India and GMOs in rice products from China). Emergency Declarations are issued when there is a serious and imminent risk to animal or public health and control measures need to be put in place rapidly.

European Union Decisions and Regulations

Positive lists:

- Commission Regulation (EC) No 669/2009 – Mandates increased level of controls of feed and food of non-animal origin. Provides for controls on emerging or re-emerging risks of high-risk FNAO. Where significant or sustained risks are identified, high-risk FNAO products may be subject to more stringent safeguard measures. The import requirements on importers and enforcement bodies of both Commission Regulation (EC) No 669/2009 and various safeguard measures include the following: documentary checks, percentage of ID and physical checks required (as specified within the safeguard measure), health

certificate requirements in some cases, sampling and analytical results required from the nation of origin in some cases, imports through designated entry points where appropriate facilities and staff are available to undertake the necessary import controls, pre-notification requirements, specified time frames official controls must be completed within, onward transportation requirements and temporary suspension of a specific food or feed from a specific nation of origin where a significant or sustained high risk has been identified. Importers are required to ensure that all listed products comply with the import requirements before they can be legally placed on the market.

- Commission Implementing Regulation (EC) No 884/2014 – Controls due to contamination risk by aflatoxins.

Standalone SIs:

- Commission Implementing Regulation (EU) No 885/2014 – Curry leaves and okra from India.
- Commission Implementing Regulation (EU) 2016/6 – Controls following the accident at Fukushima power station.
- Commission Implementing Decision 2011/884/EU – GMOs in rice products from China.
- Commission Implementing Decision 2014/88/EU – Betel leaves from Bangladesh.
- Commission Implementing Regulation (EU) 2015/175 – Guar gum from India.
- Commission Implementing Regulation (EU) 2015/943 – Dried beans from Nigeria.
- Commission Implementing Regulation (EU) 211/2013 – Imports of sprouts and seeds.
- Commission Implementing Regulation (EU) 2017/186 – Microbiological contamination.
- Council Regulation (EC) No 733/2008 – Chernobyl.
- Kava-kava in Food (England) Regulations 2002. Separate, equivalent regulations are in place in the devolved nations.

Emergency Declarations

Issued when there is a serious and imminent risk to animal or public health and control measures need to be put in place rapidly. Examples include:

- Commission Implementing Regulation (EU) 2017/186 - betel leaves and sesame seeds from India;
- Commission Implementing Regulation (EU) 2017/2058 - food and animal feed from Japan;
- Commission Implementing Regulation (EU) 2016/6;
- Commission Implementing Regulation (EU) 2016/24 – groundnuts from Brazil, capsicum annum and nutmeg from India and nutmeg from Indonesia;
- Commission Implementing Regulation (EU) 2016/166 - betel leaves from India;
- Commission Implementing Regulations (EU) 2016/884 - betel leaves from Bangladesh; and
- Commission Implementing Regulation (EU) 2016/874 - dried beans from Nigeria.

The Official Controls Regulation (EU) 2017/625 and its empowered tertiary legislation is the overarching European Union legislation that provides powers for official controls at the European Union borders. It sets out the framework for verification of compliance with food and feed law, rules on animal health and welfare, plant health and plant protection products

ANNEX 2 – SUMMARY OF RETAINED EUROPEAN UNION LEGISLATION**General food and feed law**

Regulation (EC) No 178/2002 - on General Food Law.	The General Food Law (Amendment etc.) (EU Exit) Regulations 2019 2019/641
Regulation (EC) No 852/2004 - on the hygiene of foodstuffs.	The General Food Hygiene (Amendment) (EU Exit) Regulations 2019 2019/642
Regulation (EC) No 853/2004 - laying down specific hygiene rules for food of animal origin.	The Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 2019/640
Regulation (EC) No 183/2005 - laying down requirements for feed hygiene.	The Animal Feed (Amendment) (EU Exit) Regulations 2019 2019/654
Regulation (EC) No 2074/2005 - laying down implementing measures for certain products under Regulation (EC) No 853/2004 and Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.	The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 2019/1013

Food and feed safety standards

Regulation (EC) No 1829/2003 – GMOs and Food – authorisations and labelling.	The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 2019/705
Regulation (EC) No 2283/2015– Novel foods.	The Novel Food (Amendment) (EU Exit) Regulations 2019 2019/702
Regulation (EC) No 1333/2008 – Food additives.	The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 2019/860
Regulation (EC) No 1935/2004 – Food contact materials.	The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 2019/704
Council Regulation (EEC) No 315/1993 – Food contaminants.	The Contaminants in Food (Amendment) (EU Exit) Regulations 2019 2019/639
Commission Regulation (EC) No 2073/2005 – Microbiological criteria.	The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 2019/1013
Regulation (EC) No 1831/2003 – Feed additives.	The Animal Feed (Amendment) (EU Exit) Regulations 2019 2019/654
Commission Regulation (EU) No 68/2013 - Catalogue of Feed materials.	The Animal Feed (Amendment) (EU Exit) Regulations 2019 2019/654
Regulation (EC) No 1332/2008 – Food enzymes.	The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 2019/860
Regulation (EC) No 1334/2008 – Food flavourings.	The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 2019/860

Commission Regulation (EU) No 234/2011 – Common Authorisation Procedure.	The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 2019/860
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Food and feed law enforcement (official controls)

Regulation (EU) No 2017/625 - on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.	The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020
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Public Health Controls on Imported Food

Commission Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the European Union of certain goods from certain third nations	The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2020
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ANNEX 3: FULL LIST OF DEFINITIONS

UK Food Safety Agencies:

- The **Food Standards Agency (FSA)** is a non-ministerial UK government department. It is responsible for protecting public health in relation to food and animal feed in England, Wales and Northern Ireland. It is led by a board appointed to act in the public interest. Its headquarters are in London, with national offices in Wales and Northern Ireland. The FSA is responsible for developing and implementing policy related to general food and feed hygiene and traceability. This includes the protection of public health via import controls, labelling related to food safety (such as allergens), food and feed safety standards, and biological and chemical safety. In Wales and Northern Ireland, the FSA is also responsible for general labelling related to public health and issues regarding food composition and standards. The FSA in Northern Ireland additionally has responsibility for nutrition.
- **Food Standards Scotland (FSS)** is a devolved, non-ministerial government department of the Scottish Government. It has responsibility for food and feed safety, food standards, nutrition, food labelling and meat inspection in Scotland. Established by the Food (Scotland) Act 2015, FSS took over the responsibilities previously held by the FSA in Scotland, as well as taking responsibility for nutrition and labelling in Scotland.

Frameworks:

- **Devolved administrations** refers to the Scottish Parliament, the Welsh Parliament and the Northern Ireland Assembly and to their associated executive bodies the Scottish Government, the Welsh Government and the Northern Ireland Executive.
- **Common frameworks** set out processes and governance arrangements for collaboration across the four nations of the UK to maintain consistent approaches in areas that are governed by European Union law before March 2019, but are otherwise within areas of competence of the devolved administrations. Common frameworks may consist of common goals, 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 memorandums of understanding, or by other means depending on the context in which the framework is intended to operate.
- **'Deep dive'** meetings have formed the formal official-level engagement on common frameworks for food and feed safety and hygiene jointly undertaken by all UK Administrations (as agreed by the Joint Ministerial Committee on European Union Negotiations (JMC(EN)) as part of the wider programme of work to develop common frameworks). Three 'deep dive' sessions have taken place since February with representatives from food and feed safety bodies and governments of all four nations. The deep dives have been used to discuss work carried out by working groups comprising representatives from across the four nations of the UK which have developed proposals for how the food and feed safety and hygiene framework could operate. Working group and review meetings have taken place regularly over the last six

months, and the proposals developed by these groups have formed the basis of the framework outline.

- The **framework outline** is a template agreed by JMC(EN) which all frameworks policy areas have been required to complete, providing a suggested outline for an initial UK-wide framework agreement. It is intended to facilitate multilateral policy development and set out proposed high-level commitments for the four UK Administrations. The document will be published once it is finalised.

European Union Institutions, Systems and Processes:

- The **European Food Safety Authority (EFSA)** provides independent scientific advice and risk assessments covering food, animal feed, pesticides, GMO, animal health and welfare, plant health and nutrition. EFSA supports the European Commission, the European Parliament and European Union member states in taking effective and timely risk management decisions that ensure the protection of the health of European consumers and the safety of the food and feed chain.
- The **Rapid Alert System for Food and Feed (RASFF)** is an European Union IT system that provides early alerts of contaminants in food and feed from across the European Union (often foodborne diseases), enabling rapid response to serious risks to human health.
- **Comitology** is a process by which European Union law is modified, supplemented or adjusted and takes place within "comitology committees" chaired by the European Commission. Comitology committees are part of the European Union's broader system of committees that assist in the making, adoption, and implementation of European Union laws. The Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) is the comitology committee that provides expertise to ensure food and feed legislation and measures are up to date, practical and effective. SCOPAFF is made up of multiple different sections (such as General Food Law, Biological Safety of the Food Chain and Novel Food and Toxicological Safety of the Food Chain), each with their own working/ expert groups which sit beneath the standing committees.
- **National measures** are measures that Member States may adopt where there is flexibility in European Union regulations for Member States to adopt local solutions (based on the principle of subsidiarity). National measures may be adopted to make exemptions from certain requirements laid down in annexes of European Union legislation. When making use of flexibility provisions, Member States must notify the European Commission.
- **The principle of subsidiarity** (outlined in Article 5 of the Treaty on European Union) guarantees that decisions are taken as closely as possible to the citizen. In areas in which the European Union does not have exclusive competence, the principle of subsidiarity seeks to safeguard the ability of the Member States to take decisions. In areas where the European Union does not have exclusive competence it will only take action in cases where it would be more effective than an action taken at the national, regional or local level.

International Institutions:

- **Codex Alimentarius** is a collection of internationally recognised standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety. Its texts are developed and maintained by the Codex Alimentarius Commission, whose main goals are to protect the health of consumers and ensure fair practices in the international food trade. The Codex Alimentarius is recognized by the World Trade Organisation as an international reference point for the resolution of disputes concerning food safety and consumer protection.
- The **WTO Committee on Sanitary and Phytosanitary Measures (the "SPS Committee")** was established by the WTO SPS Agreement (which sets out the basic rules for food safety and animal and plant health standards) as a forum for consultations about food safety or animal and plant health measures which affect trade, and to ensure the implementation of the SPS Agreement. It is open to all WTO member nations. Governments may send appropriate officials to participate in the meetings of the SPS Committee (e.g. food safety authorities or veterinary or plant health officials). The SPS Committee usually holds three regular meetings each year.

Food and Feed Safety and Hygiene:

- **Food and feed hygiene** refers to the conditions and measures needed to ensure that the safety of food and feed is not compromised throughout the food chain from primary production to sale or supply to the final consumer. Food and feed hygiene requirements establish the general principles for food hygiene controls, including food hygiene rules for food and feed businesses, specific controls for products of animal origin, microbiological criteria for certain commodities, and conditions and arrangements for ensuring traceability.
- **Food and feed safety** refers to the handling, preparation, and storage of food and feed in ways that prevent food-borne illness. Food and feed safety requirements lay down the high-level principles underpinning the placing of safe food and feed on the market, and establish institutions and bureaucratic functions concerning food and feed safety. The main objective of food and feed law is to guarantee a high level of protection of human life and health and the protection of consumers' interests.
- **Official controls** are activities carried out by competent authorities to verify business compliance with the requirements set out in agri-food chain legislation for ensuring the safety and quality of food and feed (as well as plant health, animal health and welfare). Official controls take place across the food chain, from plants and animal production, to food manufacturing, processing and distribution. They also cover import controls on animal products from third nations. Competent authorities organise official controls systems within their territory to verify that operators' activities and goods placed on the market comply with relevant standards and requirements. A key mechanism by which the FSA and FSS influence official control activity carried out by local and port health authorities is the Framework Agreement on Official Feed and Food Controls by Local Authorities, which sets out what the

FSA and FSS expect from local authorities in their delivery of official controls on feed and food law.

- **Regulated products** are food and feed products that require an authorisation, which involves a scientific assessment to evaluate their safety, before they can be placed on the market. Regulated products include substances used in food and feed (such as additives, enzymes, flavourings), food contact materials and pesticides, genetically modified organisms, novel foods and food-related processes, and processing aids.
- **Food and feed safety enforcement:** legislation sets out the general approaches and principles that must be taken for the monitoring and enforcement of feed and food law requirements. There is also considerable scope for national enforcement measures. National legislation allows flexibility for competent authorities to organise enforcement arrangements (in line with the general principles set out in European Union law). Each nation in the UK has scope to take different approaches to some enforcement measures. Across the UK, much enforcement work is carried out by Local Authorities.
- **Food defence** refers to procedures adopted to assure the security of food and drink and their supply chains from malicious and ideologically motivated attack leading to contamination or supply disruption.
- **Food fraud** refers to dishonest act or omission, relating to the production or supply of food, which is intended for personal gain or to cause loss to another party.

Risk Analysis:

- **Risk** is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (i.e. how likely is it that harm will be done and how severe are the health effects likely to be?).
- **Risk analysis** is a process consisting of three distinct but closely linked components: risk assessment, risk management and risk communication.
- **Risk management** is the process, distinct from risk assessment, of weighing policy, alternatives in consultation with interested parties, considering risk assessment and other factors relevant to health protection of consumers, and if needed, selecting appropriate prevention and control options.
- **Risk communication** is the interactive exchange of information and opinions throughout the risk analysis process concerns 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.

- **Risk assessment** is a scientifically based process consisting of the following four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.
- **A hazard** is a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.
- **Hazard (toxicological):** An inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent.
- **Other legitimate factors** refer to issues other than human health risk assessment that inform risk management and communication.

ANNEX 4: FRAMEWORKS MANAGEMENT GROUP TERMS OF REFERENCE

1. Purpose and Scope

1.1 The Food and Feed Safety and Hygiene Frameworks Management Group (FMG)'s principal purpose is to bring together senior officials with oversight of the functioning of the Common Framework for Food and Feed Safety and Hygiene (the Framework). The Framework sets out ways of working and governance arrangements to maintain a collaborative four nations approach to food and feed safety and hygiene after the UK's exit from the European Union. The FMG will be responsible for assessing any new needs of the framework at regular intervals and will play a role in resolving disputes related to the functioning of the Framework. The FMG will be comprised of senior food safety officials from the UK Government and devolved administrations (and, on a case by case basis, other departments if necessary).

1.2 The scope of the FMG's responsibilities include:

- **Considering amendments to the Framework:**

- Proposed amendments to the Framework can be put forward by officials in any nation. Proposals should be made in writing and should include rationale for the proposed change(s). Any proposed change to the framework Concordat would be subject to Ministerial agreement.
- The FMG should respond without undue delay to any requests for Framework amendments setting out the decision of the FMG.
- If the FMG fails to agree an approach in response to a proposed amendment to the Framework and a dispute arises, the issue should be escalated through the officials' dispute avoidance & resolution process.

- **Undertaking Framework reviews in line with the agreed protocols:**

- The first full post-implementation review should be carried out one year after the framework is implemented. After the first review, the frequency of framework reviews should be agreed by the FMG and included in the Terms of Reference (ToR).
- The FMG should agree what information it needs to see to provide assurance that the framework is operating effectively.

- **Reporting on the Framework to appropriate authorities as required:**

- The FMG should seek to provide jointly agreed updates on the functioning of the Framework to the FSA/ FSS boards, Ministers and JMC as required.

- **Resolving official-level disputes regarding the interpretation or breaches of framework processes (see process diagram in Diagram 2).**

- If a dispute arises over the functioning of the framework (i.e. if officials in one or more nation consider officials in another nation or nations to have breached an element of the agreed framework processes), the FMG will act as the first point of escalation; it should aim to reach a consensus on the approach to take to resolve the dispute.
- A summary of the dispute should be provided to the FMG in writing, including the background of the issue and the positions of all parties.
- A dispute can be escalated to the FMG at any time. The FMG should aim to meet within one month of the dispute being raised.
- If the FMG fails to resolve a dispute, the issue should progress through the officials' dispute avoidance & resolution process (it should be escalated to a bilateral meeting of Chairs/ CEOs).

1.3 The following areas are outside the scope of the FMG:

- Resolving policy risk management-related disputes (risk management related disputes will be escalated to a meeting of Directors, as outlined in the officials' dispute avoidance & resolution process).

2 Representatives & Contact Details

2.1 Group membership will consist of senior officials representing the food safety bodies in each administration.

Department	Representative	Contact Details
FSA - England	Anjali Juneja	Anjali.Juneja@food.gov.uk
FSA - Northern Ireland	Sharon Gilmore	Sharon.Gilmore@food.gov.uk
FSA - Wales	Nathan Barnhouse	Nathan.Barnhouse@food.gov.uk
Food Standards Scotland	David Johnston	David.Johnston@fss.scot

2.2 Meeting Frequency and Location

Frequency	Location	Papers Issued
<p>Initial meetings will be held quarterly in the year following the Framework's implementation.</p> <p>Thereafter, the frequency of meetings shall be determined by the FMG.</p> <p>The FMG will be required to meet within one month if a dispute is escalated to the FMG for its attempts at resolution.</p>	<p>1 meeting per year face to face; location TBC;</p>	<p>Papers issued a minimum of 1 week prior to meetings.</p>

ANNEX 5: FOUR NATIONS DIRECTOR GROUP TERMS OF REFERENCE

1 Purpose and Scope

- 1.1 The Food and Feed Safety and Hygiene Four Nations Director Group (FDG)'s principal purpose is to bring together senior officials with oversight of the official level dispute resolution process. The FDG is responsible for the initial stage of escalation within the official level disputes resolution process for policy issue disputes in which officials cannot agree a risk management approach. The FDG will be comprised of relevant directors from the food safety bodies as the dispute in hand requires. This group will meet on an ad-hoc basis as and when required.

Four Nations Director Group would act as the initial stage of escalation within the official level dispute resolution process for policy disputes

2 Representatives & Contact Details

- 2.1 Group membership will consist of senior officials representing the food safety bodies as the dispute in hand requires.

Department	Representative	Contact Details
FSA - England	Rebecca Sudworth	Rebecca.Sudworth@food.gov.uk
FSA - Northern Ireland	Maria Jennings	Maria.Jennings@food.gov.uk
FSA - Wales	Nathan Barnhouse	Nathan.Barnhouse@food.gov.uk
Food Standards Scotland	Garry Mournian	Garry.Mournian@fss.scot

- 2.2 Meeting Frequency and Location

This Four Nations Director Group will meet on an ad-hoc basis as and when required.