

UK RISK ANALYSIS PROCESS UPDATE

1 Purpose

- 1.1 In February 2019, the Board agreed that Food Standards Scotland (FSS) should work collaboratively with the Food Standards Agency (FSA) on future arrangements for risk analysis in the UK in the context of leaving the EU and the end of the transition period.
- 1.2 In March 2019, further information was presented to the Board who agreed the proposed approach to the risk analysis process (illustrated in Annex A) and that we continue to work with FSA on the method of implementation. At that time, the Board agreed to the proposed governance arrangements and specifically the joint constitution of an Advisory Forum on Food and Feed (AFFF), which sought to provide a formal mechanism for considering risk management interventions to support any future UK-wide Framework on Food and Feed Safety and Hygiene (FFSH).
- 1.3 This paper has two purposes: firstly to provide the Board with an update on the progress made on developing the proposed approach to the risk analysis process and how it will work at the end of the transition period; and, secondly, to consider these matters and agree to the recommendations contained within the paper and summarised below:
- 1.4 The Board is asked to:
 - **Agree** the proposed approach to the risk analysis process and that we continue to work with FSA on a four-country method of implementation as outlined at paragraph 4.33;
 - **Agree** proposals on the approach to prioritise and triage issues in the UK risk analysis process;
 - **Discuss** the possible options presented with regard to the publication and consultation on issues in the process and **Agree** an approach to how FSS publishes its risk assessment advice (and the analysis and evidence on which that advice is based, as well as other legitimate factors) alongside any risk management decisions made;
 - **Note** and the standing down of the AFFF and the intention to undertake some of its proposed functions through senior level risk management forums throughout the risk analysis process;
 - **Note** the proposed arrangements that will be in place including the establishment of the FSS Policy and Risk Management Group and how that will coordinate FSS input into the risk analysis process;
 - **Note** the proposed approach for the GB-wide management of the administrative functions associated with the application process for Regulated Products and that a submission has been sent to the Minister for his agreement.

- **Discuss** and **Agree** the proposal around the nature and frequency on how the Board is updated on routine matters going through the risk analysis process, including consideration of a possible sub-committee of the Board; and
- **Note** that the Executive will now look to progress the planned work of undertaking a review of the Code of Governance in the context of EU exit for consideration by the Board.

2 Strategic Aims

- 2.1 This work supports all of FSS's current Strategic Outcomes and proposed Strategic Outcomes and goals within the proposed Strategy for 2021-25.

3 Background

- 3.1 FSS's position on leaving the EU is to ensure that the level of protection afforded to consumers in Scotland is not reduced, and that FSS, with its current remit and powers, is best placed to ensure the continued protection of public health, improvement in diet and protection of the other interests of consumers in Scotland in relation to food.
- 3.2 The paper considered by the Board in [February 2019](#) set out arrangements for risk analysis, insofar as where these are currently carried out by the European institutions, would change when the UK left the EU and at the end of the current transition period. The paper also defined risk analysis in the context of FSS's work as 'a risk based approach to the identification and management of public health hazards in food'¹.
- 3.3 A further paper was presented to the Board in [March 2019](#). The paper provided the Board with an overview of how the risk analysis process would work in practice after the UK left the EU and considered these matters in the context of FSS's wider governance and assurance framework. The Board were also presented with additional detail on the overarching principles that apply to the intended approach (summarised again for the Boards information at para 4.1); the 12-steps of the risk analysis process and; the role of the FSS and FSA Boards with regards to the governance and assurance arrangements for risk analysis. The paper noted challenges being faced by FSS at that time around the capacity and expertise FSS needed to deliver this process in Scotland and agreed that the most cost-effective approach for risk analysis being one that was taken forward in a joint manner with FSA, building on the four-country approach as part of the developing UK-wide FFSH framework.
- 3.4 At the March meeting, the Board agreed to the proposed approach to the risk analysis process and that principle routine matters do not require to come to the Board before advice is provided to Ministers, but more complex/contentious ones and those linked to significant legislative changes would. At that time, the Board also agreed that the proposed AFFF be constituted under the Food

¹ <https://www.who.int/foodsafety/risk-analysis/en/>

Standards Act (1999) and the Food (Scotland) Act 2015, and that FSS would continue to be responsible for advice provided to Scottish Ministers.

4 DISCUSSION

Risk Analysis Principles

4.1 In broad terms, risk analysis is the process by which FSS and the FSA² assess, manage and communicate food and feed safety risks on a four-country basis. Both organisations have agreed to work collaboratively on risk analysis arrangements that will underpin the UK FFSH framework. The intention is that the relevant sections of the updated FSA/FSS Memorandum of Understanding (MOU) will outline the arrangements and relationships between the two bodies for undertaking risk analysis across the UK. The risk analysis principles have been agreed by the FSS and FSA Boards and will apply when the UK leaves the EU and during the transition period. The key high level principles are:

- Risk analysis comprises risk assessment, risk management and risk communication;
- The risk assessment and risk management functions should be separate;
- The risk analysis process is open and transparent. We will publish our risk management advice and the evidence and analysis in the risk assessment on which that advice is based;
- Advice and recommendations presented to Ministers will be risk, science and evidence-based and independent; and
- The risk analysis process has the capacity to provide for four-country working and deliver, where appropriate to do so, unified food and feed safety risk management recommendations for the UK.

Risk Analysis Process Update

4.2 In March 2019, the Board was presented with the detailed 12-step risk analysis process developed by FSA and supported by FSS, through the four-country food and feed safety risk analysis project. The risk analysis process has been designed to be agile and flexible to meet the requirements for individual issues when the UK exits the EU. Both organisations have reviewed and adjusted the processes so that the full risk analysis process transitions from shadow form to live operation by the end of the transition period.

4.3 As part of the ongoing development of the risk analysis process across the UK, the operational procedures underpinning the process are being refined to consider the proposed approach to prioritisation and triage of issues, and the approach to publication on issues in the process.

² FSA includes representation from FSA(W), FSA (NI) and FSA (E)

Prioritisation and Triage

- 4.4 At an operational level there will be a need to ensure that, as issues are fed into the risk analysis process, we allocate our science and policy resource appropriately alongside FSA. This will be formally coordinated in Scotland by the proposed FSS Policy and Risk Management Forum (see para 4.16) and supported by regular engagement at an officials level. **Prioritisation** will indicate the overall sense of the importance of an issue relative to others, identifying what needs to be done more quickly and where resources should best be spent; **triage** will identify non-routine issues that need greater levels of scrutiny and assurance and consideration by the relevant officials and the FSS Board as appropriate.
- 4.5 A quarterly four-country Prioritisation Forum will therefore be established to track capacity in the system, take decisions on priorities overall, and provide assurance and challenge. FSS will be working with FSA to develop and agree the terms of reference and membership of the Forum, however it is the intention that the Forum will report regularly to the FSS executive and the Board on the non-routine and high priority work going through the process. In addition, the regular Chair/CEO discussions will, as in other areas, ensure that this also takes into account the general position of the Board and identifies areas where further board engagement is required.
- 4.6 A consistent approach for discussing prioritisation and triaging issues, across all four administrations, in the process is required to ensure that:
- the correct priorities are identified from competing issues;
 - the process operates efficiently, and resources are effectively deployed;
 - issues transit through the process at the appropriate pace;
 - the level of assurance is appropriate to the nature and complexity of the issue; and
 - the system can react quickly to reprioritise resources to higher priority issues where necessary.
- 4.7 In accordance with the international norms set in Codex, the primary objective of the risk analysis process is to ensure human health protection. The prioritisation and triage approach will reflect that.
- 4.8 Issues will be prioritised based on factors such as public health and consumer protection imperatives, legal obligations, the potential impact on international trade, the relative ease or difficulty of resolving the issues, the level of political, public and stakeholder interest, and the extent to which the issue is aligned with FSS and FSA's overall strategic approach. Issues will separately be triaged as "non-routine" if they meet one or more criteria, such as:
- High level of political or ministerial interest in any one of the four administrations;
 - High level of stakeholder interest;
 - High level of consumer interest; and

- Potential for undermining existing regulation or guidance rather than supplementing it.

Publication and Consultation

- 4.9 The Board has made a commitment to publishing the risk assessment advice we provide. However consideration will need to be given to whether risk assessment advice (and the analysis and evidence on which that advice is based, as well as other legitimate factors) is published prior to any risk management decisions, or that risk assessments are only published once the risk management decisions have been taken. It may be that both approaches may need to be taken depending on the circumstances in which the risk management decisions are being made.
- 4.10 Detailed proposals for what this means in practice for the risk analysis process have been further developed and are being actively discussed by both organisations. The aim of this is to ensure that FSS continues to fulfil its principles of openness and transparency and its commitment to publishing advice in a considered and consistent way. A communication plan proportionate to the issue will be drawn up in all cases, with issues considered non-routine requiring more detailed plans to be developed at an early stage.
- 4.11 As a minimum, for issues going through the risk analysis process, the following will apply:-
- It is proposed that issues under consideration will be published on an FSS webpage with a link to the FSA website, which will perform a similar function to the EFSA Register of Questions.
 - Scientific Advisory Committees will continue to operate openly with agendas, papers and minutes routinely published unless there are specific reasons why an issue needs to be considered as reserved business in closed session (for example, where commercially sensitive confidential information needs to be considered).
 - Meaningful consultation – i.e. consultation will be carried out before final decisions are taken and allowing appropriate time for response. A key opportunity for formal public consultation on risk management options and draft impact assessment is identified at Step 8 of the risk analysis process in order to inform the development of the risk management options.
 - Where legislation is required – consultation on the draft legislation.

Advisory Forum on Food and Feed (AFFF)

- 4.12 The AFFF was initially established as an FSA committee by its Board in December 2018 and in February 2019, the Board agreed that FSS should work with the FSA jointly to constitute the Forum and develop the arrangements for it being the mechanism for providing risk management advice to support the UK-wide FFSH framework. The Forum would therefore have comprised not only FSS and FSA but also observers from other Government Departments (OGD) to assure themselves that, before any decision was taken by FSS and the FSA, that both organisations had fully considered their views.

- 4.13 In January 2020 the FSA Board suggested that the Forum was not needed given that it had been confirmed that Health Ministers in all administrations would be taking risk management decisions, based on FSS and FSA recommendations, after the transition period. Furthermore, discussions between FSA and the devolved administrations identified concerns that the AFFF may be viewed as a separate executive body that would form its own opinions and make decisions on behalf of the organisations. In fact, it had been intended as a consultative Forum and part of the quality assurance system rather than a body forming its own view.
- 4.14 Nevertheless, along with colleagues in FSA, we have reached agreement that the Forum does not need to form any part of the risk analysis process at present. The policy development process is already underpinned by collaborative working across FSS, FSA and other government departments as well as consultation with interested parties. Mechanisms are in place and being built in throughout the process to ensure FSS and FSA have the opportunity to discuss risk management proposals (particularly those triaged as “non-routine”) at a senior level and that other departments can raise relevant wider government initiatives early on in the process. Thus we can deliver risk management interventions that are effective for the UK as a whole or for individual countries as needed.
- 4.15 Whilst it will remain as a future option, it is no longer the intention to convene the AFFF as part of the risk analysis process at this time. Its functions will be delivered effectively through other routes, including a proposed UK Risk Management Group. Reference to the AFFF has therefore been removed from the flowchart graphic (Annex A).

FSS Policy and Regulatory Risk Management Forum

- 4.16 Once regulatory decision making powers for these policy areas return to Ministers in the four UK countries from 1 January 2021, at the end of the transition period, it will be important for FSS to ensure it has appropriate internal governance in place to facilitate a coordinated approach to policy development and regulatory risk management in Scotland. As part of the FSS EU Exit Programme consideration has been given to establishing a Policy and Risk Management Forum (PRMF) to agree food and feed safety management priorities and recommendations for Scotland after EU Exit, including the coordination, facilitation and involvement of FSS in UK level risk analysis groups throughout the process. In addition to the establishment of the PRMF, FSS risk managers and risk assessors will work closely with their counterparts in FSA, to ensure scientific data and knowledge is exchanged and that evidence relating to Scotland is taken into account when conclusions and risk management decisions are formulated.
- 4.17 In parallel with our engagement with FSA to progress implementation of the UK FFSH framework, FSS officials have also been working with Department of Health and Social Care (DHSC), Defra and the devolved administrations on the development of nutrition related labelling, composition and standards (NCLS), and food labelling and compositional standards (FLCS) frameworks, and the

associated cross-UK risk analysis and policy development mechanisms that will be needed to support these areas. This is notwithstanding the fact that the FFSH, NLCS and FLCS frameworks are likely to remain at different stages of development at the end of the transition period.

- 4.18 Notwithstanding the impact the UK Government Internal Market Bill may have on FSS policy areas, the PRMF would also be the primary mechanism for consideration of policy and risk management issues falling within these policy areas, but that are not subject to UK frameworks, i.e. areas of food safety and standards policy not currently harmonised at EU level where explicit Member State flexibility exists, such as the regulation of raw milk for direct human consumption. Consideration will also be given to our policy responsibilities in relation to diet and nutrition and how this work could be considered by the PRMF (e.g. prioritisation of issues to be referred to SACN or where changes to technical criteria/standards could have an impact on dietary guidelines). The PRMF's focus would be to agree the FSS risk management position in relation to proposals for regulatory change as well as key external facing policy positions in any of these areas (for example appropriate actions to take when STEC is detected in food).
- 4.19 The internal governance arrangements will be key to identifying and managing the strategic public health and consumer protection linkages across technical policy areas in Scotland. It will also ensure that FSS has the capacity to strategically consider any potential policy divergence with the rest of the UK and/or keeping pace with the EU, and the intersect with future UK trade negotiations and associated technical discussions on equivalence of Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) measures that engage devolved policy interests.
- 4.20 With the need for internal governance arrangements to be commensurate with the size of FSS and available resources, it is felt that have one group covering the breadth of our policy responsibilities whether framework related or not is the most efficient model of delivery at this time. The membership of the PRMF will also reflect the new FSS structure. This presents immediate challenges in terms of our organisational capacity to stand up the Forum at the present time, given that key posts that will need to be represented on the PRMF remain vacant. As an interim measure, an existing internal FSS group which has been set up to consider proposals for the new Forum, will continue to meet on a regular basis to progress the required future arrangements.

Regulated Products

- 4.21 One of the key repatriated functions that will fall to Ministers and food safety bodies across the UK in future is the processing of regulated product applications. FSS and FSA will have responsibility for the assessment of applications and the supporting dossiers of information on a range of regulated products and for providing advice to decision-makers on approval or authorisation. We are currently working with FSA and SGLD regarding the proposed UK administrative arrangements for handling regulated product applications and authorisations. Whilst good progress is being made around the process, there are some associated legal risks with regards to where

responsibility for these functions sit in the relevant retained EU law. FSS is discussing the matter with SG health officials and is undertaking further analysis with FSA prior to advising Ministers around the recommended approach. The submission will also seek the Ministers agreement to GB-wide administrative arrangements for managing the application, assessment and authorisation of certain regulated food and feed products after the end of the EU Exit Transition Period, insofar as they would extend to Scotland.

Resources/Organisational Capacity

- 4.22 As outlined to the Board in February 2019, FSS had existing, but limited expertise on scientific risk assessment. At that time, FSA also made it clear that FSS would have access to its capacity in this area, both on matters that are UK-wide, as well as commissioning support for risk assessments on Scottish issues and we continue to facilitate those ways-of-working through the update of the MOU between the two organisations.
- 4.23 To ensure that FSS also has the appropriate capacity, capability and internal structures in place to manage the risk assessment, policy development and risk management stages of the process, a business case was submitted to Scottish Government in August 2019 which outlined the impact that leaving the EU would have on FSS and in particular, the legal requirement to carry out new functions that were previously undertaken by European institutions, in particular the risk identification and assessment functions carried out by the European Food Safety Authority (EFSA). This business case was approved by Scottish Ministers in October 2019 and allowed FSS to proceed with recruiting staff to bolster the FSS scientific risk assessment and policy development functions. This recruitment has been ongoing since that time and we have successfully appointed new scientists to undertake the risk assessment function and are in the process of recruiting new policy staff, which has been delayed due to the impact of COVID-19 on recruitment, and it is anticipated this will be complete by the end of the year.
- 4.24 As part of the FSS future structure, the Board will also be aware of the establishment of new teams within the organisation who will be responsible for undertaking the scientific risk assessment, policy development and risk management functions at both a Scottish level and as part of the UK risk analysis process, coordinated by the FSS PRMF.

UK Frameworks, Internal Market Bill and the Northern Ireland Protocol

- 4.25 The approach outlined above aims to support four-country working as part of the UK FFSH framework, which remains subject to Ministerial agreement across the four nations. The risk analysis process in particular provides the policy making 'engine' for the Food and Feed Safety and Hygiene Framework and will be applied on a UK basis to matters within scope of that framework, notwithstanding requirements applicable to Northern Ireland as a result of the Northern Ireland Protocol. We are therefore working with FSA to develop and refine on that basis. The latest UK Government-Devolved Administration guidance on frameworks makes it clear that any associated processes or governance arrangements should be explicitly referenced as part of the

framework. Discussion on issues such as terms of reference and membership of any joint risk management groups will take place in phase four of framework development. A further paper will be brought to the Board, seeking provisional agreement to the FFSH framework before Ministers are asked to formally agree the framework by the end of the year.

- 4.26 Whilst good progress is being made with regards to the FFSH framework, the UK Government Internal Market Bill raises significant risks in relation to our statutory functions. The Bill proposes that any new food law in Scotland would have no effect as it will not apply to products placed on the market in Scotland from elsewhere in the UK, which we contend will lead to confusion for consumers and enforcement authorities. In addition, given the economic drivers within the Bill itself, we consider the proposals may lead to a lowering of standards across the UK as a whole as the least costly, most de-regulated option has the potential to undermine risk management decisions taken by any of the administrations. The position of FSS and Scottish Government is that UK frameworks are all that is needed to manage the practical regulatory implications of the UK leaving the EU and we continue to engage with FSA, DHSC and Defra on that basis.
- 4.27 The Bill also accommodates elements of the Northern Ireland Protocol, with provision for unfettered access to Northern Ireland Qualifying Goods (NIQG – as yet undefined in law), and mutual recognition. Only EU law applies to goods placed on the market in NI therefore mutual recognition will be ‘one way’ for NI – GB trade. Given the four-country basis for UK frameworks however, consideration as to how changes at EU level will be processed within the framework is ongoing. One of the key difficulties, more generally, will be in determining compliance with one of potentially 4 UK standards if a common UK regulatory approach is not taken. Whilst this is a complex area and further analysis and discussion is ongoing, our view is that the Bill does not affect the critical role that the risk analysis process will play as part of the four-country UK framework architecture.
- 4.28 In Northern Ireland, EU 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. How we consider EU risk management proposals within our risk analysis process and their relevance to risk management decisions taken in GB will also need to be understood.

Governance and Assurance

- 4.29 Whilst the processes described in this paper largely relate to operational matters, the Board will want to be assured that FSS continues to work with FSA to discharge its functions appropriately, for example, in prioritising matters for risk analysis, ensuring that priorities for Scotland are taken account of in the arrangements that are proposed (including development of the proposed UK forums that will support the operation of the risk analysis process), and ensuring that a broad set of impacts is considered in framing risk management advice in Scotland.

- 4.30 Noting the position of the Board at paragraph 4.9, publication of risk management advice, and the analysis and evidence on which that advice is based, before it goes to Ministers, should be consistent with our established ways of working. The usual vehicle for this will be the papers and discussion held in public by the Board. For more routine, technical matters the Board is asked to agree that this will be done through a public quarterly update from the Executive in written form. Consideration will also need to be given to how the timing of such updates is aligned with the scheduling of the FSA Board meetings and will be taken forward by officials in both organisations.
- 4.31 Given the level of detail and potential volume associated with risk analysis and the associated administrative arrangements for regulated products applications, the Board may wish to consider the creation of a sub-committee to consider this specific area on the Board's behalf and any additional governance measures required to support this way of working.
- 4.32 More generally, when considering both the general and specific impacts for FSS of the UK's departure from the EU, it is the Executive's intention to now undertake a review of the Code of Governance in the context of EU exit for consideration by the Board.

Communications and Stakeholder Engagement

- 4.33 A stakeholder engagement plan on risk analysis is being developed with key stakeholders to ensure that they are aware of and understand the risk analysis process, and the role of the FSA/FSS. In addition to that, work is progressing to develop and update the FSS website ahead of the 1 January to ensure it reflects the updated risk analysis process, including the areas highlighted in this paper.

Next Steps

- 4.34 This paper has outlined the progress made on developing the proposed approach to the risk analysis process, and how it will work at the end of the transition period. Whilst the high-level principles around how the UK risk analysis process will operate are advanced, there remains a reasonable body of work which is being progressed on a four-country basis to ensure the processes and procedures can be operationalised from 1 January 2020. The key aspects being taken forward over the next 3 months are summarised below:
- Development and agreement of the membership and terms of reference for any senior level risk management groups required to support the risk analysis process;
 - Finalising the FSS specific arrangements around how it intersects with the UK risk analysis process, via the proposed PRMF;
 - Updating draft guidelines for FSS/FSA staff involved in the risk analysis process, including workshops to ensure staff familiar with the ways of working which will be required for 1 January 2020;

- Developing the risk analysis content on the FSS website prior to 1 January 2020 so it fully reflects the developments in the risk analysis process as outlined in this paper;
- Agreement and signing of the respective Data Sharing Agreements for the systems being developed to support both risk analysis and regulated products applications and;
- Agreeing the risk analysis section within the updated FSA/FSS MoU and seeking FSS Board approval of the updated MoU (anticipated at the November Board meeting) and;
- Progressing the approval of the UK framework for Food and Feed Safety and Hygiene before the end of 2021.

5 Recommendations

5.1 The Board is asked to:

- **Agree** the proposed approach to the risk analysis process and that we continue to work with FSA on a four-country method of implementation as outlined at paragraph 4.33;
- **Agree** proposals on the approach to prioritise and triage issues in the UK risk analysis process;
- **Discuss** the possible options presented with regard to the publication and consultation on issues in the process and **Agree** an approach to how FSS publish its risk assessment advice (and the analysis and evidence on which that advice is based, as well as other legitimate factors) alongside any risk management decisions made;
- **Note** and the standing down of the AFFF and the intention to undertake some of its proposed functions through senior level risk management forums throughout the risk analysis process;
- **Note** the proposed arrangements that will be in place including the establishment of the FSS Policy and Risk Management Forum and how that will coordinate FSS input into the risk analysis process;
- **Note** the proposed approach for the GB-wide management of the administrative functions associated with the application process for Regulated Products and that a submission has been sent to the Minister for his agreement;
- **Discuss** and **Agree** the proposal around the nature and frequency on how the Board are updated on routine matters going through the risk analysis process, including consideration of a possible sub-committee of the Board; and
- **Note** that the Executive will now look to progress the planned work of undertaking a review of the Code of Governance in the context of EU exit for consideration by the Board.

Please direct queries to:

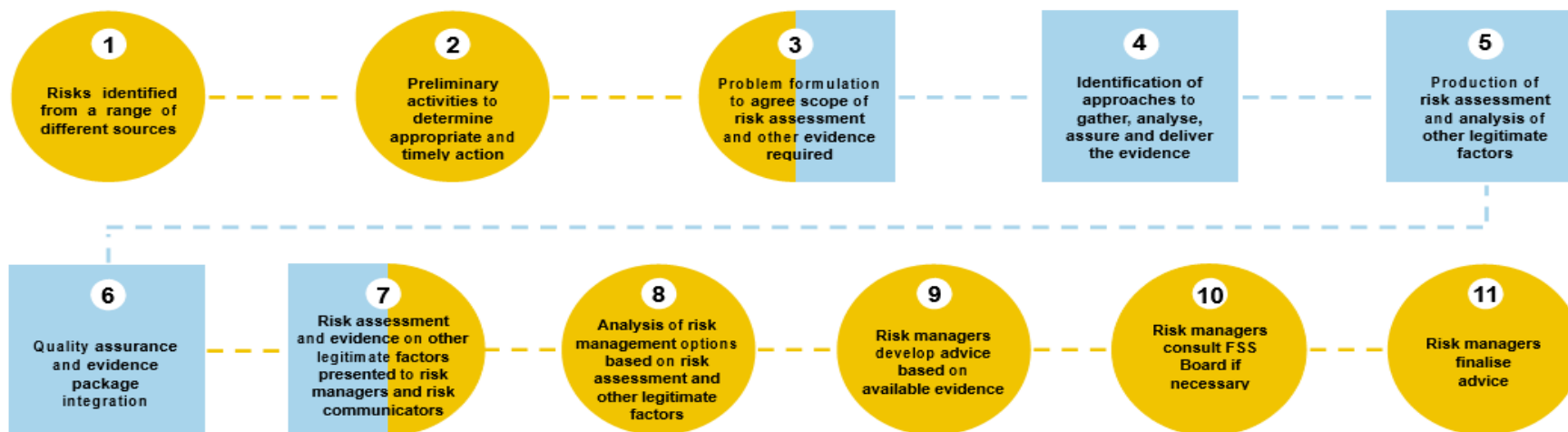
Garry Mournian
Director Policy, Science, Finance and HR
07825103873

13th October 2020

Annex A

FOOD AND FEED SAFETY RISK ANALYSIS PROCESS

This process flowchart shows the UK's risk analysis process which is one of the ways we will ensure that the high standard of food safety and consumer protection we enjoy in the UK is maintained after the Transition Period.



Our **RISK ANALYSIS PROCESS** is open and transparent. We publish the advice we provide to others and the analysis and evidence on which that advice is based. The process is underpinned by collaborative working across FSA, FSS and other government departments as well as consultation with interested parties.

Our independent risk, science and evidence-based advice and recommendations are presented to Ministers and others for decision. Decisions are then implemented and reviewed as needed. This process operates on a four-country model and can deliver, where appropriate, unified food and feed safety risk management recommendations for the UK. It will form the basis of all risk analysis activities but individual stages are flexible and can be adapted on a case-by-case basis.

RISK COMMUNICATION

We will embed effective risk communication mechanisms, ensuring interactive exchange of opinions and options throughout the process.

We will provide clear explanations of the findings of risk assessments and the analysis of other legitimate factors, and the basis of risk management decisions, using effective evidence-based and outcome-focused methods to communicate with consumers, industry stakeholders and other interested parties.

KEY

- Risk management
- Risk assessment and analysis of other legitimate factors



This diagram is for illustrative purposes.