

## LEAVING THE EUROPEAN UNION – FOOD AND FEED SAFETY RISK ANALYSIS

### 1 Purpose

1.1 In February 2019, the Board agreed that Food Standards Scotland (FSS) should work collaboratively with Food Standards Agency (FSA) on future arrangements for risk analysis in the UK in the context of leaving the EU, and that as part of that work, to develop arrangements for an Advisory Forum on Food and Feed (AFFF) as a mechanism for providing advice on proposed risk management interventions to support any future UK-wide framework on food and feed safety and hygiene.

1.2 This paper has two purposes: firstly to provide the Board with more detail of how risk analysis, including the AFFF, will work in practice after the UK leaves the EU and secondly, to consider these matters in the context of FSS's wider governance and assurance framework.

1.3 The Board is asked to:

- **Agree** the proposed approach to the risk analysis process and that we continue to work with FSA on the method of implementation;
- **Agree** the principle that 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;
- **Agree** that FSS's approval of the AFFF be contingent on agreeing a revised Memorandum of Understanding (MoU) between FSS and FSA, with particular reference to access to scientific advisory committees, within six months of agreeing the terms of the AFFF;
- **Agree** that the AFFF be constituted under both the Food Standards Act (1999) and the Food (Scotland) Act 2015, and that FSS will continue to be responsible for providing advice to Scottish Ministers;
- **Advise** if it agrees that the proposed amendments to the FSA's Terms of Reference for the AFFF are appropriate for FSS;
- **Agree** that the Executive brings forward a paper to the Board outlining the resource requirements in both numbers of personnel, skills and finance highlighted in paragraphs, 2.4, 5.1 – 5.3 of this paper;
- **Agree** that a short-life working group be established comprising members of the Executive and two non-Executive members to undertake a review of the Code of Governance in the context of EU exit for consideration by the Board, to ensure the Board is assured about how the Executive is discharging new functions that are a consequence of the UK leaving the EU.

### 2 Background

2.1 FSS's position on leaving the EU is to ensure that, whatever legislation is introduced as a consequence of the UK's exit from the EU, this should not result in any reduction in the level of protection afforded to consumers in Scotland, 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.

2.2 The paper considered by the Board in February<sup>1</sup> set out how arrangements for risk analysis, insofar as where these are currently carried out by the European institutions, will change when the UK leaves the EU. Under the current system of largely harmonised EU food and feed law, a considerable amount of risk analysis is undertaken by the European institutions, including the European Food Safety Authority (EFSA) (risk assessment) and the European Commission (EC) (risk management), with involvement of the Member States throughout the process, e.g. through EC Standing Committees.

2.3 Whilst longer-term, post-transition, arrangements in the event of a deal being agreed between the UK and EU are yet to be determined, in the event of a no-deal outcome, the food safety bodies in the UK – FSS and FSA – will become responsible, through the fixing legislation that repatriates EU law, for a number of functions currently undertaken by EFSA, including risk assessment, whilst Ministers in each administration will have responsibility for risk management decisions that are currently taken at the European level. If there is a political majority in the UK Parliament for the withdrawal agreement between the UK and EU, there is expected to be a transition period during which the future economic partnership between the EU and UK will be negotiated.

2.4 Whichever political outcome is reached however, it is expected that the repatriation of responsibility for food and feed safety and hygiene risk analysis will result in an increased workload for the food safety bodies within the UK, and greater scrutiny of the processes involved. FSS has been working with FSA, which has been leading the development of a new process to provide the infrastructure and arrangements for risk analysis in future. The Board should note that for matters that were previously carried out at EU level, this will be new activity for FSS which is currently unfunded, and to undertake this function will require work in other areas to be re-prioritised or stopped.

### **3 Risk Analysis Process**

3.1 There are some overarching principles that apply to the intended approach:

- Risk analysis comprises risk assessment, risk management and risk communication;
- The risk assessment and risk management functions should be separate;
- The risk analysis process must be open and transparent. It is therefore intended to publish the advice that is provided to others and the analysis and evidence on which that advice was based;

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<sup>1</sup>[https://www.foodstandards.gov.scot/downloads/Preparations\\_for\\_leaving\\_the\\_European\\_Union.pdf](https://www.foodstandards.gov.scot/downloads/Preparations_for_leaving_the_European_Union.pdf)

- Advice presented to Ministers will be based on all of the internationally recognised elements of risk analysis, be science and evidence-based and independent;
- The risk analysis process described here, to support any future UK-wide framework on food and feed safety and hygiene, will have the capacity to provide a model to deliver, where appropriate, unified food and feed safety risk management recommendations across the UK, or where the outcomes from the risk analysis process determine that unified recommendations are not appropriate, to provide different recommendations to Ministers.

3.2 As part of the infrastructure that will be needed in future to support the proposed UK-wide framework on food and feed safety and hygiene, FSA has been leading on developing the detail of a risk analysis process, and FSS has been fully engaged in this work. A process map is shown in Annex 1 to represent the system that is intended to apply when the UK exits the EU.

3.3 It is intended that risk managers in FSA and FSS will be alerted to the potential need for managing risks on matters that are within the scope of the proposed UK-wide framework, and this could arise from a number of sources (Step 1). Following this, preliminary risk management activities will be carried out to determine whether action is needed (Step 2). If this identifies a need for action a risk assessment will be requested, the scope of that risk assessment will be defined, and there will be agreement between risk managers about any other relevant factors, in addition to the risk assessment, required to allow a decision to be made (Step 3). The risk assessment and analysis of other factors is completed, consulting external experts, FSA and FSS Chief Scientific Advisers and the UK Scientific Advisory Committees as necessary (Steps 4-6). The risk assessment and analysis of evidence is then presented to risk managers in both FSS and FSA (Step 7). Risk managers will use this evidence to develop, analyse and identify risk management options, in consultation with other government departments across the UK (Step 8) which will be considered by the AFFF (Step 9) to develop advice (Step 10), that will be presented to the FSS and FSA Boards as necessary (Step 11), Ministers across the UK and others (Step 12).

3.4 It is expected that many of the issues that will be considered through this process will be routine and technical, for example, where food law requires businesses to seek authorisation for regulated products such as additives, flavourings or enzymes, or for materials that come into contact with food. It is proposed that matters considered to be technical and routine would not normally be considered by the FSA and FSS Boards before advice is provided to Ministers and any required statutory change is sought. Based on current levels of activity in the EU system, there may be around 150 of these authorisations in a year. On the other hand, there will be other policy issues subject to the risk analysis process that are more complex or contentious, and in those cases, it is envisaged that these would be considered by the Boards before advice is given to Ministers across the UK. This would mirror existing arrangements within the current system, where the Boards of FSA and FSS provide advice to respective Ministers across the UK on more complex or contentious issues, but do not generally do so on matters considered to be of a more routine nature.

3.5 Whilst FSA has led on developing these operating procedures for risk analysis, FSS has been involved through a Project Board, and the work continues to be a

collaborative process. The process continues being developed and tested, with FSS's involvement. The procedures will include appropriate links to existing frameworks/guidance from UK Scientific Advisory Committees e.g. the Committee on Toxicity (COT) and the Advisory Committee on Microbiological Safety of Food (ACMSF) and internationally recognised organisations; appropriate procedures for establishing priorities for risk assessment and risk management intervention; and the types of evidence that will need to be collated and assessed including the other legitimate factors that will be taken into account. Examples of other factors include animal health and welfare, health and safety, economic impact, environmental impact, trade distortion, impact on consumer choice, socioeconomic factors, consumer perceptions, acceptability and preferences, including the wider interests of consumers. FSS will need to ensure that these other legitimate factors take into account any differences of significance in relation to Scotland, to help determine whether the analysis supports consistent risk management advice be given, or whether a different approach should be recommended.

3.6 Our work throughout the risk analysis process will be focussed on fulfilling our statutory functions – protecting public health in relation to food, ensuring consumers have diets conducive to good health and protecting the other interests of consumers in relation to food. We must ensure that the outputs from risk analysis, which will include the consideration of other legitimate factors in relation to risk management provides confidence that this delivers public health protection and fully takes into account consumers' other interests in relation to food.

#### **4 Risk Management and the Advisory Forum on Food and Feed (AFFF)**

4.1 In February, the Board agreed that FSS should work with FSA to develop arrangements for an Advisory Forum on Food and Feed as a mechanism for providing risk management advice to support any future UK-wide framework on food and feed safety and hygiene. The process map at Annex 1 shows where the AFFF would be convened and how advice on risk management and interventions will be developed and flow through the process from risk managers, through the AFFF to the FSA and FSS Boards as appropriate, and on to Ministers.

4.2 The FSA has already constituted the AFFF insofar as the relevant FSA functions apply in England, Wales and Northern Ireland. FSS's participation, constituted appropriately through the Food (Scotland) Act 2015 would allow the AFFF to be a suitable mechanism to support any future UK-wide framework on food and feed safety and hygiene, and without prejudice to the views of Ministers on any such longer-term framework across the UK, would assist with having effective, practical arrangements in place in the shorter term in the event of a no-deal exit to help the food safety bodies fulfil their new responsibilities from the repatriated food law. Whilst it is proposed that the AFFF be constituted through both the Food Standards Act 1999 for FSA and the 2015 Act for FSS, it would be an advisory committee under the terms of those Acts, and would not have any powers or functions other than providing advice to FSS and FSA within wider governance frameworks to provide assurance about repatriated risk management functions.

4.3 The FSA Board has agreed Terms of Reference (ToRs) for the AFFF, attached at Annex 2. These ToRs make reference to Scotland and FSS, caveated as a provision should Scotland decide to participate in the AFFF. Annex 2 also shows a number of track changes that are proposed as appropriate for FSS's involvement.

4.4 Depending on the outcome of the risk assessment and risk management steps in the process, the AFFF may determine that the evidence supports a single UK-wide risk management approach, or different risk management options in one or more of UK nations where the evidence from risk assessment and consideration of other legitimate factors determine that different approaches to risk management are appropriate to achieve equivalent outcomes for consumers.

4.5 This paper has already highlighted the importance of openness and transparency in the risk analysis process and a likely increase in scrutiny in the work of the food safety bodies within the UK. The AFFF should help to enhance trust and confidence in the risk analysis processes by introducing greater transparency once the UK is outside of the EU framework, building on existing good policy making practise. The AFFF will also need to ensure that all relevant additional considerations are taken into account when forming risk management advice and recommendations.

4.6 It is proposed that membership of the AFFF is comprised of relevant officials in FSA (from England, Wales and Northern Ireland) and FSS, to deliver fully considered and objective risk management advice. Other departments from all four administrations across the UK should be invited to participate in the Forum as observers, where there is an intersect between their respective interests and food and feed safety. The distinction between FSA and FSS as AFFF members and other departments as observers is important, to protect the independence of the food safety authorities, whilst ensuring that those observers can assure themselves that the necessary scientific and technical contributions to the risk analysis process gathered by FSA and FSS policy developers during earlier consultations with departments have been taken into consideration in reaching their recommendations.

## **5 Resources and Capacity**

5.1 As outlined to the Board in February, FSS has existing, but limited, expertise and capacity on scientific risk assessment. FSA has been funded by UKG to develop increased capacity on scientific risk assessment, and as is presently the case through the MoU between our two organisations, FSA has made clear that FSS will have access to this capacity, both on matters that are UK-wide, as well as commissioning support for risk assessments on Scottish issues, and we would look for this to be confirmed through the revisions to the MoU. In addition, FSA is reviewing the structure and roles of the four Scientific Advisory Committees that provide advice across the UK on food and feed safety. Again, FSS has access to these Committees through the MoU. We have been working with FSA to encourage suitable applicants from Scotland to respond to FSA's call for additional experts to boost capacity on the SACs and their sub-groups. We will also be working with colleagues across Scotland, looking at where scientific capacity and capability can support risk assessment requirements.

5.2 FSS will also need to ensure it has appropriate internal structures and sufficient resources in place to manage the policy development and risk management stages of the process. This includes identifying risks, determining if action is needed to manage these risks and if so, working with risk assessors on problem formulation and to agree the scope of risk assessment and other evidence. FSS will require capacity and capability to ensure the process has appropriate regard to Scottish priorities and that risk management options take full account of scientific evidence relating to public health risks that are particular to Scotland, as well as consideration

of any other legitimate factors which may differ to other parts of the UK. This will be essential to ensure that any differences in relation to Scotland are fully considered in advance of risk management channelling through the AFFF, the Board and Ministers.

5.3 It is not yet clear how many regulated product applications will be submitted into the UK systems for risk analysis after exit. Based on current levels of activity in the EU system however, there may be around 150 in a year. The number of more complex or contentious issues for risk analysis is expected to be significantly lower. We will require to have sufficient administrative oversight of those applications, and to prepare any legislation that Scottish Ministers are required to implement to give effect to new authorisation decisions in Scotland. We will require to maintain sufficient flexibility in our planning for next year and beyond to ensure that we can fulfil the range of new responsibilities in this area, and can provide assurance to Scottish Ministers that our advice is adequately informed by science and evidence that is relevant to the situation in Scotland. This will require additional input not just from risk assessors and risk managers, but also from analysts (e.g. economists) and from other disciplines including social science. In a no deal scenario we estimate that we would require another five full-time equivalents to support our new risk analysis functions. Without additional budget, that resource will need to be found from elsewhere within FSS, and ceasing work in other areas doesn't automatically result in generating the necessary skills and expertise for risk analysis functions.

## **6 Scope of the Risk Analysis Framework**

6.1 It is the UK's exit from the EU that will lead to the repatriation of EU law to the UK, and with it, the repatriation of functions and powers to the UK as outlined in paragraph 2.3 above. From FSS's perspective, the work that is underway between officials across the UK, without prejudice to the views of the Board and Ministers, to develop proposals for a future UK-wide framework, will determine the scope for matters that will be subject to the joint processes outlined here. FSS already undertakes risk analysis on matters where there is flexibility in EU law, for example, where national measures are permitted, as well as in relation to food and feed incidents only affecting Scotland and to matters of enforcement. We do not envisage that the processes described in this paper would be applied in these circumstances, but we would continue to ensure that there was good communication and information sharing between FSA and FSS, again in line with the terms of our MoU.

## **7 Governance and Assurance**

### 7.1 EU Exit and FSS's Code of Governance

7.1.1 Food and feed safety and hygiene are devolved functions, and the Board has been kept updated on the work that the Executive is undertaking to make the necessary legislative, practical and operational arrangements for there to be an effective regulatory system both in Scotland and, working with others, across the UK in future after exit. The 2015 Act requires FSS to operate in a way that is proportionate, transparent and accountable, constitutes good decision-making

practice, and is consistent with best practice principles of good governance. Scottish Ministers have approved our Statement on Performance of Functions<sup>2</sup>, which sets out how we operate in accordance with these principles.

7.1.2 Whilst the risk analysis process described in this paper is largely an operational matter, the Board will want to be assured that FSS is discharging its new functions appropriately, for example, in prioritising matters for risk analysis, ensuring that priorities for Scotland are taken account of in the UK arrangements that are proposed including the role and operation of the AFFF, and ensuring that a broad set of impacts is considered in framing risk management advice

7.1.3 In the wider context, after exit the UK will be treated as a third country by the EU, and that will change the nature of the relationship between the UK and the European Commission's DG SANTE, which assesses Member State and third country compliance with the requirements of EU food and feed law. FSS, alongside SG, is involved with work across the UK to determine how the UK will provide assurance to trading partners in future about standards and compliance in the UK after exit. We propose that we should review FSS's current internal controls in the context of leaving the EU to ensure that they will continue to provide sufficient confidence about our ability to meet the scrutiny of the EU and others as a third country.

7.1.4 There are specific elements of the risk analysis process that will require us to review FSS's governance framework to ensure that it continues to be appropriate for any new arrangements that are put in place, and the Board will wish to consider how it would wish to receive assurance on delivery of FSS's new functions. The Board may also wish to consider what it would expect by way of performance reporting from the Executive to provide assurance related to new functions that FSS will be undertaking as a consequence of the UK leaving the EU.

7.1.5 But leaving the EU will also, in a wider context, require us to review relevant aspects of our Code of Governance<sup>3</sup>. Leaving the EU is not Scottish Government policy, but there are elements of the Framework Agreement<sup>4</sup> between the Scottish Government and FSS that will require to be reviewed in light of exit, notably around the parts of Section 2.5 which concern European aspects of regulation and enforcement. Similarly, relevant elements of Section 4 of the Scheme of Delegation<sup>5</sup> will require to be reviewed and amended to reflect the UK's departure from the EU, and the repatriation of EU food and feed law to the UK, and we will wish to review the Statement on Performance of Functions to ensure that it is clear on how we will deliver our new functions.

7.1.6 Taking into account both the general and specific impacts for FSS of the UK's departure from the EU, it is therefore recommended that the Executive undertakes a review of the Code of Governance in the context of EU exit for consideration by the Board.

## 8 Conclusion

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<sup>2</sup> [https://www.foodstandards.gov.scot/downloads/Statement\\_of\\_Performance\\_of\\_Functions.pdf](https://www.foodstandards.gov.scot/downloads/Statement_of_Performance_of_Functions.pdf)

<sup>3</sup> [https://www.foodstandards.gov.scot/downloads/Code\\_of\\_Governance\\_-\\_Introduction.pdf](https://www.foodstandards.gov.scot/downloads/Code_of_Governance_-_Introduction.pdf)

<sup>4</sup> [https://www.foodstandards.gov.scot/downloads/Governance\\_Document\\_-\\_Framework\\_document\\_revised\\_-\\_April\\_2016\\_1.pdf](https://www.foodstandards.gov.scot/downloads/Governance_Document_-_Framework_document_revised_-_April_2016_1.pdf)

<sup>5</sup> [https://www.foodstandards.gov.scot/downloads/Scheme\\_of\\_Delegation\\_-\\_version\\_3.pdf](https://www.foodstandards.gov.scot/downloads/Scheme_of_Delegation_-_version_3.pdf)

8.1 The Board is asked to:

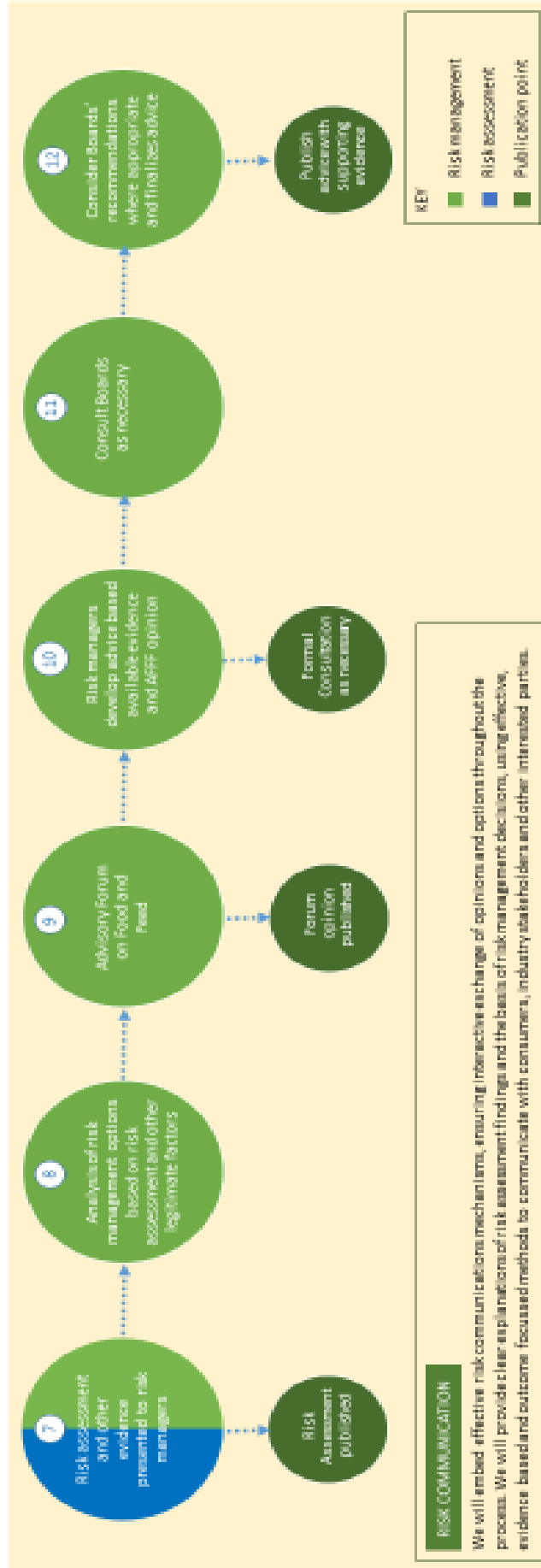
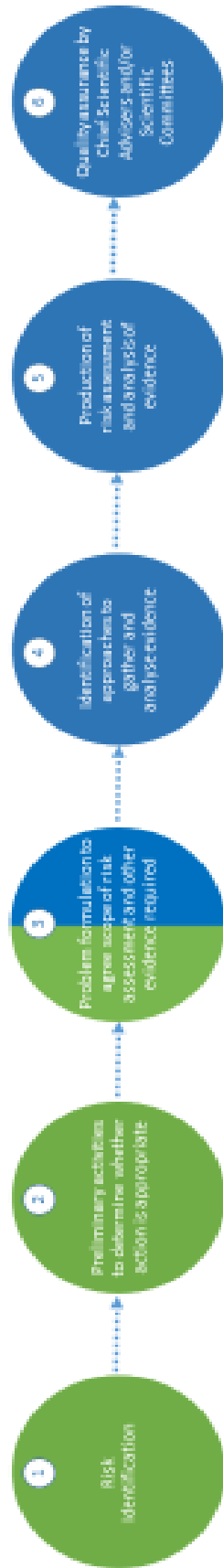
- **Agree** the proposed approach to the risk analysis process and that we continue to work with FSA on the method of implementation;
- **Agree** the principle that routine matters do not require to come to the Board before advice is provided to Ministers, but more complex/contentious ones and those linked to significant legislative changes would;
- **Agree** that FSS's approval of the AFFF be contingent on agreeing a revised Memorandum of Understanding (MoU) between FSS and FSA, with particular reference to access to scientific advisory committees, within six months of agreeing the terms of the AFFF;
- **Agree** that the AFFF be constituted under both the Food Standards Act (1999) and the Food (Scotland) Act 2015, and that FSS will continue to be responsible for providing advice to Scottish Ministers;
- **Advise** if it agrees that the proposed amendments to the FSA's Terms of Reference for the AFFF are appropriate for FSS;
- **Agree** that the Executive brings forward a paper to the Board outlining the resource requirements in both numbers of personnel, skills and finance highlighted in paragraphs, 2.4, 5.1 – 5.3 of this paper
- **Agree** that a short-life working group be established comprising members of the Executive and two non-Executive members to undertake a review of the Code of Governance in the context of EU exit for consideration by the Board, to ensure the Board is assured about how the Executive is discharging new functions that are a consequence of the UK leaving the EU.

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15<sup>th</sup> March 2018



Annex 1 – FOOD AND FEED SAFETY RISK ANALYSIS PROCESS

# FOOD AND FEED SAFETY RISK ANALYSIS PROCESS



## Annex 2 - FSA - Terms of Reference for the Advisory Forum on Food and Feed<sup>6</sup>

### PURPOSE

1. The Advisory Forum on Food and Feed (AFFF) is an ~~Food Standards Agency~~ advisory committee established<sup>7</sup> to assist UK food safety authorities (Food Standards Agency (FSA) and Food Standards Scotland (FSS)) in delivering their core objectives to protect public health and consumer interests in relation to food, helping ensure that the high standard of food safety and consumer protection we enjoy in the UK is maintained when the UK leaves the EU.

2. The AFFF will seek to provide, wherever appropriate, a cohesive UK risk management opinion on matters of food and feed after considering risk management recommendations developed by the FSA and FSS. This opinion will be taken into account by FSA and FSS risk managers as they formulate advice for their respective Ministers and others.

3. The AFFF will consider food and feed safety and hygiene matters, including those issues considered and decisions previously taken by EU Institutions. It will formalise existing cross UK and government working that has previously underpinned preparation of UK positions for EU negotiations either in EU Council or Standing Committees.

4. The AFFF will achieve this by:

(i) being open and transparent in how it has reached its risk management recommendations, upholding the public interest in relation to food and protecting public health and consumers' wider interests in food;

(ii) reviewing risk management proposals in relation to food and feed safety, prepared by FSA or (subject to agreement) FSS in consultation with other interested parties as necessary, including but not exclusively flavourings, food contact materials, food enzymes, animal feed, food and feed additives, contaminants, allergens, novel foods, microbiological and chemical food safety;

(iii) considering food safety aspects of related issues such as animal health and welfare, environmental and nutrition initiatives;

(iv) considering risk assessment, scientific evidence, other legitimate factors and how these have affected the selection of risk management options including potential risk communication strategies to reach a view on proportional risk management interventions; and

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<sup>6</sup> References here to Food Standards Scotland are dependent on this being agreed by Scotland as an appropriate means to give effect to any future UK-wide framework on food and feed safety.

<sup>7</sup> The AFFF is being established using provisions in Section 5(3) and Schedule 2 of the Food Standards Act 1999 which states that, after consulting the appropriate authorities, establish other advisory committees for the purpose of giving advice or information to the Agency about matters connected with its functions.

(v) providing advice that supports development of risk management recommendations by the FSA or the FSS. **in Scotland.**

## **SCOPE**

5. The AFFF will consider all food and feed safety issues<sup>8</sup> where a risk management recommendation **from FSA** is required. This will include:

- (i) Risk management responses that flow from new national and international (EFSA, OIE, WHO/FAO) risk assessments; both new and amendments to EU Regulations and international standards;
- (ii) approvals for regulated products e.g. novel foods and food and feed additives;
- (iii) consideration of the food safety aspects of wider initiatives and developments on, for example, animal health and welfare, environmental, food supplements, nutrition and diet.

6. The AFFF will not consider risk management advice provided to support operational management of routine food incidents.

## **PROPOSED MEMBERSHIP (Subject to agreement)**

7. The FSA and FSS will provide appropriate representation, taking into account the needs to represent interests of all 4 countries and expertise required to consider the food and feed safety matters under consideration. Other Government Departments, including the DHSC, Defra, DIT and the Devolved Administrations, will be invited to participate as observers.

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<sup>8</sup> The AFFF will consider food and feed safety issues only from end of March 2019. Processes for managing development of FSA advice on other issues that fall within its remit in Wales and NI e.g. nutrition and food labelling will be considered as future operating capability taking into account mechanisms being established by other government departments to deliver repatriated functions