FSA 22-06-19a - Risk Analysis Process Update

This paper is a regular update to the Business Committee on risk analysis activity and provides information on the status of the process in mid-2022.

Report by Michael Turner.

1. Summary

1.1 The Business Committee is asked to:

- Note the current status of the risk analysis process.
- Consider and comment on the ongoing reporting of the process.

2. Introduction

2.1 A key area of responsibility that the FSA has undertaken since EU Exit is an increased role in food and feed safety risk analysis. The FSA has developed a process to consider issues where it is necessary to make a risk management recommendation.

2.2 The Board agreed the risk analysis process in a series of discussions from 2018 to 2020 (a summary and links to previous papers are provided at Annex B). In June 2021 the Board reviewed the early delivery of the risk assessment function within the FSA and considered an outline of future priorities for the development of the regulated products service. In March 2022 the first annual review of the entire risk analysis process was presented to the Board.

2.3 Regular updates on risk analysis activity will be provided to the Business Committee. This paper provides information on the status of the process in mid-2022.

3. Objectives and Principles of the Risk Analysis Process

3.1 The aim of the risk analysis process is to provide confidence that FSA advice delivers public health protection; is informed by science and evidence; considers consumers' other interests in relation to food; and is independent. The FSA follows globally recognised frameworks for risk analysis. The process is open and transparent and provides for a four-country model.

3.2 It is a fundamental principle of accepted international standards in risk analysis that risk assessment (analysing the evidence and establishing risk) and risk management (making policy recommendations) are separate parts of the process. This ensures that risk assessment is based on science and evidence and not unduly influenced by political or other considerations. As part of our preparations for EU Exit, the FSA separated these functions internally and has embedded the principle of independent risk assessment into the risk analysis process.

3.3 Since these principles were developed, we have further discussed with the Board how our commitment to working in a three- and four-country context needs adjusting in the light of more recent developments such as the Protocol on Ireland/Northern Ireland (NIP) and the provisional UK Framework Agreements. Our commitment to working constructively and collaboratively with

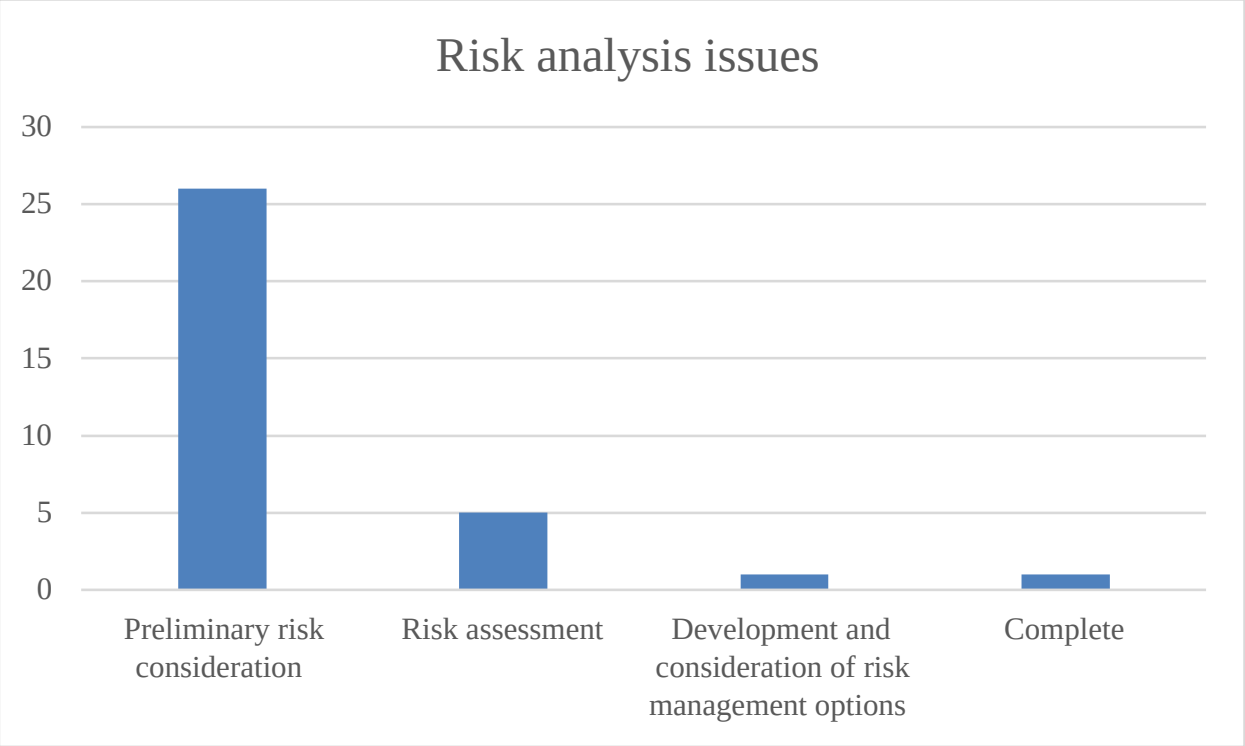
the devolved administrations is unchanged; however, we are considering how to adjust this principle to take into account the new context.

4. Risk analysis status report: January – April 2022

4.1 The number of issues logged for preliminary risk consideration has gradually increased since the implementation of the process in January 2021. Issues are considered according to the process detailed in Annex A, with details of issues undergoing risk analysis published to an online register when the risk assessment stage commences.

4.2 The stages of the risk analysis process are outlined in the flowchart in Annex A. The headline figures for the risk analysis process as of end April 2022 are:

- 33 issues are under active consideration, up from 29 at the start of 2022.
- Of these, 26 issues are at the preliminary stage of risk consideration.
- 5 issues are undergoing risk assessment.
- 1 issue is under consideration of risk management options.
- 1 issue has been completed – this was a risk assessment which the FSA conducted (the FSA was not responsible for final risk management).



5. Meeting our core principles

5.1 The FSA is committed to ensuring that the risk analysis process is transparent. We publish a register setting out the issues going through the risk analysis process. We have completed our first public consultation on an issue included in the register and published a risk assessment (further detail is provided in a case study below), with risk assessments on further issues to follow in the coming months. Updates are provided at each Board meeting on key issues undergoing risk analysis, including through the Chief Executive's report.

5.2 Four country working is embedded in the risk analysis process. The FSA advises the UK Government and the devolved administrations in Wales and Northern Ireland; Food Standards

Scotland (FSS) advises Ministers in Scotland. Under provisional UK Frameworks and our risk analysis process we have mechanisms such as cross-government working groups in place to enable a four-nation approach, so we can deliver risk management interventions that are effective for the UK as a whole or for individual countries as needed. UK Frameworks include scope for inter-ministerial discussions on decisions if needed.

5.3 Under the NIP, Northern Ireland must comply with EU food and feed law, resulting in some differences in regulatory arrangements applying in Northern Ireland than in the rest of the UK. We continue to consider the interests of consumers in Northern Ireland as part of the risk analysis process, whilst accepting that decisions on UK risk analysis outcomes will not extend to NI as a consequence of the NIP.

6. Case studies: examples of progress of risk analysis issues

6.1 We have made progress in moving issues through the risk analysis process towards risk assessment and risk management decisions. This includes the two high profile issues outlined below which have involved significant stakeholder, media or political interest, or have potential trade implications.

6.2 The issue that has progressed the furthest through the full process is a review of controls on imported food from Japan following the nuclear accident at Fukushima. This is considered high profile as there was a legal obligation to carry out a review in retained EU legislation, as well as the potential for divergence from EU and political importance to the Japanese government. This is a good working example of an issue progressing from early consideration of risk to the latter stages of developing risk management options.

- The FSA published a risk assessment in December 2021 and ran a public consultation between December 2021 and February 2022.
- Papers setting out our proposed risk management advice were presented to the FSA and FSS Boards on 9 March and 16 March, respectively.
- The NI Health Minister has been informed of the proposed recommendation, whilst a submission was provided to GB Health Ministers for decision on 28 April.
- Ministers in England, Wales and Scotland have agreed to remove restrictions on imported food from Japan. The legislation to remove the controls in England and Scotland was laid in the respective Parliaments on 16 May. Subject to ministerial agreement, legislation in Wales will be laid in early June to come into force at the same time in England, Wales and Scotland by the end of June.
- This will result in the removal of the additional (Fukushima) controls on imports of certain foods from Japan.

6.3 Titanium Dioxide (E171) also known as TiO2 is a food additive used as a whitening agent in a wide range of food products including confectionery, cakes, decorations, soups and sauces and food supplements; it is also used in medicines and consumer products such as and toothpaste. The safety of titanium dioxide has been under review in Europe since 2017 and the EU announced a proposed ban on its use in food in late 2021, to come into force after a 6-month short transition period. The authorisations for TiO2 as a food additive were removed in February 2022 and no products containing TiO2 can be placed on the EU market after 7 August 2022. As Northern Ireland continues to follow EU Food Law, the ban applies in Northern Ireland. This issue has a high level of public and stakeholder interest given the wide use and as the safety of a permitted food additive has been questioned by the European Food Safety Authority (EFSA). There is also the potential for permanent divergence if GB does not adopt the same approach.

6.4 The FSA's scientific advisory committees (SACs) conducted a review of the EFSA opinion in 2021. A joint statement from the FSA's SACs was published in January 2022 stating that 'the weight of evidence did not support the conclusions drawn by EFSA'. Given the public health implications, the SACs are now undertaking a comprehensive detailed risk assessment on the safety of titanium dioxide as a food and feed additive, as well as use in food contact materials and this is expected to conclude in the first quarter of 2023. The FSA is continuing to engage with other regulators, devolved administrations and internationally as risk assessment is progressed, before developing risk management advice.

7. Measuring Performance on Risk Analysis

7.1 The risk analysis process is used by UK food safety authorities to support the development of risk management advice based on science and evidence, including authorisation of regulated products. Proposals for regulated products service performance measures and reporting are provided separately for the Business Committee to consider. For other issues that make use of the risk analysis process, we continue to develop reporting measures which will provide a baseline for considering related performance targets. The aim is to provide assurance to the Committee that FSA is making use of the risk analysis process to provide independent, evidence-based advice on food and feed safety, and that the process is operating efficiently.

7.2 In addition to ongoing quarterly reporting of the number of active issues at each phase in the process, with further detail on individual issues included in the register of risk analysis issues, we plan to continue to iteratively develop our monitoring and reporting of measures which give an indication of FSA activity and performance in relation to the development of advice using the risk analysis process. This will focus on ensuring that our process is operating in line with our key principles in developing science-based advice in an open and transparent manner. It should be noted that the progress of issues through risk analysis is not entirely within the control of FSA. As additional issues progress towards risk management advice we continue to build baseline data and will bring forward potential performance objectives for consideration.

Conclusions and next steps

7.3 The Business Committee is asked to:

- Note the current status of the risk analysis process.
- Consider and comment on the ongoing reporting of the process.

Annex A

Risk Analysis Flow Chart

How the FSA makes evidence based recommendations and advice

The diagram outlines how the FSA makes evidence based recommendations; we call this our risk analysis process. It can apply to a range of issues from control of pathogens and allergens to applications for authorisation of regulated products and processes such as chemical washes, genetically modified food and feed.

During the process the FSA will work with Food Standards Scotland, devolved administrations other government departments and other interested parties to consider the interests of those with responsibilities for food and agriculture, health and trade.

1. The process can be triggered for different reasons. Examples include a food safety risk, an application from a business or country, trade negotiations, policy issues, a request for advice from other government department.

2. A risk assessment of the safety and other evidence, gathered and analysed by FSA and external experts. Other evidence can include consumer preferences, animal welfare, environmental and economic impacts and more.

3. FSA develops advice or recommendations based on the evidence. This might be include major policy changes, legislation or other actions.

At this point there are two different options:

Option 1:

1. FSA finalises advice when a ministerial decision or a change to legislation is required.

2. Ministers take decisions or consider changes to legislation.

3. Legislation made by parliamentary process as necessary.

Option 2:

1. FSA takes decisions on regulatory requirements and approaches

2. Ministers informed of change as necessary.

3. FSA issues advice for example, consumer advice or business guidance

All information will be published online on food.gov and our scientific advisory committee websites

- list of issues under consideration
- scientific committee papers, minutes (excluding commercially sensitive information)
- formal consultation on the options
- quarterly summary update to FSA Board
- the FSA's advice or recommendation with the evidence

Annex B

The design and development of the risk analysis process: links to previous Board papers

In September 2018 the Board discussed and agreed the governance and assurance framework for the FSA including the implications for the Board of the UK’s exit from the EU and the proposed high-level future governance and assurance arrangements for risk analysis.

In December 2018 the Board discussed the risk analysis process in more detail and agreed the principles that we should apply at each stage of the process.

In March 2019 the Board discussed and agreed proposals for assurance of the risk analysis process; and as part of this, proposals for an FSA approach to the evidencing and consideration of an appropriately broad set of impacts in risk management.

In September 2019 the Board discussed the FSA's approach to uncertainty and risk in the context of the risk analysis process.

In January 2020 the Board was updated on progress on implementation of the risk analysis process and discussed the illustrative forward work plan for risk analysis and plans for review.

In September 2020 the Board considered the development and implementation of the risk analysis process and agreed proposals for prioritisation of issues and the approach to publication and consultation.