Meeting

Quality Assurance of Microbiological Strategic Risk Assessments

Background

1. Following EU Exit, Health Ministers, alongside FSA and FSS, have taken on responsibility for ensuring that the high standard of food safety and consumer protection enjoyed in the UK is maintained. The FSA risk analysis process (presented to the Committee as Reserved Business at the June 2019 plenary meeting in ACM/1299) was developed to assess the risk associated with food and feed and provide evidence-based advice and recommendations. Within this process framework, strategic risk assessments are produced to enable the development of policy, standards and guidance, and import controls.

2. The overarching risk analysis principles apply to risk analysis for any purpose, although in the case of incident handling, the risk assessment focuses specifically on the product triggering the incident and it is usually not published or consulted on, given that it contains commercially sensitive information.

3. As one of the FSA's Scientific Advisory Committees, the ACMSF is instrumental in providing quality assurance for FSA strategic risk assessments to ensure that the outputs from risk assessment are of appropriate quality. In particular, the quality assurance process:

- enables errors to be detected and addressed
- ensures that the evidence is relevant to the question(s) posed
- ensures that the selection and application of the approaches and any assumptions are appropriate and that these and the findings are set out accurately and transparently.

4. The FSA has been following the risk analysis process since January 2021. Given the FSA's new role in deciding food- and feed-related policy and advice, this has led to an increase in the number of strategic risk assessments being produced by the FSA risk assessment unit to provide the evidence used to make such decisions. This paper seeks the Committee's input into how the quality assurance process for strategic risk assessments should be handled.

Current Process

5. Most recent strategic risk assessments produced by the microbiological risk assessment team have been reviewed by subgroups as waiting for them to be reviewed by the full Committee during plenary meetings delays delivery to Policy and other customers.

6. The particular subgroup is chosen to best match the expertise of the subgroup members with the content of the risk assessment; currently a majority of the strategic risk assessments are being reviewed by the Incidents subgroup. When an appropriate subgroup is not available, members of ACMSF have been chosen by the Secretariat based on their expertise and invited to review risk assessments.

7. The risk analysis process suggests that risk assessments should be referred to a SAC full committee if the topic is:

- Novel: e.g. it has not been considered by a SAC previously, or significant
- new information has emerged which could change the risk characterisation
- of the hazard.
- Complex: e.g. it is technically challenging or due to the level, detail and
- range of scientific input required.
- Sensitive: e.g. it is likely to be high profile or controversial for any of the

- reasons outlined above or covers areas outside FSA’s remit

8. The current process for the review of strategic risk assessments is for the Secretariat to email the subgroup members with the request and all appropriate documentation. Outside of urgent requests associated with incidents, two weeks typically is given to review the risk assessment and any additional material. Feedback is accepted either as comments added directly in the document or as recommendations and suggestions provided separately. Between two to four subgroup members usually respond to this request for review. After the subgroup members have provided their feedback, it is passed on to the risk assessment authors for consideration. The revised risk assessment undergoes one last check internally to ensure comments by subgroup members have been appropriately addressed before the final version of the risk assessment is provided to FSA Policy.

9. Members that review strategic risk assessments can claim a day’s reading fee for their work.

Development of review questions

10. To ensure that the review process is straightforward and the request to the reviewer is clear, we have developed a list of questions for members’ attention when asked to review strategic risk assessments. We will still welcome feedback as comments directly in the document, but also wish to highlight key considerations with this checklist. We plan to implement this as part of the review process soon and are seeking Members input on the suitability of the review questions.

Questions to guide review

- Does the document adequately answer the risk question described at the beginning?
- Is it a balanced and unbiased overview of current understanding?

- Are there large data/evidence gaps that could be addressed using published research?
- Is the information in the document presented clearly, concisely and following a logical structure?
- Do the uncertainties adequately capture the most significant information gaps & limitations?
- Is the risk characterisation supported by the evidence presented in the preceding sections?
- Is the lay summary sufficiently clear for a non-expert general audience?
- Are there any other comments you wish to make?
- If your answer to any question is no, please explain what changes should be made to meet the requirements.

Options for quality assurance going forward

11. The Committee may want to consider the following when discussing how the quality assurance process should be handled by ACMSF:

- What notice would Committee Members like to have that review work is expected?

o Once a delivery date to Policy has been agreed, which would be 3-4 months in advance

o When the document has gone for internal review, about 2-3 weeks before it would go to ACMSF

- What is an ideal number of ACMSF reviewers to seek for review?
- Is handling of routine risk assessments via the subgroups appropriate?
- When there is no appropriate subgroup to handle review of routine risk assessments, how would the Committee like reviewers to be identified?

o The Secretariat could identify and invite the reviewers

o A call could be put to the full Committee with volunteers to review based on expertise and time available

- When risk assessments require review by the whole Committee, how might Members like this handled as intersessional business?

Actions

The Committee is invited to:

1. Discuss and agree how they would like to see the quality assurance process handled going forward, considering routine risk assessments and those that require review by the full Committee.

2. Discuss and agree if the questions to guide the review of risk assessments are appropriate and should be implemented.

Micro RA Team and Secretariat

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