Cross-SAC working group on framework for risky foods

Thursday 30 June 2016, 10.00-13.00

Rooms 102-104 First floor Aviation House

Meeting Note

Agenda

1. Welcome and introductions
2. Introduction from Caroline Mulvihill, NICE
3. Recap on revised scope
4. Recap on revised framework and flowchart
5. Outline of case study and discussion
6. Next steps

Participants

Working Group Members:

1. David McDowell (ACMSF)
2. Gary Barker (ACMSF)
3. Alan Boobis (COT)
4. Leen Petré (GACS)
5. Dan Rigby (SSRC)
6. Joy Dobbs (SSRC)
7. Caroline Mulvihill (NICE) – co-opted expert

Secretariat:

8. Patrick Miller (GACS Secretary)
9. Gwen Aherne (GACS secretariat)

FSA:

10. Steve Wearne (Director of Policy and Science), workshop facilitator
11. Diane Benford (Head of Risk Assessment)
12. Ruth Willis (Novel foods team)

Agenda items 1 & 2 – Welcome and introductions

1. Steve Wearne welcomed everyone to the meeting and thanked Caroline Mulvihill for joining the Group as a co-opted expert. He noted that the FSA Board would discuss an update on the work on the framework at its open meeting on 13 July, which would include a slightly shorter version of the draft text circulated to the WG for comment.
2. Caroline outlined her role at NICE and noted that the Working Group (WG) may find it useful to look at the NICE manual for developing clinical guidelines. It provides advice on the technical aspects of clinical

guideline development and the methods used. There is also detailed guidance to inform the judgements made by the committees on the strength/quality and applicability of evidence.

Agenda item 3 – Recap on revised scope

3. The Secretariat had circulated revised scope and framework documents, reflecting the March workshop discussion, for the WG to consider. Steve thanked Gary Barker and Dan Rigby for providing written comments in advance of the meeting, which were discussed at the relevant stages of the subsequent discussion. The WG agreed on one such point, that the third item of the second bullet seemed to have lost some meaning following the edits - this would be changed to '*For a range of hazards the identification of factors/changes that would prompt review or reconsideration by the FSA board'* **(action Secretariat)**.

Agenda items 4 & 5 – Recap on revised framework and flowchart; Outline of case study and discussion

4. The WG discussed the revisions to the documents which had been made to reflect the March workshop discussions. The WG felt there was more work to do on the framework and flowchart to make it clear and coherent. The language could be tighter and more consistent. The WG had requested a case study to help them test the coherence of the framework. Ruth Willis, FSA Novel Food Policy, outlined a case study on Scorpion pops for the WG (see Annex 2).

5. Discussions helped to crystallise the view that the framework is intended for application in those situations where there has been (or it is plausible that there may/will be) a material change (in the hazard, potential exposure, acceptability or effectiveness of controls) *and* the current risk management approach is no longer considered suitable due to the need to consider additional issues, such as wider consumer interests. This suggests there would need to be some sense of a benefit to be balanced against the (higher) risk. To reflect this, the Working Group suggested the following changes:

    - Include a glossary of terms; be clear and consistent with wording throughout document
    - Redraft introduction to make clearer what and who the framework is for - objectives include transparency, accountability and consistency.
    - Reinstate a reference to the concept of increased risk per serving or per consumption event as a key feature of the foods to be considered (but also retaining consideration of the individual and the population risk, and the nature and severity of the effects)
    - Flowchart to be revised to focus on inputs (risk assessment; assessment of benefits/wider consumer interests) and outputs (risk management decisions). In considering wider detriments and risk-benefit, draw on existing risk-benefit frameworks to help with this and identify questions and evidence needs (e.g. EFSA guidance, Treasury guidance).
    - Develop guidance to sit behind the framework triangle and flowchart.
    - Include a standing invitation to SACs to identify and flag up changes, including a change in scientific understanding.
    - The WG emphasised the importance of reference in the framework to the need to consider the issues of informed consent and the possibility of secondary cases of illness. The WG suggested that FSA should also consider this in its approach to consumer advisory statements for rare burgers.
    - For foods in the amber zone, set process for regular review (how, when, by whom).

6. The WG reviewed the framework and flowchart in light of these comments. Detailed notes for producing the next iteration of the framework are captured in Annex 1.

7. Steve confirmed that the FSA would consider a briefer name for the framework, reflecting the revised version, with the definitions of any shorter terms to be explained clearly.

Agenda item 6 - Next steps

8. The Secretariat would write up the notes from the workshop and prepare a revised framework document for comments by correspondence. As part of the process of finalising the framework the parent SACs (COT, SSRC, ACMSF, GACS) would be invited to comment on it within a two week period. Steve did not foresee that the Working Group would need to meet again and noted that the final product would be taken to the FSA Board meeting 23 November.

Actions for WG Secretariat:

- Update the WG Scope and ToR to reflect the working group's comments
- Reformulate framework in a further working draft for consideration by correspondence
- Circulate framework to parent SACs for review
- Explore whether it is possible to share the next draft for comment in a format that allows joint editing so that all can see what others have commented.

ANNEX 1: Workshop 30 June 2016– detailed notes for producing the next iteration of the framework

Who and what the framework is for:

1. In the majority of cases the framework will be applied to foods that have a relatively low frequency of consumption (at a population level) with a relatively high possibility of detriment per consumption event (rare burgers, raw drinking milk).
2. The framework is a tool for decision making and for balancing risk against benefit, an aid for transparency, and a driver for greater consistency in decision making.
3. The framework is for use by risk managers to understand when they need to seek advice from risk assessors. This links in with the FSA Triennial Review of the SACs March 2016 Recommendation 6 on ensuring appropriate iterative dialogue between FSA and its SACs[1].
4. The framework is intended for application in those situations where
    - there has been (or it is plausible that there may/will be) a material change in
        i. The nature of the hazard;
        ii. The potential exposure;
        iii. The effectiveness of controls in practice
        iv. The acceptability/defensibility of controls (this will need to be defined but could relate to FSA's own sense of their acceptability and/or challenge by consumers, by businesses, or from a legal/enforcement perspective)
    - *and* the current risk management approach is no longer considered suitable due to the need to consider additional issues, such as wider consumer interests.[2]
5. Remove examples of foods for which the framework would not be applied
6. Use 'frequency' instead of 'likelihood'
7. When/if using 'acceptability' be clear on acceptability to whom
8. Make clear the framework covers individual and population risk
9. Refer to 'change in *potential* exposure'
10. Revise description of the 'Amber' category to match the category of 'unacceptable unless'.

Reshaping the flowchart

1. The first step is to collate the data required when first considering an issue and conducting preliminary profiling of risk and benefit.
2. The next step is a 'Prescreen' -
    - Has there been a change? **Y** → Is there an established risk management approach that we are confident will be/remain appropriate? N→ continue through framework.

[1] http://www.food.gov.uk/news-updates/news/2016/15022/triennial-review-of-six-fsa-scientific-advisory-committees
[2] Note, this refers to the suitability of the controls as they are or may be applied in the case of a specific food/risk, not to the acceptability at the macro level of the wider risk management approach e.g. risk-based regulation.

3. Where there are insufficient data to proceed, then the data needed should be defined. The risk manager will then need to make a judgement about whether to actively seek or generate these data, taking into account the cost, effort and time required as well as the nature of the potential risk.
4. Revised flowchart will mainly be made up of the content of steps 5-10 of current flowchart. It will include two inputs and one output:
    - Inputs:
        i. Risk assessment (this could include contingent risk assessment which assesses the risk that is expected to arise under different scenarios for controls)
        ii. Elucidation/description (at least in qualitative sense) of consumers' other interests and other detriments/benefits (relevant guidance from e.g. HMT may be useful here)
    - Outputs:
        i. Decision on balance of risks/benefits (this leads to three options which equate to categorising the food/risk and in the green, amber or red zones of tolerability of risk).
5. Issues to cover in revised flowchart/guidance[3]:
    - State what the current/previous situation (or other comparator) is when describing the change. Consider if the change is designed (e.g. an increase in demand/supply, in production processes or a change in policy) or if the change is unintentional (e.g. food safety incident).
    - What is out of scope? – situations where there is no change, or a lack of information. (If there is a change and sufficient information, then apply the framework).
    - Choose a clearer form of words than 'unacceptable to all individuals' at point 5 of flowchart
    - Is the risk limited to the person making the choice? Need to consider secondary cases and informed choice including capacity to make a choice. What does informed choice look like, what does uninformed choice look like? - acceptability, timeliness, understandability, risks to them and others.
    - Use existing risk benefit frameworks (such as EFSA's) to identify the sorts of questions to ask and identify evidence needs, including uncertainty, vulnerable groups
    - Consider who receives the risks or other detriments and who receives the benefits
    - There is a range of lenses through which the risk manager needs to look including consideration of aggregated costs and benefits, equity, severity of effect, no. of people and the population affected.
    - Shopping list – types of evidence, sources of evidence (including SAC advice).
    - Risk assessors could assess impact on risk of a range of RM options (including controls) to identify the most effective option.

6. Triggers
    - The 'if' questions, are the questions at the end the same as those at the beginning of the framework?

[3] Note that these points should be considered in addition to the Working Group's first thoughts on evidence needs and on triggers - see note of the first workshop March 2016

- Standing invitation to SACs to identify changes to flag as issues, including change in scientific understanding. EFSA guidance on re-evaluation of risk in different areas could be a useful tool for risk assessors considering changes in that aspect.
- Design surveillance and monitoring approaches to identify changes and whether the changes are material.
- Risk managers will also need to consider where evidence for triggers will be sought proactively or through a watching brief, or whether there will be a general review across the piece after a fixed period, taking into account the cost, effort and time required as well as the nature of the potential risk.

Scorpion Pops

Scorpion pops are part of the growing insects industry in the EU. The products are intended as novelty items where a whole insect is encased in a hard lolly matrix. The products are on the UK market mainly from internet based stockists but have been stocked in large retailers such as Selfridges. Information we have suggests some of the insects are raised in the UK and Netherlands but many are imported from third countries.

While insects have been widely consumed outside Europe for many years they are a relatively new product to Europe. Belgium, France, the Netherlands and EFSA have undertaken risk profiling exercises which highlighted specific risks for insects, from uncertain efficacy of processing methods for microbiological contamination, concerns over undesirable substances in particular toxin, venom, stings, the hard parts of insects, as well as the potential TSE and allergenicity risks. These reports also touch on the questions of consumer acceptability and sustainability of insects as a food source.

Legal status

At this point in time, the UK holds that the novel food legislation does not apply because the food contains a *complete* animal which is not captured in the scope of the current regulation. We are therefore one of the few Member States that permits (whole) insects to be sold on our market.

The revised novel food legislation will apply to foods containing a complete animal from Jan 2018 – and only those which have a history of consumption in the EU prior to 1997 will be exempt. Only one insect to date has been able to have a history of consumption demonstrated - cheese mite. So, other than cheese mites, whole insects for food use will be regulated as novel foods from Jan 2018.

While there are no specific hygiene requirements for insects, any insect products would be required to be safe and meet the general hygiene requirements. Looking forward, there is a need to ensure this emerging sector is aware of the potential food safety risks and manages these effectively.