Cross-SAC working group on framework for controls for foods with an increased risk per serving

Friday 31 March 2016, 11.00-14.00

Rooms 102-104 First floor Aviation House

Meeting Note

Agenda

1. Introductions and reminder on scope
2. Run through framework (using case studies), and discuss:
    a. Prioritisation
    b. Overall coherence of framework
    c. First thoughts on evidence needs/gaps
    d. First thoughts on triggers
3. Review progress and agree next steps (provisional dates 25 April teleconference; 14 and/or 16 June workshop)

Participants

Working Group Members:

1. David McDowell (ACMSF)
2. Gary Barker (ACMSF)
3. Alan Boobis (COT)
4. Leen Petré (GACS)
5. Dan Rigby (SSRC)

Secretariat:

6. Patrick Miller (GACS Secretary)
7. Gwen Aherne (GACS secretariat)

FSA:

8. Steve Wearne (Director of Policy and Science), workshop facilitator
9. Guy Poppy (Chief Scientific Adviser),
10. Penny Bramwell (Director of Science Evidence & Research),
11. Paul Cook (Secretary to ACMSF, head of microbiological risk assessment)
12. Darren Holland (head of operational research)

Apologies

Joy Dobbs (SSRC)

Agenda item 1 - Introductions and reminder on scope

1. Steve Wearne welcomed the Working Group and FSA representatives to the meeting. The draft scope for the group had been discussed at a teleconference on 11 March. Joy Dobbs was unable to attend the workshop, however she had sent in some comments on the scope and on the framework (these were fed into the discussion). The Working Group made some further suggestions for changes to the wording in the scope. These are captured in the Annex to this note and will be reflected in an updated scope **(action Secretariat)**.

Agenda item 2 – Run through the framework

2. Steve took the Working Group through the framework and flowchart, inviting discussion on the coherence and completeness of the framework and evidence needs/gaps at each decision point of the flowchart. Key points and questions were captured by participants and by the secretariat, using post-it notes and would be reflected in an updated version of the framework **(action Secretariat)**.
3. Discussions focussed mainly on an approach to the identification and prioritisation of risks to which the framework would be applied, which would help to determine the detailed approach, and a run through of the flowchart (it was only possible to cover the flowchart up to box 5 in the time available).
4. Over the course of discussion the Working Group advised that the primary paradigm that would inform the application of the framework is about change: a change that leads to new or increased or different exposure, or a change in the effectiveness of any existing risk management approach in controlling the risk, would prompt use of the framework. This was felt both to clarify and to make more practically achievable the selection and prioritisation of foods to which the framework would be applied (including through providing a rationale for what would be excluded) and for its detailed application. The flowchart was then discussed in this context. The key points are summarised in the Annex to this note.

Agenda item 3 - Review progress and agree next steps

5. The Working Group plans to review the updated framework and to complete the run through of the flowchart from box 5 onwards at the next workshop in June.
6. The Working Group would like to test out the next iteration of the framework to check it is complete and coherent, using one or more case studies (suggestions included an insect species or fungus).
7. Members noted it would be helpful to identify foods that illustrate different sections of the framework and flowchart, to inform its discussions; however that it would not be advisable to include this detail in the published framework. The WG considered that a fully worked up rationale would be required to support inclusion of any foods and this would need to be done on a case-by-case basis, using the overall principles and approach recommended by the WG.
8. Comments on any aspect of the work are welcome from the WG by correspondence in between meetings.

Actions

9. The following actions are to be taken forward by the secretariat in preparation for the next meeting:
   - Confirm dates for next teleconference/workshop (provisional dates 25 April teleconference; 14 or 16 June workshop).
   - Update the WG Scope and ToR to reflect the working group's comments.
   - Reformulate framework in a further working draft – colour code this to clearly distinguish between changes recommended by the working group and any further suggested changes to those sections of the flowchart not discussed, made by the secretariat to reflect the changes to the earlier sections.
   - Prepare a case study to test the next iteration of the framework e.g. an insect species.

Annex 1 Workshop 31 March – detailed notes

Scope

- Incorporate footnote on evidence into the core text of the WG role: 'It may be useful to think both in terms of the set of evidence that would ideally be available, and the minimum set of evidence which would allow reasonable judgement to be made.'
- Include 'limitations' in WG role - '....the use, further development and limitations of the framework....'
- In first paragraph of Background section of ToR - use more general phrase such as 'foods for which the level of risk is of concern/interest to the Agency'
- Use the phrase 'people' rather than 'consumers', to indicate that people base their decisions and behaviours about food on a whole range of issues, some/many of which go beyond their role as consumers.

Prioritisation (an approach to the identification and prioritisation of risks to which the framework would be applied)

- Does the framework relate to everything we do? Clarify if FSA is seeking to identify foods for which an additional layer of controls is needed to ensure adequate protection from risk**,** or defining an increment of extra risk which we are prepared to accept as it is assessed as being balanced by benefits of choice (and/or other benefits).
- A clear rationale and evidence base is needed for prioritisation - the approach needs to be defensible.
- It helps to look through multiple lenses when considering the drivers for prioritisation.
- Consider impact, probability, vulnerabilities.
- Drivers and inputs for prioritisation:
  - Published literature on hazards in foods.
  - Risk analysis (population affected, level of risk and nature of effect, for example cases per million servings). Needs to look at the risk if the food is eaten and the risk/likelihood that the food is eaten.
  - Distribution of incidence on location and time (all at once/in same place is different to spread out evenly over space/time).
  - Modelling approaches - risks per serving versus no. of servings, clustering
  - Pragmatic risk management in response to a change in a risk/profile/trend (e.g. an increase in the consumption of rare burgers)
- The primary driver of prioritisation and assessment within the framework is about change. A change in the hazard (nature of the food), the exposure (e.g. to new or different groups), or the effectiveness or defensibility of an existing risk management approach, could prompt consideration of the use of the framework. Therefore a pre-screening stage is required at the

beginning of the flow chart to consider if there has been a change, which would include changes in:

- the nature of the food/product
- the hazard (if it's a food already on our radar e.g. a new pathogen strain)
- the exposure - amount of the food people consume, the people consuming it (e.g. children, adults) or other aspects of vulnerability; how much consumption is deliberate (e.g. people making conscious decision to eat RDM or a rare burger) and how much is inadvertent (e.g. people served RDM thinking it is pasteurised or served a rare burger without knowing at the time of order it would be served this way).
- capacity to act to ensure an effective control of the risks - including the resource available to FSA to consider and address the issue, and to local enforcement and FBOs to enact a check of controls, and the effect this will have on likely behaviour, compliance etc.
- Acceptability to people, FBOs, others.
- We would also need to consider changes in the wider environment and the food system (which could in turn impact on risk, exposure, vulnerability) and changes in knowledge across any of these dimensions.

- This could also help in setting clear criteria for inclusion and exclusion of foods from the framework, perhaps with agreed list of circumstances which lead to exclusion (along the lines of there being no significant concern, or material change in the nature of the hazard, the exposure, or the defensibility of the existing approach). This could include those foods/risks for which there are well-established approaches (chemicals, nutrients, allergens, novel foods).
- Also need to consider:
  - the nature of any benefit which is seen to balance risk (e.g. choice, trade) and who this accrues to
  - issues of equity and consistency across different risks
  - the environment
  - the food system
  - how people will act in response to information or other aspects of a set of 'controls', and that views on acceptability may change in the event that they experience or become more aware of other people experiencing ill effects from the food in question
  - gains and costs - aggregated versus distributed: the comparison of risks and benefits needs to reflect the fact that distribution of risks and benefits will be very different: risks likely to be high increment for a few; benefit likely to be low increment for many.
  - the totality of hazards presented by a particular food e.g. rare burger will have risks from other pathogens besides E. coli 0157
  - normalisation of risky foods/factors could lead to a (further) change in exposure (e.g. if people mistakenly assume it is safe to serve rare burgers at home because they have eaten one in a restaurant)

Overall coherence of framework

Figure 1 – Adapted Framework for the Tolerability of Risk (Red amber green zones of tolerability)

- It is important to be clear about who is determining whether a risk is acceptable and on what basis, in each of the three proposed 'zones of tolerability' and whether it is the individual consumer or the FSA. The current model (Fig 1 and also some boxes in Fig 2) is inconsistent/unclear in this regard. It is clearer in the Tolerability of Risk Figure 1 - the amber description talks about 'risks that incrementally exceed the levels considered broadly acceptable *[by the Agency]* but which some consumers may tolerate for other benefits such as choice'.
- Figure 1 label LHS arrow 'increasing individual, societal *and FSA* concern.
- The risk triangle should have a green base in the acceptable region and a red tip in the unacceptable region.
- The 3 zones of tolerability – need to reflect that as we move from unacceptable to acceptable there are changes in
  - Who makes the judgement?
  - Acceptable to whom?
  - What is the population and the individual risk and the balance between them
  - Who is responsible for making the decision about whether the food is available/eaten if available
  - Confidence/uncertainty in the RA and nature of risk
  - Capacity to act to effect controls to manage risk
  - Gains and costs – aggregated vs distributed

Flowchart/decision tree

Box 1

- Review the evidence – understand what has changed; change 'risk per serving' to 'likelihood of harm and number of people exposed'?
- Replace 'or stratified by vulnerability' with 'or sub-groups of the population'
- The idea of a food with a heightened risk suggests this may not occur very often - which will affect the available evidence

Box 2

- Are data sufficient for quantitative risk assessment? If not sufficient need to estimate?
- Is 'data' too restrictive? E.g. consider judgement/appreciation/insight/suspicion.

Box 3

- Quantify likelihood of harm and number of people exposed. It will help to identify a comparator and to think about a risk relative to this. This could be between a current and future state (a change or trend) or between a the riskier and a less risky presentation of the food (e.g. a well-cooked burger, or cooked shellfish)

Box 4

- Capture in box 4 – has the risk changed? Are the changes of sufficient magnitude to be of concern (what is the net change, is it material)?
- What do we do with things where we see a trend but changes aren't significant? If conclude there is a change or trend, but not able to say the change is material at this stage this leads to identification of triggers or prompts in the form of information which would allow us to identify when/if it can be assessed with confidence as material (and whether this should be sought proactively or tracked through more of a watching brief)

Box 5

- Reword to clarify what is meant by 'always unacceptable' in this context. It is not 'for all time' but more ' in all circumstances as we see them at the present time.'

Box 6 & 7

- Boxes/steps which refer to controls need to consider effectiveness of controls if applied, extent to which they will be applied in practice and the effect of this potential and actual control on acceptability of risk.
- Box 6 needs expanding to allow iteration of whether controls are practicable as well as maintaining low risk.

<u>First thoughts on evidence needs/gaps</u> (the evidence which should be available to inform decisions at each of the decision points in the framework, and how these evidence needs might be met)

- Minimum evidence that is required includes changes in:
  - product,
  - amount consumed (no. of servings),
  - profile of people consuming.

- What knowledge/insights do we have in each of these areas; has the risk changed; are the combination of risks tolerable?
- When monitoring for a change in exposure, look at sales, volume, numbers of outlets etc.
- Assemble the evidence, understand the magnitude of change, iterative dialogue between RA and RM to elucidate what sorts of changes would give rise to concerns.
- Change needs to be detectable.
- Need 'soft' and 'hard' information about magnitude of change.
- Use a proactive rather than reactive approach to monitor for changes (links to triggers for review). Do we need horizon scanning capability to proactively identify changes?
- Ideally would be able to compare rate of events for those consuming the food deliberately in an informed way (choosing it) and those who consume unknowingly or not by choice. But available data is likely to be limited, and comparisons of relative risk may be more feasible.

<u>First thoughts on triggers</u> (the design of triggers for a range of hazards that would lead to reference of the issue under consideration back to the FSA Board)

- Decisions and triggers for review need to have clear rationale and evidence base as well as being transparent and consistent.
- Links closely with monitoring for changes for prioritisation i.e. a change that leads to new or increased exposure should prompt review.
- There are two elements to this:
  - The process by which we initiate a review.
  - The evidence, analysis, insight that is changed by the emerging evidence.
- In considering triggers, the approach would need to be open to identifying and responding to developments which were not and could not be foreseen, as well as specific changes which might be identified in advance as 'triggers' for a review.
- It was also suggested that the term 'trigger' could suggest a more narrow approach (e.g. one that assumes a linear scale and a clear threshold value) than was in fact the case - could a better alternative be found to capture the intention which was to identify the information and evidence (or the change in this) which would lead to a post hoc review? The trigger would ideally be multidimensional (such as the direction of an arrow in a detriment vs likelihood plot).
- The aim would be to identify at each stage those things for which a change would be a trigger and to the extent possible, what type of change this would be (nature, direction, magnitude); it could be direct evidence of a change or evidence which leads to a plausible possibility that risk has changed. This would draw on more than 'data', and could include information, insight, understanding.