# DEVELOPING PROPORTIONATE CONTROLS FOR RISKY FOODS

**Report by Steve Wearne, Director of Policy**

For further information contact Patrick Miller on 020 7276 8277,
patrick.miller@foodstandards.gsi.gov.uk

## 1 SUMMARY

1.1 This paper presents a revised framework for developing proportionate controls for risky foods. The Board is asked to:

- **agree** that the revised framework fulfils the Board's request for an approach that will support soundly-based, consistent, and transparent decisions on identifying and managing risky foods.

1.2 As shown by our work on raw drinking milk and on burgers served less than thoroughly cooked in food service, assessing a risky food using this framework can involve significant resource, with associated opportunity costs. We will therefore alert the Board where, following a screen, we have candidate risky foods for full assessment or review. In doing so we will be clear on the resource requirements and anticipated timetable for assessment or review, and when we would expect to revert to the Board for any decisions on material changes to current risk management approaches.

## 2 INTRODUCTION

2.1 The Board considered a draft framework for risky foods and its application to risks from burgers served rare at its meeting in September 2015,[1] and in July 2016 discussed an update on work to update and formalise the framework. This work is complete and the revised framework is at Annex 1.

## 3 STRATEGIC AIMS

3.1 The framework will help FSA to make soundly-based, consistent and transparent decisions on identifying and managing risky foods. This will contribute to protecting consumers and their interests, targeting of resources, and effective, innovative and sustainable regulation.

## 4 EVIDENCE

4.1 The revised framework has been developed by the FSA executive working closely with an ad hoc Working Group drawn from four of FSA's scientific advisory committees, convened by Guy Poppy as FSA's CSA.[2] We have also consulted the four SACs which provided members for the Working Group.[3]

[1] Papers FSA 15/09/04, http://www.food.gov.uk/sites/default/files/fsa150904.pdf and http://www.food.gov.uk/sites/default/files/fsa160704.pdf
[2] Working Group papers available at: https://www.food.gov.uk/science/ouradvisors/risky-foods/
[3] The Committee on Toxicity (COT), the Advisory Committee on Microbiological Safety of Food (ACMSF), the Social Science Research Committee (SSRC) and the General Advisory Committee on Science (GACS).

## 5 DISCUSSION

5.1 The revised framework comprises:
- a narrative, setting out why FSA needs a framework, its objectives, and how it will be used, including the sources in information which will provide inputs to identify candidates for assessment or review
- a revised description of the three zones of acceptability of risk (page 3)
- a decision tree and supporting guidance on use of the tree and the key areas of evidence needed at each stage

5.2 Important revisions from the previous draft version seen by the Board include:
- three clear criteria to identify risky foods for consideration using the framework
- a new screening stage to assess whether a food should be assessed as a risky food using the framework (and if it not, what other information or action is needed) (paras 27 to 33)

5.3 The framework will help FSA to make soundly-based, consistent and transparent decisions on identifying risky foods and prioritising those for consideration or review using the framework, and identifying and tracking changes which would trigger a new assessment or a review.

5.4 For foods assessed using the framework, it sets a clear approach to determine which zone of acceptability they should be managed in, and for those in the amber zone ('unacceptable unless'), what additional controls, information and measures for verification are needed, and what would trigger review.

<u>Use of the framework</u>

5.5 The primary users of the framework will be risk managers in FSA. They will use the screening stage as a tool to sift signals of change from our various evidence streams, identify which should prompt assessment (or review) as risky foods and what other information or action is needed. They will use the full process (stage two) to structure assessment of controls for new risky foods and reviews of existing ones, and to identify triggers which would prompt review of risky foods previously assessed using the framework.

5.6 The framework allows us to articulate clearly the rationale for our assessments and decisions, including the evidence and expert assessment we have drawn on and the judgement we have applied. This will promote transparency of our decision making, against a clear expectation of how the process should work.

<u>Identifying new risky foods and signals of change</u>

5.7 We will draw on a range of sources of evidence to identify possible changes or other signals for screening and possible assessment using the framework, including:
- research, data gathering and analysis on sources and impacts of food risks
- monitoring and surveillance in food and public health under established systems, including incidents, outbreaks and emerging risks*

- wider information gathering and analysis including on horizon scanning, , and food crime
- evidence gathering set up to inform review against specific triggers identified as part of a previous consideration using the framework
- information from SACs who will be asked to identify relevant changes, as part of their regular horizon scanning and forward looks

5.8 *In a reciprocal way, use of the framework will generate information needs which will inform priorities under FSA's new surveillance approach (see Paper FSA 16/11/05).

Illustrating the use of the framework

5.9 To illustrate how we would use the framework to assess such an information set, we performed a screen of emerging issues identified by EFSA's emerging risks exchange network (EREN) in 2015.[4] A summary is attached at Annex 2.

5.10 This is for illustrative purposes and is not a full or definitive assessment of each issue. It shows how the framework will be used and how it helps us to structure and articulate our assessments.

## 6 IMPACT

6.1 The revised framework will help us to:
- make better and more consistent decisions about risks and their control;
- improve the targeting and effectiveness of our risk management and regulation; and
- make our work more accessible and understandable for non-experts.

## 7 CONSULTATION

7.1 We propose to review the framework in light of experience, two years after the Board's approval of the revised framework.

## 8 DEVOLUTION IMPLICATIONS

8.1 We will apply the framework consistently across England, Wales and Northern Ireland.

## 9 CONCLUSION AND RECOMMENDATIONS

9.1 The framework has been revised in line with the Board's recommendations, drawing on input from an ad hoc expert Working Group. The Board is asked to:
- **agree** that the revised framework fulfils the Board's request for an approach that will support soundly-based, consistent, and transparent decisions on identifying and managing risky foods.

9.2 As outlined in para 1.2, we will alert the Board where, following a screen, we have candidate risky foods for full assessment or review using the framework.

[4] https://www.efsa.europa.eu/en/supporting/pub/1067e

# DEVELOPING PROPORTIONATE CONTROLS FOR RISKY FOODS

# DEVELOPING PROPORTIONATE CONTROLS FOR RISKY FOODS

## INTRODUCTION - WHY WE NEED A FRAMEWORK

1. This framework has been developed by the FSA, working with our expert advisers, to support us in developing proportionate controls for risky foods. It complements our existing approaches to managing food risks, most of which do not relate to risky foods.
2. We identified a need for a framework during consideration of our approach to controls for raw drinking milk and burgers served rare.[1,2] Both of these can be regarded as 'risky' foods, in that they present a higher risk of ill effects to consumers than the more common presentations of these foods (pasteurised milk, burgers cooked through). They are also foods which some consumers wish to eat, and some businesses wish to sell, in their more 'risky' form. Our approach to these foods needs to find the right balance between protection from risk - focusing where we can make the greatest impact on public health - and supporting consumer choice and business growth and innovation, reflecting and supporting our ambition for a future of regulation that is effective, proportionate, robust, and sustainable.
3. We recognised that in most cases we controlled foods on the basis that they were either safe, provided they comply with relevant general regulations and good practice (for example, bread, dried pasta, canned goods), or as presenting risks which were so high that they were always unacceptable (for example, specified risk materials (SRM) under TSE controls). Neither category achieves the right balance of protection and choice for risky foods, which instead fall in a third category where risks are unacceptable unless specific additional controls were designed and consistently applied. We needed a framework to help us to make sound, consistent and transparent decisions in identifying 'risky' foods and in developing proportionate specific controls for them.
4. An initial draft framework was discussed by the Board in September 2015, as part of its discussions on burgers served rare.[2] We revised it following that discussion, working closely with an *ad hoc* Working Group comprising experts from four of our independent Scientific Advisory Committees and co-opted experts, convened by our CSA. This work produced the current version of the framework.
5. The framework comprises
   - a narrative setting out the background to the framework and its aims and key concepts (including the three zones of acceptability of risk), and how we will use it including the sources in information which will provide inputs to identify candidates for assessment or review
   - a decision tree setting out the process of applying the framework in practice, including the key questions and considerations at each stage (Annex 1)
   - guidance on use of the decision tree and the key considerations and areas of evidence which should inform a judgement at each point (Annex 2)

[1] July 2015 FSA Board Paper on raw drinking milk: www.food.gov.uk/sites/default/files/fsa150704.pdf
[2] September 2015 Board Paper on rare burgers: www.food.gov.uk/sites/default/files/fsa150904.pdf).

## Aims and use

6. The aim of this framework is to help the FSA to make soundly-based, consistent and transparent decisions in identifying risky foods and in developing proportionate controls for them.

7. The primary users of the framework will be risk managers in FSA. They will use it to structure assessments of new combinations of foods and risks, reviews of decisions on controls already in place, and to identify the triggers which would prompt review of foods that have already gone through the framework.

8. It will also provide clear context for those who are asked to provide expert and other input to this process, and, as part of this, help to promote effective dialogue between FSA and its Scientific Advisory Committees, in line with recommendation 6 of the Triennial Review of the FSA's SACs[3].

9. The framework also aims to promote transparency, awareness and understanding of our approach, and of the decisions that result, helping people to engage with this process and to help us to refine it through scrutiny, comment and challenge on how we apply it in practice.

10. It is not intended to be a detailed guide to assessing risks and benefits or the other areas of evidence that will inform its use, such as regulatory impact. Risk managers applying the framework will work with FSA and external experts who are familiar with these assessments. However the framework will help risk managers by highlighting the factors and types and sources of evidence, advice and analysis they will need to consider, and flagging those which are particularly important in the context of the risky foods framework (this is covered principally in the guidance notes).

## Acceptability of risks from food

11. The concept of risky foods arises from the way FSA considers the risks presented by different foods and the extent to which those risks are acceptable, and what this means for how these risks can be controlled in an effective and proportionate way. This needs to reflect the fact that different foods presented in different ways will have different risks for different groups of people. It also needs to consider acceptability to FSA, as the regulator responsible for protecting consumers from risks associated with food, but also acceptability to consumers, to food businesses and to others, reflecting our role in represent consumers' wider interests in relation to food, and the need to act in a proportionate manner, considering costs, benefits and other factors.

12. We consider acceptability of risk with reference to three 'zones of acceptability,' shown in Figure 1 with the approach to controls which applies in each zone:
    - foods for which the risk is so high they are **always unacceptable** (such as Specified Risk Materials under TSE controls) - the **red** zone
    - foods for which the risk is low enough to be **broadly acceptable** and may be regarded as safe provided the usual controls and good practice for food production apply (many foods, such as bread or canned goods) - the **green** zone
    - foods for which the risks exceed the nature or levels considered broadly acceptable by the FSA, but which some people may accept for other benefits, such as choice. These risks are **unacceptable unless** specific additional controls are designed and consistently applied - the **amber** zone.

13. Using the model described above, risky foods would be managed in the amber zone.

[3] www.food.gov.uk/news-updates/news/2016/15022/triennial-review-of-six-fsa-scientific-advisory-committees

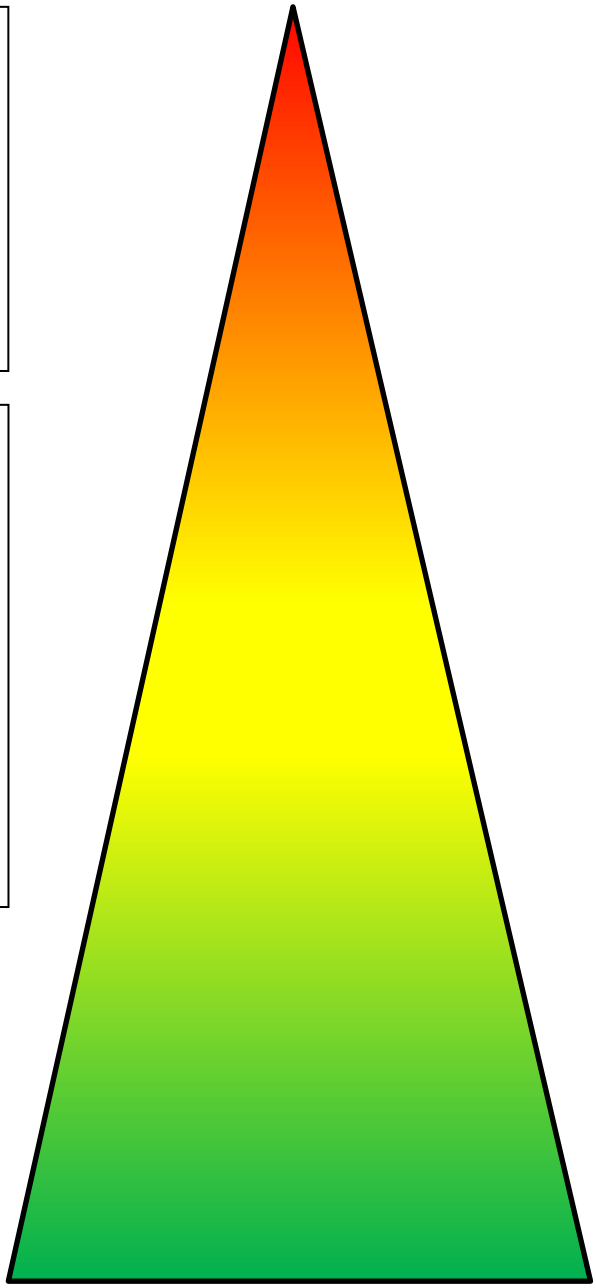
## Figure 1 - CONCEPTUAL MODEL FOR ACCEPTABILITY OF RISK[4]

Increasing individual risk and FSA/societal concern

**RED ZONE Unacceptable**
A nature and level of risk which the FSA considers to be unacceptable for any person, whatever the benefits and even if accompanied by information on that risk. Action should be taken to protect people from foods giving rise to risks in this region, until or unless changes in production and processing can be made that reduce the degree of risk so that it falls in one of the other zones.

**AMBER ZONE 'Unacceptable unless'**
A nature and level of risk that exceeds the nature and/or levels considered broadly acceptable by the FSA, but which some people may accept for other benefits, such as choice. These levels of risk would be considered by the FSA to be unacceptable unless the risks are properly assessed and control measures designed and implemented to maintain the residual risks at a level as low as reasonably practicable, people are provided with information to allow informed choice, and the risks and effectiveness of controls are regularly reviewed.

**GREEN ZONE Broadly acceptable**
A nature and level of risk which is higher than zero but, on the basis of best available expert advice, is considered by the FSA to be broadly acceptable or "safe" within the usual meaning of the word, provided that risks are adequately controlled through the application of good hygienic, manufacturing or agricultural practices, including HACCP, as appropriate.



[4] Adapted from: The Institute of Engineering and Technology (2015) *Determining the Acceptability of Risk. Health & Safety Briefing No. 36.* Available at: http://www.theiet.org/factfiles/health/hsb36-page.cfm?type=pdf
Based on: Health & Safety Executive (2001) *Reducing risks, protecting people: HSE's decision-making process.* Available at: http://www.hse.gov.uk/risk/theory/r2p2.pdf

14. In deciding which foods and risks fall within which category, we need to consider:
    - the nature of the risks and who these affect and how
    - any benefits from consumption of the food
    - the effectiveness of controls
    - the acceptability of the risks and of the controls, to FSA and to citizens, businesses, enforcement bodies and others.
15. Our assessment of all of these aspects will be informed by our best understanding of the evidence in each area and on discussion with experts and other stakeholders.
16. Given that the criteria for categorisation are multi-dimensional, and the assessment needs to reflect uncertainties in the evidence, values and other subjective factors, and the specifics of each case, it is not possible to set fixed boundaries between the three zones. Figure 1 reflects this in a simplified way, with no hard boundaries between them. Nevertheless, the FSA as a regulator has to make clear and consistent decisions about which foods fall in which category, and which controls apply, and to do this in a robust, transparent and proportionate way.

## IDENTIFYING AND MANAGING RISKY FOODS

17. We also need clear criteria for identifying risky foods for assessment using the framework. These seek to balance a number of considerations:
    - we need to identify risky foods so that we can manage them appropriately, in their own right and consistently with how we manage other risky foods
    - there is a vast range of foods and risks and we need to be able to focus on those foods which merit assessment as risky foods
    - the process of identifying risky foods and carrying out detailed assessment or review using the framework will require significant resource
    - managing foods in the amber zone involves a significant resource for us and for others to develop, implement and verify the additional controls needed
    - we need to prioritise activity with the greatest impact on public health or other benefits to consumers.
18. The framework seeks to balance these through two features:
    (i). clear criteria to identify risky foods for consideration using the framework
    (ii). a two-stage approach, with stage one a screening step to check whether a detailed assessment at stage two is merited (and if not, what other action should result).

### Risky foods

19. To be considered using the framework a risky food must meet three criteria:
    (i). a heightened risk relative to other foods or other presentations of the same food, based on risk per serving (or per consumption event) but taking into account the number and types of people affected and the severity of the effects.[5]
    (ii). a real or perceived benefit from sale or consumption specific to this food (usually this relates to some people who wish to eat it and/or businesses who wish to sell it, in its 'risky' form), or a disproportionate impact from preventing its sale/consumption

[5] Risks reflect people's vulnerabilities and behaviours as well as the properties of the food itself

(iii). existing controls to manage risks from this food are absent or there are grounds to believe that they cannot manage the risks and benefits in an effective and acceptable way (for example, the 'default' control measure would remove the food entirely or remove the characteristics valued by some consumers - such as cooking a burger thoroughly; the existing regime is no longer effective or acceptable; a new risk has emerged which the existing regime does not address effectively)

Assessing the evidence

20. The framework is intended to work on existing cases and in response to actual or possible changes as new risks emerge or evidence on known risks changes. This could be evidence that the criteria are met now, or that they might be met as a result of information indicating a real or plausible trend or future change.

21. In assessing foods against these three criteria, there are four key dimensions which form the main areas for evidence and analysis, both to identify and prioritise foods for consideration (at stage one) and in the subsequent detailed assessment at stage two. These are:

- The nature of the hazard
- The potential exposure
- The effectiveness of controls in practice

  This has two aspects: (i) effectiveness of controls in managing risk assuming they are applied as intended, and (ii) actual or expected levels and patterns of compliance in practice and how this affects the risks to which people are exposed.
- The acceptability/defensibility of controls.[6]

  This also has several dimensions, including: the other factors used to assess the impact of regulation and whether it is proportionate (benefits to health and any wider benefits, and costs, and who these accrue to, consistency, equity); and wider considerations affecting FSA's sense of their acceptability (e.g. with regard to consistency, equity); and/or challenge from consumers, businesses or from a legal/enforcement perspective.

22. This includes assessing any vulnerabilities which affect any of these dimensions (are any groups more likely to be affected or less able to benefit or exercise choice?).

23. For new food-risk combinations, and for considering the case for review of foods already assessed and managed as risky foods using the framework, this assessment will focus on whether there is evidence of a material change in one or more of these dimensions. [7] In considering existing food-risk combinations as potential candidates for assessment as risky foods using the framework, consideration of change will still be useful, but the assessment will also need to consider whether the evidence on the current situation shows that the three criteria are met, and if so, how.

Assessing risks

24. It follows that in many cases the framework will be applied to foods eaten with a relatively low frequency of consumption (at a population level) with a relatively higher

[6] Note, this refers to the suitability of controls as applied in the case of a specific food/risk, not to the acceptability at a macro level of the wider approach to risk management e.g. risk-based regulation.
[7] Change here covers changes which can be identified with confidence and changes in our understanding and assessment of one of these dimensions in the face of uncertainty.

possibility of detriment per serving. We need to consider the impact of action on public health in setting priorities for assessment using the framework.

25. It is difficult to assess absolute risks for individual foods with confidence, particularly those consumed infrequently or by relatively few people, and data on actual incidence of ill effects will often be sparse, for new and existing risks. Evidence on absolute risks should be used where relevant and possible, but it will also be useful to consider risk relative to a relevant comparator, such as a less risky presentation of the same food, or a current state versus a possible future state.

**Identifying foods to consider**

26. We will use several strands of evidence to identify possible changes that might prompt consideration using the framework. This is illustrated in Figure 2, and includes:
    - research, data gathering and analysis on sources and impacts of food risks
    - monitoring and surveillance in food and public health under established systems, including incidents, outbreaks and emerging risks
    - wider information gathering and analysis including on horizon scanning and food crime
    - evidence gathering set up to inform review against specific triggers identified as part of a previous consideration using the framework
    - information from SACs who will be asked to identify relevant changes, as part of their regular horizon scanning and forward looks

**A two-stage approach**

Stage one (screening): deciding whether to apply the framework

27. This stage has two aims:
    - to ensure that risk managers are alert to the need to consider whether a different approach might be merited in light of changes or of other evidence
    - to ensure we only deploy a full assessment using the framework where there is a clear rationale for doing so

28. This stage involves collating the data required for a first consideration of an issue including a preliminary profiling of risk and benefit, and consideration of any existing controls, to determine whether the three criteria are met. This considers evidence of a material change and/or of the current situation (for existing risks), as outlined above. There are three possible outcomes:

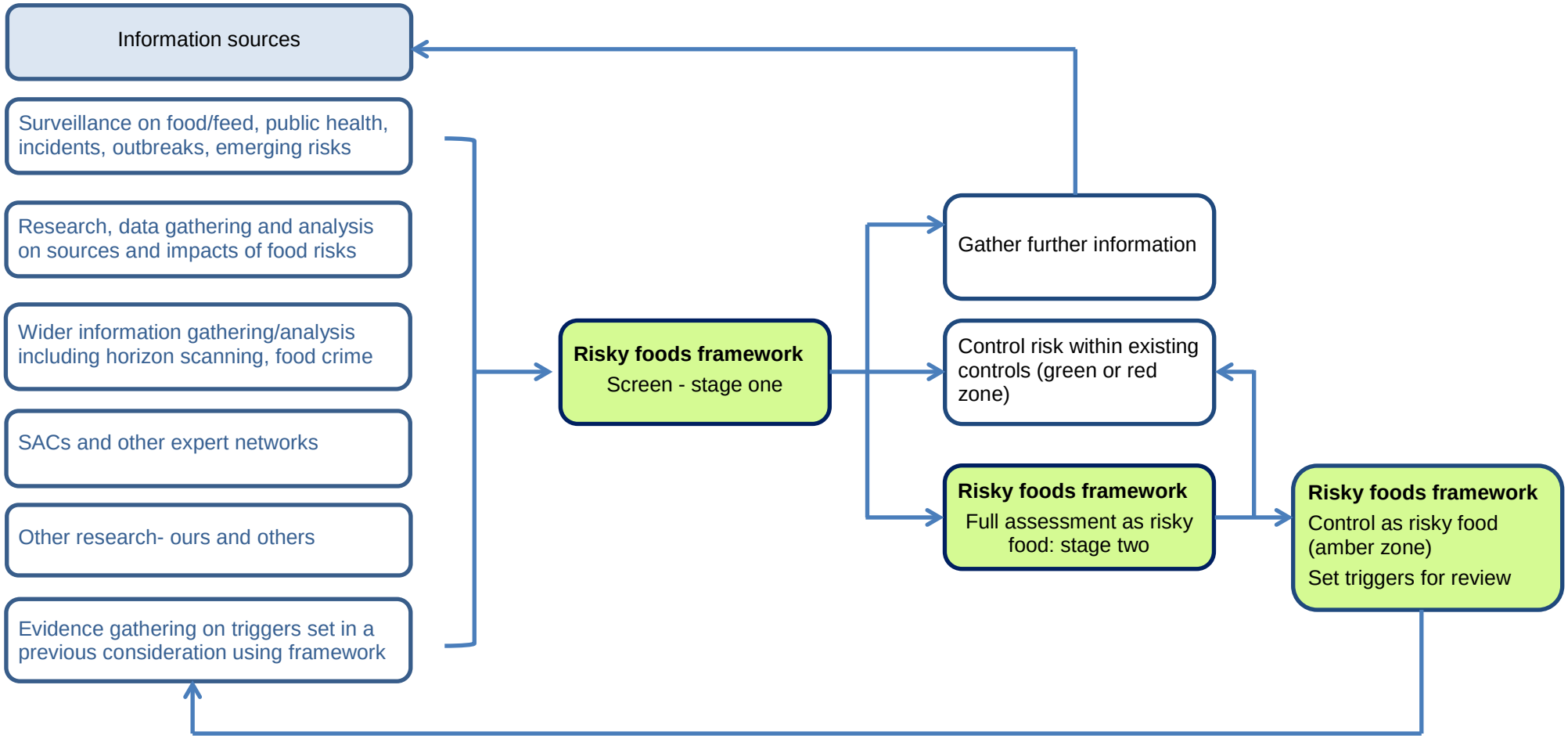
| | |
|---|---|
| Insufficient information to determine whether criteria are met. | Out of scope for stage two.<br>Information requirements should be defined.<br>Risk manager to make a judgement on whether to actively seek or generate the information, taking into account the cost, effort and time required as well as the nature of the potential risk. |
| Sufficient information to conclude the criteria are not met (no material change or rationale based on existing situation) | Out of scope for stage 2<br>May set/re-set the clock for future review |
| Sufficient information to conclude the criteria are met (is or plausibly may be material change, or rationale based on existing situation) | Apply the framework.<br>Move to full assessment in stage two **if** there is not an established risk management approach that will manage the risks and balance risks and benefits in an effective and acceptable way. |

29. This requires judgement. Gaps in information should be captured, with uncertainties in the assessment, and their effects on the conclusions and the confidence placed in them. However, if information gaps are such that it is not possible to draw a conclusion with any confidence, then the outcome is 'insufficient information to proceed' with a decision on what if any action is needed to address information gaps.

Stage two: Detailed consideration

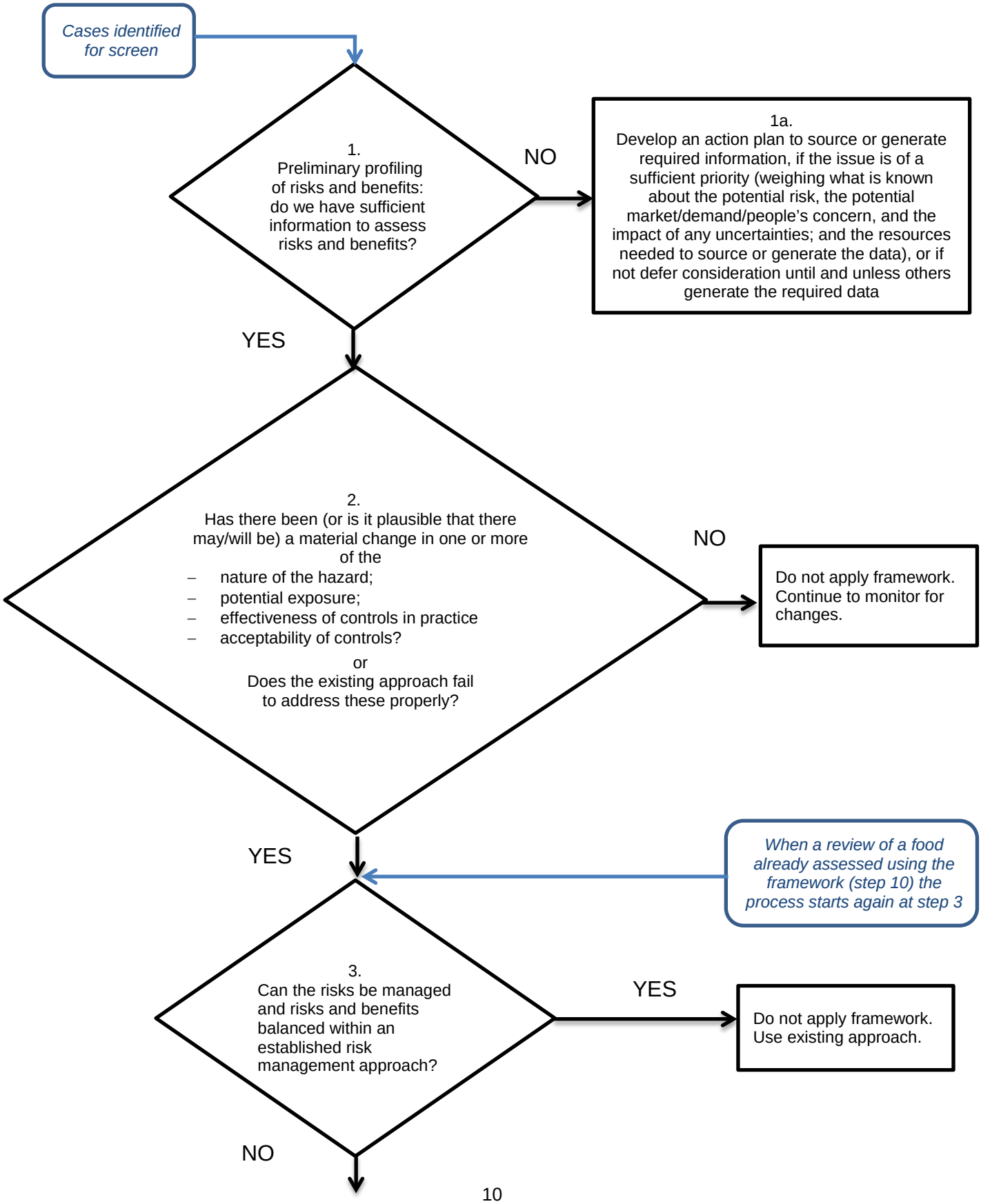
30. This stage aims to support structured assessments and decisions on three points:
    (i). where a food should sit in the zone of acceptability
    and, if this suggests it might sit in the amber zone
    (ii). what additional controls, information and measures for verification are needed
    (iii). what triggers would be for a review
31. This requires a more detailed assessment of risks and benefits and of the effectiveness and acceptability of options for controls. It may be helpful to consider contingent risk assessment (which assesses the risks that are expected to arise under different scenarios for controls). This stage will also require a description, at least in qualitative sense, of consumers' other interests and other detriments and benefits.
32. Again, gaps in information should be captured along with uncertainties in the assessment, and their effects on the conclusions and the confidence placed in them. Where possible, this should include identifying areas of uncertainty where a plausible change in the evidence would lead to a different conclusion. This in turn would inform consideration of triggers for review.
33. Where information is sparse and uncertainty high, it may not provide a clear-cut basis for assigning the food into one of the three zones of acceptability. In these cases a decision may depend particularly on judgements about acceptability of risks or controls, which have a strong subjective element. It is particularly important to set out clearly the basis for the decision and to consider whether this is consist with decisions in similar cases, the rationale for any differences in approach, and how any changes in information or assumptions which would lead to a different decision. Again, this would inform consideration of triggers for review.

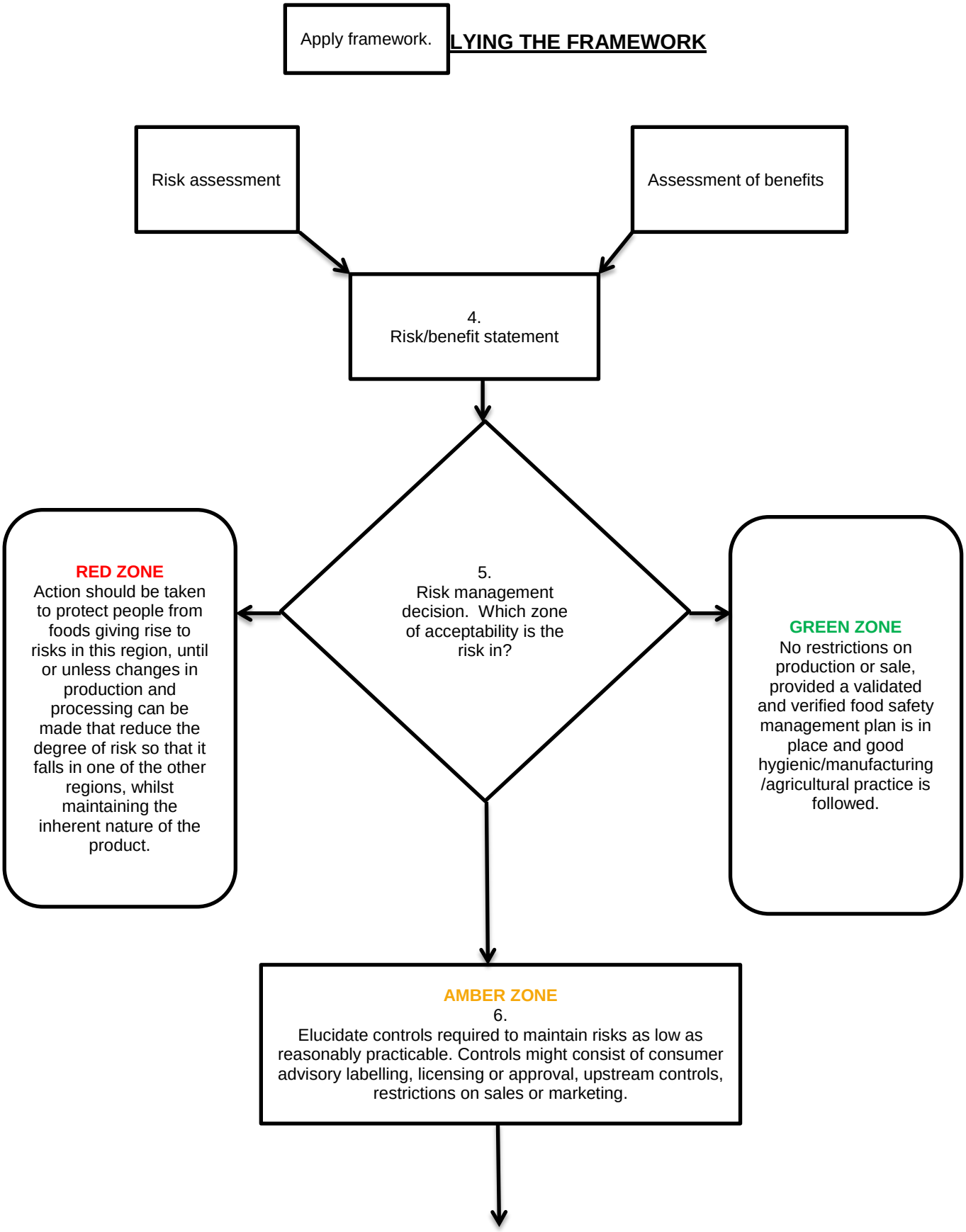
**Figure 2: Inputs to identify of possible cases for screening or review using the risky foods framework**



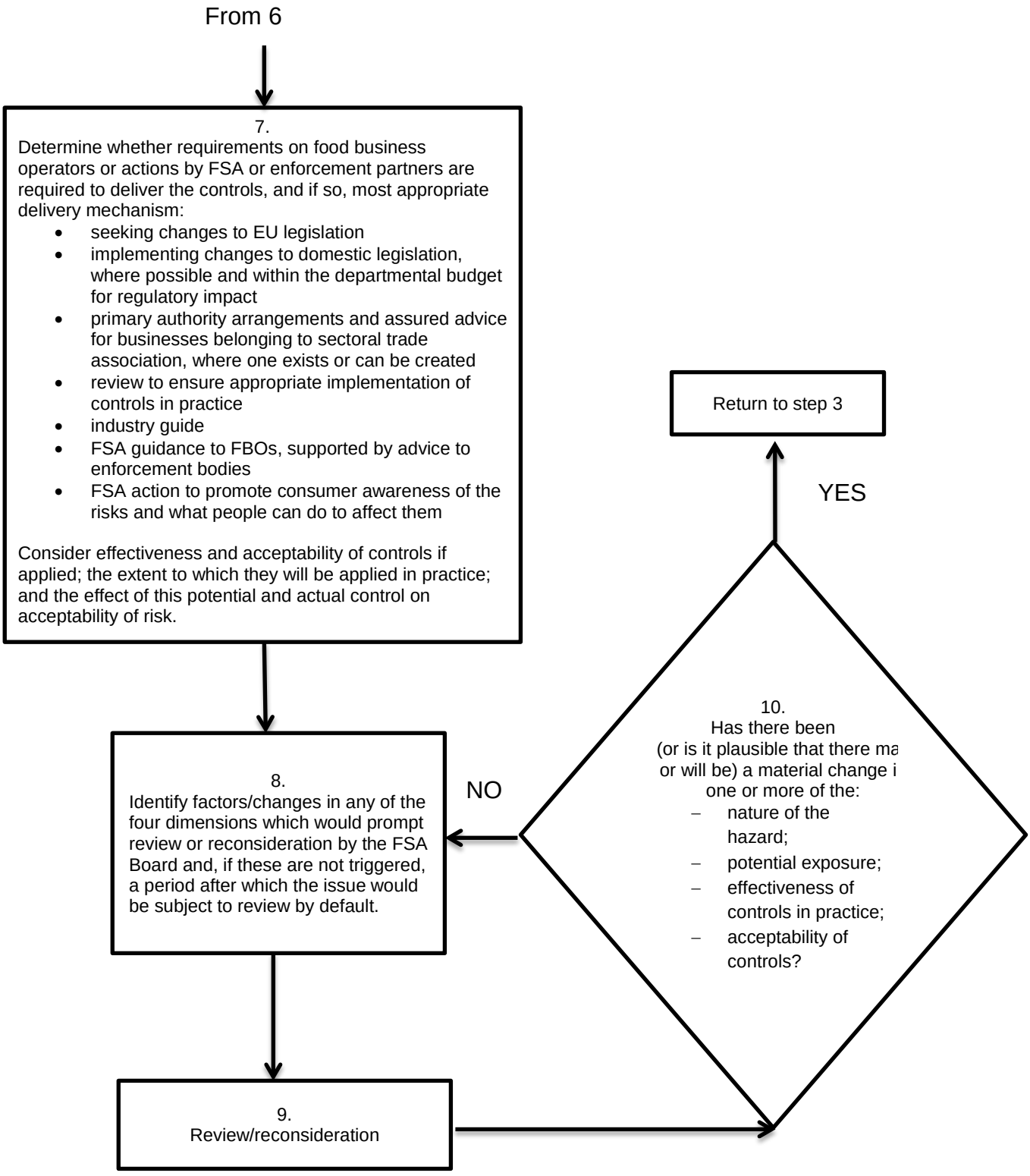
## ANNEX 1: FLOW CHART: APPLYING THE FRAMEWORK FOR PROPORTIONATE CONTROLS FOR RISKY FOODS

### STAGE ONE – DECIDING WHETHER TO APPLY THE FRAMEWORK




Apply framework.
LYING THE FRAMEWORK
Risk assessment
Assessment of benefits
4.
Risk/benefit statement
5.
Risk management decision. Which zone of acceptability is the risk in?
RED ZONE
Action should be taken to protect people from foods giving rise to risks in this region, until or unless changes in production and processing can be made that reduce the degree of risk so that it falls in one of the other regions, whilst maintaining the inherent nature of the product.
GREEN ZONE
No restrictions on production or sale, provided a validated and verified food safety management plan is in place and good hygienic/manufacturing /agricultural practice is followed.
AMBER ZONE
6.
Elucidate controls required to maintain risks as low as reasonably practicable. Controls might consist of consumer advisory labelling, licensing or approval, upstream controls, restrictions on sales or marketing.

To 7


From 6
7.
Determine whether requirements on food business operators or actions by FSA or enforcement partners are required to deliver the controls, and if so, most appropriate delivery mechanism:
seeking changes to EU legislation
implementing changes to domestic legislation, where possible and within the departmental budget for regulatory impact
primary authority arrangements and assured advice for businesses belonging to sectoral trade association, where one exists or can be created
review to ensure appropriate implementation of controls in practice
industry guide
FSA guidance to FBOs, supported by advice to enforcement bodies
FSA action to promote consumer awareness of the risks and what people can do to affect them
Consider effectiveness and acceptability of controls if applied; the extent to which they will be applied in practice; and the effect of this potential and actual control on acceptability of risk.
8.
Identify factors/changes in any of the four dimensions which would prompt review or reconsideration by the FSA Board and, if these are not triggered, a period after which the issue would be subject to review by default.
NO
10.
Has there been
(or is it plausible that there ma
or will be) a material change i
one or more of the:
nature of the hazard;
potential exposure;
effectiveness of controls in practice;
acceptability of controls?
YES
Return to step 3
9.
Review/reconsideration

## Annex 2 – Guidance for using the flowchart: points to consider and areas for evidence and advice

This is not intended as a detailed guide to carrying out assessments of risks and benefits to people's health or of the other areas of evidence that will inform the use of the framework, such as regulatory impact. Risk managers applying the framework will work with FSA and external experts who are familiar with these assessments. This guidance aims to help risk managers by highlighting some of the important issues and types and sources of evidence, advice and analysis they will need to consider, and flags those which are particularly important in the context of the risky foods framework.

| **Stage one**<br>Outcome: decision on whether to apply the framework, reflecting the three criteria (heightened risk; specific benefit; existing controls absent or not able to balance risk and benefit effectively and/or acceptably), and informed by the lens of change. | | | |
|---|---|---|---|
| **Step** | **Description** | **Points to consider** | **Areas for evidence and advice**<br>Each stage draws on evidence and advice from the preceding steps |
| 1 | Preliminary profiling of risks and benefits | Do we have the information to make an initial assessment of risks and benefits?<br>Consider to whom the risks and benefits accrue, including the possibility of secondary cases of illness. Is the risk limited to the person making the choice?<br>Consider the reason(s) for increased risks and whether they are specific to this food or more general<br>Gaps in information can and should be captured in discussing the uncertainties in the assessment and their effects on the nature of the conclusions and the confidence placed in it. However, if information gaps are too extensive then this many mean it is not possible to draw a conclusion with any confidence - that is, there is insufficient information to proceed. | <u>Nature of hazard and exposure</u><br>This follows the established process for risk assessment. Consult FSA risk assessment and analytics teams and consider whether advice is needed from one or more Scientific Advisory Committees.<br>Ideally, this will 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. Available data are likely to be limited, and comparisons of relative risk may be more feasible. It is likely to help to identify a comparator and to assess risk relative to this. This could be between a current and future state (a change or trend) or between more and less risky presentations of the food (e.g. pasteurised versus raw drinking milk)<br>Where possible consider the totality of hazards (and any benefits) presented by a particular food (for example, burgers may present risks from other pathogens besides E. coli O157).<br>Areas for consideration include:<br>– nature of the food/product<br>– nature of effect(s) including severity of (e.g. deaths, hospitalisations)<br>– amount of the food people consume (no. of servings), frequency of consumption (how commonly/rarely foods are consumed), profile of people consuming |

| | | | |
|---|---|---|---|
| | | | – level of risk (for example cases per million servings (individual risk) and total cases per year (population risk)<br>– population affected/at risk (general population or sub-groups e.g. children, adults or other aspects of vulnerability; are those more vulnerable aware of this and can/will they take any action to mitigate this) possibility of secondary cases of illness)<br>– distribution of incidence on location and time (all at once/in same place is different to spread out evenly over space/time).<br>– how the food is currently sourced, prepared, consumed and how this affects the risk<br><br><u>Evidence for any beneficial effects on health</u><br>(where possible to follow a comparable profiling based on who is affected and how and on individual and population impacts)<br><br><u>Evidence for other benefits, costs or other detriments</u><br>Definition of benefit, cost or other detriment<br>– What is it (nature, severity, scale - individual and population)<br>– Who does it accrue to?<br>– What is its impact<br>Guidance on Regulatory Impact Assessment will be relevant here |
| 1a | If insufficient information | If there is insufficient information to proceed, then the information needed should be defined.<br>The risk manager will then need to make a judgement about whether to actively seek or generate the information (or to defer consideration until and unless others generate the required data), taking into account the cost, effort and time required as well as the nature of the potential risk. | In making this judgement, consider and weigh what is known about:<br>– the potential risk<br>– the potential market/demand<br>– people's concerns<br>– the impact of any uncertainties<br>– the resources needed to source or generate the data |

| | | | |
|---|---|---|---|
| 2 | Has there been a material change?<br>Or (for existing food-risk combinations) does the existing approach fail to address these four dimensions properly? | Has there been (or is it plausible that there may/will be) a material change in one or more of the<br>• nature of the hazard;<br>• potential exposure;<br>• effectiveness of controls in practice; or<br>• acceptability of controls?<br>Or (for existing food-risk combinations) does the existing approach fail to address these four dimensions properly?<br>Consider what the reference points or comparators are that defines the change<br>**If no change (or gap in existing approach)**<br>Do not apply framework. Consider whether to set criteria/time for review.<br>**If there is/may be a material change (or gap in existing approach)**<br>If the conclusion is that there is evidence of a change or trend (or gap), but we not able to say with confidence that it is material at this stage, this should 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) | Many of the factors which would prompt consideration using the framework (subject to step 3) can be expressed as a change in one of these four dimensions, even for existing foods. Assessment for existing foods should also consider any other evidence that the current approach is not able to address these four dimensions properly, and where this exists describe it and the rationale for why it should prompt consideration using the framework.<br>Exposure<br>Consider data on sales, volume, numbers of outlets etc. as well as on who is consuming in what quantities<br>Effectiveness of controls<br>This has two elements:<br>(i) the effectiveness of controls assuming they are applied as intended,<br>(ii) actual or expected level and pattern of compliance in practice (including effectiveness of enforcement) and how this affects the exposure to risk<br>If controls include consumer information, how effective is this?<br>Consider capacity to act to ensure an effective control of the risks, including resource available to FSA to consider and address the issue, and to local enforcement and food businesses to enact and check controls, and the effect this will have on behaviour and compliance.<br>Acceptability<br>This includes the other factors used to assess the impact of regulation and whether it is proportionate (benefits to health and any wider benefits, and costs, and who these accrue to, consistency, equity) and also to wider considerations affecting FSA's own sense of their acceptability (e.g. on basis of consistency, equity) and/or acceptability to or challenge from consumers, by businesses, or from a legal/enforcement perspective.<br>Consider changes in the food system and the wider environment which could in turn impact on risk, exposure, vulnerability and changes in knowledge across any of these dimensions.<br>Describe the current/previous situation (or other comparator)<br>Is change deliberate/designed (e.g. an increase in demand/supply, in production processes or a change in policy) or unintentional (e.g. food safety incident, environmental change). |

| | | | |
|---|---|---|---|
| 3 | Is there an established risk management approach that will manage the risks and balance risks and benefits? | | See above on effectiveness and acceptability.<br>If it is not clear whether and how an existing approach would apply (for example it is clear whether a new food falls under the novel foods regulations) it may be necessary to consider whether assessment as aa risky food would be merited in the interim. |

| **Stage two**<br>Outcome: decisions on three points:<br>(i). where a food should sit in the zone of acceptability<br>and, if this suggests it might sit in the amber zone<br>(ii). what additional controls, information and measures for verification are needed<br>(iii). what triggers would be for a review | | | |
|---|---|---|---|
| **Step** | **Description** | **Points to consider** | **Areas for evidence and advice**<br>Each stage draws on evidence and advice from the preceding steps |
| 4 | Risk/benefit statement | Consider the nature of any benefit which is seen to balance risk (e.g. choice, trade)<br>Consider who receives the risks, other detriments and who receives the benefits and whether and how this raises issues of equity and of consistency across different risks | This requires a more detailed assessment of risks and benefits.<br>It will build on the information captured in Stage One and the evidence and advice considered there (see above).<br>Consider all the relevant risks (and benefits) from the food in question.<br>It may be helpful to consider at this stage contingent risk assessment (which assesses the risks that are expected to arise under different scenarios for controls). It will also require a description, at least in qualitative sense, of consumers' other interests and other detriments and benefits.<br>Existing risk-benefit frameworks (such as EFSA's) may be helpful in identifying questions to ask and in help to identify evidence needs, including around uncertainty and vulnerable groups.<br>This should include elucidation and description (at least in qualitative sense) of consumers' other interests and any other detriments or benefits<br>Assessment and comparison of risks and benefits needs to consider who they accrue to and the fact that their distributions may be different: for example, risks may be a high increment for a few people; benefits may be low increment for many. |

| | | | |
|---|---|---|---|
| 5 | Risk management decision. Which zone of acceptability is the food in? | This is a key step which brings together the issues and strands considered so far.<br>Gaps in information should be captured in discussing the uncertainties in the assessment and their effects on the nature of the conclusion and the confidence placed in it. Where possible, this should include identifying areas of uncertainty where a plausible change in the evidence would lead to a different conclusion. This in turn would inform consideration of triggers for review (step 9).<br>Where information is sparse and uncertainty high, it may not provide a clear-cut basis for assigning the food into one or other of the three zones of acceptability. If so it is particularly important to set out clearly the basis for the decision and to consider whether this is consist with decisions in similar cases (and the rationale for any differences in approach), and how any changes in information or assumptions which would lead to a different decision. | This draws on the (expanded) assessment of risks and benefits and also considers the effectiveness and acceptability of options for controls, again building on the information already captured (see guidance on Stage One).<br>For foods which present more than one hazard (or benefit) consider how different control measures and options will affect the overall risk-benefit profile)?<br>The decision needs to reflect the acceptability of the overall combination of risks (and benefits) from the food.<br>Consider whether 'normalisation' of a risky foods could lead to a (further) change in exposure (for example if people mistakenly assume it is safe to serve rare burgers at home because they have eaten one in a restaurant which applies the additional controls required to manage risk in that setting) |

| | | | |
|---|---|---|---|
| 6 | Amber zone<br>Elucidate controls | This stage examines the possible options for control in more detail and the extent to which they will manage risks effectively and appropriately | These two steps look in more detail at the options for control and what would be necessary and acceptable to manage the risks in the 'amber zone'<br>**Step 6** looks at the effectiveness of options for combinations of controls in managing risk assuming they are applied as intended |
| 7 | Determine whether requirements on food business operators are required to deliver the controls, and if so, most appropriate delivery mechanism: | Options for enacting controls include:<br>– seeking changes to EU legislation<br>– implementing changes to domestic legislation, where possible and within the departmental budget for regulatory impact<br>– primary authority arrangements and assured advice for businesses belonging to sectoral trade association, where one exists or can be created<br>– review to ensure appropriate implementation of controls in practice<br>– industry guide<br>– FSA guidance to FBOs, supported by advice to enforcement bodies<br>– FSA action to promote consumer awareness of the risks and what people can do to affect them<br><br>Consider effectiveness and acceptability of controls if applied; the extent to which they will be applied in practice; and the effect of this potential and actual control on acceptability of risk. | **Step 7** looks at what would be required to effect and to assure the application of these controls, and the actual or expected level and pattern of compliance in practice, and the effect of this on the risk to which people are exposed.<br><u>Options for enacting controls</u><br>This will draw on the guidance and evidence and analysis that support regulatory impact assessment.<br><br>If controls include consumer information, how effective are different options in communicating risks and supporting informed decisions?<br><u>Compliance</u><br>Consider capacity to act to ensure an effective control of the risks, including resource available to FSA to consider and address the issue, and to local enforcement and food businesses to enact and check controls, and the effect this will have on behaviour and compliance.<br><br><u>Acceptability of controls and resulting risks</u><br>This has a number of dimensions. It includes the other factors used to assess to impact of regulation and whether it is proportionate and also to wider considerations affecting FSA's own sense of their acceptability (e.g. on basis of consistency, equity) and/or acceptability to or challenge from consumers, by businesses, or from a legal/enforcement perspective.<br><br>Consider how people - businesses and consumers - may act in response to information or other aspects of the controls required in the amber zone, and how might views on acceptability change, for example if the food becomes more available, or if people experience ill effects themselves, or become more aware of other people experiencing ill effects from the food in question (or, conversely, eat it or are aware of other people eating it without ill effects). |

| | | | |
|---|---|---|---|
| 8 | Identify factors or changes in any of the four dimensions which would prompt review or reconsideration by the FSA Board and, if these are not triggered, a period after which the issue would be subject to review by default. | This stage establishes the criteria and timescale for review.<br>This includes identification of any triggers for review, and the mechanisms by which these triggers will be tracked. Risk managers will need to consider where evidence for triggers will be sought proactively or through a watching brief, and/or whether there will be a general review across the piece after a fixed period, taking into account the cost, effort and time required by each approach, as well as the nature of the potential risk.<br>Proactive and specific measures could include measures set up as part of the specific additional controls for this food, or proactive analysis drawing on existing mechanisms such as outbreak surveillance<br>General measures, would include a number of activities which we use to inform awareness and potential review across all risks (such as horizon scanning, emerging risks, ongoing incident and outbreak analysis) | This step involves reviewing the information and assessment that has informed the decision and identifying those things for which a change could lead to a different decision (either in terms of the classification in the three zones of acceptability or in the nature of controls deemed to be effective and acceptable to manage the risk in the amber zone).<br>These changes would then be the basis for triggers. Where possible these should describe the type of change involved (nature, direction, magnitude).<br>Triggers would ideally be multidimensional (such as the direction of an arrow in a detriment vs likelihood plot).<br>This could be direct evidence of a change, or evidence which leads to a plausible possibility that risk has changed. It would draw on more than 'data', and would include information, insight, understanding.<br>Iterative dialogue between risk managers and risk assessors (in FSA and in the SACs) will help to elucidate what sorts of changes could be useful as triggers in respect of the risk-benefit assessment. EFSA guidance on re-evaluation of risk in different areas could be a useful tool for risk assessors considering changes in that aspect.<br>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. |

| | | | |
|---|---|---|---|
| 9 and 10 | Review/ reconsideration | Has there been (or is it plausible that there may/will be) a material change in one or more of the<br>– nature of the hazard;<br>– potential exposure;<br>– effectiveness of controls in practice; or<br>– acceptability of controls?<br>Consider what the reference points or comparators are that defines the change | This is essentially the same consideration as at Step 2 of the original assessment.<br>It will draw on the evidence and advice in the previous assessment under the framework and the design of the triggers.<br>See guidance above. |

## Illustrative use of the risky foods framework to screen issues from EREN 2015

As a sense-check of the revised FSA Framework for developing proportionate controls for risky foods, and to illustrate its use with some real examples, we have used the framework to apply a preliminary 'screening' to the emerging issues identified through EFSA's emerging risks exchange network (EREN) in 2015.[1]

**This is for illustrative purposes and should not be considered a full and definitive assessment of each issue.**

However it does serve to show how the framework will be used, using one of the sources of information which will provide inputs to the framework in the form of information on actual or potential changes and signals of new risks.

The eleven issues identified by EFSA include a range of signals, from early signals without a clearly defined food risk to new information on known risks. The table below summarises the key points from applying the screening stage 1 to each issue. Note, these are not ranked in any way.

Stage 1 has three steps which pose three questions in succession:

| | |
|---|---|
| 1 | Do we have the information to make an initial assessment of risks and benefits?<br>*[If YES, proceed to step 2]*<br>*[If NO, define the information that would be needed and what action if any should follow to source/gather it]* |
| 2 | Has there been (or is it plausible that there may/will be) a material change in one or more of the<br>– nature of the hazard;<br>– potential exposure;<br>– effectiveness of controls in practice; or<br>– acceptability of controls?<br>Or does the existing approach fail to address these properly?<br>*[If YES, proceed to Step 3]* |
| 3 | Can the risks be managed and risks and benefits balanced within an established risk management approach?<br>*[If NO, proceed to full assessment using Stage Two]* |

Where an issues drops out at one step, subsequent steps are not generally discussed further.

If an issue or signal relates to a food which is already managed as a risky food (e.g. raw drinking milk), then the screening stage is bypassed and the process moves to step 10 to consider whether the new information indicates a change which would either trigger a review or change the triggers for a review at a future date.

[1] https://www.efsa.europa.eu/en/supporting/pub/1067e

| **Issue from EREN** (country reporting issue) | **Step 1** Do we have the information to make an initial assessment of risks and benefits? | **Step 2** Has there been (or may/will there be) a material change in the nature of the hazard; potential exposure; effectiveness of controls; or acceptability of controls? | **Step 3** Can the risks be managed and risks and benefits balanced within an established risk management approach? | **Other comments** |
|---|---|---|---|---|
| 1. Outbreaks of transient gastrointestinal illness linked to the consumption of raw beetroot (France) | **No.** No causative agent identified, (extensive investigation did not confirm what had caused the digestive symptoms).<br><br>No reported outbreaks in UK. | - | - | Consider tracking info on any outbreaks in UK and further info from data sharing with other countries |
| 2. Growth of *Vibrio* spp*.* in Northern waters and TTX detection in European bivalve shellfish (UK)<br><br>First report of detection of tetrodotoxin (TTX, a neurotoxin) in European bivalve shellfish, with *Vibrio spp.* as putative source.<br><br>[The focus in this report is on TTX rather than potential pathogenic effects of *Vibrio*] | **Yes**<br><br>TTX is a known hazard.<br><br>Exposure of UK consumers likely to be below levels of concern on present knowledge.<br><br>Taken alone, no clear evidence that TTX in bivalve shellfish presents a heightened risk relative to other foods/other presentations of shellfish that comply with existing legislation. | **No**<br><br>Reported levels do not indicate TTX exposure would materially change the hazard or exposure to risk from bivalves.<br><br>However in view of the known wider risks from shellfish, see Step 3. | **Yes**<br><br>There is no significant additional risk identified at this stage so no specific risk management intervention is needed for TTX. This will be reviewed as new evidence emerges.<br><br>Increases in exposure to *Vibrio* and associated toxins are known potential risks from climate change, which we would track as a potential trigger for review. | *Vibrio* spp*.* and TTX are not currently part of regular monitoring.<br><br>EFSA's opinion available by the end of March 17<br><br>UK to collect more data on contamination that could be used by the EURL. |
| 3. Putative new influenza virus that has been identified in cattle and pigs (Belgium) | **No**<br><br>The importance of this virus for livestock and humans is currently not clear. | | | Existing regime exists for monitoring and reporting animal diseases. This could pick up this issue if evidence suggested there was a case for proactive tracking. |

*Note the comments above are illustrative, to show the use of the framework; they are not full or definitive assessments of each issue.*

| | | | | |
|---|---|---|---|---|
| 4. Higher levels of mycotoxins deoxynivalenol and zearalenone in testing of maize and feedingstuffs in 2014 (Italy) | **Yes**<br>These are known hazards and exposure can be estimated.<br>There is no 'benefit' as such attaching to a specific food with higher mycotoxin levels, so not obvious how a 'risky food' could be defined. | **No**<br>This is within the known wide variation in levels of mycotoxins due to numerous environmental factors and crop varieties. | **Yes**<br>Existing regime establishes regulatory limits, monitoring and good practice to mitigate production of mycotoxins. | Should levels rise in the long term, such as to raise concerns for exposure, would need to review balance of protection from risk and benefit of maintaining supply of staple foods. |
| 5. Dermatitis due to consumption of raw or undercooked Shiitake (France) | **Yes**<br>Putative agent is known (lentinan), though info on UK consumption of raw or undercooked Shiitake likely to be sparse. No cases reported in UK.<br>Risk would be heightened relative to cooked Shiitake mushrooms. | **No**<br>Cannot say if there is a material change without info on consumption/exposure or evidence of cases. | **Yes** (consumer advice) | Consider case for tracking info on consumption of raw shiitake and data on any incidents in UK. |
| 6. Increased incidence of *Salmonella* Infantis in broiler meat and reports of human cases (Croatia) | **Yes** | **No** Evidence to date does not suggest that this represents a significant change in the overall risks associated with poultry meat.<br>No evidence that existing controls would not deal with this serovar as with other Salmonellas | **Yes**<br>Dealt with by existing controls, which reflect the view that risks from consuming raw chicken are always unacceptable. | Existing regimes for monitoring specific Salmonellas in people and livestock - this is not a regulated serovar but monitoring in farm animals and people in the UK would be expected to pick this up. |
| 7. Zoonotic spread of Carbapenemase-producing Enterobacteriaceae (CPE) and Acinetobacter (CPA) (Finland) [These bacteria are resistant to most first-choice antibiotics.] | **Yes**<br>At this stage the putative risk is of humans contaminating food-producing animals rather than a risk of infection from animals to humans. | **No**<br>A specific food risk or a food with a heightened risk relative to other foods or other presentations of the same food is not identified. | **Yes**<br>This falls into the regimes for monitoring animal disease and AMR in people and in food production. | More data in the future are needed to provide an indication of possible contamination from humans to animals |

*Note the comments above are illustrative, to show the use of the framework; they are not full or definitive assessments of each issue.*

| | | | | |
|---|---|---|---|---|
| 8. Potential fraud involving artificial 'plastic' rice (UK) | **No**<br>Insufficient information on occurrence (if any) and the composition of the product (e.g. what base materials and binding agents/resins used) | | **Yes**<br>This is a food fraud/food crime issue so would not be dealt with as a risky food. | Artificial rice might present a heightened risk compared to genuine rice but unlikely people would seek to consume it as it is a fraudulent product. |
| 9. *Yersinia pseudotuberculosis* outbreak linked to raw milk (Finland) | **Yes**<br>Already managed as risky food within the framework - the question is then whether this information significantly changes out assessment - see comments | | | FSA is already managing raw drinking milk as a risky food, using the framework. This assumes that RDM presents a higher risk of exposure to a range of pathogens. This new information does not change that assessment materially. |
| 10. Increasing use of hay (an undefined mixture of herbs, flowers and grasses) as food or food ingredient principally in the Alps region (Austria). | **No**<br>As the composition is unclear, difficult to characterise the hazards. Exposure data limited. In UK hay may be used as a wrapping to cook food in, but not to consume the hay itself. | **[No**<br>There is no specific risk identified at this stage so no specific risk management intervention is needed. This can be reviewed if new evidence emerges.] | FBOs offering hay or other non-traditional plant foods would need to demonstrate they have procedures in place to demonstrate safe supply (HACCP-based safety procedures).<br>Gathering plants for food from the wild in small quantities is likely to be exempt from the legislation. 'Conventional' farming in larger quantities is subject to legislation (Annex I of 852/2004). | If there were a change in consumption patterns and/or new cases of illness arise then the issue could be revisited. |

*Note the comments above are illustrative, to show the use of the framework; they are not full or definitive assessments of each issue.*

| | | | | |
|---|---|---|---|---|
| 11. Oxalic acid in green smoothies made with green vegetables/fruits (Germany) | **Yes**<br>Risks of oxalic acid known; but relate to chronic risks, so risk per serving unlikely to be meaningful - so consider other aspect (nature, severity, who affected, etc.)<br>Benefits relate to perceived benefit of raw versus cooked veg | **No**<br>Difficult to identify a specific food to which the risk would attach - potentially includes a wide range of veg/fruit, and other risks would come into play, as would benefits of consuming fruit and veg. | **Yes**<br>Consumer advice. People can make and consume this kind of product as long raw veg and fruit are available. | This is identified as part of a megatrend identified by EREN of consumption of raw products which were traditionally consumed as cooked |