Cross-SAC Working Group on the framework for controls related to risky foods

Scope[1]

Role

To advise the FSA through advice to the FSA's Chief Scientific Adviser and Director of Policy, on:

- an approach to the identification and prioritisation of risks to which the framework would be applied
- the use, further development and limitations of the framework focusing on:
  - its coherence;
  - 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. 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;
  - for a range of hazards the identification of factors/changes that would prompt review or reconsideration by the FSA board.

Membership*

Working Group Members:

David McDowell (ACMSF)
Gary Barker (ACMSF)
Alan Boobis (COT)
Leen Petré (GACS)
Dan Rigby (SSRC)
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Secretariat:

Patrick Miller (GACS Secretary)
Gwen Aherne (GACS Secretariat)

FSA input:

Steve Wearne (Director of Policy and Science), Guy Poppy (Chief Scientific Adviser), Penny Bramwell (Director of Science, Evidence & Research), Diane Benford (Secretary to COT, head of risk assessment), Paul Cook (Secretary to ACMSF, head of microbiological risk assessment), Helen Atkinson (Secretary to SSRC), Darren Holland (head of operational research)

*with other inputs as needed:

Caroline Mulvihill (National Institute for Health and Care Excellence (NICE))

[1] page 1 updated to reflect Working Group's discussion on 30 June 2016

Background

A draft framework for addressing risks from foods which may present an increased risk per serving, and its application to the consideration of risks from burgers served rare are discussed in more detail in the FSA Board paper from September 2015. (see http://www.food.gov.uk/sites/default/files/fsa150904.pdf).

The framework has been developed with reference to a model for considering the extent to which different levels and types of risk are acceptable, and the different types of regulatory or other intervention that might flow from this consideration. It identifies three regions of 'risk tolerability' in terms of food risks:

- A nature and level of contamination or adulteration which while not affording zero risk is, on the basis of best available expert advice, considered to be broadly acceptable or "safe" within the usual meaning of the word[2], provided that risks are adequately controlled through the application of good hygienic, manufacturing or agricultural practices as appropriate (the "green" zone in Figure 1 below);
- A nature and level of contamination or adulteration that leads to risks which would be always unacceptable for any consumer, whatever the benefits and even if accompanied by information on that risk. Action should be taken to protect consumers 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 (the "red" zone in Figure 1);
- To the extent the above two levels do not coincide, a nature and level of contamination or adulteration that leads to risks that incrementally exceed the levels considered broadly acceptable, but which some consumers may tolerate for other benefits, such as choice. These levels of risk would 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, consumers are provided with information to allow informed choice, and the risks and effectiveness of controls are regularly reviewed (the "amber" zone in Figure 1).

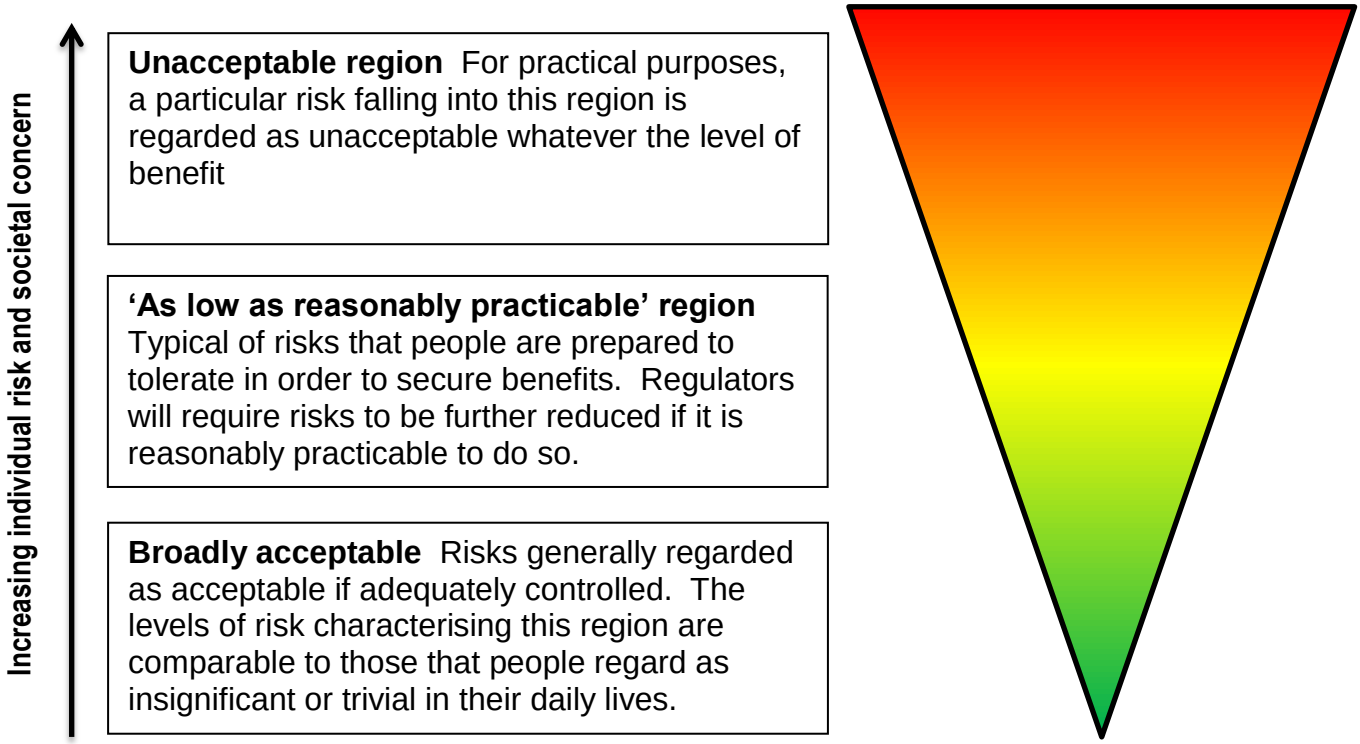
Figure one depicts these three zones, based on the formulation developed by the Health and Safety Executive.

The draft framework sets out a series of issues on which judgements need to be made, with prompts for thinking in each, in the form of a flow diagram or decision tree, which is shown at Figure 2.

[Fig 1 and 2 taken from the FSA Board paper September 2015]

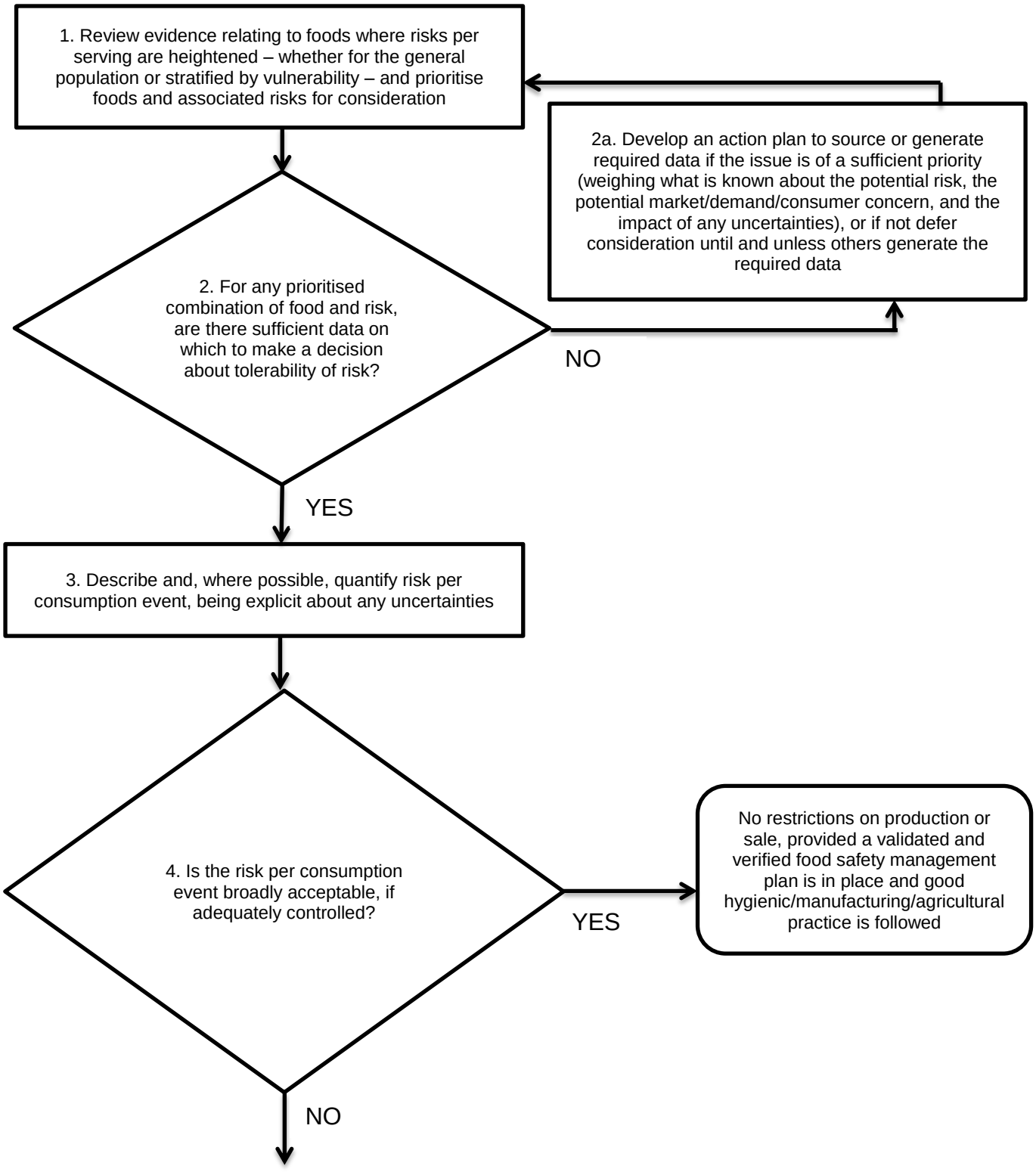
[2] Acknowledging that (i) there would be several difference scales on which to make the assessment of safety, for example for agents for which there is a 'no effect' threshold, for those with no threshold, and for those such as allergens with very different risks for different people; and (ii) acceptability and ability to make informed choices may vary by consumer and context.

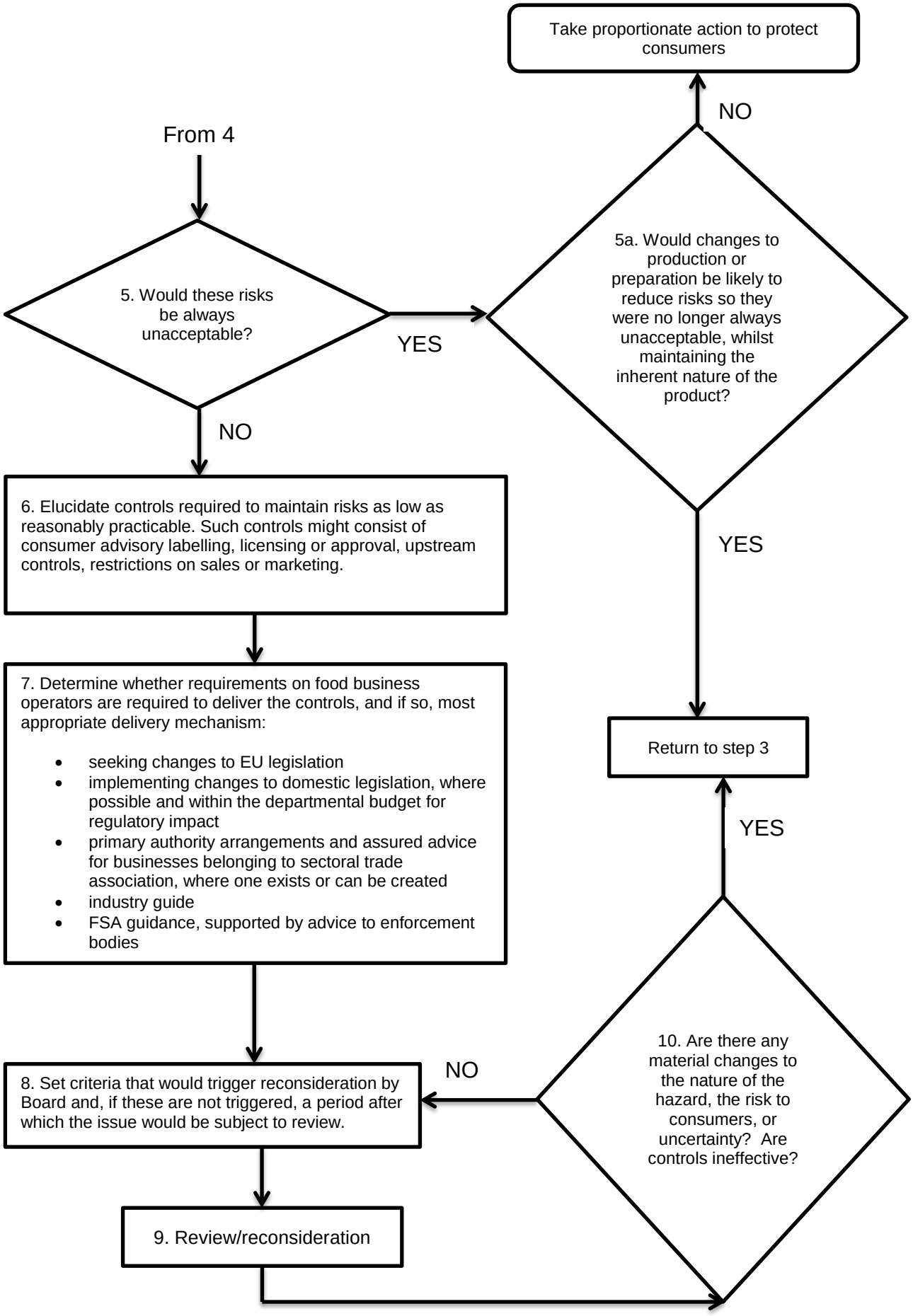
Figure 1 – HEALTH AND SAFETY EXECUTIVE FRAMEWORK FOR THE TOLERABILITY OF RISK[3]



[3] 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

Figure 2 FLOW CHART FOR APPLICATION OF THE FRAMEWORK FOR CONTROLS RELATING TO FOODS WHERE RISKS PER SERVING ARE SIGNIFICANT




From 4
5. Would these risks be always unacceptable?
YES
NO
5a. Would changes to production or preparation be likely to reduce risks so they were no longer always unacceptable, whilst maintaining the inherent nature of the product?
NO
Take proportionate action to protect consumers
YES
6. Elucidate controls required to maintain risks as low as reasonably practicable. Such controls might consist of consumer advisory labelling, licensing or approval, upstream controls, restrictions on sales or marketing.
7. Determine whether requirements on food business operators 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
• industry guide
• FSA guidance, supported by advice to enforcement bodies
Return to step 3
YES
10. Are there any material changes to the nature of the hazard, the risk to consumers, or uncertainty? Are controls ineffective?
NO
8. Set criteria that would trigger reconsideration by Board and, if these are not triggered, a period after which the issue would be subject to review.
9. Review/reconsideration