

## Information paper on risk assessment use to aid delivery of risk management and policy advice within Government

This Board information paper provides some basic definitions within the European General Food Law Regulation<sup>1</sup> for risk assessment to facilitate a common understanding of these terms. The paper indicates the different forms that risk assessment may take depending on the circumstances (for example during an incident or outbreak), how FSS may use independent science from risk assessments, the precautionary principle of risk management during incidents and the key outcomes and features of transparent approaches to decision making (risk management), agreed in principle at European level, that may be considered by FSS to produce risk management options or decisions. Those options or decisions may then be considered by the FSS Board and where appropriate form recommendations to Scottish Ministers.

### Risk Assessment

#### Definitions of hazard and risk

A **hazard** is a source of potential harm or a situation with the potential to cause a loss of something that is valued. In the EU General Food law Regulation for food and Feed, a hazard is defined as a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect. A hazard can also be seen as positive such as controlled fortification of food with a vitamin rather than a negative such as *Campylobacter* sp. in undercooked chicken. **Risk** can be thought of as a measure of the probability and consequence of an uncertain future event involving a hazard. For example the probability of falling ill from eating an undercooked burger and the severity of resulting disease. Or the probability and subsequent severity of suffering coronary heart disease from having a diet high in saturated fats.

#### Risk Assessment

Appraising a risk caused by a particular hazard involves two processes. The first is **risk assessment** which is the task of identifying and exploring, preferably in quantified/scientific terms (but this will depend on available scientific evidence relative to timescales particularly during an incident), the types, intensities and likelihood of the consequence of an uncertain future event involving a hazard. The second is **concern assessment** (involves risk communication) that conducts an analysis of the social concerns, socio-economic impacts, perceptions and risk that stakeholders may associate with a hazard.

#### Tolerability and Acceptability of risk

The outputs from the risk and concern assessments are used to inform the **tolerability** and **acceptability** judgement of the risk. 'Tolerability' does not mean 'acceptability'. It refers to a willingness to live with a risk so as to secure certain benefits with confidence that it is being properly controlled. To tolerate a risk means FSS or consumers do not regard it as negligible or something to ignore, but rather as something that FSS need to keep under review and reduce still further if possible e.g. bacteria present within a food processing environment. For a risk to be 'acceptable' on the other hand means that for the purposes of life or work, we are either satisfied that it will not lead to harm or that it has been reduced as much as possible e.g. the acceptable level of an additive used in

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<sup>1</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178>

food production. This is simply illustrated in Annex A in the tolerability of risk framework produced and used by the Health and Safety Executive to define acceptable and tolerable risks. The purpose of the tolerability and acceptability judgement is to inform a decision on the necessity and selection of appropriate risk management measures.

### **International CODEX principles for risk assessment**

The Working Principles for Risk Analysis for Food Safety for Application by Governments were adopted by Codex Alimentarius in 2007 (sections 16-29 and 30-39)<sup>2</sup> and they define that there should be functional separation between risk assessment and risk management. In practice, this means that Government should use independent scientific advice to carry out risk assessments.

### **Provision of Scientific risk assessment through European and UK structures**

Risk assessment is provided using independent scientists in various ways through the European Food Safety Authority (EFSA)<sup>3</sup>, relevant UK Scientific Advisory Committees (SACs)<sup>4</sup> and their subject specific sub-groups, through short-life working groups or through specific pieces of commissioned time-bound work. Common to all these processes is the requirement for risk assessors to be independent from Government (as defined under CODEX principles for risk assessment) and that the assessments they generate must be transparent, time-bound, robust, credible, subjected to peer review and to external consultation by stakeholders and consumers.

The risk assessment questions generated by Government need to be framed correctly to ensure that the resulting independent risk assessment will be useful to inform any subsequent risk management. Sometimes an additional risk assessment is required as the initial question, may need expansion through exploration of an additional set of questions or risk assessment of practical applications. Risk assessments can be delivered dependent on the timescales required e.g. for an incident (reactive), known hazard (short-medium-long term) or an identified emerging hazard (medium-long term). They can be based on scientific, observational and/or surveillance data. Observational and surveillance data will normally be subject to further secondary scientific analysis e.g. using statistics to look for emerging trends, scale of the hazard and potentially timescales. Any risk assessment should also specify any gaps, assumptions and uncertainties that were made during the analysis.

### **Involvement of FSS staff in directing risk assessments**

FSS staff will continually use their professional skills (e.g. science, enforcement, audit, operations and communications) to be fully aware of current or potential hazards under our remit. This will happen through regular engagement with relevant SACs, research funders and programs, individual scientists, with other Government departments, stakeholders (including industry) and consumers. Our engagement with SACs and other Government department's e.g. through our MOU with FSA and assessor status on SACs, will aim to ensure that FSS is involved in framing the risk assessment question, that assessments can be prioritised to meet Scottish needs, that Scottish data can be included or enhanced (e.g. by specific industry information or by consumer focus groups in Scotland) and assessments can provided within the necessary timescales. FSS staff

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<sup>2</sup> <http://www.codexalimentarius.org>

<sup>3</sup> <https://www.efsa.europa.eu/>

<sup>4</sup> <http://www.food.gov.uk/science/ouradvisors>; <https://www.gov.uk/government/groups/scientific-advisory-committee-on-nutrition>

may also use their professional skills to aid the preparatory work for a risk assessment e.g. sifting scientific papers for review or providing resource to help draft reports to deliver an assessment within a shorter timeframe.

## **Risk Management**

### **The risk management cycle**

The risk management cycle or process<sup>5</sup> is well documented academically, in the EU General Food Law Regulation recognising that any organisation will need to consider other factors such as the economic and social issues of any options or advice that may be provided<sup>6</sup>. Central to this is **risk communication** through the interactive exchange of information and opinions throughout the risk analysis process with regard to hazards and risks, risk-related factors and risk perceptions. This must include the explanation of risk assessment findings and the basis of risk management decisions among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, For FSS staff this means the management process, distinct from risk assessment, weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

### **General Key principles and approaches to risk management**

In 2014, a European Heads of Agencies network considered the key principles and features necessary for approaches to risk management to ensure transparency of the resulting decisions, their rationale and justification. They concluded that it was not appropriate to recommend a single framework for use since a flexible approach is required that can be adapted to the specific contexts of the country and the issue being considered. It proposed a set of common objectives and features that any approach should seek to meet, some conclusions on the factors to be considered in risk management decisions (Annex B) and the scope of application of these approaches (Annex C). These provide two sensible and common sense frameworks to aid decision making in risk management, much of which is already being used by staff within FSS.

### **FSS production of risk management options or controls**

FSS will produce risk management options through considering all the appropriate evidence, contexts and communication in order to make transparent and open decisions. These can then be considered and discussed by the FSS Board and where appropriate form recommendations to Scottish Ministers. Post implementation of any risk management decision or controls, it is important to ensure, through appropriate monitoring, subsequent evaluation and communication, that the desired impact is produced and that there are no unintended consequences that would negatively impact on public health or protecting Scottish consumers. The FSS Chief Scientist is currently preparing a guidance document on risk for FSS staff to use which will be available in due course.

### **Risk management during incidents**

When situations arise when there is a lack of evidence to support a full risk assessment, or when a decision has to be taken before all of the necessary evidence is available,

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<sup>5</sup>Dreyer, M. and Renn, O. Editors. (2009) Food Safety Governance: Integrating Science, Precaution and Public Involvement (Risk, Governance and Society), Springer-Verlag, Berlin Heidelberg, Germany.

<sup>6</sup> Yoe, C. (2012) Principles of Risk Analysis: decision Making Under Uncertainty, CRC Press, Boca Raton, Florida, USA.

FSS would ordinarily adopt the precautionary principle as per Article 7 of the EU general food law<sup>7</sup>. Article 7 states that, in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure a high level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment. These Measures should be proportionate and no more restrictive of trade than is required to achieve a high level of health protection and must consider the technical and economic feasibility and other factors.

The measures should be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment. Guidance in Scotland, on the application of the precautionary principle for Environmental and Health regulation was produced in 2006 by SNIFFER through a group which included the Food Standards Agency in Scotland<sup>8</sup>.

### **Review of risk management decisions**

It is important to remember that any specific scientific risk assessment used in risk management will only provide a snapshot of the given risk at that particular point in time. Therefore, it is good practice to review risk management decisions when significant pieces of risk assessment work on a topic emerge e.g. another review or assessment become available but not usually on the publication of an individual paper unless it is considered highly significant. This review process based on any new risk assessment or emerging risk is of particular importance within the space that FSS works in public health and protecting consumers to provide a process for ensuring that any risk management decision or advice is based on the most appropriate risk assessment.

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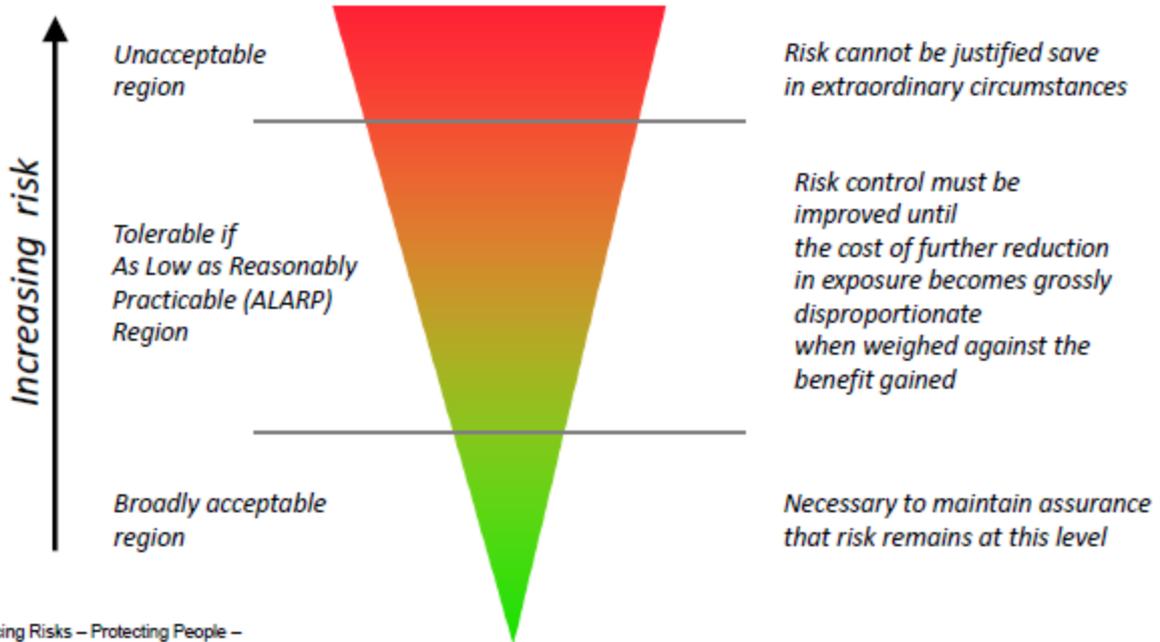
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<sup>7</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178>

<sup>8</sup> [http://www.sniffer.org.uk/files/6613/8202/4944/Precautionary\\_Principle.pdf](http://www.sniffer.org.uk/files/6613/8202/4944/Precautionary_Principle.pdf)

Annex A: HSE tolerability of Risk Framework

## Tolerability of Risk Framework



Reducing Risks – Protecting People –  
HSE's decision making process.  
2001. [www.hse.gov.uk](http://www.hse.gov.uk)

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**Annex B Key outcomes of transparent approaches to decision making**

<b>Transparency</b>	<p>This is the key overarching outcome: to ensure transparency on the process and its outcomes and rationale. This includes:</p> <ul style="list-style-type: none"> <li>• the context and nature of the decision and its basis and rationale</li> <li>• the issue(s) to be addressed and options considered</li> <li>• the factors considered the main evidence and analysis for each and how these were used in decision; uncertainties and gaps, how these were addressed.</li> </ul> <p>It is also important to be transparent that a decision has been made.</p>
<b>Clear structure and process</b>	<p>The approach should provide a clear structure and process for decisions, including the desired results, the timeline, inputs (people and information), the stage at which the decision will have an impact, and what comes next.</p>
<b>Consistency</b>	<p>The process and outcome should be consistent for similar issues and contexts - and where there are differences, it should be clear why.</p>
<b>Sound understanding of evidence and analysis</b>	<p>The approach should achieve a clear, sound understanding of the evidence and analysis needed and used in the decision, across all factors. This includes the main conclusions from the evidence, key uncertainties and gaps and their impact on the decisions, and, where possible, how new information or assumptions might change the decision, to inform review.</p>
<b>Openness</b>	<p>The process should allow for stakeholders to engage with and contribute to the process, to the extent that the nature of the issue and the time and resource available allow. This will not always be appropriate, but the process should ensure the approach to openness is considered and the rationale for the selected approach is clear.</p>

**Table C: Key features of transparent approaches to decision making**

<b>Flexible</b>	The approach should be able to adapt to reflect the context of the country/body making the decision and the nature of the issue, while aiming to achieve the key principles in all cases, as far as possible.
<b>Proportionate</b>	The information, resource and time involved should be proportionate to the importance and complexity of issue and of the decision, and to the time and resource available.
<b>Scalable</b>	<p>The approach should be capable of operating at a simple level but also to be 'scaled up' to bring in more extensive and complex approaches where the nature of the issue and available information and resource allow or require.</p> <p>It should be clear how the scale of approach is selected and there should be appropriate supporting tools for each level.</p> <p>An initial, 'framing' stage to decide the initial level of approach could be a common a step across all decisions. In some cases, no further development would be needed, while for others this would set out the next stages for more extensive consideration.</p>
<b>Participation, iteration and dialogue</b>	<p>There should be a clear approach to deciding who participates and for their involvement. The process should support dialogue between different parties, based on iteration rather than linear/compartmentalised approaches, while respecting the distinct roles of different parties (such those of risk assessors and risk managers; and of decision-makers and stakeholders).</p> <p>The process should involve those responsible for implementing the final decision wherever possible.</p> <p>The extent and scale of stakeholder participation will depend on the nature and importance of the issue and the time/resource available.</p>
<b>Review and reflection</b>	The process should have a clear approach to review, and should operate in a way that facilitates review at the appropriate point. This includes having clear objectives, analysis and reasons for the decision, identifying any needs for collection of data on baselines for and changes in key parameters, and understanding how a change in evidence or assumption might change the outcome.