Technical Brief

Food Risks vs. Hazards

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There is a fundamental difference between a hazard and a risk. A hazard is the intrinsic potential for something to cause harm. That does not mean that it will cause harm, or even that it is likely to do so. Risk is related to the likelihood of a harm occurring and the potential magnitude of that harm.

Harm may be:

- acute – a one-off exposure leading to a relatively rapid effect
- delayed – a one-off exposure leading to a long-term effect, e.g. genetic damage
- chronic – repeated long-term exposure leading to a cumulative effect.

This document focusses on the decision process, and potential actions once a food safety hazard has occurred.

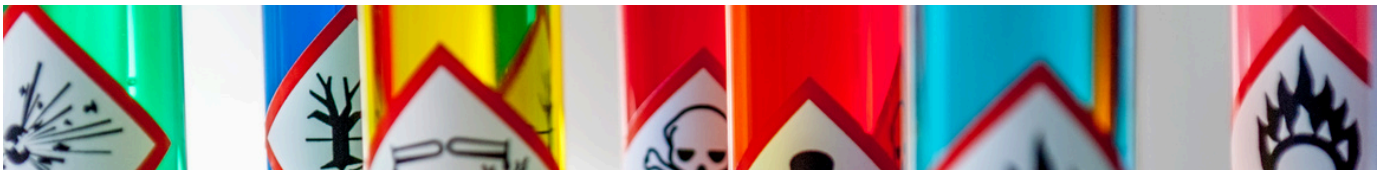
Risk - Scope and Terminology

ISO have taken great care to define the scope and terminology around risk assessment and risk management (ISO 31000)[1]. The terminology and definitions are important. Using too narrow a definition could leave blind spots in an organisation's risk controls.

Risk is the 'effect of uncertainty on objectives'. Note that this can either be positive or adverse. In a food safety context, we normally only consider adverse risks.

The magnitude of a risk is a combination of factors:

- **Risk Event**
- **Risk Source** - termed hazard within a food safety context: 'a biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect' (ISO 22000)[2]
- **Vulnerability** - 'intrinsic properties of something resulting to susceptibility to a risk source'
- **Likelihood** - includes qualitative assessments; ISO avoid using 'probability' which only implies a quantitative assessment
- **Consequence**.



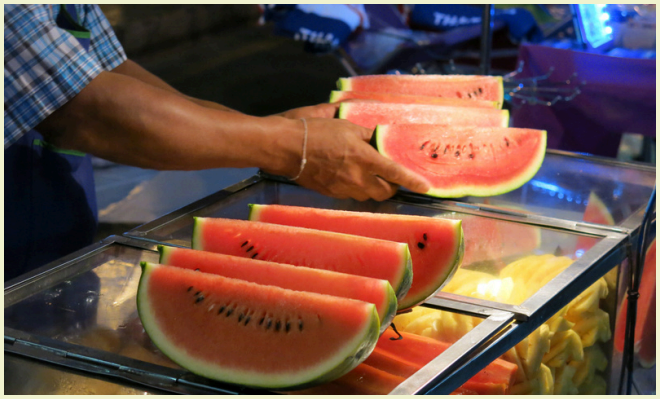


Illustration: unpacked pre-cut melons sold from a street vendor's cart

- **Risk Event -** food poisoning of customers
- **Risk Source** - contamination by bacteria from vendor's hands, bacterial survival and growth on the fruit
- **Vulnerability** - high, due to moisture, protein and sugar content of fruit and ambient conditions
- **Likelihood** - high, due to poor hygiene controls
- **Consequence -** acute illness, non-fatal, of a proportion of people who consume the fruit

Risk Management

If the magnitude of a risk is deemed unacceptable then the risk must be managed.The most effective management is to eliminate the risk source. Risk management also can include both measures to reduce the vulnerability/likelihood and measures to mitigate the consequences. Zero risk is unattainable. International food safety agreements (WTO)[3] talk of a 'tolerable level of risk' or an 'appropriate level of protection'.

Measures to reduce the vulnerability/likelihood

This is the basis of Hazard Analysis and Critical Control Points (HACCP) methodology (Codex)[4] which is the bedrock of all food safety management systems and should be familiar to all food business operators, hence not covered here. The ethos of HACCP is that the likelihood of unacceptable risks must be reduced such that it is negligible.

Measures to reduce the consequence

The impact of a risk event can be reduced by, for example, reducing the number of consumers exposed to a contaminated food. Measures can either be pre-emptive or after a hazard has occurred.

Pre-emptive measures

These are required by most third-party food safety management certification schemes and are good practice for any food business. They include:

- efficient traceability systems, so that contaminated ingredients can be traced through to product, through to customers, and quickly recalled if necessary
- checks of the traceability system - speed of results, mass-balance checks
- recall scenario rehearsals
- pre-written communication templates and communication plan.

Measures taken after a hazard has been identified

At this point, the likelihood can no longer be managed. For example, if:

- an ingredient, already used, is subsequently found to have been contaminated
- a risk control, such as allergen management procedures, has subsequently found not to have been operating as envisaged, although there is no evidence of allergen cross-contamination in the product.

In these situations, there are a range of potential actions depending on the magnitude of the risk:

- take no action on affected stock, but fix the problem at source for future stock
- quarantine stock pending further investigation
- withdraw and destroy stock without recalling stock already sold
- public recall

In the UK, as in most countries, it is illegal to sell food that is 'injurious to health' or 'unfit for human consumption' (Retained regulation EC/178/2002)[5]. It is a legal requirement to notify the regulator (FSA)[6] of unsafe food already on the market. If there is evidence that a contaminant is above a statutory limit then it is illegal to trade the food, irrespective of the safety assessment. There are, however, many situations that do not reach these statutory bars. In these cases, the company must decide their own course of action. Their decision may be informed by other (non-food safety) considerations such as potential reputational damage, or damage to the company's culture, i.e. employees or suppliers incorrectly believing that food safety risks are tolerated. Financial loss is an inevitable consideration.

Illustration: chemical contaminant above the Acceptable Daily Intake (ADI)

- The contaminant is below the Maximum Limit, so the food is legal to trade
- The ADI is set on the basis that a consumer can safely ingest this same residue quantity every day of their life
- This is a product expected to be consumed only on an occasional basis.
- It is expected that, in years to come, the source of the contaminant will be addressed and resolved
- Decision required: should the company recall or withdraw the contaminated batch?

There are often unknowns and uncertainties in taking this decision, but it is less theoretical than a HACCP risk assessment. Once the likelihood has been understood then it is the **consequence** that drives the risk magnitude. Consequence can be modelled in an analogous way to a classical risk assessment, in order to guide the decision for example.

Consequence

	Number or vulnerability of consumers who will be exposed (or increasing certainty of evidence that consumers will be exposed) →
Severity of health effect ↑	

Red: immediate public recall; Food Standards Agency (FSA) must be informed.
Amber: withdraw stock and stop supply, or quarantine for further investigation.
Green: trade through, if legal to do so, but action to solve issue and/or intensified checks in future.
If a legal non-compliance, then treat as Amber.

Examples of scenarios that might drive the Y-axis (severity):

Low	Retrospective test result – pesticide MRL exceedance in an ingredient already fully used. Ingredient (hence the residue) is diluted in the product, which has since been distributed. MRL was set based on Good Agricultural Practice rather than consumer safety and is substantively below the Acute Reference Dose (ARfD) and Acceptable Daily Intake (ADI). Risk event is non-compliant trade (of the ingredient, not the product) rather than a health effect. Osmophilic yeasts in soft drinks. Risk event is the plastic bottle exploding, rather than a health effect
Medium	Blue plasters missing, strongly suspected to be in product, too large to be a realistic choking risk. *S.aureus* in cheese. pH showed a slow vat process, so a risk of growth and toxin production, if present
High	Allergen mislabelling, unlabelled allergen present in product at substantive quantities. *L.monocytogenes* detected at more than 100 cfu/g from routine end of product testing of salad. High severity for vulnerable consumers (children and elderly). Above legal level

Examples of scenarios that might drive the X-axis (evidence for, or scale of consumer exposure):

Low	Routine audit showed that cleaning chemicals stored incorrectly. No evidence that they had been used incorrectly, and no evidence that they had contaminated product. Routine testing detects pathogenic bacteria marginally over specification in 'gastro' ready meal. Product cannot be consumed without cooking, product is unlikely to appeal to vulnerable consumers, sales are relatively low, short shelf-life so likely that most on market is already consumed
Medium	Environmental monitoring detects pathogenic bacteria in factory producing ready-to-eat food. No evidence in product, but factory results are persistent and widespread including in open-food areas. pH is the only CCP for a mayonnaise producer. Calibration checks show that pH meter has been reading low, i.e. pH of product has been above believed, and likely above the critical limit. Extensive product testing results have been negative for pathogens, but 100,000 units sold per week including supply to hospitals
High	Egg-containing dessert packed into the wrong sleeve, which does not list egg as an ingredient. Product is targeted at children. 2% of UK children are known to have an egg allergy. Aflatoxins detected in peanuts used for confectionery, following a random ingredients assessment to cross check supplier assurance. Not destroyed by any manufacturing cook process. Ingredient is used across supply chain in a variety of products, all with national distribution at high sales volumes. Snack products have 18-month life, consumers known to store them at home

The grading of the risk matrix, and the decision on action in a specific situation, can be subjective and difficult. Decision makers rarely have all the information they would want. Effective risk management in this case goes back to the previous point about pre-emptive rehearsals. Companies should identify, in advance, who needs to be in the 'war room' to make the decision (a team decision is better than an individual). This should include emergency contacts for specialist advisers, if needed – for example, an expert microbiologist or toxicologist, or an expert in sampling statistics. Escalation decisions, if needed, must be taken quickly. The faster the team can be assembled the better.

References

[1] ISO 31000:2018 Risk Management Guidelines, 2nd Edition
[2] ISO 22000:2018 Food Safety Management Systems – Requirements for any Organisation in the Food Chain, 2nd Edition
[3] The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm
[4] Codex General Principles of Food Hygiene, CXC 1-1969, Revised 2023, FAO
[5] Retained Regulation EC 178/2002 laying down the general principles and requirements of food law
[6] https://www.food.gov.uk/contact/businesses/report-safety-concern/report-a-food-safety-incident