Food safety risk assessment: part 2 – triggers for undertaking a rapid risk assessment

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In the January-March 2025 issue of *food australia*, we provided an overview of the risk analysis process, focussing on the steps undertaken in a risk assessment.[1] The content largely related to formal risk assessments undertaken to identify regulatory approaches to addressing and ultimately managing those emerging microbiological and chemical hazards.

For food industry professionals operating within processing environments, risk assessments need to be performed in a timely manner to address an urgent problem or a shifting situation. They require different strategies and approaches depending on the nature of the issue but can be broadly grouped into:

- Changes in ingredients, suppliers, or packaging material
- Introduction of a new technology or changes to a processing operation
- Follow-up of a process or product failure
- Changes in an agricultural production practice
- Changes in environmental conditions through climate change
- Changes in consumer demographics.

Many of the formal third-party food safety management programs require processors to undertake risk assessments to assess hazards associated with, for example, the introduction of new ingredients, new suppliers, or changes in water sources. The revised Codex Alimentarius Commission Hazard Analysis Critical Control Points (HACCP) guidelines now state that during the hazard analysis step, a food manufacturer should identify the hazard, the likelihood of its occurrence and the likelihood and severity of adverse health effects.[2] While this change has blurred the lines between hazard analysis and risk assessment, they remain fundamentally different and separate processes.

Hazard analysis versus risk assessment

Hazard analysis was adopted as the first principle of the HACCP system. It encompasses qualitatively identifying and analysing information on hazards associated with the foodstuff under consideration, with little specification on how to perform this task. The challenge has always been that HACCP teams would identify a plethora of hazards, without information on their likelihood of occurrence. This complicated the task of focussing on which hazards were significant and needed to be addressed in the HACCP plan.

Recent changes to the HACCP Guidelines (***General principles of food hygiene*** CXC 1-1969), effectively expand hazard analysis to include estimates of their likelihood and severity, in order to focus attention on those hazards of most significance to public health and safety.

Whilst determining the likelihood and severity of a hazard eventuating is crucial, the full process of risk assessment involves a more detailed and structured evaluation, which focusses on first identifying and characterising a specific hazard, determining the consumer exposure, and integrating this information to produce a risk characterisation. The output can be qualitative, quantitative, or a combination of both. The risk assessor needs significant time and resources, along with full access to the scientific literature and detailed data on the food, the hazard, and dose-response models in order to interrogate modes of exposure to the hazard.

Rapid risk assessments

The food industry operator is often faced with a situation that calls into question the safety of an ingredient, process or product. With limited time or resources, they are required to make a recommendation on whether to accept a raw material or ingredient, release a product to the market, or explore the need to withdraw or recall a product from the market.

This requires the operator to undertake a rapid risk assessment, where the focus is on the likely consumer exposure to the hazard rather than on hazard identification and characterisation. They already know the hazard should not be present in the ingredient, the processing environment or the finished product. The task is to determine the likelihood that an identified hazard may be present in a final product, estimate the exposure of consumers, and generate guidance on how it can be managed, without

delay. In this situation, the food safety operator is both a risk assessor and a risk manager.

A rapid risk assessment scenario

The risk assessor must assemble all the relevant information quickly and efficiently. This is best achieved by assembling a small team with appropriate knowledge of the product, manufacturing and distribution. It is expedient to utilise a template to assist in gathering and collating information, and in identifying gaps ahead of any interpretation of the risk.

In this example, *Listeria monocytogenes* is confirmed in a ready-to-eat food that has been released into the market. The decision on whether to initiate a recall is shown in Table 1 - the information identifies what is known.

Given the severity of this pathogen to vulnerable populations, and the manufacturer's low-risk appetite, further assessment of the risk is justified. This needs to consider the consumer, the product's shelf-life, and how the product is handled, stored and consumed. Further consideration of the test results is also warranted.

This requires an exposure assessment to gather intelligence on the above issues as shown in Table 2.

Given the time-sensitive nature of decisions, and the fact that a product containing *L. monocytogenes* is in the marketplace, a manufacturer with a strong food safety ethos would recall this product. With laboratory confirmation of the pathogen in food, the relevant food regulator would have been informed and they too will have interest in the results of the risk assessment.

In the next edition of *food australia,* we will focus on exposure assessments, resources and tools, and databases available to support risk assessment.

Scenario – *what we know*	Next step	What we determined
The issue *Listeria* spp. has been found in a test sample of ready-to-eat (RTE) food which has been released to market	Test results imply *L. monocytogenes* may be present, so the first step is laboratory confirmation of the species	**PATHOGEN DETECTED** *L. monocytogenes* confirmed in the food (qualitative test)
The product This RTE food will not support the growth of *L. monocytogenes* Finished product specification: pH 4.4, Aw 0.92	Review production records and test retention samples from the affected batch	**MEETS SPECIFICATIONS** No anomalies with production and the Implicated batch meets specifications
Regulatory requirements Does the level of contamination exceed limits in the Food Standards Code – food that will not support growth of this pathogen may contain up to 100 *L. monocytogenes*/gram	Retest the product to determine if it meets the limit of n=5, c=0, m= <100 *L. monocytogenes*/gram	**COMPLIANT WITH CODE** The product is found to be compliant

Table 1: Details of the scenario and the required information gathering for a risk assessment.

Exposure assessment	Details and observations	What we know
Consuming public	General public: including vulnerable consumers (the young, the elderly, pregnant women, and immunocompromised individuals)	At-risk consumers may be exposed
Shelf life	The product has a shelf life of 30 days – labelled as a use-by-date – how much time remains? Will the attributes of the product change during storage e.g. will spoilage organisms change the pH	Consumer understanding and adherence to use-by-dates varies Little change in product attributes during its shelf-life
Handling	This is a refrigerated product and should be stored between 0-5°C Is there a chance it may be subjected to temperature abuse?	Opportunities for temperature abuse exist along the supply chain and in the household
Consumption	The product is sold in a 200-gram, single serve pack	200 grams represents a significant exposure to *L monocytogenes* if the count is around 100 cfu/gram
Test results	Qualitative testing found *L. monocytogenes* present in the product Quantitative testing found <100 cfu/gram (the limit of detection)	Listeria may be unevenly distributed throughout a batch of product Quantitative enumeration of *L. monocytogenes* in food with low level contamination is poor, indicating a higher uncertainty of measurement

Table 2: Essential elements of exposure assessment for the scenario.

References

1. Sarkar, D. and Mahoney, D. (2025). Food safety risk assessment: part 1 - risk assessment primer. *food australia*, 77 (1), 41-42. https://bit.ly/3QOWiZZ
2. FAO and WHO (2023). General Principles of Food Hygiene. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome. https://doi.org/10.4060/cc6125en

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