

Risk Analysis in Food Safety

In this issue of the Irish Microbial Quantitative Risk Assessment Networks Tutorial Series, Dr Ursula Gonzales Barron explains the importance of Risk Analysis in Food Safety.

Within the context of food safety, risk analysis is used to quantify the risks caused by food-borne hazards to human health, and to identify, assess and implement appropriate measures of intervention to control the risks. According to the Regulation EC No.178/2002 of the European Parliament

(http://www.fsai.ie/legislation/food/eu_docs/Labelling/Cor_Reg1924_2006.pdf)

, risk analysis should be seen as a structured decision-making system comprised of three highly interrelated components: risk management, risk assessment and risk communication. The role of 'risk managers' is generally played by governmental food safety officials, who have the ultimate responsibility for selecting and implementing the most efficient food safety control measures. Thus, risk managers need to fully understand the logic and the outcome of a risk assessment study in order to make appropriate risk management decisions.

The Risk Management Framework

After a food safety issue has been identified (for example, the presence of the carcinogenic acrylamide in starchy fried foods), preliminary risk management activities will be initiated. With available scientific information, a

risk profile will be generated normally by the risk assessors, and this profile will assist in identifying the questions that need to be answered by the risk assessment. Typical information that may be included in a risk profile are: the description of the hazard, how and where the hazard enters the food supply, which foods expose consumers to the hazards, frequency, distribution and levels of occurrence of the hazard in foods, information about possible risk management control measures and preliminary identification of important scientific data gaps that may limit a risk assessment study.

Following the risk profile, a risk assessment team, ideally a multidisciplinary one, will develop a risk assessment of the food hazard in question. A good risk assessment study should provide valuable insights of the effects of interventions or control measures on the risk. Risk managers should then be able to select the risk management options that have the capability to resolve the food safety issue. In some situations, the effective control of a hazard in a food production chain will require a systems approach, for example, the control of faecal contamination of carcasses during the many steps of the slaughter process.

In the case of microbial hazards in food, regulatory standards that arise from the risk assessment may include specific quantitative microbiological metrics such as food safety objectives (FSO), performance objectives (PO) and performance criteria (PC) (Table 1). However, the development of these metrics should be careful enough as to reach a trade-off between flexibility for the industry that will implement them and the level of consumer protection. For further information on the risk-based food safety metrics, the International Commission on Microbiological

Specifications for Foods (ICMSE) provides an easy-to-follow guide to understanding FSOs and POs (<http://www.icmsf.iit.edu/pdf/Simplified%20FSO9nov05.pdf>)

Finally, after risk managers have selected the best risk management options, they should be implemented by a variety of parties including government officials, food industry and consumers. Food processors will generally implement complete food control systems using GAP, GMP, GHP and HACCP systems (Figure 1).

Table 1. Quantitative microbiological food safety measures, as defined by the Codex

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|-----------------------------|---|
| Food safety objective (FSO) | The maximum frequency and/or concentration of a hazard in a food at the point of consumption that contributes to the achievement of the ‘appropriate level of protection’ (ALOP). |
| Performance objective (PO) | The maximum frequency and/or concentration of a hazard in a food at a specific step in the food chain that contributes to the achievement of the ALOP. |
| Performance criterion (PC) | The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to contribute to a PO. |

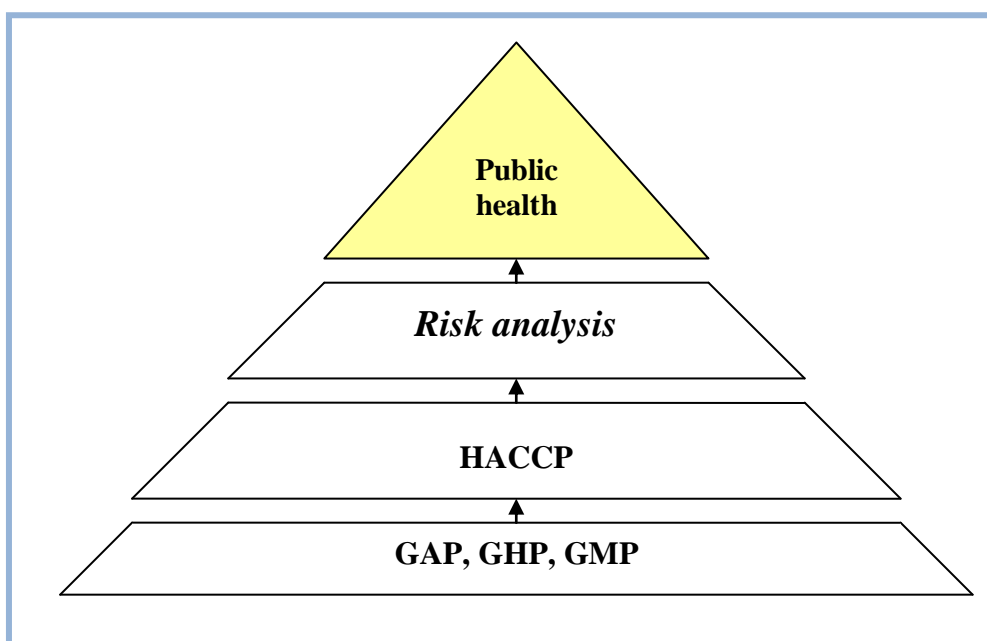


Figure 1. Position of risk analysis in the food safety paradigm

The Risk Assessment Framework

A risk assessment study is the scientific component of risk analysis, and it should ultimately characterise the potential adverse effect to life and health resulting from exposure to food-borne hazards, with the additional advantage of being able to model the effect of various interventions. Typically, a risk assessment study consists of three components: hazard characterisation, exposure assessment and risk characterisation. Nevertheless, the way these steps are applied differs for chemical hazards and for microbiological hazards. For chemical hazards, maximum exposure levels are generally identified to fit a 'notional zero risk' outcome (a dose level that is reasonably certain to pose no appreciable risk to the consumer).

In contrast, for microbiological hazards, the occurrence and level of the pathogen at the various stages from food production to consumption are evaluated; taking into account the processing effects, possible growth, inactivation or survival of the pathogen. Among the regulatory authorities, there has been an increasing understanding of the need to rank either chemical or microbial risks, as they commonly face a series of food safety issues that need to be prioritised. Thus, risk ranking can be considered a tool of risk assessment that relies on knowledge of risk factors to rank risks and prioritise regulatory controls. An example of an application tool for risk ranking can be found at <http://www.foodsafetycentre.com.au/riskranger.php>

The sought outputs of a risk assessment study can be qualitative, semi-quantitative or quantitative. Qualitative risk estimates provide less information for decisions, yet they can be still adequate for certain purposes such as evaluating relative impacts on risk reduction of different control measures. On the other hand, quantitative risk assessments can be deterministic or stochastic. Given the variability present in the level of a hazard, in the effect of food production processes, in the foodstuff themselves or even in the consumer preferences, a stochastic model is favoured over a single-point-estimate one. Thus, variability is a characteristic that differs from one observation to the next; for example: people eat different amounts of food, and the level of a particular hazard present in a food also varies from one serving to another.

In stochastic modelling, apart from the variability concept, there is also the uncertainty concept which is due to the 'quality of being unknown'. This could arise because of inadequate data or because the biological phenomenon modelled is not well understood yet. Although building a stochastic modelling is complex and demands more data resources, this approach reflects better the real world, because when some of the model inputs are changed (i.e., level of the hazard in the raw food, conditions of processing, chilling temperature, etc), the effect of different scenarios on the risk can be analysed.

Returning to the components of the risk assessment framework, during hazard

characterisation, the nature and extent of the adverse health effects known to be caused by the specific hazard will be described. If possible, a relationship is established between the different levels of exposure to the hazard in food (at the point of consumption) and the likelihood of the adverse health effects (dose-response models). A food-chain exposure pathway up to the point of consumption is developed for the hazard so that a dose-response curve can be used to generate estimates of the risk. During risk characterisation, the outputs from the previous steps are integrated to generate an estimate of risk. Also, a risk characterisation often includes "what-if" scenarios and further scientific work needed to reduce the identified data gaps.

As explained before, a risk assessment team should ideally be an interdisciplinary team that may include experts with biological, chemical, toxicological, food technology, veterinarian, epidemiological, microbiological, statistical and modelling background. A series of models such as epidemiological models, bacterial growth models, survival models, dose-response models, generalised linear models and/or meta-analysis models can be harmoniously combined in order to find precise estimates of the risk of a food-borne hazard.

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