What is Microbiological Risk Assessment?

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General Concepts

In the past decade, the Food Safety discipline has addressed the assessment of hazards in foods within the framework of Risk Analysis, a new science-based paradigm intended to guarantee human health protection contemplated by EU legislation (Reg.178/2002). The objectives of risk analysis are to estimate the risk to human health of a hazard associated with food consumption; and most importantly, to assess appropriate management strategies in the food chain capable of reducing the risks. Risk analysis represents a structured decision-making process with two closely connected components: risk management and risk assessment.

Risk management is the process of evaluating policy alternatives in consultation with stakeholders and is generally performed by a food safety authority. It encompasses the identification and selection of risk management options or intervention strategies, as well as their implementation. Risk managers are responsible for verifying that the risk mitigation measures that were selected and implemented are in fact achieving the intended results, which they carry out by monitoring and surveillance activities. On the other hand, risk assessment is the central scientific component of risk analysis. Building a risk assessment model is central not only for the characterisation or estimation of the potential adverse effects to health resulting from exposure to hazards (i.e., risk), but most importantly for the prediction of the risk reduction attained by each of the potential intervention strategies under consideration.

As hazards can be of chemical or microbiological origin, risk assessments, which are mostly quantitative, are divided into chemical and microbiological. Different mathematical approaches and modelling tools have been and are being developed distinctively for each; although the main stages are basically the same for both: exposure assessment, hazard
characterisation and risk characterisation. Exposure assessment describes the degree of exposure to the hazard likely to occur from consumption of the product. To estimate the level of risk of a hazard, an exposure assessment model is built that entails all the food chain. The level of human exposure depends of many factors: initial contamination of raw materials, characteristics of the food process, survival of microorganisms, multiplication and death during storage, storage conditions and preparation before consumption. Because the food chain is considered, any microbiological risk assessment should explicitly consider the dynamics of the microbe growth, survival and death during the processing stages. Thus, an exposure assessment model makes use of predictive microbiology.

Hazard characterisation describes the nature and extent of the adverse health effects known to be associated with the specific hazard. 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 different adverse health effects such as infection or illness. During risk characterisation, the results of the two previous stages, exposure assessment and hazard characterisation, are integrated to generate a risk estimate. If a risk assessment is quantitative, the risk may be characterised in terms of risk per serving, risk per annual consumption or even in number of cases for a target population. In microbial risk analysis, the derivation of efficient management strategies should be assisted by these three elements: food chain data availability; predictive microbiology; and sampling strategies.

**Microbiological Risk Assessment and the Food Industry**

The growing acceptance of the principles of risk analysis has led to its use expanding beyond regulatory standard setting and international trade. The application of risk assessment serves as well as a basis for sound food safety policy, and to validate and specify criteria for safety programmes. Risk assessment also can be used to identify data gaps and target research that should have the greatest value in terms of public health impact. Dynamic risk assessment models can be developed by industry organisations covering the entire farm-to-table continuum, considering each step that influences the overall risk. Risk assessment can find many applications in industry, such as:

Risk assessment models can be integrated into the more ‘qualitative’ HACCP plans to help decide unacceptable levels of contaminants and provide a scientific rigour to the
process to better withstand third-party auditing. In the future, risk assessments will help industry to scientifically develop effective HACCP plans. For instance, plants can use a risk assessment to help identify hazards that are reasonably likely to occur. The best information plants may have now is qualitative-for example, whether a hazard presents a high, medium, or low risk. The real benefit to this change is that a hazard would be defined in terms of the risk of an adverse human health consequence, rather than in terms of contamination of the food. Such models can sequentially help derive control measures in the form of critical limits for critical control points or sampling plans.

Risk assessment models that incorporate simulation techniques provide a means for dealing with the variability associated with food raw materials and processes. For products lacking a lethal processing step, risk assessment models can be critical in demonstrating product safety. The ability to perform sensitivity analyses and conduct what-if scenario potentially provides a more analytical approach to identifying critical points. The effect of both critical points and critical control points can be integrated to consider the overall effectiveness of the entire process. A risk assessment model may allow individual companies to amend the control parameters to reflect their individual production system.

The food industry can benefit from risk assessment to answer questions such as: “Would slightly altering the pH of this formulation be likely to reduce the growth of this pathogen? Or, would reducing the temperature in the display case at the store be more effective?

**Risk assessment of Salmonella in Irish pork and pork sausages**

Salmonella has been long recognized as an important zoonotic pathogen of economic significance in animals and humans. The common reservoir of Salmonella is the intestinal tract of a wide range of animals which result in a variety of foodstuffs both food of animal and plant origin as sources of infections. Although the incidence of salmonellosis in Ireland is much lower (10.2 cases per 100 000) than the average for the EU (31.1 cases per 100 000), in the last five recorded years (2003–2008), the confirmed annual cases of salmonellosis in Ireland have not declined (440 cases) despite the current effort of the national salmonellae control program, which aims to reduce the incidence of Salmonella in
slaughter pigs. Thus, it was necessary to conduct a risk analysis of Salmonella in pork to characterise the adverse health effects and identify possible strategies to control the risk.

The prevalence of Salmonella in pork carcasses and pork cuts produced in Ireland was estimated by means of an exposure assessment simulation model, considering that within the slaughter groups, there is an association between the proportion of infected animals entering the slaughter lines and the resulting proportion of Salmonella-positive eviscerated carcasses (Figure 1).

![Figure 1. Bubble plot of the caecal Salmonella carriage rate in slaughter pigs and the resulting Salmonella-positive eviscerated carcasses. Each bubble represents results from a different published study, and the bubble size is proportional to the confidence assigned to such study.](image)

The model estimated that the prevalence of Salmonella in Irish pork cuts is 4% (95% CI 0.3-12.0%), and this prediction was validated by the results of a large scale survey of Salmonella in pork cuts carried out in four abattoirs (mean 3.3%; 95% CI 2.0-4.6%) (Figure 2). For more information about the complete exposure assessment model, see: [http://www.ingentaconnect.com/content/iafp/jfp/2009/00000072/00000002/art00007?crawler=true](http://www.ingentaconnect.com/content/iafp/jfp/2009/00000072/00000002/art00007?crawler=true)
Figure 2. Output distribution of prevalence of Salmonella in Irish pork joints from the exposure assessment model, along with validation results (95% CI).

As in any exposure assessment model, a sensitivity analysis highlighted the most important stages that considerably reduce the occurrence of the hazard in the final product. In this case, the sensitivity analysis reinforced the importance of final carcass rinsing ($r=-0.382$) and carcass chilling ($r=-0.221$) to control the total carcass contamination in the abattoir. It also indicated that hygiene practices during jointing seemed to moderate only marginally the amount of contaminated pork joints. This occurs because 75-80% of the total contaminated carcasses at the beginning of the clean line is explained by the contamination force introduced by the carrier animals themselves (Figure 1). During further processing of meat, such as cutting and mincing, Salmonella from contaminated cuts may then spread into meat preparations. Thus, a second risk assessment was conducted for the Irish fresh pork sausage, a highly consumed meat preparation that can support the growth of Salmonella.

Another exposure assessment model estimated that an average of 4.6% of the packs of raw sausages at retail are contaminated with Salmonella, with concentrations expected to be 70 CFU/g. However, after 30 hours of refrigerated storage at home, the Salmonella concentration in contaminated packs may increase up to 8 log CFU/g (Figure 3). Out of 100 000 refrigerated sausage packs, an average of 83 packs would have hazardous levels of Salmonella above 3 log CFU/g prior to cooking.
Figure 3. Influence of the cold storage time on the mean concentration of Salmonella Typhimurium in contaminated pork sausage prior to cooking (n=10 000)

Figure 4. Probability that a pork sausage pack prior to cooking bears Salmonella Typhimurium in hazardous mean concentrations above 3, 4, 5, 6 and 7 log CFU/g for different scenarios.

Scenario analysis revealed that a decrease in the refrigeration temperature by 2 degrees (from 7°C to 5°C) and a decrease of the initial prevalence of Salmonella in the meat preparation from (4.6% to 2%) would have a comparable level of reduction in the frequency of contaminated packs with Salmonella counts higher than 3 log CFU/g.
However, a decrease in the refrigerated storage time by 8 hours would have by far the highest level of reduction (Figure 4).

The process of cooking reduces dramatically the concentrations of Salmonella in sausages from contaminated packs, which are lower in fried sausages (0.05 CFU/g) than in grilled sausages (0.08 CFU/g). The simulation model estimated that the mean exposure to Salmonella (0.12 CFU in fried servings, and 0.20 CFU in grilled servings) originated from only a few contaminated servings, since the model predicted that the survival of Salmonella after cooking is very low (0.45-0.85% probability of survival). However, in these very few contaminated servings, Salmonella counts can still be very high: 250 CFU for fried sausages and 690 CFU for grilled sausages. For more information about the complete consumer-phase exposure assessment model, see:


Scenario analysis revealed that the best actions (intervention strategies) that the consumer can take to decrease the current risk level of Salmonella from consumption of pork sausage are both decreasing the product’s refrigerated storage by 8 hours and cooking for an additional half minute. Both control measures can reduce the current risk level of Salmonella by 70%. Additionally, the model proved useful in the definition of recommended cooking times (9 min for frying, and 12 min for grilling) that with a safety margin of 99.95% would inactivate Salmonella up to a negligible level of 0.001 CFU/g (Figure 5). Thus, a risk assessment model can also sustain an informative product label that provides a cooking protocol. In the risk characterisation stage, it was observed that the raw pork sausage may have an average contribution of 30% to the total cases of Salmonellosis in Ireland within the category of meat and meat products. For more information about the hazard characterisation and risk characterisation stages, see:

Figure 5. Distributions of variability of the frying and grilling time for complete inactivation of Salmonella Typhimurium (-3 log CFU/g) in contaminated fresh sausages
Conclusions
A quantitative risk assessment allows the representation of the flow of contamination along food processing.
The quantitative model enables a better understanding of the relationship among the process or food-related variables, and an assessment of those variables having a stronger effect on the contamination levels.
Valuable information about critical stages and possible intervention strategies can be extracted from the model so that an objective assessment can be gained.
Given the food-chain nature of a risk assessment, it makes it possible to compare the risk reduction effects of intervention strategies or control measures adopted by industry against those adopted by the consumer; and if needed, to combine them to attain a targeted risk level.

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