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What risk assessments can tell us about setting criteria

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ABSTRACT

The Food Safety Objective (FSO) paradigm has been developed as a risk-based approach to microbial food safety. To be operational, this paradigm requires that an Acceptable Level of Protection (ALOP) and a FSO be quantitatively defined. It then becomes the industry's task to produce foods that achieve the FSO. A two-dimensional risk assessment, which separates variation and uncertainty, can help design a process or validate an existing process. If the initially proposed or existing process parameters do not meet the FSO, the sensitivity analysis can show which parameters have high uncertainty or variability that can be better controlled or how much a parameter must change for the process to achieve the FSO.

1. Introduction

With the development of microbial risk assessment concepts, it was recognized that the focal point for controlling microbial pathogens and determining the food's safety should be on the numbers of a pathogen in the food at the time of consumption, not just the performance of a single processing step (ICMSF, 2002). Therefore, the concept of the Food Safety Objective (FSO) was developed. This concept establishes that the initial contamination, reductions through inactivation steps, potential recontamination, and possible growth during storage should be such that at the time of consumption, the pathogen will be below a specific level in every serving, termed the FSO (CAC, 1997, 1999; CCFI, 2003; ICMSF, 2002; Whiting & Buchanan, 2007, 2008). The FSO concept is symbolically expressed as:

$$H_0 + \sum I + \sum R < \text{FSO}$$

where H_0 is the initial contamination, ΣI is the sum of all the increases in population, and ΣR is the sum of all the reductions (negative value). Summed, these must be less than the FSO. This concept implies that there are many potential processes for a food that can vary in their individual processing steps, but still meet the FSO.

Risk assessment techniques expand on the FSO concept by considering the variation in a parameter's values that exist in commercial production and the quality of the knowledge about the values (uncertainty). Initial contamination, for example, is not a single value, but is a distribution skewed toward low levels with a decreasing frequency of high contamination levels. Using stochastic/iterative calculations, a risk assessment uses the distributions of the processing parameters to calculate a distribution of contamination levels at consumption. Whereas the average level of contamination can be easily calculated, the fraction of highly contaminated samples that exceed specific levels is much more important to determine the real risk. This recognizes that the average or median serving of even high risk foods do not cause illness; rather it is the high levels of contamination in the minority of servings that must be prevented. Therefore, by definition, the FSO should not be exceeded by any serving; the average contamination level in a food lot does not determine the acceptance or failure in achieving the FSO by itself (CCFI, 2005; ICMSF, 2002). This also means that reducing variability may achieve the FSO as readily as lowering the parameter's mean value.

However, the numbers of a pathogen consumed are not the most important metrics for public health. The most important metrics are the risk of illness per serving or number of cases in a population per year. The acceptable level of protection (ALOP), therefore, defines the level of risk that the public is willing to accept (CCFI, 2005). The FSO and ALOP are linked by the dose–response relationship which estimates the risk of illness given a specified consumption of a pathogen. This relationship is affected by numerous parameters for the pathogen (strain, virulence, cell history), person consuming the pathogen (age, immune status) and food matrix (fat level, acidity). The setting of ALOP and FSO are ultimately value judgments, not scientific calculations. Factors in the risk management decision for the ALOP and FSO includes a country's legal traditions, technical feasibility, sensory and nutritional quality, costs, and what risk consumers are willing to accept to enjoy a food they desire. To have acceptance of these metrics, this process needs to be conducted in a public arena with input from all stakeholders.

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Determining the changes in pathogen numbers during food processing is the exposure assessment. This is the area of expertise for food microbiologists, technologists and engineers. The dose–response relationship or hazard assessment is determined by epidemiologists and experts in human susceptibility and pathogen virulence. The FSO is the common parameter between these two different areas of expertise. The regulatory process requires establishment of a specific criteria, a bright line, for a lot to either pass or fail. Without acceptance of a procedure to establish a FSO and ALOP, the FSO paradigm will not become a working concept for food safety and the designers and operators of a food process will have no safety criteria for their product. This paper discusses different approaches that can be taken to establish a quantitative FSO and ALOP and describes how risk assessments can be used to design a new food process or bring an existing process into compliance with a FSO.

2. Risk management considerations

Risk managers have to evaluate several aspects as they consider establishing a quantitative FSO and ALOP (Whiting & Buchanan, 2008). Pathogens causing more severe illnesses or chronic conditions would likely be given a lower ALOP; this is similar for pathogens that target particular populations, such as children. Having the same ALOP for all foods would need to overcome inherent differences in contamination, processing and preparation. The technical feasibility of achieving a specific ALOP will not be the same for all foods. Having a single ALOP also ignores the different consumption patterns and social settings for different foods.

Risk managers may make allowances high levels of uncertainty or variability in either process or dose–response model parameters. Managers may base the FSO on a susceptible group or highly virulent strain, for example, or assign a high degree of variation or uncertainty to the growth of a pathogen during storage, if they feel that is appropriate.

3. Approaches to setting FSO and ALOPs

The FSO and ALOP are linked by the dose–response relationship for a microorganism and defined group of consumers, e.g., the elderly population. The process of setting of these two metrics can be approached by initially considering either the FSO or ALOP.

3.1. An approach from an ALOP

A numerical value for the ALOP can be based on societal values and expectations of an appropriate risk. A non-food example is with chemical toxins where one additional cancer case in a million lifetimes is often used.

An initial value for the ALOP can be determined from the current rate of illness from epidemiological data and a goal set for a specified percent reduction. For instance, this approach is utilized in the U.S. Healthy People 2010 initiative (FDA, 2000) which aims to reduce the rates of listeriosis by 50 percent, to 2.5 illnesses per million people per year. The goal is defined on a population basis and is the summation of servings from all foods over all contamination levels. However, it is difficult to directly translate this to a risk per serving for a specific food (ALOP) and to calculate a FSO that a food processor can use. However, epidemiological data can be used as a departure point. For example, the U.S. population listeriosis rate is 7.9×10^{-6} cases per ready-to-eat (RTE) serving (FDA/FSIS, 2003) and the overall foodborne illness rate is 2.4×10^{-4} cases per meal (derived from CDC, 2002 and FDA/FSIS, 2003).

With the provisional specification of an ALOP, a dose–response model for the appropriate population is used to determine the FSO. Because of the variations and uncertainties, the FSO can't be directly calculated from the ALOP; estimates of the FSO must be made and the distribution of risks per serving calculated. An iterative, stochastic process would be followed by searching for the FSO that gives a distribution which meets the ALOP (possibly operationalized as the mean risk per serving being 2.5 or 3.0 standard deviations below the ALOP). Greater variations and/or uncertainties in the dose–response relationship increase the spread in the risk per serving distribution and decrease the FSO value that achieves the ALOP.

3.2. An approach from a FSO

The distribution of current contamination levels after manufacturing can be determined from a survey of commercial products. It is assumed most of the illnesses come from the higher portions of the contamination distribution or out-of-process events. The FSO could eliminate the products with the highest 20% of the contamination, for example. This approach was used by U.S. Food Safety and Inspection Service in their approach to setting criteria for *Salmonella* and *Escherichia coli* in meat and poultry carcasses (Federal Register, 1996). An advantage of this approach is that if the majority of the industry can manufacture the food with lower levels of the pathogen and do so profitably and with high quality, then the minority of producers who have high contamination levels should also be able to.

This approach to setting a FSO could be used by risk managers to set regulatory limits without calculation of the ALOP, thereby avoiding direct consideration of the dose–response relationship, susceptible subpopulations, and strain variations. It is simple, direct, and less likely to be misunderstood; a numerical ALOP with an "acceptable level of illness" does not need to be declared. Nevertheless, an implied ALOP could be calculated even if it were not explicitly stated in the regulatory process.

3.3. Other approaches/considerations

Consumption data, contamination surveys and epidemiological data can be combined to determine the frequency of consuming servings with different numbers of the pathogen. With the assumption that illnesses are most likely to arise from the servings with highest contamination levels, the pathogen consumption levels that account for most illnesses can be estimated. The FSO would be set at a level that would eliminate the desired number of cases. An example of this approach to estimate the contamination levels most likely to cause listeriosis, is in the proposed U.S. FDA Compliance Policy Guide for *Listeria monocytogenes* (Federal Register, 2008).

Full implementation of the FSO concept calls for a quantitative FSO so that Performance Objectives (PO) and Performance Criteria (PC, the change in microbial levels at a process step) can be specified, and a Hazard Analysis and Critical Control Point (HACCP) plan developed. Ideally, all the approaches described above would converge on an appropriate FSO for a food.

4. Using risk assessments to achieve a FSO or PO

With the setting of a FSO or PO, the exposure assessment can determine whether a specific food process can achieve these metrics, i.e., validate the process (Whiting & Buchanan, 2008). The distribution of values within a data set originates from variability and uncertainty. Variability is the real difference that exists between different samples, e.g., different packages from a lot are not all stored for the same time period before consumption. Additional data or better measurements will not minimize or eliminate this variability.