Use of food safety objectives as a tool for reducing foodborne listeriosis

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Abstract

Listeria monocytogenes is a foodborne pathogen that can cause listeriosis, a rare but severe disease whose invasive form has an estimated fatality rate of 20–30% of those who become ill. Typically, listeriosis occurs in individuals who have one or more underlying conditions that depress immune function, which makes them susceptible to the illness. Risk management strategies are required throughout the food chain to reduce the incidence of foodborne listeriosis. Public health objectives can be established to ensure continuous improvement in the health of the population with respect to a particular hazard and ideally should be based on an assessment of the risk to the population by the hazard. Food safety systems can be based on meeting a specific public health objective, to reduce the burden of foodborne disease. The International Commission on Microbiological Specifications for Foods has proposed the establishment of Food Safety Objectives (FSO) to provide a link between a public health objective and performance objectives and performance criteria that are established to control a foodborne hazard. An FSO can be used as a risk management tool for L. monocytogenes in ready-to-eat foods as the FSO establishes the stringency of the measures being used to control the hazard by specifying the frequency and/or cell number of L. monocytogenes in the food that should not be exceeded at the time of consumption. To establish an FSO based on a public health objective, the level of exposure that meets the public health objective must be determined. This requires an understanding of the risk characterization curve and the dose–response relationship for both the normal and the susceptible populations. This may be difficult, as there is considerable variation in the degree of susceptibility of individuals to L. monocytogenes, depending on their age, whether or not they are pregnant, and the severity of any underlying illness. It is likely that when establishing an FSO for L. monocytogenes both the normal and susceptible subpopulations will have to be considered. If the FSO is being met, there should be a concomitant reduction in illness as long as the main factors influencing the risk at the population level remain within the boundaries of the risk assessment. A reduction in illness can be measured through disease surveillance. Once a public health goal is achieved, new, technologically feasible goals should be considered to foster continuous improvement in reductions of listeriosis. Implementing effective food safety control measures, which ensure that the FSO is being met consistently, is key to reducing foodborne listeriosis.

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1. Introduction

Listeria monocytogenes is a foodborne pathogen that can cause listeriosis. In adults, listeriosis occurs in an invasive or a noninvasive form. After initial flu-like symptoms (fever, fatigue, malaise, nausea, cramps, vomiting, and diarrhea), invasive listeriosis in adults is characterized by the onset of septicemia and meningitis. In a pregnant woman, invasive listeriosis can lead to spontaneous abortion (CDC, 1998; Linnan et al., 1988). Invasive listeriosis typically occurs in susceptible individuals who have one or more underlying conditions that depress immune function, which pre-dispose them to this disease. Susceptible individuals include patients with...
cancer or undergoing treatment with steroids or cytotoxic drugs; pregnant women or neonates; renal transplant recipients; patients with acquired immunodeficiency syndrome (AIDS); and the elderly (Gellin & Broome, 1989; Goulet & Marchetti, 1996; Jensen, Frederiksen, & Gerner-Smidt, 1994; Slutsker & Schuchat, 1999). Invasive listeriosis has an estimated fatality rate of 20–30% of those who become ill (Mead et al., 1999). A noninvasive form of listeriosis resulting in febrile gastroenteritis has been documented in several outbreaks (Dalton et al., 1997; Salamina et al., 1996). The frequency of febrile gastroenteritis as a result of L. monocytogenes infection is undetermined, as are host characteristics associated with this syndrome.

Reducing the incidence of foodborne listeriosis requires controls throughout the food chain to minimize the likelihood that food becomes contaminated with L. monocytogenes and to prevent growth of L. monocytogenes to high numbers in ready-to-eat foods that support growth of this pathogen. This is achieved by implementing Good Hygiene Practices (GHP), Good Management Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) systems. Food safety expectations are often based on how well an industry is capable of performing, i.e., the concept of ALARA (As Low As Reasonably Achievable) rather than a stated degree of stringency. The current standard for L. monocytogenes in the USA for regulatory purposes is no L. monocytogenes cells detected in the sample size tested. For a sample size of 25 g, this standard equates to <0.04 cfu/g. If this were achieved for all foods, the predicted number of cases of listeriosis would be <1 per year, based on estimates from the FDA risk assessment (HHS/USDA, 2003) and the draft FAO/WHO risk assessment (FAO/WHO, 2003). As there are an estimated 2500 cases of listeriosis in the USA per year (Mead et al., 1999) this standard is clearly not being achieved for all foods.

2. Public health goals

A public health goal is a statement of a country’s appropriate level of protection (ALOP). Public health goals are established to ensure continuous improvement in the health of the population and ideally should be based on an assessment of the risk to the population by a particular hazard. Food safety standards should be set to meet public health goals. The ALOP concept was introduced in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which promotes the use of risk assessment based on objective and accurate scientific data when setting food safety standards. The ALOP is defined as the level of protection deemed appropriate by the member-country establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within a territory. The ALOP is viewed as the degree of risk that a society is willing to tolerate, or accept, and measures what is achievable before “costs” to society become too great. Costs may be human, economic, ethical, medical, legal, etc. The ALOP will be influenced by the perception of risk, which is a function of the ability of a consumer to control the hazard, the severity of the hazard, and the degree of outrage associated with a hazard. The ALOP may include safety margins deemed appropriate for minimizing illnesses and to account for uncertainty. The safety margins employed should be proportional to the uncertainty as measured by the underlying risk assessment. As uncertainty is reduced through acquiring more information, the ALOP can be readjusted.

In the USA, a public health objective of 0.25 cases of listeriosis per 100,000 population per year has been proposed (Healthy People 2010 (www.healthypeople.gov)); a public health goal that has been interpreted as being a statement of the country’s ALOP. Unlike chemical agents where there may be a distinct threshold below which a compound is not toxic, an ALOP for an infectious agent should not be viewed as an absolute end point, i.e., once it is achieved, there should be continued efforts to reduce the impact of the disease on public health. However, an underlying assumption is that it is not possible to have zero risk for most microbial food safety hazards.

3. Food safety objectives

Food safety management systems can be based on meeting a specific public health objective if the degree of stringency of the system is related to the public health objective rather than based on ALARA. However, a major hurdle to implementing the ALOP concept is that metrics used to articulate public health goals are typically not in a form that can be employed by the food industry or food control agencies to establish the required stringency for food safety systems. The International Commission on Microbiological Specifications for Foods (ICMSF, 2002) has proposed the establishment of Food Safety Objectives (FSO) at the time of consumption to provide a link between public health objectives and target points earlier on in the supply chain, referred to as performance criteria (PC). The FSO is defined as “the maximum frequency and/or concentration of a microbial hazard in a food considered tolerable for consumer protection at the time of consumption”. Setting the FSO at the time of consumption requires consideration of the likelihood and impact of contamination at all points further back in the food chain. In the ICMSF concept, PC could refer to both a change in a hazard level as well as to
a hazard level. To clarify this, two new terms have been proposed, Performance Objectives (PO) and Performance Criteria (PC). A PO is the maximum level (frequency and/or concentration) of a hazard in a food at a specified point in the food chain that should not be exceeded in order to achieve an FSO. A PC is the outcome of one or more steps in the food safety management system that must be met in order achieve an FSO. For example, the outcome could be a particular minimum reduction in the hazard level required, or a maximum increase in the hazard level tolerable. Processors or legislative authorities may need to set POs or PCs at lower levels than the FSO to ensure that the FSO is met. The intention of FSO is that they be established by government regulatory agencies and serve as a means of communicating public health goals to industry and other stakeholders in a form that they can measure and influence.

When establishing PC for \( L.\ monocytogenes \), consideration must be given to the initial levels of the organism and to any changes that may occur during production, distribution, storage, preparation, and use of a product. The PC can be expressed conceptually by the following equation introduced by the ICMSF (2002):

\[
H_0 - \sum R + \sum I \leq \text{FSO}
\]

where \( H_0 \) = initial level of the hazard; \( \sum R \) = total (cumulative) reduction of the hazard; \( \sum I \) = total (cumulative) increase of the hazard; FSO = food safety objective.

FSO, \( H_0 \), \( R \) and \( I \) are expressed in log\(_{10}\) units and, by definition, \( R \) is negative (reduction) and \( I \) positive (i.e., an increase).

4. Establishing a food safety objective—scientific considerations

Setting an FSO can involve:

(1) Identification of a public health concern and the need for management actions.
(2) Evaluation of the level of risk (e.g., by conducting a risk assessment).
(3) Articulation of the public health goal.
(4) Determination of the maximum level of exposure that would achieve the public health goal (including consideration of the need to build in an extra margin of safety to account for variability in food safety management performance and uncertainty in our knowledge on the level of risk)—this is the FSO.
(5) Evaluation of the feasibility of complying with the FSO.
(6) Implementation of the FSO by the industry.

Clearly, \( L.\ monocytogenes \) poses a public health concern and risk management actions are required to reduce the levels of listeriosis that currently exist. The prevailing level of risk can be determined by conducting a risk assessment. A risk assessment is a systematic means for assessing the severity of hazards, their level and the likelihood of occurrence. When assessing risks, the nature of the hazard, the likelihood that an individual or population will be exposed to the hazard, and the likelihood that exposure will result in an adverse health effect are considered. Details of how to undertake microbial risk assessments are described elsewhere (Buchanan et al., 1998, Buchanan, Smith, & Long, 2000; CAC, 1999; ILSI RSI, 1996, 2000; Lammerding & Fazil, 2000; Miller, Whiting, & Smith, 1997). The information developed during the risk assessment process can be used to help make risk management decisions, i.e., determine the most appropriate way to prevent or minimize harm from the hazard.

An FSO can be used as a risk management tool for \( L.\ monocytogenes \) in ready-to-eat foods, i.e., the FSO establishes the stringency that the measures used to control \( L.\ monocytogenes \) must achieve by articulating the frequency or cell number of \( L.\ monocytogenes \) in the food that should not be exceeded at the time of consumption. The establishment of an FSO based on a public health goal requires an understanding of risk characterization curves which relate, via an established dose–response curve, the relationship between exposure and public health outcome for susceptible populations. A dose–response analysis is undertaken as part of a risk assessment, to characterize the relationship between dose, infectivity and the likelihood and severity of the spectrum of adverse health effects associated with the hazard in an exposed population. Dose–response relationships may be determined by human volunteer feeding trials, but for \( L.\ monocytogenes \), such trials are not ethical as listeriosis is a life-threatening disease and may not be meaningful if conducted in healthy adults, because healthy adults are not the at-risk population and rarely contract listeriosis. Mice have been used to develop dose–response models for \( L.\ monocytogenes \), but their utility is limited due to the uncertain correlation with the human response to the pathogen. In addition, there is considerable variation among strains of \( L.\ monocytogenes \) in their ability to cause disease, and this should be considered when developing dose–response curves. Despite these uncertainties, dose–response relationships have been estimated based on studies in animal models and human illness data for both the normal healthy population and for many at risk populations (Buchanan, Damart, Whiting, & van Schothorst, 1997; Farber, Ross, & Harwig, 1996; HHS/USDA, 2003; Lindqvist & Westoo, 2000).
Once an assessment of risks has been made, a public health goal can, in principle, be articulated. Following this, an FSO can be established with consideration to the dose–response relationship, and other factors (e.g., economic, societal) that the authority establishing the FSO determines appropriate. When establishing an FSO, the susceptible populations who are most likely to become ill should be considered. One challenge lies in adequately defining this population, which is not monolithic and may contain a wide range of degrees of susceptibility. At the extreme, there may be individuals (e.g., transplant patients immediately after surgery) who are so susceptible to L. monocytogenes and opportunistic pathogens that the only protective FSO would be the total exclusion of foodborne exposure to the pathogen until the patients once again have a reasonable level of immune function (Lyytikäinen et al., 2000). In these populations, strict avoidance of foods that pose an increased risk of listeriosis may be necessary, and the only practical safety strategy may be the consumption of only commercially-sterile foods.

When establishing the FSO, an evaluation should be made to determine whether the FSO is achievable, i.e., whether food safety management systems can be implemented that will ensure that the FSO is met. For certain products it may be that current technologies in the industry do not allow the FSO to be met. In such instances, the food control agency and the industry have effectively three choices, revise the FSO, identify a surrogate product (e.g., consumption of pasteurized milk instead of raw milk), or remove the product from commerce. If an FSO has been deemed technically feasible, food industries will use GHP/GMP and HACCP approaches to control the hazard at the appropriate level and manage the risk. A broad range of food control measures are available which can either prevent contamination of foods by L. monocytogenes or prevent growth of L. monocytogenes in ready-to-eat foods such as (a) reformulation of foods so they do not support the growth of L. monocytogenes, (b) post-packaging listericidal treatments, (c) reduction of shelf life, or (d) use of competitive flora to minimize growth of L. monocytogenes.

FSOs will generally have to be implemented via the establishment of POs and PCs because an FSO is at the time of consumption so that it can be related directly to the public health goal. In the case of a ready-to-eat product that does not support growth of L. monocytogenes, the PC or PO at the manufacture may be the same as the FSO (e.g., the frequency and level of L. monocytogenes in a hard cheese). Alternatively, the PO or PC for a product may be substantially different at specific steps in the food chain in order to achieve the stated FSO. For example, if a ready-to-eat product supports the growth of L. monocytogenes during normal refrigerated storage (e.g., cooked turkey roll, hummus) the PO at the point of manufacture will likely be more stringent than the FSO to account for the potential growth of the microorganism during distribution and home-use. Conversely, if a product is reliably and consistently cooked just prior to consumption (e.g., reheated frankfurters), a PO set at the time of manufacture could be less stringent than the FSO. However, care must be taken in such instance to ensure that L. monocytogenes infections are not caused by the product cross-contaminating other foods before it is reheated. By defining food safety goals in terms of FSO and their corresponding PO and PC, the focus is on defining what needs to be accomplished and allows the manufacturers to decide what strategy will be effective for their products and technological capabilities. This flexibility is one of the advantages of the FSO concept.

If the FSO is being met, the public health goal upon which it is based should be met. Assuming that the public health goal relates to a risk reduction, a reduction in the extent of illness in the population related to the particular hazard should become apparent through disease surveillance. However, the relationship between compliance and concomitant reduction in illness should not be blindly assumed. A reduction might not be apparent if the main factors influencing the risk as identified in the risk assessment have changed (significantly) outside the boundaries captured in the assessment. In this case the new burden of disease is not comparable anymore to the one prevailing when the risk assessment was performed. Verification through the acquisition of disease and food surveillance data is needed to estimate the burden of disease and relate it to the level of compliance to the FSO. Verification should be a critical component of the post-implementation activities of national food safety management systems. However, this requires that the disease and food surveillance systems be integrated in such a manner that they are capable of differentiating the efficacy of the FSO from a failure to achieve the necessary degree of compliance. If such enhanced surveillance capability could be integrated with enhanced risk assessment capabilities, we should be much closer to the goal of being able to establish and implement transparent, public health-based, risk-based, verifiable food safety systems at both national and international levels.

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