United States Department of Agriculture
Food Safety and Inspection Service
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Executive Summary: A Demonstration of the Application of the *C. perfringens* Risk Assessment for Estimation of Risk Management Metrics

Introduction

The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) is exploring quantitative risk assessment methodologies to incorporate the use of Codex Alimentarius' newly adopted risk management metrics, *e.g.,* Food Safety Objective (FSO), Performance Objective (PO) and Microbiological Criterion (MC). It is suggested that use of these metrics would tie more closely to the results of quantitative microbial risk assessments (QMRAs) to public health outcomes and a country's Appropriate Level of Protection (ALOP). For the purpose of this demonstration, the ALOP is set as the number of human illnesses caused by the hazard within ready-to-eat (RTE) and partially cooked meat and poultry products. The FSO is the maximum frequency and/or concentration of the hazard in a food at the time of consumption and is preceded by the PO, which is the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption. Finally, the MC defines the acceptability of a product or a food lot as determined by a sampling plan that is based on absence/presence, or concentration testing of the hazard.

While the U.S. is currently not using the newer metrics, there have been a few demonstrations of methodologies examining the possible use of risk management metrics, including consideration of quantified uncertainties. For the most part though, attempts to apply such metrics lack sufficient characterization of uncertainty for practical application. In other words, the extent to which uncertainty should and can be incorporated, and how best to incorporate that uncertainty, has not been well characterized to date. Here, a general methodology that begins with an ALOP and allows evaluation of corresponding metrics at appropriate points in the food chain associated with that ALOP is demonstrated[1]. It is shown that a more detailed characterization of uncertainty is sufficient for the practical application of quantitative microbial risk assessment as an approach to implement the risk management metrics adopted by Codex. This report serves as a guidance document on how to practically apply the food safety metrics to the specific set of conditions outlined. Lessons learned for future projects also are provided.

Methods

[1] Crouch EA, Labarre D, Golden NJ, Kause JR, Dearfield KL. Application of quantitative microbial risk assessments for estimation of risk management metrics: *Clostridium perfringens* in ready-to-eat and partially cooked meat and poultry products as an example. J Food Prot. 2009 Oct;72(10):2151-61.

A *C. perfringens* risk assessment was developed previously that evaluated the effect on human illnesses of allowing different amounts of growth of *C. perfringens* during the critical "stabilization" (cool-down) preparation step for RTE and partially cooked foods containing meat or poultry[2]. This 2-dimensional (2-D) Monte Carlo QMRA tracked *C. perfringens* vegetative cells and spores in individual servings of RTE and partially cooked foods from their initial production until final consumption.

The feature of the *C. perfringens* risk assessment that makes it suitable as a demonstration for the methodology examined here is its incorporation of a 2-D probabilistic approach. This approach mathematically incorporates and separates the two dimensions of variability and uncertainty. To simplify the demonstration, a single RTE food type, "hot dogs," was chosen because of its high consumption rate and its ease of use within the *C. perfringens* risk assessment model. This particular QMRA is used here solely as a vehicle to demonstrate the practicality of the methodology.

To estimate an ALOP from which the FSO, PO, and MC are determined, the risk assessment model was used to provide an upper uncertainty confidence limit on the risk. This upper limit provides the ALOP. For this example the 95^{th} and 99^{th} percentiles of the upper confidence limit were used.

For this demonstration, the risk assessment model is used to determine the relationship between the FSO and ALOP. This information is then used to specify the FSO in such a way that the ALOP is achieved with the required confidence. A PO may then be defined at any point in the food chain, and the same approach used to evaluate the FSO may be followed. In addition, the risk assessment model is used to determine the relationships and uncertainties between the PO, FSO, and the ALOP. This information is ultimately needed to select a value for the PO so that either the FSO or the ALOP is achieved with suitable confidence. Finally, given a PO, the number of samples taken and the criteria defining compliance or noncompliance (the MC) may be defined using standard approaches to sampling and experimental design.

Results

An ALOP for *C. perfringens* in RTE foods has not been currently established by the United States. In principle, establishment of an ALOP could depend on the appropriate level of protection that is considered desirable by a country within its territory; however, in practice, current conditions within a country are considered appropriate. Once an ALOP is determined, a country could set a goal for a more appropriate ALOP to improve food safety and pubic health.

[2] http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp#RTE

Defining the ALOP: The risk assessment is used to generate an uncertainty distribution of the number of illnesses per hotdog servings. The 95^{th} and 99^{th} percentiles were chosen as two potential ALOPs: 13 and 21 illnesses per million hotdog servings, respectively. Establishing an ALOP at the 95^{th} percentile would result in a 5% chance (or less) that current conditions fail the ALOP and establishing an ALOP at the 99^{th} percentile would result in a 1% chance (or less) that current conditions fail the ALOP.

Defining the FSO: Evaluation of the FSO for *C. perfringens* is sufficient using prevalence. The number of illnesses produced by *C. perfringens* in the food servings examined is evidently directly proportional to the prevalence of *C. perfringens* in those food servings at the level of the consumer. However, this demonstration assumes that the distribution of cell counts (*i.e.*, the level) in the servings still containing *C. perfringens* does not change.

The FSO for an ALOP of 13 illnesses per million servings of hotdogs is estimated to be 0.72%. The FSO for an ALOP of 21 illnesses per million servings is estimated to be 1.16%. That is, in the example of the 21 illnesses per million servings, if 1.16% of all hotdog servings are contaminated with *C. perfringens* at the point of consumption, the ALOP will not be exceeded.

Defining the PO: Evaluation of PO for *C. perfringens* is sufficient using prevalence. The PO for an ALOP of 13 illnesses per million servings of hotdogs is estimated to be 1.57%. The PO for an ALOP of 21 illnesses per million servings is estimated to be 2.52%. That is, in the example of the 21 illnesses per million servings, if 2.52% of all hotdog servings are contaminated with *C. perfringens* at the point of processing, the ALOP will not be exceeded.

Defining the MC: Design of a sampling plan to evaluate an MC requires a test program that can detect the prevalence as defined by the PO. For example, choosing a PO of 1.3% gives the minimum number of required samples as 727, with 14 or more positive *C. perfringens* results indicating noncompliance in 1-gram samples.

Discussion

With this demonstration, it was shown that the methodology evaluating ALOPs corresponding to current practices, and FSOs, POs, and MCs corresponding to such ALOPs, can be used when a suitable QMRA is available. A QMRA that accounts for both variability between food servings and uncertainties is essential to the methodology.

Preliminary attempts using just the summary results of the *C. perfringens* risk assessment and assumptions about the shape of various distributions (*e.g.*, assumptions about lognormal or uniform distribution shapes) were inadequate to allow for an adequate definition of FSOs or POs. The actual distributions differed substantially from such idealizations, indicating the results depended critically on those differences.

The approach demonstrated here is entirely general, provided a 2-D QMRA (*i.e.,* one that separates uncertainty and variability) is available. For example, the same approach may be used to develop a PO at any point within the food chain, provided only that the QMRA suitably models the food chain and provides access to that point in the food chain within the model.

While the approach demonstrated is general, the choices made in this particular demonstration are specific to *C. perfringens*, which has characteristics substantially different from other foodborne disease organisms. Evaluation of FSOs and POs for other organisms will be sufficiently different than drawing general conclusions based on the specific results obtained in this one demonstration (*e.g.*, the use of prevalence alone) may not be advisable. This demonstration project has established the feasibility of estimating these risk management metrics; however, the usefulness of the sampling plan generated here needs to be evaluated for practicality.