A Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat and Poultry Products

Executive Summary

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The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) conducted a quantitative risk assessment of *Clostridium perfringens* (*C. perfringens*) in ready-to-eat (RTE) and partially cooked meat and poultry products. The purpose of the risk assessment was twofold: 1) evaluate the public health impact of changing the allowed maximal growth of *C. perfringens* during manufacturing stabilization (cooling after the cooking step) of RTE and partially cooked meat and poultry products; and 2) examine whether steps taken to limit the growth of *C. perfringens* occurring in RTE and partially cooked foods would also be adequate to protect against growth of *Clostridium botulinum.*

Public Health Regulatory Context

The bacterium *C. perfringens* grows well on meat and poultry products in the absence of oxygen, and grows best at relatively high temperatures. Since *C. perfringens* is ubiquitous in the environment, sources of raw meat[1] are occasionally contaminated with this organism, either in the form of vegetative cells or as spores. Vegetative cells are destroyed during heating in the production of RTE foods, though may survive the incomplete cooking used to prepare partially cooked foods. Spores, on the other hand, are not destroyed by heat and other processes applied to RTE foods. Rather, heat can activate spores to germinate and develop into vegetative cells capable of growth during the stabilization processes of RTE food manufacture.

Consuming foods contaminated with high levels of certain strains of *C. perfringens* vegetative cells (those known as type A, that produce the *C. perfringens* enterotoxin, CPE) may lead to diarrheal illness. Illness is generally mild, and typically self-limiting, lasting one or two days. Symptoms include diarrhea, nausea, and some abdominal pain. No known foodborne illnesses have been caused by the ingestion of *C. perfringens* spores; rather, it is necessary to consume the vegetative cells for illness to occur.

As the public health regulatory agency responsible for ensuring the safety and wholesomeness of meat, poultry, and egg products in the United States, FSIS has taken steps to address *C. perfringens* in Agency regulated products. On January 6, 1999, FSIS published a final rule in the Federal Register (FSIS Docket No. 95-033F; 64 FR 732) establishing performance standards for *C. perfringens* in cooked beef, roast beef, and cooked corned beef products; fully and partially cooked meat patties; and certain fully and partially cooked poultry products, in an effort to address the public health risk posed by *C. perfringens*. The production requirements for these products included performance

[1] Throughout this document, "meat" generally means meat or poultry, except for specific cases that should be clear in context, *e.g.* where referring to an experiment on a specific meat.

standards limiting multiplication of *C. perfringens* to a maximum of 1-$\log_{10}$ (a factor of 10)[2] within the product during RTE food manufacture.

On February 27, 2001, FSIS published a proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* [66FR12590, February 27, 2001]. The intent of this rule with regard to *C. perfringens* was to extend the existing performance standards to all RTE and all partially cooked meat and poultry products.

The risk assessment was initiated in FY2003 in response to specific FSIS risk management questions formulated for the Risk Assessment Division, to garner information in response to public comments on the FSIS proposed rule released in 2001. Several comments requested greater evaluation of the current performance standard that limits multiplication of *C. perfringens* to a maximum of 1-$\log_{10}$ within the product. To better understand those concerns, FSIS requested public input as part of the proposed rule for RTE meat and poultry products (66FR12601, *op. cit.*) and initiated a risk assessment.

Risk Management Questions

The risk assessment was designed to addresses the following risk management questions:

1. What is the impact on the probability of human illness if the allowable growth of *C. perfringens* is raised from 1-$\log_{10}$ (that is, 10-fold) during stabilization to 2-$\log_{10}$ (that is, 100-fold) or 3-$\log_{10}$ (that is, 1000-fold)?
2. What would the relative growth of *C. botulinum* (relative to the growth of *C. perfringens*) be for each of these stabilization standards?

Structure and scope of the current risk assessment

The *C. perfringens* risk assessment is a plant-to-table probabilistic risk assessment. The risk assessment incorporates a data-driven model that tracks *C. perfringens* spores and vegetative cells on raw meat and poultry products from the processing plant through the point of consumption. The risk assessment uses a computer program to perform Monte Carlo simulations on meat-containing food servings selected from the Continuing Survey of Food Intakes by Individuals (CSFII) (USDA, 2000). The selection of servings was made to limit analysis to those servings that could contain RTE or partially cooked foods, and that were considered capable of supporting growth of *C. perfringens* (omitting, for example, shelf-stable foods and foods high in salt and nitrite).

For each such food serving, the original amount of contamination by spores and vegetative cells of *C. perfringens* is obtained, the resultant amount after manufacture (including stabilization step(s)) is calculated, and the amount of contamination is tracked as spores germinate and vegetative cells grow and die during storage between manufacture and retail, during storage between retail sale and preparation, and during preparation. Ultimately, the number of vegetative cells consumed in the serving, the

[2] In this standard jargon, growth is expressed on a base 10 logarithm scale. So 1-$\log_{10}$ corresponds to a factor of 10, 2-$\log_{10}$ corresponds to a factor of 100, 3-$\log_{10}$ to 1000, 1.7-log10 would be a factor of 50, and so forth.

likelihood of those cells to cause illness, and whether that particular serving actually causes illness, is calculated for each serving. The Monte Carlo simulation also provides information on the certainty of the risk assessment estimates.

Risk Assessment Outputs

The primary results of the risk assessment are summarized as follows:

1. Approximately 79,000 illnesses per year in the U.S. from RTE and partially cooked meat and poultry products (at 1-$\log_{10}$ growth).

2. A change in growth during stabilization from 1-$\log_{10}$ to 2-$\log_{10}$ and 3-$\log_{10}$ results in a median 1.23 and 1.59 fold increase in annual diarrheal illness, respectively.

3. Improper cold storage of RTE and partially cooked meat and poultry products at retail and the home accounts for approximately 90% of the predicted *C. perfringens* foodborne illness. Improper hot-holding of RTE and partially cooked meat and poultry products accounts for approximately 8% of the predicted illnesses at 1-$\log_{10}$ growth during stabilization, although the risk assessment probably underestimates this fraction.

4. Stabilization at processing plants accounts for 0.05% and 0.4% of predicted illnesses at 1-$\log_{10}$ and 2-$\log_{10}$ allowable growth, respectively. Therefore, relatively few predicted illnesses are associated with stabilization at processing plants.

5. The growth rate of *C. botulinum* is observed to be higher at low temperatures in laboratory experiments, and it probably grows at temperatures below the minimum temperature for *C. perfringens* growth. Any measures taken to reduce or prevent growth of *C. perfringens* will not necessarily have the same effects on growth of *C. botulinum*.

Uncertainty and sensitivity analysis

In addition to obtaining a single estimate of the number of illnesses per year, the Monte Carlo simulation takes account of the known uncertainties in the data and assumptions used as model inputs. That is, how sure we are of the result of the number of illnesses each year. The uncertainty estimate is an underestimate of our true ignorance, since it does not incorporate unknown uncertainties.

Sensitivity to a particular parameter or assumption in the risk assessment was examined by running scenarios in which all inputs except one were set to baseline values. The remaining input was changed by a substantial amount, making it comparable to its likely upper or lower bound. By doing so, the relative contribution of each parameter to the final estimate of annual illnesses can be assessed and the drivers of risk determined.

Research Needs

Based on sensitivity analyses, areas for further research include:

1. The categorization of foods as RTE and partially cooked foods based on the CSFII.
2. Growth characteristics of *C. botulinum* in heat treated products.
3. The fraction of RTE and partially cooked foods that are hot-held.
4. The prevalence and concentration of type A, CPE-positive *C. perfringens* spores in spices and herbs.
5. Maximum *C. perfringens* vegetative cell density in various meat and poultry products.
6. Consumer re-heating and hot-holding time behavior.
7. Additional retail and consumer storage times and temperatures of RTE and partially cooked foods.
8. The prevalence and concentration of type A, CPE-positive *C. perfringens* spores in raw meat and poultry products.

Conclusions

The risk assessment for *C. perfringens* in RTE and partially cooked meat and poultry products is based on scientific evaluation of all available evidence. The risk assessment received stakeholder input through public comment and underwent peer review consistent with current Office of Management and Budget (OMB) guidelines. The model is a tool to evaluate the effect of interventions and risk management options, rather than predict the absolute number of illnesses.

Most of the human health risks associated with *C. perfringens* in RTE and partially cooked meat and poultry products are associated with improper consumer and retail refrigeration and, to a lesser extent, consumer hot-holding of these products. While the risk assessment indicates that few predicted illnesses are associated with growth during stabilization corresponding to the current regulatory limit on cooling practices at processing plants, there is an increase in predicted illnesses as this growth is increased.