1 Executive Summary

1.1 Context of Assessment

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. As part of this responsibility, FSIS has proposed regulations that would require processors to achieve a specified level of lethality in the processing of Ready-to-Eat (RTE) meat and poultry products. This specification is described in terms of the probability of survival of *Salmonella spp.* (or equivalently, the number of log-reductions of *Salmonella spp.*) that may be present in raw materials. This specification may also be termed the *required lethality* of the process.

The required lethality, in concert with a number of other factors, influences the level of public health risk associated with the consumption of RTE meat and poultry products. The purpose of this assessment is to respond to a number of risk management questions. The specific risk management question addressed by this report is concerned with the link between various alternative values of the *required lethality* and the resulting level of public health risk. This link is to be considered across a range of RTE meat and poultry products.

1.2 Risk Management Question Addressed

This component of the risk assessment addresses the following risk management question.

> The proposed RTE rule has a minimum lethality performance standard of a 6.5-log reduction of *Salmonella* in meat for all categories (cooked, fermented, salt-cured, dried). What would be the public health impact of alternative lethality standards of 5.0-log and 6.5/7.0-log reductions of *Salmonella* (7-log for products containing poultry)?

A supplementary document provides responses to a series of other risk management questions of smaller scope. This document describes the primary effort in the risk assessment process.

1.3 Scope of Assessment

While it is recognized that changes to the required lethality for *Salmonella* will have impacts on other pathogens in raw materials, for reasons of technical feasibility, the scope of the impact on public health is limited to the estimation of impacts on the number of cases of salmonellosis.

Due to the nature of the risk management questions posed, this risk assessment does not address all of the cases of salmonellosis that might be associated with RTE meat and poultry products. Figure 2-1(in Section 2.2) provides an illustration of the scope of this risk assessment.

Health risk associated with pathogens ingested via RTE meat and poultry products can arise from a number of exposure pathways:

- pathogens that contaminate raw materials and subsequently survive the lethality step in processing
- pathogens that contaminate products after the lethality step (e.g. during handling, before or during packaging)
- pathogens that contaminate the RTE meat and poultry products during subsequent handling in food preparation

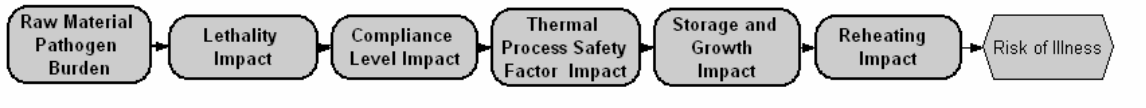
This risk assessment is concerned only with the variation in the number of cases of salmonellosis that would result from changing the required lethality in the production of RTE meat and poultry products. Therefore, only the first of the exposure pathways listed above is addressed in this assessment. While the other two pathways can contribute to the total public health risk associated with these products, the level of risk associated with these latter pathways is not sensitive to changes in the lethality standard. For example, increasing the lethality standard from a 5-log reduction to a 6-log reduction has no impact on the risk associated with post-lethality product recontamination.

1.4 Summary of Risk Estimation Process

The public health risk associated with RTE meat and poultry products is estimated by combining evidence related to the following factors:

- the level of contamination of raw materials
- the required lethality standard
- the extent of compliance with the standard
- thermal processing safety factors (associated with any thermal lethality process)
- storage of the product and potential growth of surviving organisms
- the frequency and extent of consumer re-heating

- the amount of consumption of the product



A risk assessment and policy analysis software tool was developed to accommodate the high level of uncertainty and variability. This is achieved by simplifying the assignment of important risk factor characteristics to product categories (e.g. raw material source, growth potential, storage conditions, reheating pattern, etc.). The model then calculates a composite risk level from these characteristics. This tool provides a transparent representation of the assumptions and their combination that is compatible with the sparse data available for the estimation of risk associated with RTE products. While more complex analysis (e.g., detailed representation and simulation of specific products and processes) is possible for a problem of smaller scope, providing risk estimates for a broad variety of RTE meat and poultry products requires considerable simplification of the problem to make the analysis tractable.

The essence of the risk assessment is as follows:

1) calculate the level of contamination (i.e., the concentration) of *Salmonella* in raw materials
2) calculate the concentration of surviving organisms in finished product, given the required level of lethality
3) adjust the concentration of surviving organisms to take into account compliance with the required level of lethality and any thermal process safety factors associated with any lethality treatment applied
4) estimate the extent of population growth (if any) during storage
5) estimate the reduction in population associated with consumer re-heating of the product
6) estimate the probability of illness from the ingested dose of pathogens
7) calculate the expected number of cases of salmonellosis for a fixed mass of product (one million kilograms) and for the mass of each product that is consumed in a year
8) estimate the risk for alternate assumptions and explore the sensitivity of the risk estimate to various key variables.

1.5 Limitations and Uncertainties

The risk estimates generated in this assessment should be considered to fall within wide bounds of uncertainty. There are a number of factors in the risk assessment that carry a considerable burden of uncertainty, specifically:

Categorization – to make the analysis compatible with policy analysis, other data sources, and generally practical, RTE meat and poultry products have been assigned to product categories. This categorization necessarily results in somewhat crude representations of diverse products.

Pathogen Burden in Raw Materials – the risk associated with surviving pathogens is generally proportional to the number of organisms in the raw materials. Current estimates of the number of organisms in raw materials are not available. This assessment has relied upon the FSIS Microbiological Baseline Surveys which may not be representative of current production.

Thermal Process Safety Factors - the risk estimation process employs thermal process safety factors. These factors are included to capture important adjustments to the estimate of the lethality of the process that is applied. These adjustments are applied where it is assumed that the actual *effective lethality* that is achieved would be considerably greater than the *required lethality*. These factors are considered to be the most uncertain element in the assessment.

Storage and Growth – There is uncertainty in the extent of growth of pathogen populations. By considering products in broad categories, there is uncertainty in the growth rates, in the storage conditions of products, and in estimating the maximum population density.

Consumer Reheating – while consumers will certainly reheat some products, the extent to which that reheating will reduce the population of pathogens is highly uncertain. Consumers may reheat the product minimally (e.g., simply to make it palatably warm), or they may reheat it quite thoroughly in some cases. Estimates of the level of lethality in this process are quite uncertain.

Dose-Response Relationship – there remains considerable uncertainty in the risk associated with very small numbers of pathogens. For many of the products in this assessment, it is assumed that no growth will occur (e.g., due to product dryness, or other formulation factors). In these cases, the ingested dose in contaminated RTE products that do not allow growth will be a single organism. It is now generally accepted that there is no minimum exposure threshold in microbial dose-response relationships and that there is a low probability of becoming ill from ingesting a single organism, however the probability of such illness is quite uncertain.

Production Volumes – to produce a population health risk estimate, estimates of production volume are required. There is limited data on the production of specific RTE meat and poultry products. Databases such as the U.S. economic census and nutritional survey databases provide imperfect information from which estimates have been derived. For some product categories, very little direct evidence was available.

1.5.1 Impact of Net Uncertainty

Full quantitative uncertainty analysis across a broad spectrum of product categories would be extremely burdensome. Even where some uncertainties are quantifiable, significant uncertainties remain that are much less readily quantifiable.

With this in mind, risk estimates should be considered to fall within a broad range of uncertainty including the possibility that they may be orders of magnitude smaller or larger. Given this uncertainty, the relative ranking (or attribution of total risk) among products should not be considered robust.

The risk assessment and the accompanying risk assessment model allow the implications of a broad range of factors to be considered quantitatively and transparently. The impact of alternate assumptions, and ultimately, of alternate levels of *required lethality* can be measured and more fully understood within this context.

1.6 Results of Risk Estimation

In the context of the limitations and uncertainties described above, risk estimates were generated. The estimates below, in addition to being uncertain, should be considered within the context of estimates of approximately 1 million cases of salmonellosis per year in the United States from all sources. The total contribution of RTE meat and poultry to this estimate is not known. This assessment addresses only those cases *that* result from *Salmonella spp* surviving the lethality process during the production of RTE meat and poultry products taking into account compliance, thermal process safety factors (for any lethality treatment that may be applied) and growth that may occur.

The estimates below compare three alternate standard-setting scenarios. The first scenario (‘All 5-log’) assumes that all product categories are required to achieve a 5-log reduction. In the second scenario (‘Split’), cooked products are assigned a required lethality of 6.5-log (or 7.0-log if they contain poultry), and all other products (fermented, dried, cured) are assigned a 5-log reduction. In the third scenario (‘All 6.5/7-log’) all product categories are required to achieve a 6.5-log reduction (or 7.0-log if they contain poultry). Estimates have been rounded to two significant digits.

The first table provides estimates on an ‘equal mass’ basis, where the units are the expected number of cases per million kilograms of product produced. The second table provides estimates on a population basis, where the units are the number of cases per year. The latter table considers the estimates the production volume in each product category.

RTE Product Category	Risk of Illness by Product		
	Number of cases /MKg		
	All 5	Split	All 6.5/7.0
Roast Beef, Corned Beef	$1.37x10^{-4}$	$8.27x10^{-5}$	$8.27x10^{-5}$
Fully Cooked Beef Patties	1.51	1.51	0.07
Cooked Pork (Cooked Ham, Pork BBQ)	$4.59x10^{-5}$	$2.10x10^{-6}$	$2.10x10^{-6}$
Cooked Turkey (non-Deli)	3.24	0.05	0.05
Cooked Chicken (Nuggets, Tenders, non-Deli)	30.27	0.43	0.43
Cooked Poultry Deli Meat	33.99	0.86	0.86
Cooked Chicken Patties	30.27	0.43	0.43
Beef / Pork Frankfurters	0.64	0.03	0.03
Beef / Pork Bologna	1.23	0.06	0.06
Poultry Frankfurters	10.70	0.15	0.15
Summer Sausage, Thuringer, Cooked Pepperoni	13.01	13.01	5.39
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	12.35	12.35	5.29
Meat Sticks	24.18	24.18	10.24
Beef Jerky	20.40	20.40	8.65
Uncooked Country Ham	0.01	0.01	$3.61x10^{-3}$
Prosciutto, cappicola, pancetta, basturma	0.02	0.02	0.01

RTE Product Category	Number of Cases per year		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	$1.2x10^{-2}$	$7.0x10^{-3}$	$7.0x10^{-3}$
Fully Cooked Beef Patties	0.1	0.1	$5.0 x10^{-3}$
Cooked Pork (Cooked Ham, Pork BBQ)	$4.6 x10^{-3}$	$2.1x10^{-4}$	$2.1 x10^{-4}$
Cooked Turkey (non-Deli)	1250.0	17.9	17.9
Cooked Chicken (Nuggets, Tenders, non-Deli)	40740.0	584.1	584.1
Cooked Poultry Deli Meat	15460.0	389.4	389.4
Cooked Chicken Patties	3541.0	50.8	50.8
Beef / Pork Frankfurters	256.6	11.6	11.6
Beef / Pork Bologna	162.5	7.4	7.4
Poultry Frankfurters	3263.0	46.8	46.8
Summer Sausage, Thuringer, Cooked Pepperoni	715.3	715.3	296.4
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	679.1	679.1	290.8
Meat Sticks	442.4	442.4	187.3
Beef Jerky	208.1	208.1	88.2
Uncooked Country Ham	0.3	0.3	0.1
Prosciutto, cappicola, pancetta, basturma	0.1	0.1	<0.1
Total	66,720	3,150	1,970

This assessment will be updated in the coming months in response to public and stakeholder comments. It is recommended that readers consider consulting both this report and the model software to gain an in-depth understanding of the risk assessment. The accompanying risk assessment model provides users with the

capacity to review the model structure, to run the model, and to modify selected input assumptions and to study their impact.