Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products

Final Report

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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

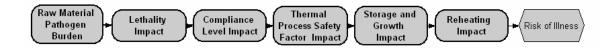
This risk assessment is concerned only with the variation in the number of cases of salmonellosis that would result from changing the required lethality in the production of RTE meat and poultry products. Therefore, only the first of the exposure pathways listed above is addressed in this assessment. 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
- 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
- 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.

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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.

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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 y		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.

2 Estimating the Public Health Impact of Varying Lethality Standards

2.1 Authorship

This risk assessment was prepared under a contract issued by the Risk Assessment Division of the Office of Public Health Science of the Food Safety and Inspection Service (FSIS). The assessment was conducted by Decisionalysis Risk Consultants, Inc. (DRC) in collaboration with the Risk Assessment Division of the Office of Public Health Science of FSIS. This assessment (consisting of draft reports and the software model) has been peerreviewed by a panel of 5 external reviewers and considerable changes have been made. This version is provided for public review and comment. Further changes in the assessment are expected in response to received comments.

Authors are Mr. Greg Paoli (DRC), Mr. Todd Ruthman (DRC), Dr. Emma Hartnett (DRC).

2.2 Scope of Analysis

This 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 risk assessment model was constructed to answer this question using the modeling software, Analytica® (version 3.0, Lumina Decision Systems, Los Gatos, CA). It models the flow of pathogens from raw materials through lethality treatment, and includes the impacts of growth during storage, the impact of reheating and applies a dose-response relationship to predict the probability of illness given the final ingested doses. Following discussions with FSIS, the model was developed with a user-interface *that* considers the scenarios of particular interest, specifically those involving log reduction values of 5.0, 6.5 and 7.0 for various products.

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. A discussion of issues related to predicting changes in risks due to other pathogens is provided in the supplementary document (risk management question 2).

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

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

- pathogens that contaminated 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 may have contaminated the RTE meat and poultry products during subsequent handling in retail, foodservice and home preparation

This risk assessment is concerned only with the variation in health risk that would result from changing the lethality standards applied to RTE meat and poultry products. Therefore, only the first of the exposure pathways is relevant to this assessment. While the other two pathways can contribute to the public health risk associated with these products, this portion of the risk 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.

This analysis estimates the risk associated with *changes* in the lethality standard applied to different meat and poultry products. As such, the actual mechanisms by which the lethality is achieved are not directly modeled or applied in the analysis. For these reasons, it is unnecessary to provide detailed characterization of the mechanisms and techniques that are applied to achieve the lethality, other than those related to general product distinctions (for example drying, curing, heating), assumptions regarding the level of compliance with the standard and, in the case of non-compliance, the extent of deviation from the candidate standard.

DRAFT FOR PUBLIC REVIEW Risk Assessment of Lethality Standards for RTE Meat and Poultry Products

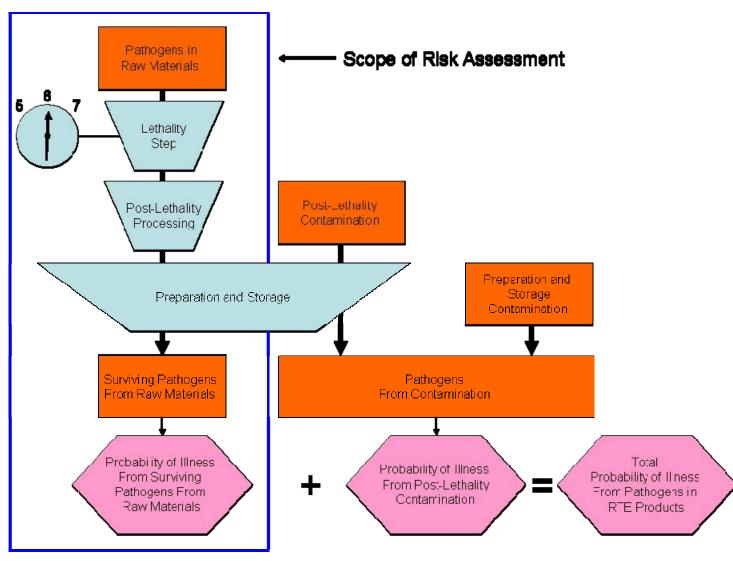


Figure 2-1: Scope of the Risk Assessment

2.3 Risk Assessment Model

A key component of the risk assessment is a decision-support application prepared using the software Analytica® (Enterprise version 3.0, Lumina Decision Systems, Los Gatos, CA). This model is intended to be used by FSIS Risk Assessment Division staff to support policy analysis within the Agency. In addition, the model can be reviewed by any interested party with access to the Analytica® Player (this version of the software is free-of-charge and can be downloaded from www.lumina.com).

The publicly available risk assessment model allows the user to browse the model, view data and calculations, make changes to specified inputs and view results. In order to make overall changes to the model (beyond what is available in the user interface), a paid license to the software is required. The model itself contains considerable internal documentation *that* can also be viewed through the Analytica® Player version of the software. Users can familiarize themselves with browsing and analyzing models by reviewing the first few chapters of the Analytica® User's Guide (included with any version of the Analytica® software).

2.4 Risk Assessment Report and Appendices

This report provides an overview of the risk assessment process, the assumptions and data, and the responses to the risk management questions. The focus of this document is the response to the risk management question stated in section 2. In addition to this question, nine other questions related to this risk assessment process were also posed but the risk managers. The answers to these questions are provided in the accompanying document. Note that throughout these documents the following abbreviations are used:

- RTE Ready-to-eat
- MKg Million Kilograms
- g grams
- CFU Colony Forming Units

To simplify the text, the following apply:

- Log refers to Logarithm to the base 10 unless otherwise specified
- RTE product always refers to ready-to-eat meat or poultry product

2.5 Sample Lethality Calculations

In the risk assessment model, calculations of the predicted contamination levels are carried out in units of CFU/MKg, and are reported in this document in both

CFU/g and CFU/MKg. This 'scale up' from CFU/g was chosen to highlight the importance of seemingly low per-gram contamination levels that might be found in RTE meat and poultry products. When considered in terms of mass production (for example, millions of kilograms), these low levels can result in a non-negligible risk of illness to the population.

Table 2-1 translates log reductions into the percentage of the microbial population that is removed. It can be seen that if a given standard is to achieve a 7-log reduction, and the starting contamination level is 7 log CFU per gram the result of treatment is an average contamination level of 1 CFU per gram (0 log CFU = 1CFU). The percentage of contamination remaining is always non-zero, is independent of the lot size (that is grams or MKgs), and is the average percentage that remains. This can also be interpreted as the probability that an organism survives the process. Specifically, for a 1-log reduction, each organism has a probability of 0.1 of surviving the process, and therefore a probability of 0.9 of not surviving the process. This is described as binomial lethality.

Table 2-1: The relationship between log reductions and percentage of organisms that			
remain for a population of 7 log CFU. Note that the percentage of organisms remaining			
is always non-zero.			

Log	Resulting	Resulting	Percentage of
reduction	contamination level	contamination level	organisms remaining
	(log CFU)	(CFU)	(%)
-	7	10,000,000	100
1	6	1,000,000	10
2	5	100,000	1
3	4	10,000	0.1
4	3	1,000	0.01
5	2	100	0.001
6	1	10	0.0001
7	0	1	0.00001

To illustrate this point, assume a uniform contamination level in a product of 1 CFU per 100 grams. On average, there are therefore 1/100 CFU per gram, *that* is equivalent to -2 logs CFU per gram. Although it is not possible to have 1/100CFU in 1 gram (as bacteria are discrete units), this can be understood as the contamination **rate** per gram of product such that, on average, for 100 grams of product there will be 1 CFU, 200 grams there are 2 CFU, 300 grams there are 3 CFU and so on. This scales up to 7 logs CFU in 1MKg. Note that 1 MKg is equal to a billion grams (9 log grams).

The application of a 4-log lethality treatment results in a reduction in this contamination rate to -6-log CFU per gram with, on average, 0.01% of the starting population surviving the process. This means that there is now an expected contamination rate of 1 CFU per 1,000,000g of product. At small levels

of production, this level of contamination might be interpreted as negligible. However, at higher levels of production, say 100 MKg, this translates to a contamination level of 100,000 organisms distributed throughout this large mass of finished product. Therefore, although the majority of servings will not be contaminated, this level of contamination is sufficient to pose a non-negligible risk of illness to the consuming population. This is an important issue to understand, and is the basis for the use of a large mass (Millions of kilograms) as the denominator in many subsequent calculations.

3 Hazard Identification

There are over 2,500 serotypes of *Salmonella enterica* recognized. In the United States, it has been estimated that infection with *Salmonella* serotypes causes 1.34 million illnesses, 15,608 hospitalizations, and 553 deaths each year (Mead et al., 1999). The cost associated with such disease rates has been estimated to be in excess of \$2 billion (Frenzen et al., 1999). The number of reported *Salmonella* clinical isolates in the U.S. increased from 1976 to 1988, declined from 1988 to 1992, and fluctuated between 30,000 and 40,000 from 1993 to 2000 with S. Enteritidis and S. Typhimurium the most commonly reported *Salmonella* serotypes reported in the U.S. (Dibb-Fuller et al., 1999; CDC, 2000), accounting for half of all human salmonellosis cases (CDC, 2000).

Many Salmonella spp. are considered zoonotic, and have been associated with a wide variety of animal and food sources. Some serotypes are confined to particular animal reservoirs, but many are capable of crossing between species to cause disease in man, often via food. Most Salmonella infections in animals are asymptomatic. Food producing animals are recognized as reservoirs of the organism. In the US, a variety of serotypes have been isolated in cattle, pigs, chickens and turkeys (Schlosser, 2000) with the profile of the serotypes varying by animal species. Animal feeds made from animal products may be contaminated by Salmonella and Salmonella can also be found in fish, terrapins, frogs and birds, with pet reptiles a recognized risk factor for salmonellosis (Mermin, 2004). The CDC estimates that 74,000 cases of salmonellosis per year are associated with exposure to reptiles or amphibians (directly or indirectly).

Food associated outbreaks of salmonellosis have been attributed to a number of food groups including dairy products, for example milk (CDC, 2003), ice cream (CDC, 1994); meat products, for example ground beef (CDC, 1995), beef jerky (CDC, 1995a), fruits and vegetables, for example cantaloupe melon (CDC, 2002) and alfalfa sprouts (CDC, 2001), and other foodstuffs, for example raw almonds (CDC, 2004).

Salmonellae commonly grow between 7 and 50 °C, with the optimum growth in the range 35 - 37 °C, although there is evidence for growth at temperatures around 5 °C this is serotype specific (ICMSF, 1996). Salmonellosis commonly presents with an incubation period in the range of 6 to 48 hours followed by symptoms including diarrhea, abdominal pain, nausea and vomiting lasting 1 to 7 days. Salmonellosis is usually self-limiting however, there is an estimated 22.1% hospitalization rate, and an estimated 0.8 % fatality rate (WHO, 2002).

4 Hazard Characterization

The Hazard Characterization provides a description of the public health outcomes, pathogens, and host characteristics and other factors, for example, vehicle related, that may affect the probability with which ingested *Salmonella* could cause illness. For a full discussion of the organisms, host and matrix characteristics, results of experimental studies into human infection, and a review of available epidemiological information the reader is referred to this document for a full hazard characterization (WHO, 2002).

4.1 Salmonella Dose-Response Model

To predict and assess the impact of exposure to defined levels of pathogens such as *Salmonella*, probability models are currently being widely used. These models are specified by a dose-response relationship for each pathogen thus assuming that risk depends upon the number micro-organisms ingested. The dose-response relationship for *Salmonella* has been investigated by several researchers, and a number of model candidates have been proposed. These models have been reviewed, and a model based upon available epidemiological outbreak data developed (WHO, 2002). This model is adopted here. To describe the probability of developing illness, P_{ill} , a Beta-Poisson dose response model was found to provide the best fit to the data. The model has the form

 $P_{ill} = 1 - \left(1 + \frac{D}{\beta}\right)^{-\alpha}$ where *D* is the dose of salmonella ingested and α and β are

parameters of the model. Using outbreak data to fit the model, the expected values of the best fit α and β are 0.1324 and 51.45 respectively (WHO, 2002). These parameter values are adopted in this assessment. Note that Hazard Characterization guidelines (WHO, 2003) do not support the concept of minimum infectious dose as a basis on which to predict the probability of illness.

5 Exposure Assessment

5.1 Approach and Model Structure

The risk of exposure per serving, as illustrated in Figure 5-1, is a composite of:

- Raw Material Quality
- Lethality Standard and Compliance Pattern
- Thermal Processing Safety Factors
- Storage and Growth of Surviving Organisms
- Consumer Re-heating Behavior

In this chapter, a process is described for integrating evidence regards these components into a risk estimate for RTE meat and poultry products. The evidence is included in the form of several multiplicative factors.



Figure 5-1: Overview of the stages of the risk assessment

Each factor corresponds to a probability (e.g. probability of a pathogen being present in a serving, probability of its survival of a lethality process, probability of growth and survival of subsequent reheating, probability of illness given the final dose). For each of these factors, there is logarithmic variability (meaning that the products may vary amongst themselves spanning factors of 10) and logarithmic uncertainty (meaning the true value of the probabilities of each factor for a given product could be higher or lower by factors of 10).

A risk estimation and policy analysis tool was developed to accommodate the high level of uncertainty and variability by simplifying the assignment of important risk factor characteristics to products (e.g. raw material source, growth potential, storage conditions, reheating pattern, etc.) and then calculating a composite risk level from the assigned characteristics. This tool provides a transparent representation of the assumptions and their combination that is more compatible with the very sparse data available for the estimation of risk associated with RTE products. While more complex analysis (e.g., detailed representation and simulation) is possible for a problem of smaller scope, providing risk estimates for

a considerable number and variety of RTE meat and poultry products requires considerable simplification of the problem to make the analysis tractable.

5.2 Classification of Products Considered in the Assessment

A significant challenge in assessing the risks associated with RTE products is finding an appropriate classification of products to satisfy a number of requirements including the practical consideration of data and evidence compatibility, for example:

- Inclusive of product classes specifically identified in risk management questions
- Need to distinguish among meat and poultry since *Salmonella* contamination in raw materials varies considerably
- Compatible with scientifically and practically important product distinctions (e.g. ground vs. intact, thermal versus non-thermal inactivation)
- Compatible with sources of production volume data
- Compatible with Research Triangle International (RTI) compliance data (RTI, 2005)
- The categories and specific products considered should also provide reasonable coverage of the spectrum of RTE meat and poultry products.

The product characterizations and product classes required a compromise among competing needs, including those described above.

5.2.1 Product Risk Categories

For purposes of this risk assessment, six product risk categories have been identified within which all RTE products could be categorized. The product risk categories are given in Table 5-1. In other risk assessments of the same products (e.g. for growth of other pathogens such as *C. perfringens* during cooling and hot-holding of RTE product), a different set of categories would be considered appropriate.

Table 5-1: Product risk categories identified as applicable to the categorization of RTE products for this assessment.

Risk Category	Description
CUNSS	Fully Cooked, Uncured, Non-Shelf-Stable
CCNSS	Fully Cooked, Cured, Non-Shelf-Stable
FCSS	Fermented or Direct Acidified, Cooked, Shelf-Stable
FUSS	Fermented or Direct Acidified, Uncooked, Shelf-stable
DH	Dried (incl. heat treatment)
DN	Salt-cured (dried, no heat)

The above product risk categories can be characterized by 5 descriptive risk factors *that* are used here to guide the assignment of RTE products to the product risk categories and to assign risk factors in the risk assessment. The factors are Primary Control Mechanism, Controllability, Role of Formulation in Lethality, Margin of Safety, and Re-growth of Pathogens. These factors are described as follows.

Primary Control Mechanism: Variation in the primary control mechanism is important in determining the overall risk in the product. Thermal processes are seen as much more controllable and predictable, while processes *that* depend more upon biological and formulation-related phenomena (for example, fermentation and curing) are seen as less controllable and less predictable, when compared to thermal processing.

Controllability: Each risk category is assigned a degree of controllability related to the ability to manage the primary control mechanism (note this does not refer to the potential variability that may be inherent in the control mechanisms applied).

Role of Formulation in Lethality: To the extent that formulation is an important component of achieving lethality, the risk can be expected to increase due to process variability and due to variability in processors' ability to understand, predict and ensure a prescribed degree of lethality.

Margin of Safety: For various reasons, the processing of products may have varying margins of safety relative to a prescribed degree of lethality. This can be due to quality considerations (consistency of coloration or organoleptic properties

tending toward more thorough cooking), yield considerations (tending toward less thorough cooking) or concerns regarding other pathogens (for example, *Escherichia coli* O157:H7, perhaps resulting in more thorough cooking than prescribed). An additional contributor to the margin of safety is related to the nature of contamination of the product. Intact product is much more likely to achieve complete lethality where contamination is limited to the surface. Comminuted product reduces the margin of safety due to the distribution of pathogens throughout the product and further from the source of heat.

Re-growth of Pathogens: Though the ideal is removal of all pathogens, when considering a large volume of RTE meat, some survival of organisms is expected. Given otherwise equivalent pathogen survival potential, products that allow the resuscitation and re-growth of pathogens lead to higher ingested doses, and therefore an associated higher risk of illness.

Table 5-2 provides characterizations of the risk categories with respect to the risk factors described above.

Table 5-2: Description of risk factors by product category that are used to classify RTE products

Risk Category	Description of Risk Factor						
	for Risk Category						
Risk Factor: Primary Control Mechanism							
CUNSS (Fully Cooked, Uncured, Non-	Thermal process is the primary control						
Shelf-Stable)	mechanism.						
CCNSS (Fully Cooked, Cured, Non-Shelf-	Thermal process is the primary control						
Stable)	mechanism.						
FCSS (Fermented or Direct Acidified,	Fermentation or direct acidification is primary						
Cooked, Shelf-Stable)	control mechanism with thermal processing						
	providing additional lethality.						
FUSS (Fermented or Direct Acidified,	Fermentation is the primary control						
Uncooked, Shelf-stable)	mechanism.						
DH (Dried (incl. heat treatment))	Thermal process provides primary lethality						
	and water activity provides further control						
DN (Salt-cured (dried, no heat))	Water activity (control of brine concentration)						
Disk Frates, Oractes Hability	is primary control mechanism.						
Risk Factor: Controllability	Manyllinh						
CUNSS	Very High						
CCNSS	Very High						
FCSS	Moderate						
FUSS	Low						
DH DN	Moderate						
	Low						
Risk Factor: Role of Formulation in Le	, ,						
CUNSS	Not Critical						
CCNSS	Not Critical						
FCSS	Critical						
FUSS	Critical						
DH	Critical						
DN	Critical						
Risk Factor: Relative Margin of Safety							
CUNSS	Large						
CCNSS	Large						
FCSS	Variable						
FUSS	Small						
DH	Small						
DN	Variable						
Risk Factor: Re-Growth of Pathogens							
CUNSS	Permits Growth						
CCNSS	Permits Some Growth						
FCSS	Controlled						
FUSS	Controlled						
DH	No Growth						
DN	No Growth						

5.2.2 Product Classes

For purposes of this risk assessment, a range of product classes have been assessed to represent the spectrum of RTE meat and poultry products available. Based upon consideration of the categorization of the product risk categories (as presented in Table 5-2) the product classes have been assigned to risk categories as presented in Table 5-3. Note that some degree of compromise is necessary when grouping products together to allow assignment to risk categories. For example, Corned beef is included with Roast beef because it is assumed that they are both made from intact product. From a risk estimation point of view, this is a much more important distinction, as it is then assigned a high thermal process safety factor (as described later in this report), than the fact that it is cured and cooked.

Product Class	Risk Category Assignment
Roast Beef, Corned Beef	CUNSS
Fully Cooked Beef Patties	CUNSS
Cooked Pork (Cooked Ham, Pork BBQ)	CUNSS
Cooked Turkey (non-Deli)	CUNSS
Cooked Chicken (non-Deli Meat, non-patty)	CUNSS
Cooked Poultry Deli Meat	CUNSS
Cooked Chicken Patties	CUNSS
Beef / Pork Frankfurters	CCNSS
Beef / Pork Bologna	CCNSS
Poultry Frankfurters	CCNSS
Semi-Dry FS: Summer Sausage, Cervelat, Thuringer	FCSS
Dry FS: Salami, Pepperoni, Chorizo, Soudjuk	FUSS
Meat Sticks	DH
Beef Jerky	DH
Country Ham	DN
Prosciutto, Cappicola, Pancetta, Basturma	DN

Table 5-3: Risk category assignment of RTE products

5.3 Raw Material Pathogen Burden

A primary factor in estimating the impact of lethality standards is the quality of the raw materials used in the product to which the lethality process is applied. The most common assumption applied in estimating the impact of thermal inactivation processes is that, for any given process, each organism has an individual and identical chance of survival in that process. When applying such a binomial survival process across multiple production units (that is, a process where there are only two discrete outcomes: survival or inactivation), one of the implications is that the total number of surviving organisms in the total production volume is

governed by the total number of organisms in the system, and the chance of survival in the process. In other words, the exact allocation of organisms among the production units before lethality does not have an impact on the total number of survivors. The implication of this binomial assumption is that the number of surviving organisms can be estimated by the combination of the total number of organisms in the system and the lethality of the process, regardless of the variability of contamination levels among the production units. Therefore, the most appropriate measure of the raw material quality is the total pathogen burden in the raw materials of the process. This can be calculated by estimating the arithmetic mean level of organisms in a unit of product (including the prevalence of organisms) and then extrapolating the mean to an entire raw material lot. This lot can be defined as the total for a day's production, a plant's annual production, or the total production of an industry using a given raw material.

5.3.1 Estimating the Raw Material Pathogen Burden

The raw material quality estimates are based on the FSIS Baseline Microbiological Surveys carried out in 1992-1997 (FSIS, 1994; FSIS 1996a-g; FSIS, 1998). This data collection program sampled ground beef (by mass) and carcass surfaces (by surface area). There are no complete datasets readily available that provide current estimates of the levels of salmonella in the range of raw materials considered in this risk assessment, therefore the assumption is made that the FSIS Baseline surveys represent the current situation. Samples were taken post chilling, prior to any further processing. Therefore, all stages prior to further processing that may influence the microbial profiles of the product are represented in these data sets. However, any growth or other factors that influence the level of contamination with Salmonella that occur post-chilling are not incorporated. The assumption is made that the contribution of factors affecting contamination levels post-chill is minimal. The estimation process considers two main streams of raw materials: ground product and intact product. These sources are also broken down by the animal source from which they are derived, specifically beef, pork, chicken and turkey.

The pathogen load for a given raw material is computed by multiplying sample prevalence with the mean MPN (Most Probable Number) concentration in contaminated samples. Prevalence is computed by dividing the number of contaminated samples by the total number of samples to generate a prevalence fraction. The MPN concentration of positive samples is extracted from the survey data by taking the mean of MPN values from positive samples.

While the general method of calculation is the same for each raw material, the exact method depends on whether the raw material is ground or intact. The total pathogen burden was determined for ground and intact beef, chicken, turkey, and pork. The total pathogen load for a raw material is expressed in units of CFU/MKg, where CFU (colony forming units) measures the number of organisms

and MKg refers to millions of kilograms. For convenience this is also presented in CFU/g where ever possible (note this is a difference of 9 on the log scale).

5.3.1.1 Ground Raw Materials

Data for ground raw materials (e.g. ground beef, ground poultry, ground pork) is derived from the Microbiological Baseline Surveys. For ground product, raw data was available in spreadsheet form (Marks, personal communication).

For each sample set, two methods were used to estimate the pathogen burden of the raw materials. In both methods, a mean MPN/g pathogen burden in contaminated samples is multiplied by the prevalence of contaminated samples to compute a mean MPN/g concentration for each raw material supply. This value was then scaled up by a factor of 10⁹ to derive an estimate of the pathogen burden in units of CFU/MKg (a million kilograms is equivalent to 10⁹ grams).

Method 1: Excluding Non-Detects

In this method, only those samples that were found to be qualitatively positive, and whose MPN/g concentration could be quantitatively established were used.

The mean MPN/MKg, M_{GM} , is given by equation 1, where S_q is the number of samples that were qualitatively positive and enumerated, *S* is the number of samples, m_p is the mean MPN of the positive samples, and the multiplication factor of 10⁹ is applied to scale up to MKg.

$$M_{GM} = \frac{S_q}{S} \times m_p \times 10^9 \tag{1}$$

Method 2: Including Non-Detects

A second method was investigated where all samples that were found to be qualitatively positive were included. The lowest detected value was 0.03 MPN/g. Those samples whose MPN/g concentration could not be established quantitatively were assigned a value of 0.04 MPN/g. Using method 2, the mean MPN/MKg in ground materials, M_{GM} , is given by equation 2. Here, *S* is the total number of samples, S_p is the number of samples that were qualitatively positive, S_q is the number of samples that were qualitatively positive and enumerated, m_p is the mean MPN of the positive samples, *n* is the assumed MPN of positive samples that were not enumerated, and the multiplication factor of 10^9 is applied to scale up to MKg.

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$$M_{GM} = \frac{S_p}{S} \times \frac{\left(m_p \times S_q\right) + \left(m_{ne} \times \left(S_p - S\right)_q\right)}{S_p} \times 10^9$$
(2)

Comparison of Methods

The two methods were compared using ground beef as an example. For ground beef there were 563 samples (S = 563), of these samples 29 were qualitatively positive ($S_p = 29$) and 8 samples were enumerated ($S_q = 8$), the mean MPN of positive samples was 31 CFU/g ($m_p = 31$). Assuming positive samples that were not enumerated have a mean MPN of 0.04 CFU/g ($m_{ne} = 0.04$), method 1 results in an estimate of 440x10⁶ CFU/MKg and method 2 an estimate of 442x10⁶ CFU/MKg. This difference between the two calculation methods is negligible in the context of the overall uncertainty.

5.3.1.2 Assumed Mean MPN/g for Non-quantified Positive Samples

Given the lowest level in the quantified samples was 0.03 MPN/g, a value of 0.04 MPN/g is a reasonable assumption for non-quantified positive samples. We can examine the sensitivity to this assumption. Increasing this value 10 fold from 0.04 MPN/g to 0.4 MPN/g increases the final M_{GM} from 442 x 10⁶ CFU/MKg to 455 x 10⁶ CFU /MKg. Decreasing the value 10 fold to 0.004 MPN/g reduces the final M_{GM} from 442 x 10⁶ CFU /MKg. Decreasing the value 10 fold to 0.004 MPN/g reduces the final M_{GM} from 442 x 10⁶ CFU /MKg to 441 x 10⁶ CFU /MKg. As the assumed concentration is reduced further, the final M_{GM} value will approach that of Method 1 in which the assumed value is effectively 0 MPN/g. As such, the value of M_{GM} is relatively insensitive to the value selected for the non-quantifiable concentration, if that concentration remains within reasonable bounds.

5.3.1.3 Assumed Maximum Concentration in Quantifiably Positive Samples Due to limitations of the quantification method used to establish the pathogen concentration in qualitatively positive samples, a value of 240 MPN/g was assumed for samples where all tubes of the MPN procedure were positive resulting in a report of 'higher than 110 MPN/g' (Marks, personal communication). Only one sample was assigned this value (ground beef). Exploring the sensitivity of this assumption, a four-fold increase in this value results in a approximately four-fold increase in the final M_{MKg} value. A forty-fold increase results in a approximately forty-fold increase. The relationship for higher values is approximately linear. Reducing the value to 110 MPN/g reduces the final M_{GM} value to 200 x 10⁶ CFU /MKg. The final M_{GM} value, therefore, is dominated by this single assumption. This assumption does not apply to the chicken, turkey or pork samples. A summary of the pathogen burden estimate for intact product used in the assessment is given in Table 5-4.

Ground Product	Beef	Chicken	Turkey	Pork
Number of samples (S)	563	285	296	543
Number positive and enumerated (S_q)	8	76	32	26
Number positive not enumerated ($S_p - S_q$)	21	56	63	50
Mean MPN enumerated positives (m_p)	31	33	8	3
Assumed mean MPN positives not enumerated (m_{ne})	0.04	0.4	0.4	0.04
Mean MPN/MKg ($M_{_{GM}}$)	4.42 x 10 ⁸	8.88 x 10 ⁹	9.50 x 10 ⁸	1.47 x 10 ⁸
Log $M_{_{GM}}$	8.65	9.95	8.98	8.17

Table 5-4 Summary of Salmonella Pathogen Burden Results for Ground Product

* For data sources and associated assumptions see Appendix 1

5.3.1.4 Intact Raw Materials

The total pathogen load for intact raw materials is derived from carcass data in the FSIS Baseline Microbiological Surveys. In this case, only summary data was available as binned MPN data.

Prevalence is computed similarly to ground materials in that the number of positive samples is divided by the total number of samples to generate a prevalence fraction.

MPN concentration is computed as follows. Each positive sample is assigned to one of five bins based on the observed concentration. The bins range from < 0.03 MPN/unit to > 30 MPN/unit. The unit is *ml* for poultry carcass rinse samples and cm^2 for beef and pork carcass surface swab samples. The designated MPN/unit of each bin is multiplied by the percentage of positive samples whose measurement fell in each bin. The sum of these values is taken to be the mean concentration across all positive samples. The mean concentration in positive samples is multiplied by the prevalence fraction to determine a mean concentration for the raw material. This value is multiplied by a surface-area to mass conversion factor to convert to a standard CFU/kg value. The mean MPN/MKg in intact raw material, M_{RM} , is given by equation 3, where S_q is the number of samples that were qualitatively positive and enumerated, S is the number of samples, m_n is the mean MPN of the positive samples, A is the area of the carcass it is assumed there is contamination. This area is used to extrapolate the MPN samples to a total level of contamination. This is not known, but is less than the total surface area of the carcass ($cm^2/carcass$), W is the mass of the carcass (kg), and the multiplication factor of 10^6 is applied to

scale up to MKg. These steps are similarly implemented for cattle, broilers and turkeys. Note that for broilers and turkeys *A* and m_p are measured in relation to ml/carcass rather than cm²/carcass.

$$M_{RM} = \frac{\frac{S_q}{S} \times m_p \times A}{W} \times 10^6$$
 (3)

Mean MPN/cm²

The assumed MPN/cm² was taken as the midpoint of the bin. For the minimum, a value of half of the minimum was assumed. For the bin > 30.0 (no samples for pork) a value of 5 times the maximum (150) was assumed.

Sensitivity to assumptions

As the data were provided in bins of concentration ranges, a mean value was assumed for each bin. However, the final bin is quantified as > 30. Similarly to ground products, the final M_{RM} value will be dominated by any samples in the final bin since they will contribute significantly to the mean value. This does not apply to pork, as there were no samples in this bin. However, even in pork one can observe that the final M_{RM} value is heavily weighted by the number of samples in the bin with the highest concentration. A summary of the pathogen burden estimate for intact product used in the assessment is given in Table 5-5.

Intact Product	Chicken	Turkey	Cattle	Pork
Number of samples (S)	1297	1221	4201	2112
Number positive and enumerated (S_q)	260	227	72	169
Mean MPN enumerated positives (m_p)	2.29 ml	0.23 ml	4.03 cm ²	0.91 cm ²
Area of extrapolation (A)	400 ml	600 ml	10000 cm ²	2500 cm ²
Mass of carcass (W)	1.36	4.77	350	86
Mean CFU/MKg (M_{RM})	1.35 x 10 ⁸	3.61 x 10 ⁶	1.97 x 10 ⁶	2.11 x 10 ⁶
Log M _{RM}	8.13	6.56	6.30	6.32

Table 5-5: Summary of Salmonella spp. Burden Results for Intact Product

* For data sources and associated assumptions see Appendix 1

5.3.2 Uncertainty in the Estimation of the Raw Material Pathogen Burden

When considering the application of the FSIS Microbiological Baseline Surveys data to estimate the raw material pathogen burden there are two dominant sources of uncertainty. The first key uncertainty is based on the time *that* has elapsed since this data collection was performed. Major changes in the industry related to *Salmonella*-based performance standards may have had a considerable impact on the average microbiological quality of the raw materials used in RTE products. Without a renewed and comparable baseline study it is not possible to fully characterize this effect and the attendant uncertainty.

A second key source of uncertainty that concerns the FSIS Microbiological Baseline Surveys data relates to the sampling and enumeration processes applied. In the generation of the baseline data, the enumeration of contamination levels was undertaken using the MPN method. The adequacy of the collection methods, the representativeness of the samples taken, the sensitivity of the tests that were performed, and the use of the MPN enumeration method makes it very challenging to provide a best estimate for the aggregate level of contamination in the raw materials, and equally difficult to provide a full characterization of the range of uncertainty. As an example, in at least one case, the overall estimate of contamination of the raw materials is highly dependent upon an assumed value for the maximum concentration (for example, the value of 240 MPN/g was assumed in a data set to represent the concentration of organisms in the case where all tubes at all dilutions were positive in an MPN enumeration sample). As the highest value among the enumerated samples, the mean contamination is acutely sensitive to this value. Clearly, in this case, the actual concentration could have been somewhat lower or very much higher.

Various statistical techniques and arguments might be employed to correct the MPN estimates for the sensitivity associated with sampling collection (carcass rinse recovery, surface swab recovery, qualitative detection, and enumeration) though no formal analysis of the sensitivity was available. However, it is judged that this effort would be largely uninformative, as the bounds of uncertainty would remain quite broad given the numerous substantial sources of uncertainty that are more difficult to quantify.

Arguably, consideration of the efforts of processors (since the FSIS Microbiological Baseline Surveys study was performed) toward meeting raw material performance standards would imply downward pressure on estimates of the current levels of contamination. Conversely, the impact of test sensitivity on the prevalence and concentration estimates in the Baseline study would exert upward pressure on the Baseline estimates. Given these competing potential revisions to estimates of current contamination levels (with the recognition that

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other potential revisions are worthy of consideration) an assumption is made that the Baseline microbial data will serve as a surrogate for the current microbiological quality of raw materials. It should be recognized that the uncertainty bounds surrounding these best estimates would span orders of magnitude (i.e., factors of 10 in either direction) even after detailed characterization. This assessment can be repeated with updated information on raw material quality in the future.

5.3.3 Assignment of Raw Materials to RTE Products

Section 5.3.1 presents the estimation process for the raw material pathogen burden for ground and intact beef, chicken, pork, and turkey. This burden is expressed as a concentration in units of CFU/MKg. For use within the risk assessment process, this value must be translated to a pathogen burden for the RTE product categories. This is achieved by defining the composition of each RTE product category in terms of its raw materials.

The assignment of raw materials (ground and intact beef, chicken, pork, and turkey) to each RTE product category is given in Table 5-6. When more than one raw material is assumed, fractions were assigned as indicated. The model allows for alternate assignments of raw materials and alternate fractions to be applied to the raw materials. This assignment of raw materials in Table 5-6 results in estimates of the pathogen burdens in the RTE products before the lethality process is applied using the pathogen burdens described in section 5.3.1 weighted by the contribution the raw material to a given product.

Table 5-6: Assignment of raw materials (ground and intact beef, chicken, pork, and	
turkey) to each RTE product category	

RTE Product Category	Raw Material Composition
Roast Beef, Corned Beef	Intact Beef
Fully Cooked Beef Patties	Ground Beef
Cooked Pork (Cooked Ham, Pork BBQ)	Intact Pork
Cooked Turkey (non-Deli)	Ground Turkey
Cooked Chicken (Nuggets, Tenders, non-Deli)	Ground Chicken
Cooked Poultry Deli Meat	50% Ground Chicken, 50% Ground Turkey
Cooked Chicken Patties	Ground Chicken
Beef / Pork Frankfurters	50% Ground Beef, 50% Ground Pork
Beef / Pork Bologna	50% Ground Beef, 50% Ground Pork
Poultry Frankfurters	50% Ground Chicken, 50% Ground Turkey
Summer Sausage, Thuringer, Cooked	50% Ground Beef, 50% Ground Pork
Pepperoni	
Salami, Uncooked Pepperoni, Chorizo,	50% Ground Beef, 50% Ground Pork
Soudjuk	
Meat Sticks	Ground Beef
Beef Jerky	Ground Beef
Uncooked Country Ham	Intact Pork
Prosciutto, cappicola, pancetta, basturma	Intact Pork

5.4 Impact of Lethality Standard

Given the pathogen burden determined for each RTE product prior to processing one can estimate the post-processing pathogen burden for each RTE product. Specifically, the pathogen load post lethality, in terms of the pathogen load per MKg, R_L , is given by $R_L = P_B - L$ where P_B is the raw pathogen burden (on the log scale), and L is the lethality treatment applied (on the log scale). Note, this assumes that the lethality standard is the exact lethality achieved in the process. Modifications to this assumption are described in subsequent sections. For comparison purposes, three standard-setting scenarios were considered. The scenarios are labeled and described as presented in Table 5-7. Based upon the lethality scenarios, lethality standards are assumed for each product category. These standards are given in Table 5-8.

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Lethality Standard Scenario	Interpretation
All 5	All products are assigned a lethality standard of a 5-log reduction.
Split	A subset of products are assigned a lethality standard of 5-log and the remaining products are assigned a lethality standard of 6.5-log or 7-log (products containing poultry).
All 6.5/7.0	All products are assigned a lethality standard of 6.5-log or 7-log (for products containing poultry).

Table 5-7: Lethality standard scenarios considered in this risk assessment process

Table 5-8: Lethalities assigned to product categories under each lethality scenario considered in the assessment

RTE Product Category	Lethali	ty Standarc	I Scenario
	All 5	Split	All 6.5/7.0
Roast Beef, Corned Beef	5.0	6.5	6.5
Fully Cooked Beef Patties	5.0	5.0	6.5
Cooked Pork (Cooked Ham, Pork BBQ)	5.0	6.5	6.5
Cooked Turkey (non-Deli)	5.0	7.0	7.0
Cooked Chicken (Nuggets, Tenders, non-Deli)	5.0	7.0	7.0
Cooked Poultry Deli Meat	5.0	7.0	7.0
Cooked Chicken Patties	5.0	7.0	7.0
Beef / Pork Frankfurters	5.0	6.5	6.5
Beef / Pork Bologna	5.0	6.5	6.5
Poultry Frankfurters	5.0	7.0	7.0
Summer Sausage, Thuringer, Cooked Pepperoni	5.0	5.0	6.5
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	5.0	5.0	6.5
Meat Sticks	5.0	5.0	6.5
Beef Jerky	5.0	5.0	6.5
Uncooked Country Ham	5.0	5.0	6.5
Prosciutto, cappicola, pancetta, basturma	5.0	5.0	6.5

5.5 Incorporating Compliance with Lethality Standards

The extent of compliance with the standard is the first factor *that* can alter the effective lethality. For some products, processors may be assumed to consistently meet or exceed the standard, while others may have a portion of producers not meeting the standards. The goal of including this factor is to describe the relationship between a performance standard and the actual lethality achieved in practice.

Effective Lethality is defined as a composite measure of lethality where simple binomial lethality measures are combined to estimate the total number of surviving organisms across a heterogeneous set of binomial processes. The heterogeneity can be a result of changes in the physical process that is applied to destroy the organisms, variations in the physical location of the organisms such that they experience different processes, changes in the properties of the food medium affecting the probability of survival of a given process, or heterogeneity among the organisms themselves in their probability of survival of a given process. The composite measure is calculated as the total number of surviving organisms as a proportion of the total number of organisms being processed throughout the heterogeneous system.

As an alternate definition, the Effective Lethality is numerically equivalent to the level of Simple Binomial Lethality that, were it applied homogeneously across all of the processing units, would yield the same number of surviving organisms as the corresponding heterogeneous system.

As an example of Simple Lethality and Effective Lethality, consider a product made of two distinct parts. Part A contains 1,000 organisms and experiences a process that allows, on average, 0.1% of the organisms to survive (i.e., a 3-log process). Part B also has 1,000 organisms and experiences a process that allows, on average, 10% of the organism to survive (i.e., a 1-log process). In each part, a simple binomial calculation can be performed such that Part A will have, on average, 1 surviving organism. Part B will have, on average, 100 organisms. The total number of surviving organisms in the total product will be, on average, 101 organisms.

Note that the original population of 2,000 organisms (taking both Part A and B into account) has been reduced to an expected population of 101. The composite survival rate is (101/2000) or 5.05%. On the logarithmic scale, this constitutes a reduction of approximately 1.3-log. Note that the *Effective Lethality* of 1.3-log is considerably different from the 2-log reduction *that* might be estimated by taking the average of the two Simple Lethality values (i.e., 1-log and 3-log). If it were erroneously assumed that the Effective Lethality would be a 2-log reduction, this would generate an estimate that the number of survivors would be, on average, 20 (i.e., an underestimation of the number of survivors by a factor of 5).

Effective Lethality, L_{ef} (in log₁₀ units), can be calculated for a discrete heterogeneous system according to the following equation:

$$L_{ef} = -\log_{10} \left(\sum_{i} f_{i} \cdot 10^{-S_{i}} \right) = -\log_{10} \left(f_{1} \cdot 10^{-S_{1}} + f_{2} \cdot 10^{-S_{2}} + \dots \right)$$

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where *S* represents the lethality level, f_i represent appropriate fractions (which must sum to 1) for each of the discrete units of the heterogeneous system. For example, depending on the nature of the heterogeneity being considered, f_1 may indicate the fraction of the product mass in compartment 1, the fraction of pathogens that are from some sub-population (or strain) 1, or the fraction of plants achieving some specified lethality level, S_1 . Where there is heterogeneity in the lethality that varies continuously, the corresponding notation is:

$$L_{ef} = -\log_{10}\left(\int_{R} p_{S_x} \cdot 10^{-S_x} dx\right)$$

where p_s is the probability density of the distribution of *S* (on the log₁₀ scale).

In the special case of a uniform distribution (on the log10 scale) of variability in the lethality (e.g., where the lethality is equally likely anywhere in logarithmic intervals from 6 to 7 \log_{10} reductions), this integral evaluates to equation 5:

$$L_{ef} = -\log_{10} \left(\int_{a}^{b} \frac{1}{(b-a)} 10^{-s_{x}} dx \right) = -\log_{10} \left(\frac{10^{-a} - 10^{-b}}{(b-a) \cdot \log_{e}(10)} \right)$$
(5)

To illustrate the implementation of this formulation, consider a performance standard of 6-log. Assume that the performance of the industry in meeting this standard is such that 50% of the industry achieves between 5- and 6-log reduction and the other half achieves between a 6-log to 7-log reduction. Assume a log-uniform distribution between the endpoints such that all values between the endpoints are equally likely. The overall Effective Lethality achieved by the industry using equation 5 is 5.67-log. Now consider a possible change where the performance standard were changed to 6.5-log. If the industry responded such that 50% of the industry achieved between 5- and 6.5-log and the other half achieved between 6.5-7.0 log (in other words, the median lethality followed the performance standard, but the two extremes stayed the same) this would yield a resulting Effective Lethality of 5.82-log. Here, note that despite the 0.5-log shift in the performance standard, the Effective Lethality shifted only 0.15-log. This is a result of the failure of the worst-performing segments of the industry (i.e., those achieving lethalities near 5-log) to shift significantly higher.

Within the assessment, three levels of compliance are defined, a baseline assumption for those meeting and exceeding the standard, denoted S+1 to S; and two levels where the standard is not met denoted S to S-1.5, and S-1.5 to S-2.5. S indicates the standard and S+1 indicates 1 log above standard; S-1.5 indicates 1.5 logs below standard, and S-2.5 indicates 2.5 logs below standard. The assumption is that for each of these three categories there is a log-uniform

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distribution between the lower and upper bound, for example S and S+1. Using this assumption, the effective lethalities are calculated as previously described. Note that equation 5 can be used to estimate the compliance adjustment that should made to the lethality applied to give the overall effective lethality. For example, for S+1 to S using equation 5 the adjustment for compliance that needs to be made to the lethality is -0.4 therefore if the standard were 6.5, the effective lethality would be 6.9. A negative effective lethality indicates that the lethality achieved would be improved. The resulting compliance adjustment factors are given in Table 5-9

	Lower bound	Upper bound	Effective lethality
S+1 to S	0	1	-0.408
S to S-1.5	-1.5	0	0.9477
S-1.5 to S-2.5	-2.5	-1.5	2.092

Table 5-9: Upper and lower bound and compliance adjustment factors for the compliance levels considered in the assessment.

Based on data from an expert elicitation process (RTI, 2005), a set of compliance patterns have been assumed. The data indicates expert opinion regarding the proportion of processors that comply with a 6.5 or 7.0-log reduction and an alternate lower level of 5-logs. The RTI data presents the percentage of producers likely to obtain "less than 5 log reduction", "Between 5.0 and 6.5/7.0 log reduction", and "Reduction of 6.7/7.0 or above". This provides an indication of the level of lethality obtained. For split scenario the lethality standard is consistent with the RTI categories. The category "less than 5 log reduction" is used for the S-1.5 to S-2.5 level of lethality, "Between 5.0 and 6.5/7.0 log reduction" is used for S to S-1.5, and "Reduction of 6.7/7.0 or above" is used for S+1 to S. For the All 5 Log scenario the total of "Between 5.0 and 6.5/7.0 log reduction", and "Reduction of 6.7/7.0 or above" is used for the S+1 to S category, and "less than 5 log reduction" is used for S to S-1.5. Table 5-10 and Table 5-11 give the assumed percentage of the total industry supply that falls into each category of compliance based upon the available information. Note that for the products where the compliance with the 6.5 standard is 100%, it is assumed that under a 5-log standard they would relax to meet the lower standard rather than maintain the 6.5 level. An alternative scenario is included in the model *that* allows the impact of these processors maintaining the higher lethality; however, this is not described in this report.

RTE Product Category	S ₊₁ to S	S to S-1 5	S-1.5 to S-2.5
		_	0-1.0 10 0-2.0
Roast Beef, Corned Beef	100	0	0
Fully Cooked Beef Patties	100	0	0
Cooked Pork (Cooked Ham, Pork BBQ)	100	0	0
Cooked Turkey (non-Deli)	100	0	0
Cooked Chicken (Nuggets, Tenders, non-Deli)	100	0	0
Cooked Poultry Deli Meat	100	0	0
Cooked Chicken Patties	100	0	0
Beef / Pork Frankfurters	100	0	0
Beef / Pork Bologna	100	0	0
Poultry Frankfurters	100	0	0
Summer Sausage, Thuringer, Cooked Pepperoni	75	25	0
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	65	35	0
Meat Sticks	79	21	0
Beef Jerky	83	17	0
Uncooked Country Ham	95	5	0
Prosciutto, cappicola, pancetta, basturma	99	1	0

Table 5-10: For a 5-log Standard based on expert survey (RTI, 2005)

Table 5-11: For a 6.5/7.0-log Standard based on expert survey (RTI, 2005)

RTE Product Category	S+1 to S	S to S-1.5	S-1.5 to S-2.5
Roast Beef, Corned Beef	84	11	5
Fully Cooked Beef Patties	98	2	0
Cooked Pork (Cooked Ham, Pork BBQ)	98	2	0
Cooked Turkey (non-Deli)	98	2	0
Cooked Chicken (Nuggets, Tenders, non-Deli)	98	2	0
Cooked Poultry Deli Meat	93	7	0
Cooked Chicken Patties	98	2	0
Beef / Pork Frankfurters	98	2	0
Beef / Pork Bologna	98	2	0
Poultry Frankfurters	98	2	0
Summer Sausage, Thuringer, Cooked Pepperoni	54	20	25
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	42	23	35
Meat Sticks	46	33	21
Beef Jerky	45	38	17
Uncooked Country Ham	48	47	5
Prosciutto, cappicola, pancetta, basturma	48	51	1

The compliance adjustments given in Table 5-12, that result from calculating the effective lethality based upon the compliance levels given in Table 5-10 and

Table 5-11, are used to offset the effective lethality relative to the standard applied. Using Roast Beef as an example, the performance is assumed to just 'meet or exceed' the reduced standard of 5-log, resulting in an offset of 0.4 and an overall effective lethality of 5.4.

Table 5-12 : Adjustments for compliance by product category. Note: Negative Values imply that the effective lethality would exceed the assigned standard. Positive values imply that the effective lethality would be below the standard.

Product category	Compliance Adjustments to Post-Lethality Surviving Pathogen Burden (Change in Log ₁₀ CFU / MKg relative to simple lethality calculation)				
	All 5 Split All 6.5/7				
Roast Beef, Corned Beef	-0.41	-0.41	-0.41		
Fully Cooked Beef Patties	-0.41	-0.41	-0.41		
Cooked Pork (Cooked Ham, Pork BBQ)	-0.41	-0.41	-0.41		
Cooked Turkey (non-Deli)	-0.41	-0.41	-0.41		
Cooked Chicken (Nuggets, Tenders, non-Deli)	-0.41	-0.41	-0.41		
Cooked Poultry Deli Meat	-0.41	-0.41	-0.41		
Cooked Chicken Patties	-0.41	-0.41	-0.41		
Beef / Pork Frankfurters	-0.41	-0.41	-0.41		
Beef / Pork Bologna	-0.41	-0.41	-0.41		
Poultry Frankfurters	-0.41	-0.41	-0.41		
Summer Sausage, Thuringer, Cooked Pepperoni	-0.07	-0.07	0.93		
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	0.26	0.26	1.38		
Meat Sticks	0.26	0.26	1.36		
Beef Jerky	0.34	0.34	1.44		
Uncooked Country Ham	-0.41	-0.41	0.09		
Prosciutto, cappicola, pancetta, basturma	0.09	0.09	1.10		

5.6 Application of Thermal Process Safety Factors

For the purposes of this risk assessment, a thermal process is defined as any process that incorporates some form of heat treatment. When the required lethality of the process is defined (or interpreted) as that required to achieve a specified log reduction at the coolest point in the product, this results in a net effective lethality that is considerably higher than the defined lethality. This is

primarily due to the necessity of transferring heat through to the inside of the product. This requires that most of the mass of the product will experience a much higher level of lethality than the coolest point. In other instances, product quality considerations may dictate a higher level of lethality than is required by regulation. For perfectly intact products that are heated to cook the inside of the mass, yet are assumed free of pathogens below the surface of the product, the thermal process safety factor for any such lethality process can be quite high.

The problem arises as the typical implementation of a process to comply with a lethality standard for thermal inactivation will yield a much lower probability of survival for pathogens than is implied by a literal translation of the lethality standard. For example, the implementation of a process to comply with a 5-log standard results in a probability of survival that is much lower than 10⁻⁵. By ignoring this reality, the risk assessment would over-estimate the risk for certain classes of products. At the same time, by including this reality there is a considerable challenge of attempting to distill the complex and variable situations that determine these safety factors for a large variety of products *that* may be treated using varying, and proprietary, processes.

There is no direct evidence available detailing the proportion of the wide variety of processes applied in the production of RTE foods that might be associated with certain safety factor characteristics. In addition, process experts are primarily accustomed to designing and assessing processes on the basis of compliance, ensuring that processes satisfy specific regulatory criteria, and do not directly employ the concept of the effective lethality that is achieved in the process if it is above the criteria. However, the health risk associated with any process is proportional to the actual net effective lethality achieved, not the numeric value of the standard that is applied.

To address this issue, Thermal Process Safety Factors (TPSF) are used to adjust the level of lethality for a given product. In the absence of available data enabling the detailed specification of the lethality treatments and simulations of all of the many alternate combinations of treatments that may be applied in the production of any given RTE product, there is no alternative to applying these safety factors as a matter of judgment. As a result, this estimate of safety factors is an area of the risk assessment associated with a high degree of uncertainty. With this in mind, the risk model has been developed with the option to exclude the application of the TPSF. This results in significantly higher risk estimates for most products and results in a much higher estimate of overall public health risk. Despite the problems with estimating these safety factors, their exclusion is not necessarily preferable.

The model considers three levels of the TPSF: small (no adjustment), moderate (a further 2-log reduction), and large (a further 4-log reduction). The TPSF are assigned to the RTE products as shown in Table 5-13.

Table 5-13: Assignment of Thermal process safety factors (TPSF) by RTE product category.

RTE Product Category	TPSF	Rationale
Roast Beef, Corned Beef	Large	Product is typically intact (meat is sterile at coolest point) and requires considerable heating of the surface and near-surface mass to cook the internal mass of the product.
Fully Cooked Beef Patties	Moderate	Ground product, assumed to be cooked with fixed temperature and holding time requirements based on current regulatory requirements yielding high margin of safety.
Cooked Pork (Cooked Ham, Pork BBQ)	Large	Product is typically intact (meat is sterile at coolest point) and requires considerable heating of the surface and near-surface mass to cook the internal mass of the product. Consumer aesthetic preferences may dictate that the product be well- cooked.
Cooked Turkey (non-Deli)	Moderate	Not assumed to be intact, but assumed to be thoroughly cooked as a large mass.
Cooked Chicken (Nuggets, Tenders, non-Deli)	Moderate	Not assumed to be intact, but assumed to be thoroughly cooked for product quality and consumer preferences.
Cooked Poultry Deli Meat	Moderate	Not assumed to be intact, but assumed to be cooked as a large mass.
Cooked Chicken Patties	Moderate	Ground product, not large mass. Quality and consumer preferences may dictate a well-cooked product.
Beef / Pork Frankfurters	Moderate	Comminuted product, but quality considerations may dictate cooking in excess of minimal lethality requirements
Beef / Pork Bologna	Moderate	Comminuted product, but cooked in large mass. Quality considerations may dictate cooking in excess of lethality requirements.
Poultry Frankfurters	Moderate	Product quality considerations may dictate that higher lethalities are likely.
Summer Sausage, Thuringer, Cooked Pepperoni	Small	Desirable product characteristics require minimizing product heating such that significant over-cooking is unlikely.
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	Small	Desirable product characteristics require minimizing product heating such that significant over-cooking is unlikely.
Meat Sticks	Small	Lethality process is slow, variable and does not involve lethal heat treatments. Unlikely to result in significant over-treatment.
Beef Jerky	Small	Lethality process is slow, variable and does not involve lethal heat treatments. Unlikely to result

		in significant over-treatment.
Uncooked Country Ham	Small	Lethality process is slow, variable and does not involve lethal heat treatments. Unlikely to result in significant over-treatment.
Prosciutto, cappicola, pancetta, basturma	Small	Lethality process is slow, variable and does not involve lethal heat treatments. Unlikely to result in significant over-treatment.

5.7 Impact of Storage and Growth

Following lethality treatment, a significant majority of the finished products will contain no *Salmonella*. However, there will be some products *that* remain contaminated with *Salmonella* that survived lethality treatment. The contaminating organisms may grow during storage, increasing the number of organisms. Therefore, the impact on public health of a change in the effective lethality achieved is dependent on the downstream storage and resulting growth potential of pathogens in the product.

5.7.1 Number of Organisms in Contaminated RTE Product

For a product that is initially contaminated at a level well below 10^{L} per serving where *L* is the lethality of the process to be applied, the surviving organisms will be sufficiently sparsely populated within the final product as to be distributed as one surviving organism in individual contaminated serving-sized portions. For example, consider the combination of serving sizes and pre-lethality pathogen concentration levels given in Table 5-14.

Concentration	Serving Size (g)						
(CFU/g)	1 10 100 100						
0.001	0.001	0.01	0.1	1			
0.01	0.01	0.1	1	10			
0.1	0.1	1	10	100			
1	1	10	100	1 000			
10	10	100	1 000	10 000			

Table 5-14: Mean pathogen count per serving for a range of concentrations (CFU/g) and serving size (g).

In the above scenarios, the mean number of pathogens in a single serving before lethality treatment ranges from 10^{-3} to 10^4 pathogens. A model was built to evaluate the probability of survival for each of these scenarios given lethality values from two to six logs. The probability that some pathogens survive in a

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serving undergoing the lethality treatment was established using a binomial survival model. The mean results, expressed as percentages, are summarized in Table 5-15.

Table 5-15: Mean probability of pathogen survival resulting from a binomial survival model, specifically the probability that more than 1 organisms per serving (p>1) and the probability that more than 2 organisms (p>2) survive the lethality process for given pathogen counts per serving (CFU). [Note: only lethalities of 5 and above are considered in this assessment.]

	Lethality Value									
	21	og	31	log 4 log 5 log 6		5 log		6 I	og	
CFU	p>1	p>2	p>1	p>2	p>1	p>2	p>1	p>2	p>1	p>2
10 ⁻³	>0	>0	>0	>0	>0	>0	>0	>0	>0	>0
10 ⁻²	>0	>0	>0	>0	>0	>0	>0	>0	>0	>0
10 ⁻¹	2x10 ⁻³	7x10 ⁻⁷	2x10 ⁻⁴	7x10 ⁻⁹	2x10⁻⁵	7x10 ⁻⁹	2x10⁻ ⁶	5x10 ⁻¹¹	2x10 ⁻⁷	2x10 ⁻⁹
10 ⁰	0.2	4x10 ⁻⁴	0.02	4x10 ⁻⁶	2x10 ⁻³	4x10 ⁻⁸	2x10 ⁻⁴	4x10 ⁻¹⁰	2x10 ⁻⁵	1x10 ⁻⁹
10 ¹	4	0.1	0.4	1x10 ⁻³	0.04	1x10⁻⁵	4x10 ⁻³	1x10 ⁻⁷	4x10 ⁻⁴	4x10 ⁻⁹
10 ²	40	10	5	0.2	0.5	2x10 ⁻³	0.05	2x10 ⁻⁵	5x10 ⁻³	2x10 ⁻⁷
10 ³	99.9	99.7	40	10	5	0.2	0.5	2x10 ⁻³	0.05	2x10 ⁻⁵
10 ⁴	100	100	99.9	99.7	40	10	5	0.2	0.5	2x10 ⁻³

The results show that when L is 2 logs higher than the mean number of pathogens in a serving (for example a lethality of 2 logs for a pathogen count of 1 CFU (10⁰) per serving), the proportion of servings where there is survival that contain more than one pathogen is less than 1 percent. The proportion where more than two survive is less than 0.0004 percent. When L is only 1 log higher than the mean population, then there is more than one survivor 4 percent of the time, but more than two only 1 time in a 1000. When L is the same as the mean count, there is more than one survivor 40 percent of the time, and more than two 10 percent of the time. When L is less than the mean number of pathogens, there is typically more than one survivor. Therefore, even for situations where L is at least one log higher than the mean pathogen count in a serving, the single CFU per contaminated serving is a reasonable assumption. The condition cited above (that the product be contaminated at less than 10^{L} in serving-sized portions) would need to be considered in determining the scope of application of this assumption. For the lethality standard values (L=5 to 7 log₁₀) and contamination levels (up to 10 CFU/g) discussed in this report, this condition is readily met. However, at lethality levels of 4 and lower this assumption may not apply.

There will inevitably be situations where a product has highly localized levels of contamination that may exceed 10^{L} in a serving size and may therefore result in more than 1 surviving organism per serving. The net incremental impact of these particular servings is proportional to their frequency and the incremental risk associated with having more than 1 organism. It is assumed here that the rare

nature of locally high levels of contamination that would result in multiple surviving organisms in serving-sized portions of the final product counteracts the incremental risk associated with these portions such that the net impact of these particular servings on public health is not significant relative to the great majority of contaminated servings.

Based on the above assumptions, for present purposes servings of RTE products *that remain contaminated following the lethality treatment* will be considered to have 1 surviving organism per serving-sized portion at the end of the process. The properties of the product and its storage conditions (and reheating) will determine the amount of population growth and thereby, the final number of organisms at the time of consumption.

The great majority of those products that would remain contaminated after a suitable lethality process will have very low level contamination and are therefore assumed to have a single surviving organism in any serving-sized portion. Further, as products are subject to thermal processing, it is likely that any surviving organism will be imbedded deep in the product and would therefore be less likely to be involved in any scenarios of cross-contamination associated with simple handling of the product. The imbedded nature of the surviving organisms may also have impacts on the maximum population density. These factors have not been included in the current analysis, but further investigation may show them to be important.

5.7.2 Storage and Growth model

Modeling the storage of RTE products and any subsequent growth of any contaminating salmonella allows the examination of the contribution of growth during retail and consumer storage to the final doses consumed. For products that have the potential to allow growth, the amount of growth experienced by any given serving will range from no-growth to the achievement of the maximum population density. In situations where growth is permitted, the growth rate will depend on temperature and product characteristics. Given the diversity both within and between RTE products, a complete characterization of the growth potential of products considered is beyond the scope of this analysis. The estimation of the degree of growth *that* occurs in RTE products is estimated through consideration of the duration and temperature of storage during retail and consumer storage as illustrated in Figure 5-2.

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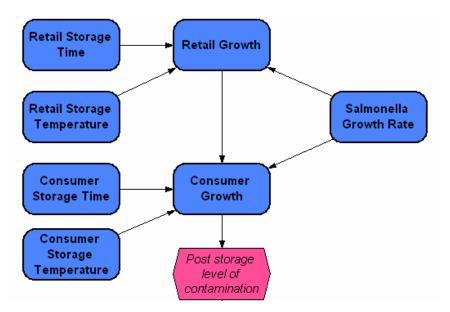


Figure 5-2: Schematic of the model to estimate the degree of growth that may occur during storage of RTE products.

To describe the growth of salmonella in RTE products the square root model for suboptimal temperatures is used. The model is defined as $\sqrt{k} = b(T - T_{min})$. Here, k is the exponential growth rate, T is the temperature of storage, T_{\min} is the temperature at which an extrapolation of a plot of \sqrt{k} versus temperature intersects the temperature axis, and b is the associated slope (McMeekin et al., 1993). Within the model, a T_{min} value of 3.24°C is adopted (McMeekin et al., 1993). The value of b is estimated using the information that the exponential growth rate of 8.4 log-change per day has been measured at 25°C (Oscar, 2000). As the products considered do not provide optimal growth conditions for any contaminating salmonella, it is assumed that no growth will occur below 7°C (ICMSF, 1996). No data could be identified that have examined the maximum population density for Salmonella in RTE foods. A maximum population density of 9 logs has been predicted for other organisms (see for example Tamplin, 2002 for *E. coli* in ground beef). However, RTE products will also be contaminated with other organisms, including spoilage organisms. The presence of such competing organisms is likely to result in a reduction in the maximum population density in any RTE product. This has been demonstrated for E. coli in ground beef (Tamplin, 2002). In the absence of data specific to salmonella in RTE foods, a maximum population of 8.5 logs per serving is assumed.

The temperature and time values used to estimate the extent of growth during storage are based upon available data. For retail storage (which includes all storage that may occur between manufacture and point of sale), the duration is described by a triangular distribution with a minimum duration of 1 day, a most

likely duration of 3 days and a maximum of 30 days. The temperature of storage is described by an empirical distribution derived from available data recording temperatures of pre-packaged lunch meat at retail (Audits, 1999). For consumer storage, the duration of storage is described by a betapert distribution with a minimum duration of 0.5 day, a most likely duration of 6 days and a maximum of 25 days. The temperature of storage is described by an empirical distribution derived from available data (Audits, 1999). The assumptions regarding time of storage are compatible with assumptions made regarding the consumer storage of frankfurters and deli meats in the FDA-FSIS risk assessment for Listeria monocytogenes in RTE foods (FDA-FSIS, 2003) that in turn were based upon data from the American Meat Institute (2001 – see FDA-FSIS, 2003). Through simulation, using Monte-Carlo methods, the model samples a temperature and duration of storage and then uses the growth model to estimate the extent of growth that occurs. Note that when temperatures below 7°C are sampled for storage the model is set to return no growth. As 7°C is the 75th percentile for retail storage (that is 75% of the time the model samples a temperature below 7°C), and the 90th percentile for consumer storage, the majority of the iterations of the model do not permit growth to occur.

The model above is a generic growth model for Salmonella, specified only by the temperature and time of storage. However, the spectrum of RTE products under consideration pose varying levels of pH, salt, water activity, growth inhibiting additives and other possibly important growth modifying parameters that are not considered explicitly in the growth model adopted. At this time, there is insufficient information available to extend the growth model to take account of these factors, and it is beyond the scope of this assessment. Therefore, to address the issue of variation in growth conditions afforded by the spectrum of RTE products, Storage and Growth Patterns are applied to product classes corresponding to different possible growth scenarios. These scenarios range from foods that will result in further pathogen inactivation in storage, to products that permit growth during refrigerated storage. These Storage and Growth Patterns are assigned by considering the relative level of growth that might be obtained for different products held under the same conditions (for example temperature and time). For products that do not allow growth, labeled no growth, the assumption is a final pathogen load of one CFU per serving. This, in a sense, provides a baseline. For foods that do not allow growth and may result in reduced viability, labeled *low-survival* foods, a nominal 1-log reduction from this baseline value is assumed. Foods that may support growth are split between "low-growth refrigerated storage" and "normal growth, refrigerated storage". For these scenarios, the model samples storage temperature and time distributions for both retail and consumer storage as specified above. These values are then used to determine growth. For "low-growth refrigerated storage", the exponential growth rate used in the model is assumed to be half that for normal growth. This is based upon data for growth of Salmonella in cured ham (data recorded on ComBase, record ID O142_1). The output from the growth model is an estimation of the level of contamination in products following storage.

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For this analysis, a relatively crude growth model is employed. The effort to carefully characterize the shape and parameters of the growth curve is likely to be largely wasted in this particular analysis for the following reasons. While a more complex growth model could be considered, it would not contribute appreciably to increased accuracy in estimating final cell numbers. It is difficult to improve accuracy in the growth calculations in the absence of detailed knowledge of:

- the fraction of products having varying levels of pH, salt, water activity, growth inhibiting additives or other important growth modifying parameters,
- the fraction of individual products that may experience elevated storage temperatures due to their customary storage and use patterns,
- knowledge of the maximum population density in a given product as a result of formulation, competitive microflora, water activity or other factors,
- the distribution of strains with respect to their growth potential (particularly considering those that are also most likely to survive the lethality process),
- the conditions for growth and population density at the site of the surviving organisms (e.g., anaerobic versus aerobic, fat content, brine concentration, etc.) as opposed to generically within the product,
- the fraction of products, or the fraction of product within a product class, that will be stored in frozen, refrigerated and room temperature conditions,
- the impact of stress responses resulting from the lethality process on the subsequent growth rate,
- the potential for die-off of organisms that have survived the lethality treatment, before they experience conditions that might allow growth,
- combinations of the above conditions that are interdependent.

Manufacturers, or product-specific specialists with detailed knowledge of a particular product and its expected conditions of storage, can determine or test the growth potential of organisms in individual products. However, there would still be numerous uncertainties in assessing the distribution of growth in the product as a function of storage temperatures and durations.

5.8 Estimating the Impact of Reheating

Products that are reheated have the potential to generate a lower percontaminated-serving risk than a similarly contaminated product that is not reheated. The model considers the effective lethality associated with five patterns of product reheating: *Never, Rarely, Usually, Always, and Always thoroughly reheated*.

Each pattern corresponds to a fraction of the product achieving different levels of log reduction in contaminating *Salmonella*. An effective log reduction is

computed for each pattern from the weighted average of the proportionate heating. The three levels of log reduction are considered in the model; however, the model provides the facility to compute the impact of any log reduction ranging from 0 (no reheating) to 5 logs. The levels considered are

- No reheating associated reduction is 0
- Minimal reheating associated reduction is 2 logs
- Thorough reheating associated reduction is 4 logs

These reheating levels were applied to these patterns in the proportions given in Table 5-16, with the reheating pattern assigned to the RTE product categories as shown in Table 5-17. Note that the proportion of products that fall in various categories is a rough estimate and is associated with some uncertainty. The resulting level of contamination after reheating is assumed to be the level of exposure experienced by the consumer. This level is used to predict the probability of illness in the Risk Characterization.

Pattern	No	Minimal	Thorough
	Reheating	Reheating	Reheating
Never Reheated	100	0	0
Rarely Reheated	90	5	5
Usually Reheated	20	40	40
Always Reheated	0	20	80
Always Reheated Thoroughly	0	5	95

Table 5-16: Levels of reheating by reheating pattern assigned on a product category bases

	E
RTE Product Category	Reheating Pattern
Roast Beef, Corned Beef	Rarely
Fully Cooked Beef Patties	Always
Cooked Pork (Cooked Ham, Pork BBQ)	Usually
Cooked Turkey (non-Deli)	Always
Cooked Chicken (Nuggets, Tenders, non-Deli)	Always
Cooked Poultry Deli Meat	Rarely
Cooked Chicken Patties	Always
Beef / Pork Frankfurters	Usually
Beef / Pork Bologna	Rarely
Poultry Frankfurters	Usually
Summer Sausage, Thuringer, Cooked Pepperoni	Rarely
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	Rarely
Meat Sticks	Never
Beef Jerky	Never
Uncooked Country Ham	Usually
Prosciutto, cappicola, pancetta, basturma	Rarely

Table 5-17: Assignment of reheating pattern to product categories

5.8.1 Assumption Caveat

The impact of surface re-heating will certainly affect the population of organisms that are on the surface of the product due to product re-contamination in postlethality processing. However, in considering the potential to inactivate specifically those pathogens that have survived lethality, it is important to recognize that these are not likely to be easily inactivated. The fact that they have survived the original lethality treatment suggests that they may be somehow protected (e.g., thermally protected by being positioned far below the surface, protected through other forms of thermal insulation such as fat, dryness, or because of the inherent thermal resistance of the surviving organism).

In addition, the consumer re-heating process is not likely to be, in most cases, as thorough or as well-controlled as the original treatment. This is because the goal in many cases will only be to make the product palatably warm for immediate consumption (i.e., that it be not too hot and that the cooking process not take too long) as opposed to a goal of achieving an adequate level of lethality.

This would suggest that re-heating of products to inactivate organisms that have already survived a lethality process (as opposed to surface contamination) should not necessarily be assumed to inactivate the surviving (i.e., non-surface) organisms. In addition, care should be taken regarding assumptions of the net impact of multiple lethality processes when they are carried out in sequence, to account for the fact that prior lethality processes *will have selected for the most protected or thermally resistant organisms*.

A summary of the inputs to the exposure assessment and their associated values are given in the Appendix 1.

6 Risk Characterization

6.1 Probability of Illness Per Serving

The result of the exposure assessment is an estimate of the ingested dose of *Salmonella* from RTE products associated with the specified lethality scenarios. Through the dose response model, the mean probability of illness is estimated as described in section 4.1. The output of the growth and storage of the model is different levels of contamination categorized by the four Storage and Growth Patterns considered: low survival, no growth, low growth refrigerated storage and normal growth refrigerated storage. The model estimates the probabilities of illness given in Table 6-1 for the different Storage and Growth patterns to which products are assigned.

Table 6-1: Probability of illness by growth scenario as estimated by the risk model with	
no consideration of reheating	

Storage and Growth Pattern	Probability of Illness
Low-Survival	0.00025
No Growth	0.0025
Low Growth, Refrigerated Storage	0.0114
Normal Growth, Refrigerated Storage	0.185

As described in section 5.2.1 six lethality risk groups were identified to categorize the RTE products. These risk groups were assigned to the growth patterns using the proportions presented in Table 6-2. For example, 25% of FCSS products, (*Fermented or DA, Cooked, Shelf-stable*) were assumed to correspond to low-survival, while 75% were assumed to be associated with no growth. The resulting probability of illness per risk group was then determined as by weighting the probabilities of illness (given in Table 6-1) by the assignment to product risk groups. The resulting risk, in terms of the probability of illness per serving prior to reheating, are given in Table 6-3.

Risk Group	Low-	No	Low Growth,	Growth,
	Survival	Growth	Refrigerated	Refrigerated
CUNSS	0	0	0	100
CCNSS	0	0	100	0
FCSS	25	75	0	0
FUSS	50	50	0	0
DH	0	100	0	0
DN	0	100	0	0

Table 6-2: Assignment of growth patterns to product categories.

Table 6-3: Probability of illness per pathogen surviving lethality categorized by product risk grouping prior to reheating.

Label	Probability of Illness per surviving Pathogen
CUNSS	0.1852
CCNSS	0.1140
FCSS	0.0020
FUSS	0.0014
DH	0.0025
DN	0.0025

Based on the assignment of each RTE product to the lethality risk groups in the above table (as discussed in section 2.1.2), the risk of illness was calculated for each product and then converted to the log scale for inclusion with other model elements. For each RTE Product, the risk per contaminated serving (in the absence of reheating) is given in Table 6-4.

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Table 6-4: Probability of illness from a surviving pathogen including population growth and decline afforded by storage (does not include reheating)

RTE Product Category	Probability of	Probability
	Illness per	of Illness per
	serving (logs)	serving
Roast Beef, Corned Beef	-0.73	0.186
Fully Cooked Beef Patties	-0.73	0.186
Cooked Pork (Cooked Ham, Pork BBQ)	-0.94	0.115
Cooked Turkey (non-Deli)	-0.73	0.186
Cooked Chicken (Nuggets, Tenders, non-Deli)	-0.73	0.186
Cooked Poultry Deli Meat	-0.73	0.186
Cooked Chicken Patties	-0.73	0.186
Beef / Pork Frankfurters	-0.94	0.115
Beef / Pork Bologna	-0.94	0.115
Poultry Frankfurters	-0.94	0.115
Summer Sausage, Thuringer, Cooked Pepperoni	-2.71	0.002
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	-2.86	0.001
Meat Sticks	-2.60	0.003
Beef Jerky	-2.60	0.003
Uncooked Country Ham	-2.60	0.003
Prosciutto, cappicola, pancetta, basturma	-2.60	0.003

To incorporate reheating, for each of these Storage and Growth Patterns the probability of illness is estimated given reheating and the associated log reductions that occur according to the assigned reheating pattern. The resulting probabilities of illness are given in Table 6-5.

Table 6-5: Probability of illness per serving following reheating categorized by reheating pattern

Reheating Pattern	Low survival	No growth	Low- growth	Growth refrigerated
			refrigerated	-
Never Reheated	0.0003	0.0025	0.114	0.185
Rarely Reheated	0.0002	0.0023	0.107	0.177
Usually Reheated	0.0001	0.0005	0.056	0.119
Always Reheated	5.04x10 ⁻⁷	5.04x10⁻ ⁶	0.032	0.087
Always Reheated Thoroughly	1.26x10 ⁻⁷	1.26x10⁻ ⁶	0.027	0.079

Products were assigned to the reheating patterns as shown in Table 6-6. The weighted average of the probabilities of illness are then calculated across reheating pattern and growth scenario. This results in estimates of the risk of illness per serving as given in Table 6-6. Note that the pattern *Always Reheated Thoroughly* is not currently assigned to any of the products.

Table 6-6: Storage & Growth and Reheating patterns assigned to product categories and the associated probability of illness per serving from a surviving pathogen following storage and reheating.

RTE Product Category	Storage & Growth Pattern	Reheating Pattern	Probability of illness per serving
Roast Beef, Corned Beef	Growth	Rarely	0.177
Fully Cooked Beef Patties	Growth	Always	0.087
Cooked Pork (Cooked Ham, Pork BBQ)	Growth	Usually	0.056
Cooked Turkey (non-Deli)	Growth	Always	0.087
Cooked Chicken (Nuggets, Tenders, non- Deli)	Growth	Always	0.087
Cooked Poultry Deli Meat	Growth	Rarely	0.177
Cooked Chicken Patties	Growth	Always	0.087
Beef / Pork Frankfurters	Low Growth	Usually	0.056
Beef / Pork Bologna	Low Growth	Rarely	0.107
Poultry Frankfurters	Low Growth	Usually	0.056
Summer Sausage, Thuringer, Cooked Pepperoni	25% Low-Survival; 75% No Growth	Rarely	0.002
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	50% Low Survival; 50% No Growth	Rarely	0.001
Meat Sticks	No Growth	Never	0.003
Beef Jerky	No Growth	Never	0.003
Uncooked Country Ham	No Growth	Usually	0.001
Prosciutto, cappicola, pancetta, basturma	No Growth	Rarely	0.002

6.2 Probability of Illness Per MKg RTE Product

Applying the assumption of a single CFU per contaminated RTE serving, the total risk per MKg after considering reheating is given by the sum of the log probability of illness per serving after reheating (by product type) and the log contamination level predicted following the application of the thermal process safety factor. The risk of illness for each product per MKg (including the thermal process safety factor and after considering reheating) is provided in Table 6-7. The model provides the option to exclude reheating considerations from the simulation through the user interface *that* accompanies the model. If it is excluded, the final product risk per MKg is equivalent to that after the storage and growth and dose-response calculations

Table 6-7: Estimates of the number of cases of salmonellosis per product class on an equal mass basis (per MKg), including reheating for the three lethality standards scenarios considered in the assessment.

RTE Product Category	Risk of Illness by product (after reheating)					
	Log Number of cases Number of cases /MKg				/MKg	
		/MKg				
	All 5	Split	All	All 5	Split	All 6.5/7.0
			6.5/7.0			
Roast Beef, Corned Beef	-3.85	-4.06	-4.06	1.43x10 ⁻⁴	8.65 x10 ⁻⁵	8.65 x10 ⁻⁵
Fully Cooked Beef Patties	0.51	0.51	-0.84	3.20	3.20	0.15
Cooked Pork (Cooked Ham,				9.40 x10 ⁻		
Pork BBQ)	-4.03	-5.37	-5.37	5	4.27 x10 ⁻⁶	4.27 x10 ⁻⁶
Cooked Turkey (non-Deli)	0.84	-1.01	-1.01	6.88	0.10	0.10
Cooked Chicken (Nuggets,						
Tenders, non-Deli)	1.81	-0.04	-0.04	64.27	0.92	0.92
Cooked Poultry Deli Meat	1.55	-0.05	-0.05	35.56	0.90	0.90
Cooked Chicken Patties	1.81	-0.04	-0.04	64.27	0.92	0.92
Beef / Pork Frankfurters	0.12	-1.23	-1.23	1.31	0.06	0.06
Beef / Pork Bologna	0.12	-1.23	-1.23	1.31	0.06	0.06
Poultry Frankfurters	1.34	-0.50	-0.50	21.88	0.31	0.31
Summer Sausage,						
Thuringer, Cooked						
Pepperoni	1.16	1.16	0.78	14.45	14.45	5.98
Salami, Uncooked						
Pepperoni, Chorizo,						
Soudjuk	1.14	1.14	0.77	13.71	13.71	5.87
Meat Sticks	1.38	1.38	1.01	24.15	24.15	10.23
Beef Jerky	1.31	1.31	0.94	20.42	20.42	8.65
Uncooked Country Ham	-1.36	-1.36	-1.75	0.04	0.04	0.02
Prosciutto, cappicola,						
pancetta, basturma	-1.60	-1.60	-2.00	0.03	0.03	0.01

6.3 Relative Risk of Illness by Product Class

Table 6-7 presents the risk per year broken down by RTE product category on an equal mass basis. To ease comparison, these risk estimates are presented in purely relative terms in Table 6-8. This is a useful measure since it indicates the risk associated with the product, relative to others, while controlling for variable production volumes. Note: The value in the table is relative to the value of 1.0 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

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	F		
RTE Product Category	Relative Product Risk		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	2.4x10 ⁻³	1.5x10 ⁻³	1.5x10 ⁻³
Fully Cooked Beef Patties	53.7	53.7	2.4
Cooked Pork (Cooked Ham, Pork BBQ)	1.6x10 ⁻³	7.2x10 ⁻⁵	7.2x10 ⁻⁵
Cooked Turkey (non-Deli)	115.5	1.7	1.7
Cooked Chicken (Nuggets, Tenders, non-Deli)	1,078.9	15.5	15.5
Cooked Poultry Deli Meat	597.0	15.0	15.0
Cooked Chicken Patties	1,078.9	15.5	15.5
Beef / Pork Frankfurters	22.0	1	1.0
Beef / Pork Bologna	22.0	1.0	1.0
Poultry Frankfurters	367.3	5.3	5.3
Summer Sausage, Thuringer, Cooked Pepperoni	242.7	242.7	100.5
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	230.1	230.1	98.6
Meat Sticks	405.5	405.5	171.8
Beef Jerky	342.8	342.8	145.2
Uncooked Country Ham	0.7	0.7	0.3
Prosciutto, cappicola, pancetta, basturma	0.4	0.4	0.2

Table 6-8: The relative risk of each product class on an equal mass basis (number of cases of salmonellosis per MKg) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

6.4 Number of Illnesses Per Mass of RTE Product Consumed Per Year

The final step is to convert the risk per MKg to the annual product risk (i.e., for the entire supply of that product class in a year). This requires determining the production mass of each RTE Product Category.

6.4.1 Estimating the Consumption Volume for RTE Product Categories

Determining the consumption volume of these product categories presents several considerable challenges. The main sources for consumption volume information are:

- the U.S. Economic Census (conducted by the Department of Commerce)
- the Continuing Survey of Food Intake by Individuals (CSFII) carried out by the Agricultural Research Service of the Department of Agriculture (USDA, 1998)

Each of these sources of data was designed for different purposes than are intended here. As a result, they are generally not directly appropriate for estimating the consumption volume of the RTE products of interest in this

assessment. Some examples of the difficulties related to these sources are described in Table 6-9.

Table 6-9: Difficulties associated with available information sources used to estimate consumption volumes of RTE meat and poultry products.

Source	Concern
CSFII	No indication of whether the food consumed was RTE or cooked by food
	service or final consumer.
CSFII	Vagueness or lack of specification in the definition of foods with respect to
	processing method applied.
CSFII	Vagueness or lack of specification in the definition of foods with respect to
	raw materials.
Economic	Lumping of RTE products under a category of 'processed products' that may
Census	or may not be RTE (e.g., frozen).
Economic	Survey conducted only on products produced outside of meat packing
Census	plants.
Both	Confidence in representativeness of data (reporting biases, etc.) and
	appropriateness of any extrapolations to whole population.
Both	Changes in production volume between when measurements were taken
	and current situation.

Estimating the consumption of RTE sausages provides an example of the uncertainty associated with using CSFII data. CSFII data may refer to a meal consisting simply of "sausage" such that it is not clear a) whether it was fresh or RTE, b) whether it was made from beef, pork, poultry, lamb, etc., c) if it is RTE, whether it was cooked, fermented, dried, cured or some combination.

The data sources available for each product category are given in Table 6-10 and the value selected for use with rationale given in Table 6-11. The volume of consumption is summarized in Table 6-12.

Where the source of the consumption estimate is from the CSFII data (as indicated in Table 6-10) the 1994-96, 1998 CSFII datasets were used. From these data, the following procedure was used to form the consumption estimates for the RTE categories:

- 1. CSFII food codes were assigned to each RTE category (for a list of the food codes assigned to each category see Appendix 2)
- 2. 2-Day consumption data were extracted for each category given the following constraints:
 - a. The population group was restricted to those of 2 years of age and older
 - b. Only individuals who reported data for both days were considered
- 3. The meat fraction of each food code was computed based on the recipe data in the CFSII dataset

- 4. The mass of each eating occasion was adjusted by computed meat fraction of each food code.
- 5. The per individual consumption data were further adjusted by the weight assigned to that individual for day 2 (since the data only included data where consumption was reported for both days)
- 6. The sum of the weighted consumption over two days was divided by twice the total population weight to produce a daily average consumption per person
- 7. This value was multiplied by the total population weight to compute the daily average consumption for the entire population
- 8. This value was multiplied by 365 to produce the total annual consumption figure

For the CSFII data, the basic equation to estimate the annual consumption level is as follows:

$\frac{\text{Serving Mass} \times \text{Meat Fraction} \times \text{Day 2 Weight} \times \text{Population Weight} \times 365}{2 \times \text{Population Weight}}$

which simplifies to:

Mass of Serving \times Meat Fraction \times Day 2 Weight \times 365

2

Where the source of the consumption estimate is from the Economic Census, the value reported in the census is used (translated to MKg).

The Product Class Risk and Total Supply Risk were then computed. The product risk was computed by multiplying the production mass by the risk per MKg for each product category. This risk can be interpreted as the expected number of cases of salmonellosis per year. The estimates are reported in Table 6-13, and include the impact of the thermal process safety factors and reheating.

Product Class	Source	Estimate (Million Kg)	Comment		
Roast Beef, Corned Beef	CSFII	85	To estimate the amount of roast beef which might be ready-to-eat, foodcodes associated with the combination of "roast beef" and "sandwich" were extracted to determine the production volume (65 Mkg). For corned beef, the foodcodes were simply those containing the words "corned beef" (20 Mkg).		
Fully Cooked Beef Patties	CSFII	< 725	Foodcodes extracted having the words, "hamburger, cheeseburger," etc. This includes non-RTE hamburgers, so an adjustment must be made to estimate the fraction that is RTE.		
	Economic Census	< 658	Product defined in census as "Frozen ground meat patties (processed, frozen or cooked), not made in meat packing plants." NAICS 311612A221, Table 6a, p. 11; 1,447 million Lbs. An adjustment is required, since not all frozen ground meat patties will be cooked.		
Cooked Pork (Cooked Ham,	CSFII	< 747	Includes all references to ham, so adjustment is required to estimate the fraction that is ready-to-eat.		
Pork BBQ)	Economic Census	100	Product defined in census as "Boiled ham, barbecue pork, and other cooked pork, including frozen, except canned meat and sausage, not made in meat packing plants." NAICS 3116121671, Table 6a, p. 11; 238 million Lbs		
Cooked Turkey (non-Deli)	Economic Census	386	Product defined in census as "Cooked or smoked turkey, including frozen (except frankfurters, hams and luncheon meats)" NAICS 311615D121, Table 6a, p. 11; 848 million Lbs		
Cooked Chicken (non-Deli, non patty)	Economic Census	< 1346	Product defined in census as "Cooked or smoked chicken, including frozen (except frankfurters, hams and luncheon meats)" NAICS 311615D131, Table 6a, p. 11; 2,960 million Lbs.		
	CSFII	> 216	Based solely on CSFII foodcodes with "chicken nuggets", "chicken tenders", etc.		
Cooked Poultry Deli Meat	Economic Census	455	Product defined in census as "Cooked or smoked poultry hams and luncheon meats, including frozen," NAICS 311615D151, Table 6a, p. 11, 1,001 million Lbs.		
Cooked Chicken Patties	CSFII	117	Based solely on CSFII foodcodes containing "chicken" and "sandwich" or "patty".		
Beef/Pork	CSFII	401	Foodcodes with "frankfurters"		
Frankfurters	Economic	352	Product defined in census as "Frankfurters, including wieners, not made in meat		

Table 6-10: Evidence regarding annual consumption volume of product classes from CSFII, Economic Census and other sources

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	Census		packing plants." NAICS 3116124331, Table 6a, p. 11; 774 million Lbs
Bologna,	CSFII	> 132	Based only on foodcodes with "bologna"
Liverwurst, Polish Sausage, other Cooked Sausages	Economic Census	728	Product defined in census as "Other sausage, smoked or cooked (bologna, liverwurst, Polish sausage, packaged luncheon meats, minced roll, smoked pork sausage, etc.), not made in meat packing plants." NAICS 3116124441, Table 6a, p. 11; 1,601 million Lbs.
Poultry Frankfurters	Economic Census	305	Product defined in census as "Cooked or smoked poultry frankfurters, including wieners, not made in meat packing plants." NAICS 311615D141, Table 6a, p. 11; 670 million Lbs
Semi-Dry FS: Summer Sausage, Thuringer, Cervelat	FDA-FSIS Listeria RA (based on CSFII)	< 110	FDA-FSIS Listeria Risk Assessment (based on total of dry and semi-dry fermented sausage).
	Economic Census	< 266	Product defined in census as "Dry or semi-dry sausage and similar products (salami, cervelat, beef jerky, summer sausage, pork roll, etc.), not made in meat packing plants." NAICS 3116124221, Table 6a, p. 10; 585 million Lbs.
Dry FS: Salami, Pepperoni, Chorizo, Soudjuk	FDA-FSIS Listeria RA (based on CSFII)	< 110	FDA-FSIS Listeria Risk Assessment (based on total of dry and semi-dry fermented sausage). (FDA-FSIS, 2003)
	Economic Census	< 266	Product defined in census as "Dry or semi-dry sausage and similar products (salami, cervelat, beef jerky, summer sausage, pork roll, etc.), not made in meat packing plants." NAICS 3116124221, Table 6a, p. 10; 585 million Lbs.
Meat Sticks	Website Data, CSFII	28.5 – 10.2 = 18.3	Based on industry data for all meat snacks (62.7 million lbs), and subtracting value CSFII estimate for Beef Jerky (see below). Exact quote from website: "Meat-snack popularity can be confirmed by taking a look inside a typical convenience store since convenience stores were responsible for 43.4% of the 62.7 million pounds of meat snacks sold in 1997, according to SFA." (original data from SFA not accessed). http://www.foodproductdesign.com/archive/1999/0199ap.html
Beef Jerky	CSFII	10.2	Foodcodes containing "jerky".
Country Ham	Economic Census	32	Product defined in census as "Sweet-pickled or dry-cured pork (not smoked, cooked, canned, or made into sausage, not made in meat packing plants." NAICS 3116121111, Table 6a, p. 10; 71 million Lbs.

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Prosciutto,	CSFII	> 1.7	Based on CSFII foodcodes containing prosciutto. No entries found for other
Cappicola,			products. An assumption is required to extrapolate to all such products.
Pancetta,			
Basturma			

Table 6-11: Judgments regarding best estimate in annual consumption volume for product classes (estimates are in Millions of Kilograms per year).

Product Class	Assessor's	Comment
	estimate used in	
	the model	
Roast Beef,	85	Estimate from CSFII, only data available
Corned Beef		
Fully Cooked Beef Patties	725/10,000=0.07	Estimate from CSFII adjusted to estimate volume of beef patties that are
		sold as RTE products, assumed to be 1/10,000 per MKg (Economic census
		is for frozen patties only).
Cooked Pork (Cooked Ham, Pork	100	Direct estimate available from Economic Census. Product description
BBQ)		matches RTE product category used in this assessment.
Cooked Turkey (non-Deli)	386	Direct estimate available from Economic Census. Product description
		matches RTE product category used in this assessment.
Cooked Chicken (non-Deli, non-	1,346	Direct estimate available from Economic Census. Product description
patty)		matches RTE product category used in this assessment.
Cooked Poultry Deli Meat	455	Direct estimate available from Economic Census. Product description
		matches RTE product category used in this assessment.
Cooked Chicken Patties	117	CSFII only available estimate.
Beef/Pork Frankfurters	400	Estimate from CSFII. Apparent consistency with Economic census
		estimates and FDA-FSIS Listeria Risk Assessment.
Bologna, Liverwurst, Polish Sausage,	132	Estimate from CSFII. Economic census includes products that would be
other Cooked Sausages		categorized as Deli meat in this assessment
Poultry Frankfurters	305	Estimate from Economic census. Product description matches RTE
		product category used in this assessment.
Semi-Dry FS: Summer Sausage,	55	Estimate from CSFII. Since source combine dry and semi-dry sausages
Thuringer, Cervelat		the CSFII estimate (110MKg) is split between Semi-dry and dry products
Dry FS: Salami, Pepperoni, Chorizo,	55	Estimate from CSFII. Since source combine dry and semi-dry sausages
Soudjuk		the CSFII estimate (110MKg) is split between Semi-dry and dry products
Meat Sticks	18.3	Only estimate available, Industry data
Beef Jerky	10.2	Estimate from CSFII, only estimate available.

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Country Ham	32	Census data does not directly define "country ham" but refers to "sweet-
		pickled or dry-cured pork".
Prosciutto, cappicola, pancetta,	3.4	CSFII data found only for prosciutto (1.7MKg) Assumption is made that
basturma		prosciutto represents 50% of the production in this product class.

Table 6-12: Consumption volume estimates (MKg) used in the assessment.

RTE Product Category	Consumption volume
	(MKg)
Roast Beef, Corned Beef	85
Fully Cooked Beef Patties	0.1
Cooked Pork (Cooked Ham, Pork BBQ)	100
Cooked Turkey (non-Deli)	386
Cooked Chicken (Nuggets, Tenders, non-Deli)	1,346
Cooked Poultry Deli Meat	455
Cooked Chicken Patties	117
Beef / Pork Frankfurters	400
Beef / Pork Bologna	132
Poultry Frankfurters	305
Summer Sausage, Thuringer, Cooked Pepperoni	55
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	55
Meat Sticks	18
Beef Jerky	10
Uncooked Country Ham	32
Prosciutto, cappicola, pancetta, basturma	3

Table 6-13: Estimate of the number of cases of salmonellosis per year that may result under differing lethality standards.

RTE Product Category Number of Cases per			s 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	3,153	1,971

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6.5 Relative Risk of Illness by Product Class

Table 6-13 presents the risk per year broken down by RTE product category. To ease comparison, these risk estimates are presented in purely relative terms in Table 6-14. Note: The value in the table is relative to the value of 1 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

Table 6-14: The relative risk of each product class (cases of salmonellosis per year) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

RTE Product Category	Rela	tive Produ	ct Risk
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	1.0x10 ⁻³	6.0x10 ⁻⁴	6.0x10 ⁻⁴
Fully Cooked Beef Patties	9.4 x10 ⁻³	9.4 x10 ⁻³	4.3 x10 ⁻⁴
Cooked Pork (Cooked Ham, Pork BBQ)	4.0 x10 ⁻⁴	1.8 x10 ⁻⁵	1.8 x10 ⁻⁵
Cooked Turkey (non-Deli)	107.5	1.5	1.5
Cooked Chicken (Nuggets, Tenders, non-Deli)	3,503.0	50.2	50.2
Cooked Poultry Deli Meat	1,329.3	33.5	33.5
Cooked Chicken Patties	304.5	4.4	4.4
Beef / Pork Frankfurters	22.1	1	1.0
Beef / Pork Bologna	14.0	0.6	0.6
Poultry Frankfurters	280.6	4.0	4.0
Summer Sausage, Thuringer, Cooked Pepperoni	61.5	61.5	25.5
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	58.4	58.4	25.0
Meat Sticks	38.0	38.0	16.1
Beef Jerky	17.9	17.9	7.6
Uncooked Country Ham	2.4 x10 ⁻²	2.4 x10 ⁻²	9.9 x10 ⁻³
Prosciutto, cappicola, pancetta, basturma	6.7 x10 ⁻³	6.7 x10 ⁻³	2.6 x10 ⁻³

6.6 Total Supply Risk Per Year From RTE Products

The total supply risk, interpreted as the total expected number of cases of salmonellosis per year, is simply the sum of the individual product risks. This risk is given in Table 6-15. For this value, we compare the results for including and excluding thermal process safety factors and reheating, as well as the baseline lethality standard scenarios of all 5-log reductions and all 6.5/7.0 log reductions. The number of significant digits has been suppressed in this presentation. Though the model calculates these numbers with more precision, the accuracy of the model does not justify presenting precise estimates.

Table 6-15: Total supply risk, interpreted as the estimated number of cases of salmonellosis per year, from RTE products under each lethality standard considered (All 5-log reduction, Split reductions and All 6.5/7-log reductions). The numbers of cases are shown with and without the inclusion of thermal process safety factors and/or reheating.

Cases per year: All 5-log Reduction					
Include Reheating Include Thermal Process Safety Factors					
Yes No					
Yes	66,720	6,470,000			
No	122,400	12,030,000			

Cases per year: Split Reductions					
Include Reheating Include Thermal Process Safety Factors					
Yes No					
Yes 3,150 112,90					
No 4,120 194,4					

Cases per year: All 6.5/7.0 Log Reduction					
Include Reheating Include Thermal Process Safety Factors					
Yes No					
Yes 1,970 111,700					
No	2,850	193,100			

7 Risk Assessment: Model Implementation

7.1 Worked Example for Single Product

The estimation process in this model is multi-faceted, considering multiple lethality scenarios, compliance with the lethality scenarios, thermal safety factors, the effect of growth and storage on contamination levels, impacts of consumer reheating, the likelihood of infection following exposure and the level of consumption. A summary of the inputs to the risk assessment, and their associated values, are given in Appendix 1. In this section, to demonstrate how the model calculations are aggregated to estimate the impact of the lethality scenarios on public health, one RTE product is used as an exemplar and the calculations applied to result in an estimate of the risk of illness per year. This section follows the model framework as shown in Figure 7-1. The product chosen is a beef/pork frankfurter, commonly referred to as a hotdog. Beef/pork frankfurters are chosen because they are a product associated with a particularly high degree of familiarity to increase the comprehension of the model.

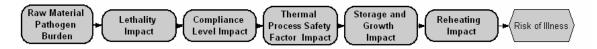


Figure 7-1: Overall model framework to estimate the impact of lethality standards on RTE foods.

7.1.1 Worked Example: Determination of Product Risk Categories and Selection of Product Classes

Beef/pork frankfurters are assigned to CCNSS - a product *that* is considered to be fully cooked, cured, non-shelf-stable.

7.1.2 Worked Example: Raw Material Pathogen Burden

Frankfurters are assumed to consist of both beef and pork in the proportions 50% ground beef and 50% ground pork. Ground beef has a pathogen burden of 8.6 and ground pork has a pathogen burden of 8.2 log CFU/MKg. Therefore aggregating these pathogen loads results in a pathogen burden of 8.5 log CFU per MKg ($\log_{10}(0.5 \times 10^{8.6} + 0.5 \times 10^{8.2}) = 8.5$) (note for clarity the values used here are rounded).

7.1.3 Worked Example: Lethality Impact

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The assessment considers the impact of three lethality scenarios: "All log 5", "Split", and "All 6.5/7". Pork frankfurters are assigned the following lethality treatments for the 3 lethality scenarios considered in the assessment:

- 5-logs in the "All log 5" scenario,
- 6.5 logs in the "Split" scenario, and
- 6.5 in the "All 6.5/7" scenario.

The level of contamination post lethality, in terms of the pathogen load per MKg, R_L , is given by $R_L = P_B - L$ where *L* is the lethality treatment applied. Applying this formulation, without considering compliance or thermal safety factors, the pathogen burden post lethality is given in Table 7-1.

Table 7-1: Pathogen burden associated with Beef/Pork Frankfurters before and after lethality treatment.

Lethality scenario	Pathogen burden post Lethality treatment (log CFU/MKg)				
	All log 5 split All 6.5/7				
Prior to lethality	8.47	8.47	8.47		
Post Lethality	3.47	1.57	1.97		

7.1.4 Worked Example: Compliance Level Impact

The level of compliance incorporates the concept of effective lethality. In essence this incorporates the implications that varying levels of industry wide compliance, and the resulting effect on the actual lethality achieved in practice, may have upon the public health impact. For beef/pork frankfurters, based upon available data (RTI, 2005) that industry wide, the lethality achieved is at least at standard, as shown in

Table 7-2, and assumed to be uniformly distributed between the standard and 1 log higher.

Table 7-2: Proportionate compliance with lethality standards for Beef/Pork Frankfurters.

Lethality scenario	Compliance Level		
	S+1 to S	S to S-1.5	S-1.5 to -2.5
All log 5	100%	0	0
Split	98%	2%	0
All 6.5/7	98%	2%	0

As described in section 5.5 the compliance adjustment factor, C, that is applied to the level of lethality to give the effective lethality achieved following consideration of the level of compliance is calculated from

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$$C = -\log_{10}\left(\frac{10^{-a} - 10^{-b}}{(b-a) \cdot \log_{e}(10)}\right)$$

where a and b are the lower and upper bounds of the lethality. For example, for beef/pork frankfurters in the all log 5 scenario this is S+1 to S, therefore the lower bound is 0 and the upper bound 1.

$$C = -\log_{10} \left(\frac{10^{-0} - 10^{-1}}{(1 - 0) \cdot \log_{e}(10)} \right) = -0.408$$

Therefore the effective lethality for beef /pork frankfurters adjustment for compliance is -0.408 under the all log 5 scenario. Note that as this is a negative number it implies that the lethality achieved exceeds the standard. The level of contamination post lethality per MKg, R_c , is given by $R_c = R_L + C$ where *C* is the adjustment for compliance. Incorporating compliance, the risk post lethality is given in Table 7-3.

Table 7-3: Level of contamination for Beef/Pork Frankfurters before and after lethality treatment incorporating compliance with standard.

Lethality scenario	Pathogen burden post lethality treatment following inclusion of compliance (log CFU/MKg)						
	All log 5 split All 6.5/7						
Prior to compliance	3.47	1.97	1.97				
After compliance	3.06						

7.1.5 Worked Example: Thermal Process Safety Factor Impact

Beef/pork frankfurters are assigned a moderate TPSF (see Table 5-13). This is because it is a comminuted product, but quality considerations may dictate cooking in excess of minimal lethality requirements. A moderate TPSF corresponds to a TPSF of -2 log. The level of contamination following the inclusion of TPSF, in terms of the pathogen load in logs CFU per MKg, R_{TPSF} , is given by $R_{TPSF} = R_C + T$ where *T* is the TPSF. Incorporating the TPSF the risk is given in Table 7-4.

Table 7-4: The level of contamination associated with Beef/Pork Frankfurters before and after lethality treatment incorporating compliance with standard and thermal process safety factor.

Lethality scenario	Pathogen burden following inclusion of TPSF (log CFU/MKg)				
	All log 5 split All 6.5/7				
Prior to inclusion of TPSF	3.06 1.72 1.72				
After TPSF	1.06	-0.28	-0.28		

7.1.6 Worked Example: Storage and Growth Impact

Using the model described in section 5.7.2, the extent of growth that might occur in RTE products was estimated. The model was adapted to describe four categories of RTE product: *low-survival, no growth, low growth refrigerated storage,* and *normal growth refrigerated storage.* Assignment to these categories is dependent upon product class assignment. Beef/pork frankfurters are assigned to CCNSS (a product *that* is considered to be Fully Cooked, Cured, Non-Shelf-Stable). These are assigned to *low growth refrigerated* (see Table 7-5).

Table 7-5: Allocation of product risk categories to the growth patterns considered in the model.

Risk Group	Low-Survival	No Growth	Low Growth, refrigerated	Growth, Refrigerated
CUNSS	0	0	0	100
CCNSS	0	0	100	0
FCSS	25	75	0	0
FUSS	50	50	0	0
DH	0	100	0	0
DN	0	100	0	0

Therefore, to assess Beef/Pork Frankfurters, the growth model is implemented with the assumption that the exponential growth rate is half that of normal growth. The assumption is that prior to any growth there is a contamination rate of 1 CFU per serving. The result of the growth model is the level of contamination following storage. The cumulative distribution of dose per serving for Beef/Pork frankfurters *prior to reheating* is shown in Figure 7-2. It can be seen that for approximately 70% of servings the dose is 1 CFU per serving, indicating no growth has occurred.

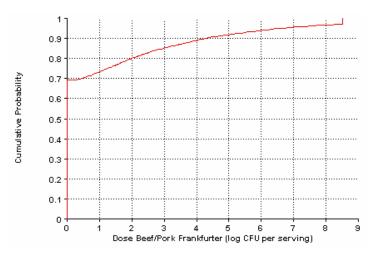


Figure 7-2: Cumulative distribution of doses per serving for Beef/Pork Frankfurters. Note that this distribution applies to all products categorized *Low Growth* Worked Example: Reheating Impact

There are three levels of reheating considered in the model:

- No reheating associated reduction is 0
- Minimal reheating associated reduction is 2 logs
- Thorough reheating associated reduction is 4 logs

In addition there are 5 reheating patterns to which products are assigned. Beef/pork frankfurters are assigned to the "Usually Reheated" reheating pattern (Table 5-17). The level of reheating that Beef/Pork Frankfurters are subjected to depends upon the reheating pattern as shown in Table 7-6. The final level of contamination per serving is given but the level after growth and storage minus the reduction afforded by reheating.

Pattern	No Reheating	Minimal Reheating	Thorough Reheating
Never Reheated	100	0	0
Rarely Reheated	90	5	5
Usually Reheated	20	40	40
Always Reheated	0	20	80
Always Reheated Thoroughly	0	5	95

 Table 7-6: Proportioning of the reheating levels according to reheating pattern

The cumulative distribution of dose per serving for Beef/Pork frankfurters *prior to reheating* is shown in Figure 7-3. It can be seen that for approximately 80% of servings the dose is 1 CFU or less per serving.

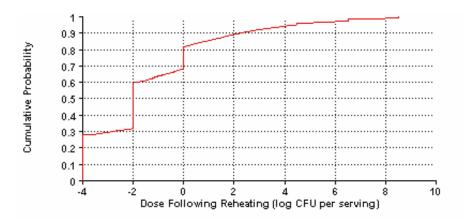


Figure 7-3: Cumulative distribution of doses per serving for Beef/Pork Frankfurters. Note that this distribution applies to all products categorized *Low Growth* and a reheating pattern of *Usually Reheated*

7.1.7 Worked Example: Number of Cases

Using the final level of contamination, the probability of illness is estimated using the dose response model as described in section 4.1. As all contaminated products are assumed to have a contamination level of 1 CFU per serving, the probability of illness, categorized by growth scenario, is equal for all products assigned to any given growth pattern at the per serving level.

The Probability of illness per serving by Storage and Growth Pattern and Reheating Pattern is given in Table 6-4. Beef/Pork Frankfurters are assigned to the "Low growth, Refrigerated" growth pattern and the "*Usually Reheated*" category. Therefore, the probability of illness per serving is 0.056. The risk from Beef/Pork frankfurters per MKg is given by the product of the probability of illness following storage, growth and reheating and the level of contamination post lethality. To estimate the number of cases of salmonellosis per year, the risk per MKg is multiplied by the consumption volume (in MKg per year). The consumption volumes are given in Table 6-12. For Beef/Pork Frankfurters it is estimated that 400MKg are consumed per year. The resulting numbers of cases for Beef/Pork frankfurters are:

RTE Product	Number of Cases per year				
	All 5.0 Split All 6.5/7.0				
Beef / Pork Frankfurters	257	12	12		

7.2 Application To All Products

The following section summarizes the risk at each of the key stages of model, specifically lethality, inclusion of compliance, incorporation of thermal safety

process factors, storage and growth, and reheating. This section also discusses the impact of some of the key assumptions on risk estimates. A summary of the inputs, related assumptions and associated values are given in the Appendix 1.

Estimates of risk are presented in logarithmic terms due to the significant ranges that are spanned. For example, risk estimates range across 9 orders of magnitude (factor of 1 billion). This is impossible to view in any graph, and is difficult to clearly discern the ranges in a table, without conversion to a logarithmic scale. For ease, the product categories are assigned a product code which the figures, and some tables, use as the key for product categories. The product codes are given in Table 7-7.

Table 7-7: Product codes assigned to the product categories.

Product category	Product
	code
Roast Beef, Corned Beef	RBCB
Fully Cooked Beef Patties	FCBP
Cooked Pork (Cooked Ham, Pork BBQ)	CPCH
Cooked Turkey (non-Deli)	CTND
Cooked Chicken (Nuggets, Tenders, non-Deli)	CCND
Cooked Poultry Deli Meat	CPD
Cooked Chicken Patties	CCP
Beef / Pork Frankfurters	BPF
Beef / Pork Bologna	BPB
Poultry Frankfurters	PF
Summer Sausage, Thuringer, Cooked Pepperoni	SSCP
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	SUP
Meat Sticks	MS
Beef Jerky	BJ
Uncooked Country Ham	UCH
Prosciutto, cappicola, pancetta, basturma	PCPB

7.2.1 All products: Pathogen Burden

In the same manner as demonstrated with Beef/Pork Frankfurters, the pathogen burden for each product is given by the sum of the pathogen burden of the constituents, weighted by their relative contributions. The raw material compositions and resulting pathogen burdens are given in Table 7-8.

Product code	Raw material composition	Pathogen burden (log)	
code		CFU/g	CFU/MKg
	Intert Deef	0	U U
RBCB	Intact Beef	-2.7	6.3
FCBP	Ground Beef	-0.3	8.7
CPCH	Intact Pork	-2.7	6.3
CTND	Ground Turkey	0 *	9.0
CCND	Ground Chicken	1	10.0
CPD	50% Ground Chicken, 50% Ground Turkey	0.7	9.7
CCP	Ground Chicken	1	10.0
BPF	50% Ground Beef, 50% Ground Pork	-0.6	8.4
BPB	50% Ground Beef, 50% Ground Pork	-0.6	8.4
PF	50% Ground Chicken, 50% Ground Turkey	0.7	9.7
SSCP	50% Ground Beef, 50% Ground Pork	-0.6	8.4
SUP	50% Ground Beef, 50% Ground Pork	-0.6	8.4
MS	Ground Beef	-0.3	8.7
BJ	Ground Beef	-0.3	8.7
UCH	Intact Pork	-2.7	6.3
PCPB	Intact Pork	-2.7	6.3

Table 7-8: Raw material composition and resulting estimated pathogen burdens for the RTE product categories.

* note that 0 on the log scale corresponds to 1CFU/g

7.2.2 All Products: Lethality Scenario

The post lethality pathogen burden, is dependent upon the lethality standard applied and the starting pathogen burden with the risk post lethality for any given product category, R_L , given by $R_L = P_B - L$ where *L* is the lethality treatment applied. Application of the lethalities given in Table 7-9 to the pathogen burden pre-lethality (Table 7-8) results in the post-lethality contamination estimates given in Table 7-10. The impact that the lethality treatment has upon this risk in the Split scenario is illustrated in Figure 7-4.

Table 7-9: Lethality standards applied by product category for the three scenarios considered

Product category	RTE Product	Lethality Standard Scenario		lard
	code	All 5	Split	All 6.5/7
Roast Beef, Corned Beef	RBCB	5.0	6.5	6.5
Fully Cooked Beef Patties	FCBP	5.0	6.5	6.5
Cooked Pork (Cooked Ham, Pork BBQ)	CPCH	5.0	6.5	6.5
Cooked Turkey (non-Deli)	CTND	5.0	7.0	7.0
Cooked Chicken (Nuggets, Tenders, non-Deli)	CCND	5.0	7.0	7.0
Cooked Poultry Deli Meat	CPD	5.0	7.0	7.0
Cooked Chicken Patties	CCP	5.0	7.0	7.0
Beef / Pork Frankfurters	BPF	5.0	6.5	6.5
Beef / Pork Bologna	BPB	5.0	6.5	6.5
Poultry Frankfurters	PF	5.0	7.0	7.0
Summer Sausage, Thuringer, Cooked	SSCP	5.0	5.0	6.5
Pepperoni				
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	SUP	5.0	5.0	6.5
Meat Sticks	MS	5.0	5.0	6.5
Beef Jerky	BJ	5.0	5.0	6.5
Uncooked Country Ham	UCH	5.0	5.0	6.5
Prosciutto, cappicola, pancetta, basturma	PCPB	5.0	5.0	6.5

RTE Product	Post-Lethality Surviving Pathogen Burden					
	L	_og ₁₀ CFU / g	g	Lo	g ₁₀ CFU / M	Kg
	All 5	Split	All	All 5	Split	All
			6.5/7.0			6.5/7.0
RBCB	-7.71	-9.20	-9.20	1.30	-0.20	-0.20
FCBP	-5.36	-6.86	-6.86	3.65	2.15	2.15
CPCH	-7.68	-9.18	-9.18	1.32	-0.18	-0.18
CTND	-5.02	-7.02	-7.02	3.98	1.98	1.98
CCND	-4.05	-6.05	-6.05	4.95	2.95	2.95
CPD	-4.31	-6.31	-6.31	4.69	2.69	2.69
CCP	-4.05	-6.05	-6.05	4.95	2.95	2.95
BPF	-5.60	-7.10	-7.10	3.41	1.91	1.91
BPB	-5.60	-7.10	-7.10	3.41	1.91	1.91
PF	-4.31	-6.31	-6.31	4.69	2.69	2.69
SSCP	-5.60	-5.60	-7.10	3.41	3.41	1.91
SUP	-5.60	-5.60	-7.10	3.41	3.41	1.91
MS	-5.36	-5.36	-6.86	3.65	3.65	2.15
BJ	-5.36	-5.36	-6.86	3.65	3.65	2.15
UCH	-7.68	-7.68	-9.18	1.32	1.32	-0.18
PCPB	-7.68	-7.68	-9.18	1.32	1.32	-0.18

Table 7-10: Level of contamination post lethality in terms of the surviving pathogen burden

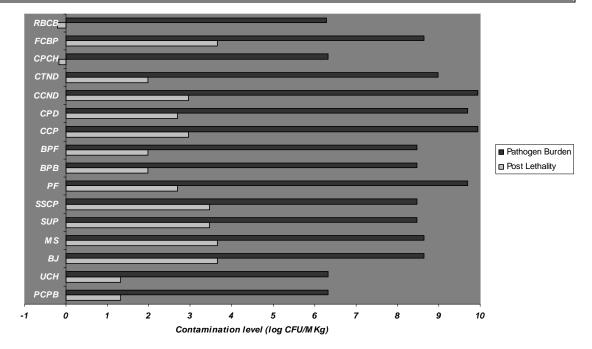


Figure 7-4: Comparison of the pathogen burden by RTE product category before (indicated as Pathogen Burden) and after (indicated as Post Lethality) application of the associated lethality standard under the Split scenario.

7.2.3 All Products: Compliance

Inclusion of compliance attempts to incorporate the variability that may exist across an industry when applying any lethality standard. For each product category an overall level of compliance is assigned. Based upon this level, a compliance adjustment factor is calculated as demonstrated for Beef/Pork Frankfurters (section 7.1.4). This represents an adjustment factor that modifies the impact of the lethality standard to represent what might actually be achieved in practice.

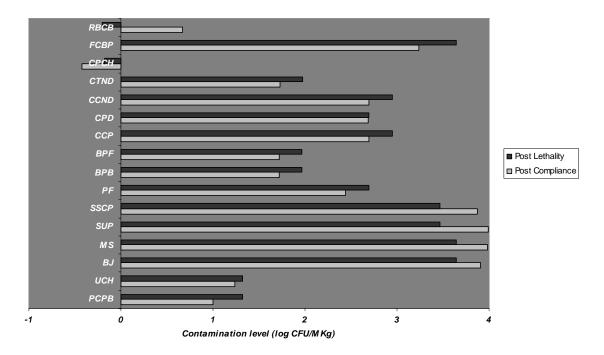
Table 7-11 gives the post lethality level of contamination, effective lethality adjustment, *C*, based upon the level of compliance, and the resulting post-compliance level of contamination estimates by product category for the Split scenario.

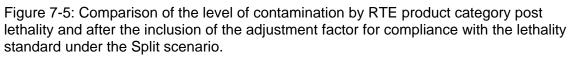
RTE Product	Let	hality Standard Sce	nario
	Post lethality	Adjustment factor	Post Compliance
	(log CFU/MKg)		(log CFU/MKg)
RBCB	-0.20	-0.41	0.67
FCBP	2.15	-0.41	3.24
CPCH	-0.18	-0.41	-0.43
CTND	1.98	-0.41	1.73
CCND	2.95	-0.41	2.70
CPD	2.69	-0.41	2.69
CCP	2.95	-0.41	2.70
BPF	1.91	-0.41	1.72
BPB	1.91	-0.41	1.72
PF	2.69	-0.41	2.44
SSCP	3.41	-0.07	3.87
SUP	3.41	0.26	4.00
MS	3.65	0.26	3.98
BJ	3.65	0.34	3.91
UCH	1.32	-0.41	1.24
PCPB	1.32	0.09	1.00

Table 7-11: The post lethality contamination level, adjustment factor based upon the level of compliance, and the resulting post-compliance contamination estimates by product category. Values correspond to the Split scenario.

Figure 7-5 presents the level of contamination after the proposed required lethality treatment and then the level of contamination following adjustment for compliance for the Split scenario. It can be seen that for most products the inclusion of compliance reduces the risk estimate (given that full compliance often implies exceeding the standard). The exceptions are products SUP (Salami, Uncooked Pepperoni, Chorizo, Soudjuk), MS (Meat Sticks), BJ (Beef Jerky) and PCPB (Prosciutto, cappiola, pancetta, basturma) where the inclusion

of compliance factors results in an increase in the estimate of risk (where compliance is thought to be less than 100%). Table 7-12 presents the level of contamination post compliance for each lethality scenario





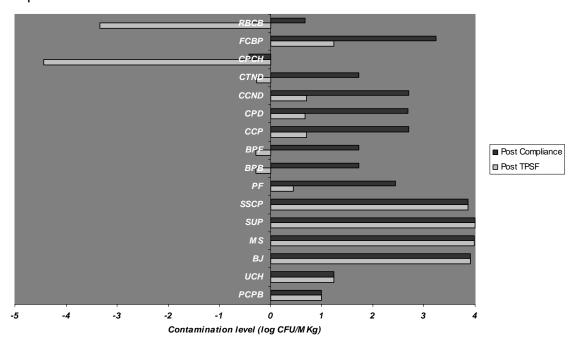
RTE Product	Post-Compliance Surviving Pathogen Burden						
	L	.og ₁₀ CFU / ថ្	9	Log ₁₀ CFU / MKg			
	All 5	Split	All	All 5	Split	All	
			6.5/7.0			6.5/7.0	
RBCB	-8.11	-8.33	-8.33	0.89	0.67	0.67	
FCBP	-5.76	-5.76	-7.11	3.24	3.24	1.89	
CPCH	-8.08	-9.43	-9.43	0.92	-0.43	-0.43	
CTND	-5.43	-7.27	-7.27	3.57	1.73	1.73	
CCND	-4.46	-6.30	-6.30	4.54	2.70	2.70	
CPD	-4.72	-6.32	-6.32	4.28	2.69	2.69	
CCP	-4.46	-6.30	-6.30	4.54	2.70	2.70	
BPF	-5.94	-7.28	-7.28	3.06	1.72	1.72	
BPB	-5.94	-7.28	-7.28	3.06	1.72	1.72	
PF	-4.72	-6.56	-6.56	4.28	2.44	2.44	
SSCP	-5.13	-5.13	-5.51	3.87	3.87	3.49	
SUP	-5.01	-5.01	-5.37	4.00	4.00	3.63	
MS	-5.02	-5.02	-5.39	3.98	3.98	3.61	
BJ	-5.09	-5.09	-5.46	3.91	3.91	3.54	
UCH	-7.77	-7.77	-8.15	1.24	1.24	0.85	
РСРВ	-8.00	-8.00	-8.40	1.00	1.00	0.60	

Table 7-12: Level of contamination following the inclusion of the adjustment factor to account for compliance with the lethality standard

7.2.4 All Products: Thermal Process Safety Factors

Following compliance, TPSFs are applied based upon product category. The post compliance level of contamination, the TPSF assigned to each product category, and the resulting post-TPSF contamination estimates are given in Table 7-13. The level of contamination post-compliance and post-TPSF are

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compared in

Figure 7-6. It can be seen that the incorporation of the thermal safety process factor results either in a reduction, or in no change, in the contamination estimate. The levels of contamination for all three lethality scenarios are given in Table 7-14. Inclusion of thermal safety factors has a relatively large impact upon the estimate of risk for all products classes except for those assigned risk categories as FCSS (Fermented or Direct Acidified, Cooked, Shelf-Stable), FUSS (Fermented or Direct Acidified, Uncooked, Shelf-stable), DH (Dried (incl. heat treatment)) or DN (Salt-cured (dried, no heat)). This is because these products are assigned a small TPSF, as described in Table 5-13.

Table 7-13: The post compliance level of contamination, thermal process safety factor (TPSF) assigned based upon product category, and the resulting post-TPSF risk estimates by product category. Values correspond to the Split scenario.

Product	Code	Lethality St	andard S	Scenario
		Post Compliance (log CFU/MKg)	TPSF	Post TPSF (logCFU/MKg)
Roast Beef, Corned Beef	RBCB	0.67	-4	-3.33
Fully Cooked Beef Patties	FCBP	3.24	-2	1.24
Cooked Pork (Cooked Ham, Pork BBQ)	CPCH	-0.43	-4	-4.43
Cooked Turkey (non-Deli)	CTND	1.73	-2	-0.27
Cooked Chicken (Nuggets, Tenders, non- Deli)	CCND	2.70	-2	0.70
Cooked Poultry Deli Meat	CPD	2.69	-2	0.68
Cooked Chicken Patties	CCP	2.70	-2	0.70
Beef / Pork Frankfurters	BPF	1.72	-2	-0.28
Beef / Pork Bologna	BPB	1.72	-2	-0.28
Poultry Frankfurters	PF	2.44	-2	0.44
Summer Sausage, Thuringer, Cooked Pepperoni	SSCP	3.87	0	3.87
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	SUP	4.00	0	4.00
Meat Sticks	MS	3.98	0	3.98
Beef Jerky	BJ	3.91	0	3.91
Uncooked Country Ham	UCH	1.24	0	1.24
Prosciutto, cappicola, pancetta, basturma	PCPB	1.00	0	1.00

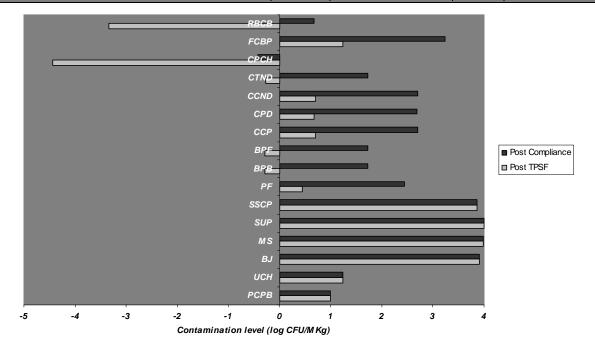


Figure 7-6: Comparison of the risk by RTE product category before (indicated as Post Compliance) and after (indicated as Post TPSF) the inclusion of a thermal process safety factor (TPSF) under the Split scenario.

RTE Product	Post-TPSF Surviving Pathogen Burden						
	Log ₁₀ CFU / g			Log ₁₀ CFU / MKg			
	All 5	Split	All 6.5/7.0	All 5	Split	All 6.5/7.0	
RBCB	-12.11	-12.33	-12.33	-3.11	-3.33	-3.33	
FCBP	-7.76	-7.76	-9.11	1.24	1.24	-0.11	
CPCH	-12.08	-13.43	-13.43	-3.08	-4.43	-4.43	
CTND	-7.43	-9.27	-9.27	1.57	-0.27	-0.27	
CCND	-6.46	-8.30	-8.30	2.54	0.70	0.70	
CPD	-6.72	-8.32	-8.32	2.28	0.68	0.68	
CCP	-6.46	-8.30	-8.30	2.54	0.70	0.70	
BPF	-7.94	-9.28	-9.28	1.06	-0.28	-0.28	
BPB	-7.94	-9.28	-9.28	1.06	-0.28	-0.28	
PF	-6.72	-8.56	-8.56	2.28	0.44	0.44	
SSCP	-5.13	-5.13	-5.51	3.87	3.87	3.49	
SUP	-5.01	-5.01	-5.37	4.00	4.00	3.63	
MS	-5.02	-5.02	-5.39	3.98	3.98	3.61	
BJ	-5.09	-5.09	-5.46	3.91	3.91	3.54	
UCH	-7.77	-7.77	-8.15	1.24	1.24	0.85	
PCPB	-8.00	-8.00	-8.40	1.00	1.00	0.60	

Table 7-14: Level of contamination for RTE products post-TPSF.

7.2.5 All Products: Storage and Growth

For each product the probability of illness resulting from the growth that may occur during storage of a contaminated serving is weighted by the proportion of products within each category that are assigned to the four growth scenarios – as given in Table 6-2. The result is the Storage and Growth impact. In essence, this is the risk of illness per contaminated serving for each product category prior to the consideration of reheating. The risk of illness per contaminated serving, that is the Storage and Growth impact, is multiplied by the number of contaminated servings per MKg, which is given by the concentration of per MKg post TPSF. The level of contamination post TPSF, the impact of storage and any growth that may occur, and the resulting risk of illness post storage for the Split lethality scenario are given in Table 7-15. The risk estimates for all three lethality scenarios are given in Table 7-16 (on the log scale) and in Table 7-17.

Table 7-15: The post thermal process safety factor level of contamination, storage and growth (S&G) impact (assigned based upon product category), and the resulting post-storage and growth risk estimates by product category. Values correspond to the Split scenario.

RTE Product	Lethality	Standard	Scenario
	Post TPSF (Log CFU/MKg)	S&G impact	Post S&G (log risk per MKg)
Roast Beef, Corned Beef	-3.33	-0.73	-4.06
Fully Cooked Beef Patties	1.24	-0.73	0.51
Cooked Pork (Cooked Ham, Pork BBQ)	-4.43	-0.94	-5.37
Cooked Turkey (non-Deli)	-0.27	-0.73	-1.01
Cooked Chicken (Nuggets, Tenders, non- Deli)	0.70	-0.73	-0.04
Cooked Poultry Deli Meat	0.68	-0.73	-0.05
Cooked Chicken Patties	0.70	-0.73	-0.04
Beef / Pork Frankfurters	-0.28	-0.94	-1.23
Beef / Pork Bologna	-0.28	-0.94	-1.23
Poultry Frankfurters	0.44	-0.94	-0.50
Summer Sausage, Thuringer, Cooked Pepperoni	3.87	-2.71	1.16
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	4.00	-2.86	1.14
Meat Sticks	3.98	-2.60	1.38
Beef Jerky	3.91	-2.60	1.31
Uncooked Country Ham	1.24	-2.60	-1.36
Prosciutto, cappicola, pancetta, basturma	1.00	-2.60	-1.60

RTE Product	Risk of illness on the log scale per unit mass (post storage)						
		Log ₁₀ risk / g		L	.og ₁₀ risk / MK	g	
	All 5	Split	All 6.5/7.0	All 5	Split	All 6.5/7.0	
RBCB	-12.85	-13.06	-13.06	-3.85	-4.06	-4.06	
FCBP	-8.49	-8.49	-9.84	0.51	0.51	-0.84	
CPCH	-13.03	-14.37	-14.37	-4.03	-5.37	-5.37	
CTND	-8.16	-10.01	-10.01	0.84	-1.01	-1.01	
CCND	-7.19	-9.04	-9.04	1.81	-0.04	-0.04	
CPD	-7.45	-9.05	-9.05	1.55	-0.05	-0.05	
CCP	-7.19	-9.04	-9.04	1.81	-0.04	-0.04	
BPF	-8.88	-10.23	-10.23	0.12	-1.23	-1.23	
BPB	-8.88	-10.23	-10.23	0.12	-1.23	-1.23	
PF	-7.66	-9.50	-9.50	1.34	-0.50	-0.50	
SSCP	-7.84	-7.84	-8.22	1.16	1.16	0.78	
SUP	-7.86	-7.86	-8.23	1.14	1.14	0.77	
MS	-7.62	-7.62	-7.99	1.38	1.38	1.01	
BJ	-7.69	-7.69	-8.06	1.31	1.31	0.94	
UCH	-10.36	-10.36	-10.75	-1.36	-1.36	-1.75	
PCPB	-10.60	-10.60	-11.00	-1.60	-1.60	-2.00	

Table 7-16: Risk of illness on the log scale following storage and growth per MKg and	
per g.	

RTE Product	Risk of illness per unit mass post storage					
		Log ₁₀ risk / g		L	og ₁₀ risk / MK	g
	All 5	Split	All 6.5/7.0	All 5	Split	All 6.5/7.0
RBCB	1.43x10 ⁻¹³	8.65x10 ⁻¹⁴	8.65x10 ⁻¹⁴	1.43x10 ⁻⁴	8.65x10 ⁻⁵	8.65x10 ⁻⁵
FCBP	3.20x10 ⁻⁹	3.20x10 ⁻⁹	1.45x10 ⁻¹⁰	3.20	3.20	0.15
CPCH	9.40x10 ⁻¹⁴	4.27x10 ⁻¹⁵	4.27x10 ⁻¹⁵	9.40x10 ⁻⁵	4.27x10 ⁻⁶	4.27x10 ⁻⁶
CTND	6.88x10 ⁻⁹	9.86x10 ⁻¹¹	9.86x10 ⁻¹¹	6.88	0.10	0.10
CCND	6.43x10 ⁻⁸	9.21x10 ⁻¹⁰	9.21x10 ⁻¹⁰	64.27	0.92	0.92
CPD	3.56x10 ⁻⁸	8.96x10 ⁻¹⁰	8.96x10 ⁻¹⁰	35.56	0.90	0.90
CCP	6.43x10 ⁻⁸	9.21x10 ⁻¹⁰	9.21x10 ⁻¹⁰	64.27	0.92	0.92
BPF	1.31x10 ⁻⁹	5.96x10 ⁻¹¹	5.96x10 ⁻¹¹	1.31	0.06	0.06
BPB	1.31x10 ⁻⁹	5.96x10 ⁻¹¹	5.96x10 ⁻¹¹	1.31	0.06	0.06
PF	2.19x10 ⁻⁸	3.14x10 ⁻¹⁰	3.14x10 ⁻¹⁰	21.88	0.31	0.31
SSCP	1.45x10 ⁻⁸	1.45x10 ⁻⁸	5.98x10 ⁻⁹	14.45	14.45	5.98
SUP	1.37x10 ⁻⁸	1.37x10 ⁻⁸	5.87x10 ⁻⁹	13.71	13.71	5.87
MS	2.42x10 ⁻⁸	2.42x10 ⁻⁸	1.02x10 ⁻⁸	24.15	24.15	10.23
BJ	2.04x10 ⁻⁸	2.04x10 ⁻⁸	8.65x10 ⁻⁹	20.42	20.42	8.65
UCH	4.34x10 ⁻¹¹	4.34x10 ⁻¹¹	1.77x10 ⁻¹¹	0.04	0.04	0.02
PCPB	2.53x10 ⁻¹¹	2.53x10 ⁻¹¹	1.00x10 ⁻¹¹	0.03	0.03	0.01

Table 7-17: Risk of illness on the absolute scale following storage and growth given per MKg and per g.

7.2.6 All Products: Reheating

Once storage is complete, the product may be reheated. When reheating is incorporated, the process is the same as for estimating the impact of storage and growth, except that the post storage and growth level of contamination is translated into the risk of illness through the reheating impact (note that this is carried out on the log scale). The reheating impact incorporates the effect of storage, growth and reheating in the estimation process. It is therefore applied to the level of contamination following application of the TPSF. The level of contamination post TPSF, the reheating impact (on the log scale), and the resulting risk of illness post reheating (including storage and growth) for the Split lethality scenario are given in Table 7-18. Figure 7-7 shows the change in risk that occurs with the inclusion of reheating post storage compared to no reheating following storage. The inclusion of this stage results in a reduction in the risk for all products except those products classified with reheating frequencies of 'Rarely' (products RBCB, CPD, BPB, SSCP, SUP, & PCPB) or 'Never' (products MS & UCH). The reduction in risk following reheating is minimal, resulting in these products ranking highest in final risk estimates on a risk per MKg basis.

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Table 7-18: The post thermal process safety factor risk, reheating impact, and the resulting risk estimates per MKg post reheating by product category. Values correspond to the Split scenario.

RTE Product	Product code	Lethality Standard Scenario			
		Post TPSF (log CFU/MKg)	reheating impact (log risk)	Risk Post reheating (log/per MKg)	Risk post reheating (non- log/per MKg)
Roast Beef, Corned Beef	RBCB	-4.06	-0.75	-4.08	8.26x10 ⁻⁵
Fully Cooked Beef Patties	FCBP	0.51	-1.06	0.18	1.51
Cooked Pork (Cooked Ham, Pork BBQ)	CPCH	-5.37	-1.25	-5.68	2.08x10-6
Cooked Turkey (non-Deli)	CTND	-1.01	-1.06	-1.33	0.05
Cooked Chicken (Nuggets,	CCND				
Tenders, non-Deli)		-0.04	-1.06	-0.36	0.43
Cooked Poultry Deli Meat	CPD	-0.05	-0.75	-0.07	0.86
Cooked Chicken Patties	CCP	-0.04	-1.06	-0.36	0.43
Beef / Pork Frankfurters	BPF	-1.23	-1.25	-1.54	0.03
Beef / Pork Bologna	BPB	-1.23	-0.97	-1.25	0.06
Poultry Frankfurters	PF	-0.50	-1.25	-0.81	0.15
Summer Sausage, Thuringer, Cooked Pepperoni	SSCP	1.16	-2.76	1.11	13.00
Salami, Uncooked Pepperoni,	SUP				
Chorizo, Soudjuk		1.14	-2.90	1.09	12.36
Meat Sticks	MS	1.38	-2.60	1.38	24.15
Beef Jerky	BJ	1.31	-2.60	1.31	20.42
Uncooked Country Ham	UCH	-1.36	-3.29	-2.05	0.01
Prosciutto, cappicola,	PCPB				
pancetta, basturma		-1.60	-2.64	-1.64	0.02

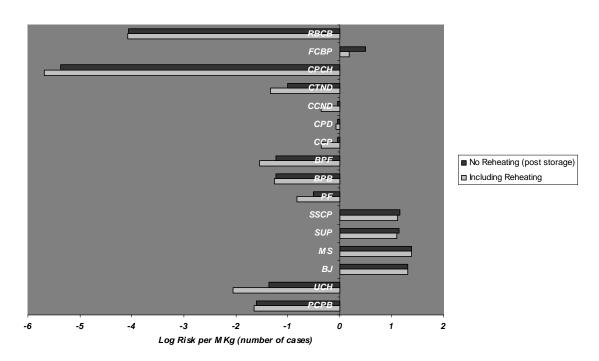


Figure 7-7: Comparison of the risk per MKg (in terms of the log number of cases of salmonellosis) by RTE product category after storage with no reheating and including reheating under the Split scenario

7.2.7 All Products: Number of Cases

The estimates of the number of cases of salmonellosis per year by product for each lethality scenario are given in Table 7-19, and compared graphically in Figure 7-8. For example, raising the lethality scenario from 5-log to the 'split' scenario reduces the risk attributed to Cooked chicken 100-fold. Note that in the split scenario Cooked Chicken receives a lethality treatment of 7 logs.

RTE Product	Risk (Number of cases) per unit mass						
	Lo	og ₁₀ Cases /	g	Log	10 Cases / M	lKg	
	All 5	Split	All	All 5	Split	All	
			6.5/7.0			6.5/7.0	
RBCB	-12.86	-13.08	-13.08	-3.86	-4.08	-4.08	
FCBP	-8.82	-8.82	-10.17	0.18	0.18	-1.17	
CPCH	-13.34	-14.68	-14.68	-4.34	-5.68	-5.68	
CTND	-8.49	-10.33	-10.33	0.51	-1.33	-1.33	
CCND	-7.52	-9.36	-9.36	1.48	-0.36	-0.36	
CPD	-7.47	-9.07	-9.07	1.53	-0.07	-0.07	
CCP	-7.52	-9.36	-9.36	1.48	-0.36	-0.36	
BPF	-9.19	-10.54	-10.54	-0.19	-1.54	-1.54	
BPB	-8.91	-10.25	-10.25	0.09	-1.25	-1.25	
PF	-7.97	-9.81	-9.81	1.03	-0.81	-0.81	
SSCP	-7.89	-7.89	-8.27	1.11	1.11	0.73	
SUP	-7.91	-7.91	-8.28	1.09	1.09	0.72	
MS	-7.62	-7.62	-7.99	1.38	1.38	1.01	
BJ	-7.69	-7.69	-8.06	1.31	1.31	0.94	
UCH	-11.05	-11.05	-11.44	-2.05	-2.05	-2.44	
PCPB	-10.64	-10.64	-11.05	-1.64	-1.64	-2.05	

Table 7-19: Risk (in terms of the number of cases of salmonellosis) on the log scale by product category for the lethality scenarios considered: All log 5, Split, and All 6.5/7.0.

Table 7-20: Risk (in terms of the number of cases of salmonellosis) on the absolute scale by product category for the lethality scenarios considered: All log 5, Split, and All 6.5/7.0.

RTE Product	Risk (Number of cases) per unit mass					
	Log	110 Cases / g		Log	10 Cases / M	ИKg
	All 5	Split	All	All 5	Split	All 6.5/7.0
			6.5/7.0			
RBCB	1.37x10 ⁻¹³	8.27x10 ⁻¹⁴	8.27x10 ⁻¹⁴	1.37x10 ⁻⁴	8.27x10 ⁻⁵	8.27x10 ⁻⁵
FCBP	1.51x10 ⁻⁹	1.51x10 ⁻⁹	6.83x10 ⁻¹¹	1.51	1.51	0.07
CPCH	4.59x10 ⁻¹⁴	2.10x10 ⁻¹⁵	2.10x10 ⁻¹⁵	4.59x10 ⁻⁵	2.10x10 ⁻⁶	2.10x10 ⁻⁶
CTND	3.24x10 ⁻⁹	4.64x10 ⁻¹¹	4.64x10 ⁻¹¹	3.24	0.05	0.05
CCND	3.03x10 ⁻⁸	4.34x10 ⁻¹⁰	4.34x10 ⁻¹⁰	30.27	0.43	0.43
CPD	3.40x10 ⁻⁸	8.56x10 ⁻¹⁰	8.56x10 ⁻¹⁰	33.99	0.86	0.86
CCP	3.03x10 ⁻⁸	4.34x10 ⁻¹⁰	4.34x10 ⁻¹⁰	30.27	0.43	0.43
BPF	6.41x10 ⁻¹⁰	2.91x10 ⁻¹¹	2.91x10 ⁻¹¹	0.64	0.03	0.03
BPB	1.23x10 ⁻⁹	5.57x10 ⁻¹¹	5.57x10 ⁻¹¹	1.23	0.06	0.06
PF	1.07x10 ⁻⁸	1.53x10 ⁻¹⁰	1.53x10 ⁻¹⁰	10.70	0.15	0.15
SSCP	1.30x10 ⁻⁸	1.30x10 ⁻⁸	5.39x10 ⁻⁹	13.01	13.01	5.39
SUP	1.23x10 ⁻⁸	1.23x10 ⁻⁸	5.29x10 ⁻⁹	12.35	12.35	5.29
MS	2.42x10 ⁻⁸	2.42x10 ⁻⁸	1.02x10 ⁻⁸	24.18	24.18	10.24
BJ	2.04x10 ⁻⁸	2.04x10 ⁻⁸	8.65x10 ⁻⁹	20.40	20.40	8.65
UCH	8.84x10- ¹²	8.84x10 ⁻¹²	3.61x10 ⁻¹²	0.01	0.01	3.61x10 ⁻³

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PCPB 2.28x10 ⁻¹¹ 2.28x10 ⁻¹¹ 9.00x10 ⁻¹² 0.02 0.02 0.02
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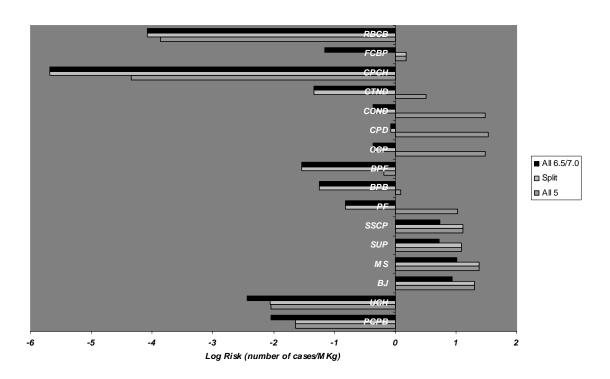


Figure 7-8: Risk (in terms of the log number of cases of salmonellosis per MKg) by product category for each of the lethality scenarios considered in the assessment.

Looking at the contribution to total estimate of risk, shown in Table 7-21, Cooked Chicken (Nuggets, Tenders, non-deli) is by far the greatest contributor to the estimate of the number of cases of salmonellosis per year under the 'all 5' scenario, accounting for 61% of the total estimate of the risk. For the 'split' scenario, the greatest contributor is still Cooked Chicken (Nuggets, Tenders, non-deli), however to a much lesser extent. Other products *that* contribute significantly to the risk under the Split scenario are the products assigned FUSS (Salami, Uncooked Pepperoni, Chorizo, Soudjuk), and DH (meat sticks and beef jerky), and to a lesser extent FCSS (Summer Sausage, Thuringer, Cooked Pepperoni).

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Product category	Number of Cases		% Con	% Contribution	
	all 5	split	all 5	split	
Roast Beef, Corned Beef	0.01	0.01	<0.001%	<0.001%	
Fully Cooked Beef Patties	0.11	0.11	<0.001%	<0.001%	
Cooked Pork (Cooked Ham, Pork BBQ)	<0.001%	<0.001%	<0.001%	<0.001%	
Cooked Turkey (non-Deli)	1,250	18	1.87%	0.57%	
Cooked Chicken (Nuggets, Tenders, non-Deli)	40,740	584	61.06%	18.53%	
Cooked Poultry Deli Meat	15,460	389	23.17%	12.35%	
Cooked Chicken Patties	3,541	51	5.31%	1.61%	
Beef / Pork Frankfurters	257	12	0.38%	0.37%	
Beef / Pork Bologna	163	7	0.24%	0.23%	
Poultry Frankfurters	3,263	47	4.89%	1.48%	
Summer Sausage, Thuringer, Cooked					
Pepperoni	715	715	1.07%	22.69%	
Salami, Uncooked Pepperoni, Chorizo,					
Soudjuk	679	679	1.02%	21.54%	
Meat Sticks	442	442	0.66%	14.03%	
Beef Jerky	208	208	0.31%	6.60%	
Uncooked Country Ham	0.28	0.28	<0.001%	0.007%	
Prosciutto, cappicola, pancetta, basturma	0.08	0.08	<0.001%	0.01%	
Total	66,720	3,153	100%	100%	

Table 7-21: Contribution of product types to the estimate of the number of cases of salmonellosis per year from RTE foods.

The above estimates of risk are the result of the accumulation of the estimate of risk per MKg and the estimated level of consumption associated with the different product categories. Examining the influence of the level of consumption upon the estimate of risk. Table 7-22 compares the level of risk per MKg, the level of consumption in MKg per year, and the final estimates of risk. The consumption mass is multiplied directly with the risk per MKg, therefore products with relatively large risk estimates per MKg and a large consumption mass will be associated with larger estimates of risk at the product level. To illustrate this, consider Cooked Chicken and Cooked Chicken Patties. Both products have an estimated risk of 0.3 cases of salmonellosis per MKg. However, Cooked Chicken has an estimated consumption mass of 1,346 MKg, compared to a consumption mass of 117 MKg for Cooked Chicken Patties. These consumption masses result in divergent product risks of ~600 and ~50 cases of salmonellosis per year for Cooked Chicken and Cooked Chicken Patties, respectively. The resulting risks of illness in terms of the number of cases per year by product for each lethality scenario are given in Figure 7-9.

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Table 7-22: The risk of illness per MKg, the consumption mass by product type (MKg)	
and the resultant product risk for RTE foods.	

Products	Risk Per	Consumption	Product
	MKg	mass (MKg)	Risk
Roast Beef, Corned Beef	8.27x10 ⁻⁵	85	7.03x10 ⁻³
Fully Cooked Beef Patties	1.51	0.07	0.11
Cooked Pork (Cooked Ham, Pork BBQ)	2.10x10 ⁻⁶	100	2.08x10 ⁻⁴
Cooked Turkey (non-Deli)	0.05	386	17.92
Cooked Chicken (Nuggets, Tenders, non-Deli)	0.43	1346	584.1
Cooked Poultry Deli Meat	0.86	455	389.4
Cooked Chicken Patties	0.43	117	50.77
Beef / Pork Frankfurters	0.03	400	11.63
Beef / Pork Bologna	0.06	132	7.37
Poultry Frankfurters	0.15	305	46.78
Summer Sausage, Thuringer, Cooked Pepperoni	13.01	55	715.3
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	12.35	55	679.1
Meat Sticks	24.18	18	442.4
Beef Jerky	20.40	10	208.1
Uncooked Country Ham	0.01	32	0.28
Prosciutto, cappicola, pancetta, basturma	0.02	3	0.08

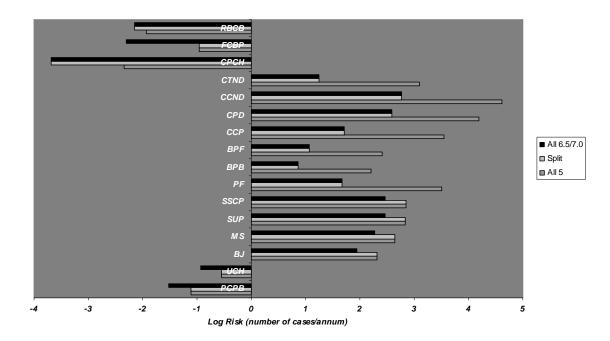


Figure 7-9: Risk (in terms of the log number of cases of salmonellosis per year) by product category for each of the lethality scenarios considered in the assessment.

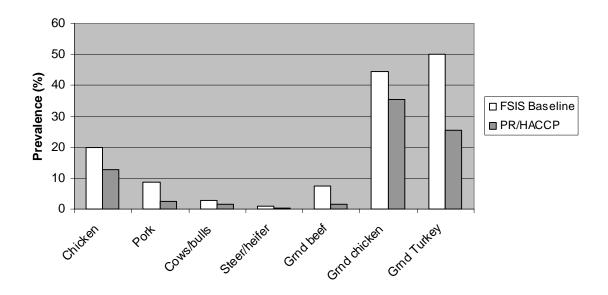
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8 Sensitivity Analyses

8.1 Risk Estimates given updated prevalence data

These estimates are a result of using the estimates of prevalence reported for 2003 from PR/HACCP Verification Testing Program (FSIS, 2005) in place of the prevalence estimated from the FSIS Baseline Microbiological Surveys (FSIS, 1994; FSIS, 1996a-g; FSIS, 1998). Note that as no updated enumeration data is available for the pathogen burden estimates the assumption is that the FSIS Baseline is a suitable surrogate for the raw material contamination levels in 2003 associated with the prevalence estimates.

The following graph compares the Baseline survey estimates of prevalence and the 2003 PR/HACCP Verification Testing Program estimates of prevalence. There are no data in the 2003 PR/HACCP Verification Testing Program for turkey carcasses, therefore the assumption is made that the relative change in the prevalence of chicken carcasses also applied to turkey.



8.1.1 Probability of Illness Per MKg RTE Product

Table 8-1: Estimates of the number of cases of salmonellosis per product class on an equal mass basis (per MKg), including reheating for the three lethality standards scenarios considered in the assessment.

RTE Product Category	Risk of Illness by product (after reheating)					
	Log Num	ber of cas	ses /MKg		er of case	s /MKg
	All 5	Split	6.5/7.0	All 5		
Roast Beef, Corned Beef	-4.2	-5.7	-5.7	6.4x10 ⁻⁵	2.0x10 ⁻⁶	2.0x10 ⁻⁶
Fully Cooked Beef Patties	-0.3	-0.3	-1.8	5.0x10 ⁻¹	5.0x10 ⁻¹	1.6x10 ⁻²
Cooked Pork (Cooked Ham,						
Pork BBQ)	-4.8	-6.3	-6.3	1.4x10 ⁻⁵	5.0x10 ⁻⁷	5.0x10 ⁻⁷
Cooked Turkey (non-Deli)	0.4	-1.6	-1.6	2.56	0.03	0.03
Cooked Chicken (Nuggets,						
Tenders, non-Deli)	1.4	-0.6	-0.6	23.2	0.2	0.2
Cooked Poultry Deli Meat	1.4	-0.6	-0.6	26.1	0.3	0.3
Cooked Chicken Patties					0.23	
	1.4	-0.6	-0.6	23.2		0.2
Beef / Pork Frankfurters	-0.5	-2.0	-2.0	0.3	0.01	0.01
Beef / Pork Bologna	-0.2	-1.7	-1.7	0.6	0.02	0.02
Poultry Frankfurters	0.9	-1.1	-1.1	8.2	0.08	0.08
Summer Sausage,						
Thuringer, Cooked						
Pepperoni	0.3	0.3	-0.2	2.2	2.2	0.7
Salami, Uncooked						
Pepperoni, Chorizo, Soudjuk	0.5	0.5	0.1	3.4	3.4	1.4
Meat Sticks	0.8	0.8	0.4	6.7	6.7	2.7
Beef Jerky	0.9	0.9	0.5	8.0	8.0	3.2
Uncooked Country Ham	-2.9	-2.9	-3.9	1.3x10 ⁻³	1.3x10 ⁻³	1.3x10 ⁻⁴
Prosciutto, cappicola,						
pancetta, basturma	-1.7	-1.7	-2.2	0.02	0.02	0.01

8.1.2 Relative Risk of Illness by Product Class

Table 6-7 presents the risk per year broken down by RTE product category on an equal mass basis. To ease comparison, these risk estimates are presented in purely relative terms in Table 6-8. This is a useful measure since it indicates the risk associated with the product, relative to others, while controlling for variable production volumes. Note: The value in the table is relative to the value of 1.0 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

Table 8-2: The relative risk of each product class on an equal mass basis (number of cases of salmonellosis per MKg) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

	F		1
RTE Product Category	Relative Product Risk		
	All 5.0	Split	All 6.5/7.0
Roast Beef, Corned Beef	6.3x10 ⁻³	2.0x10 ⁻⁴	2.0x10 ⁻⁴
Fully Cooked Beef Patties	49.3	49.3	1.6
Cooked Pork (Cooked Ham, Pork BBQ)	1.4 x10 ⁻³	5.0 x10 ⁻⁵	5.0 x10 ⁻⁵
Cooked Turkey (non-Deli)	254.0	2.5	2.5
Cooked Chicken (Nuggets, Tenders, non-Deli)	2298.9	23.0	23.0
Cooked Poultry Deli Meat	2589.6	25.9	25.9
Cooked Chicken Patties	2298.9	23.0	23.0
Beef / Pork Frankfurters	31.6	1	1.0
Beef / Pork Bologna	60.6	1.9	1.9
Poultry Frankfurters	815.1	8.2	8.2
Summer Sausage, Thuringer, Cooked Pepperoni	219.0	219.0	69.2
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	332.1	332.1	136.4
Meat Sticks	667.2	667.2	262.4
Beef Jerky	790.7	790.7	315.2
Uncooked Country Ham	0.1	0.1	1.3 x10 ⁻²
Prosciutto, cappicola, pancetta, basturma	1.8	1.8	0.6

8.1.3 Number of Illnesses Per Mass of RTE Product Consumed Per Year

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This risk can be interpreted as the expected number of cases of salmonellosis per year. The estimates are reported in Table 6-13, and include the impact of the thermal process safety factors and reheating.

Table 8-3: Estimate of the number of cases of salmonellosis per year that may result	
under differing lethality standards.	

RTE Product Category	Number of Cases per year			
	All 5.0	Split	All 6.5/7.0	
Roast Beef, Corned Beef	5x10 ⁻³	1.7x10 ⁻⁴	1.7x10 ⁻⁴	
Fully Cooked Beef Patties	3.6x10 ⁻²	3.6x10 ⁻²	1.1x10 ⁻³	
Cooked Pork (Cooked Ham, Pork BBQ)	1.4x10 ⁻³	4.5x10 ⁻⁵	4.5x10 ⁻⁵	
Cooked Turkey (non-Deli)	989	10	10	
Cooked Chicken (Nuggets, Tenders, non-Deli)	31,230	312	312	
Cooked Poultry Deli Meat	11,890	119	119	
Cooked Chicken Patties	2,714	27	27	
Beef / Pork Frankfurters	128	4	4	
Beef / Pork Bologna	81	3	3	
Poultry Frankfurters	2,509	25	25	
Summer Sausage, Thuringer, Cooked Pepperoni	122	122	38	
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	184	184	76	
Meat Sticks	123	123	48	
Beef Jerky	81	81	32	
Uncooked Country Ham	4.2×10^{-2}	4.2x10 ⁻²	4.2x10 ⁻³	
Prosciutto, cappicola, pancetta, basturma	6.3x10 ⁻²	6.3x10 ⁻²	2.0x10 ⁻²	
Total	50,050	1010	695	

8.1.4 Relative Risk of Illness by Product Class

Table 6-13 presents the risk per year broken down by RTE product category. To ease comparison, these risk estimates are presented in purely relative terms in Table 6-14. Note: The value in the table is relative to the value of 1 assigned to "Beef/Pork Bologna at 6.5-log Reduction".

Table 8-4: The relative risk of each product class (cases of salmonellosis per year) set relative to the risk estimate associated with "Beef/Pork Frankfurters".

RTE Product Category	Relative Product Risk			
	All 5.0	Split	All 6.5/7.0	
Roast Beef, Corned Beef	1.3x10 ⁻³	4.3x x10 ⁻⁵	4.3 x10 ⁻⁵	
Fully Cooked Beef Patties	8.9 x10 ⁻³	8.9 x10 ⁻³	2.8 x10 ⁻⁴	
Cooked Pork (Cooked Ham, Pork BBQ)	3.6 x10 ⁻⁴	1.1 x10 ⁻⁵	1.1 x10 ⁻⁵	
Cooked Turkey (non-Deli)	245.1	2.5	2.5	
Cooked Chicken (Nuggets, Tenders, non-Deli)	7,735.9	77.4	77.4	
Cooked Poultry Deli Meat	2,945.3	29.5	29.5	
Cooked Chicken Patties	672.3	6.7	6.7	
Beef / Pork Frankfurters	31.6	1.0	1.0	
Beef / Pork Bologna	20.0	0.6	0.6	
Poultry Frankfurters	621.5	6.2	6.2	
Summer Sausage, Thuringer, Cooked Pepperoni	30.1	30.1	9.5	
Salami, Uncooked Pepperoni, Chorizo, Soudjuk	45.7	45.7	18.8	
Meat Sticks	30.5	30.5	12.0	
Beef Jerky	20.2	20.2	8.0	
Uncooked Country Ham	1.1 x10 ⁻²	1.1 x10 ⁻²	1.1 x10 ⁻³	
Prosciutto, cappicola, pancetta, basturma	1.6 x10 ⁻²	1.6 x10 ⁻²	5.1 x10 ⁻³	

8.1.5 Total Supply Risk Per Year From RTE Products

The total supply risk, interpreted as the total expected number of cases of salmonellosis per year, is simply the sum of the individual product risks. This risk is given in Table 6-15. For this value, we compare the results for including and excluding thermal process safety factors and reheating, as well as the baseline lethality standard scenarios of all 5-log reductions and all 6.5/7.0 log reductions. The number of significant digits has been suppressed in this presentation. Though the model calculates these numbers with more precision, the accuracy of the model does not justify presenting precise estimates.

Table 8-5: Total supply risk, interpreted as the estimated number of cases of salmonellosis per year, from RTE products under each lethality standard considered (All 5-log reduction, Split reductions and All 6.5/7-log reductions). The numbers of cases are shown with and without the inclusion of thermal process safety factors and/or reheating.

Cases per year: All 5-log Reduction					
Include Reheating	Include Thermal Process Safety Factors				
	Yes N				
Yes	50,050	4,954,000			
No	92,600 9,211,00				

Cases per year: Split Reductions				
Include Reheating	Include Thermal Process Safety Factors			
	Yes			
Yes	1,010	50,500		
No	1,500	93,500		

Cases per year: All 6.5/7.0 Log Reduction					
Include Reheating	Include Thermal Process Safety Factors				
	Yes				
Yes	700	50,200			
No	1,100	93,000			

8.1.6 Comparison of results

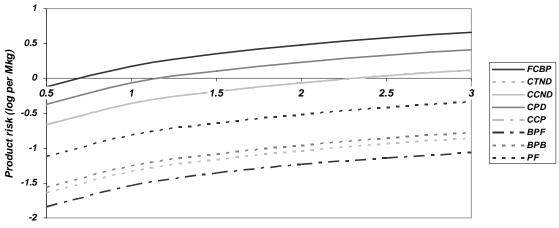
Comparing the risk estimates using the PR/HACCP prevalence estimates it can be seen that the annual number of cases for each scenario is lower. For All log 5 scenario this corresponds to a decrease from 66,000 to 50,050 cases; for the Split scenario this corresponds to a decrease from 1,900 to 1,010 cases per year and for the All 6.7/7 log scenario from 1,100 to 700 cases per year. However, the percentage contribution of the product categories to the estimates of the total number of cases per year does not change significantly with the adjustment to the input prevalence data. The contribution to the overall estimates of risk are given in Table 8-6.

Table 8-6: The percentage contribution of each product category to the estimate of the number of cases of salmonellosis per year using the FSIS Baseline surveys and the PR/HACCP data for prevalence estimates in raw materials.

RTE Product Category	Risk of Illness by product (after reheating)					
	FSIS	Basline Su	urveys	PR/HA	CCP 2003	3 Survey
	All 5	Split	6.5/7.0	All 5	Split	6.5/7.0
Roast Beef, Corned Beef	1.5x10 ⁻⁵	2.1x10 ⁻⁵	3.5x10 ⁻⁵	1.1x10 ⁻⁵	1.7x10 ⁻⁵	2.5x10 ⁻⁵
Fully Cooked Beef Patties	1.7x10 ⁻⁴	5.8x10 ⁻³	2.7x10 ⁻⁴	7.2x10 ⁻⁵	3.6x10 ⁻³	1.6x10 ⁻⁴
Cooked Pork (Cooked Ham,						
Pork BBQ)	7.0x10 ⁻⁶	5.3x10 ⁻⁶	8.8x10 ⁻⁶	2.9x10 ⁻⁶	4.5x10 ⁻⁶	6.5x10 ⁻⁶
Cooked Turkey (non-Deli)	1.9	0.7	1.2	2.0	1.0	1.4
Cooked Chicken (Nuggets,						
Tenders, non-Deli)	61.8	21.5	36.0	62.4	30.9	44.9
Cooked Poultry Deli Meat	23.5	8.2	13.7	23.8	11.8	17.1
Cooked Chicken Patties	5.4	1.9	3.1	5.4	2.7	3.9
Beef / Pork Frankfurters	0.4	0.4	0.7	0.3	0.4	0.6
Beef / Pork Bologna	0.2	0.3	0.4	0.2	0.3	0.4
Poultry Frankfurters	5.0	1.7	2.9	5.0	2.5	3.6
Summer Sausage,						
Thuringer, Cooked						
Pepperoni	0.4	12.9	6.8	0.2	12.0	5.5
Salami, Uncooked						
Pepperoni, Chorizo, Soudjuk	0.6	19.6	13.5	0.4	18.2	10.9
Meat Sticks	0.6	19.7	13.0	0.2	12.2	7.0
Beef Jerky	0.4	13.1	8.7	0.2	8.1	4.7
Uncooked Country Ham	2.1x10 ⁻⁴	7.4x10 ⁻³	8.8x10 ⁻⁴	8.5x10 ⁻⁵	4.2x10 ⁻³	6.1x10 ⁻⁴
Prosciutto, cappicola,						
pancetta, basturma	3.0x10 ⁻⁴	1.1x10 ⁻²	6.2x10 ⁻³	1.3x10 ⁻⁴	6.2x10 ⁻³	2.9x10 ⁻³

8.2 Sensitivity of Model Results to the Estimation of the Pathogen Burden

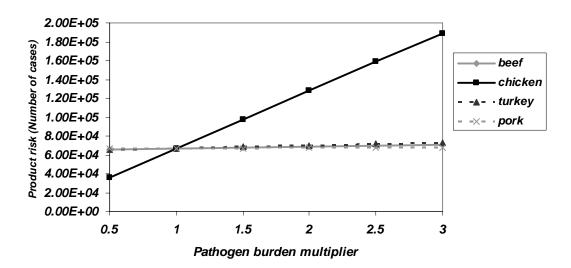
The magnitude of the estimated pathogen burden directly influences the estimate of risk on the product weight basis. Figure 8-1 shows the predicted product risk per MKg for a range of pathogen burden multiplying factors. In each case, the pathogen burden is adjusted across all meat types (i.e. chicken, beef, pork and turkey). Multipliers greater than 1 represent a systematic underestimation in the pathogen burden, whereas multipliers less than 1 represent an overestimation in the pathogen burden. It can be seen that as the multiplier increases (and therefore the pathogen burden estimate) so does the estimate of the risk on an MKg basis. However, the figure also shows that the relationship between the estimate of risk and the multiplier is conserved over all product types (only products FCBP, CTNB, CCND, CPD, CCP, BPF, BPB, and PF are shown in the figure). Therefore, although an under or over estimate in the pathogen burden may affect absolute estimates of risk, these findings suggest that the relative relationship of product types in terms of determining the pattern of risk would not be affected by a consistent under- or over-estimation in the pathogen burden.



Pathogen burden multiplier

Figure 8-1: The predicted product risk per MKg for a range of pathogen burden multiplying factors

To investigate the importance of an underestimation in a pathogen burden multiplier that only affects one type of meat, the multiplier was applied to beef, chicken, turkey and pork in isolation and results obtained. The results are shown in Figure 8-2. For the lethality scenario 'All log 5', it can be seen that an underestimation in the pathogen burden of chicken meat would have the greatest influence upon the total estimate of risk. However, under the lethality scenario 'Split', beef products dominate the risk estimate, and an underestimation in the associated pathogen burden would greatly influence estimates of risk. For all pathogen multipliers, Cooked poultry deli meat (product CPD) is the greatest contributor to the risk for the 'all log 5' lethality scenario, and Beef Jerky the greatest contributor for the 'split' lethality scenario.



Lethality scenario: All Log 5

Lethality scenario: Split

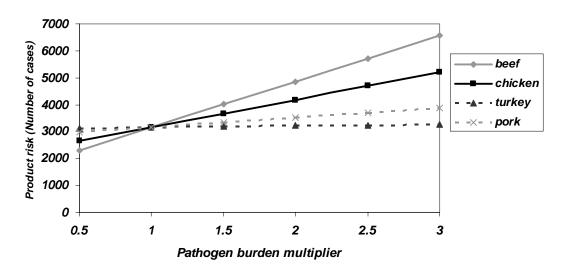


Figure 8-2: The impact of applying pathogen burden multiplier on meat type

8.3 Sensitivity of Model Results to the Estimation of the Level of Compliance

The percentage compliance is an area of uncertainty in the model. To investigate the impact of estimates of compliance on risk estimates, the proportion of processors that achieve S to S+1 lethality was adjusted across a range from 20% to 100%. To demonstrate the effect, 6 products were investigated: Cooked Chicken (Nuggets, Tenders, non-Deli) (CCND), Cooked Poultry Deli Meat (CPD) Cooked Chicken Patties (CCP), Summer Sausage, Thuringer, Cooked Pepperoni (SSCP), Salami, Uncooked Pepperoni, Chorizo, Soudjuk (SUP) and Meat Sticks (MS). Figure 8-3 shows that as the level of compliance with the standard increases, the number of cases of salmonellosis predicted by the model decreases. Note that the relative risk of some products is so low that the scale of the graph does not adequately represent the change in risk.

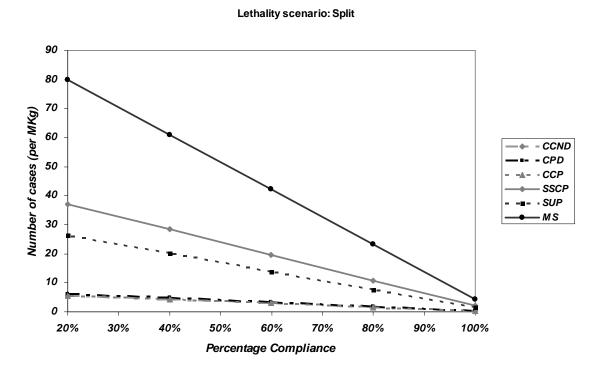


Figure 8-3: The impact of the level of compliance on risk estimates

8.4 Sensitivity of Model Results to the Estimation of the Thermal Process Safety Factor

September 2005

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To investigate the impact of TPSF on estimates of risk, estimates relative to the base case (model as defined in section 2) were obtained for 5 scenarios:

- 1. Products assigned a large TPSF were changed to a moderate safety factor (applies to roast beef and cooked pork)
- Products assigned a low TPSF were assigned a moderate safety factor (applies to Summer Sausage, Thuringer, Cooked Pepperoni, Salami, Uncooked Pepperoni, Chorizo, Soudjuk, Meat Sticks, Beef Jerky, Uncooked Country Ham, Prosciutto, cappicola, pancetta, basturma)
- 3. All products are assigned a small TPSF
- 4. All products are assigned a moderate TPSF
- 5. All products are assigned a large TPSF

The risk estimates relative to the base model are presented in Table 8-7. It can be seen that lowering the safety factor for products assigned 'high' (scenario 1) has a negligible impact on overall estimates of risk across all lethality scenarios. Increasing the TPSF for those assigned a small factor (scenario 2) reduces the risk relative to the base case, with the largest reduction obtained in the split lethality scenario. Assigning all products a small TPSF (scenario 3) increases the risk, with an almost 100-fold increase under the 'all log 5' lethality scenario. Assigning all products a moderate (scenario 4) or large (scenario 5) TPSF results in reductions in the estimate of risk.

Table 8-7: The change in the total estimate of risk (number of cases of salmonellosis per year) under each lethality scenario in line with the test scenarios for TPSF. In each case the risk is relative to the baseline for each lethality scenario.

Scenario	Description		lity Scenari Relative to seline Scen)
		all log 5	split	all 6.5/7
Baseline	TPSF assigned as in Table 5-13	1	1	1
Scenario 1	Large TPSF reduced to moderate TPSF	1	1	1
Scenario 2	Low TPSF increased to moderate TPSF	0.97	0.36	0.57
Scenario 3	All products are assigned a small TPSF	96.97	35.81	56.67
Scenario 4	All products are assigned a moderate TPSF	0.97	0.36	0.57
Scenario 5	All products are assigned a large TPSF	0.01	0.004	0.01

The assignment of TPSF also influences the profile of the risk. The percentage contribution of each of the products to the estimate of risk (number of cases of salmonellosis per year) under the base case and each of the 5 scenarios is given

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in Table 8-8. Highlighted in the table are the 5 products contributing most to the risk under each scenario. These findings are based upon the 'split' lethality scenario. Examination of the table shows that in the base case, product SSCP (Summer Sausage, Thuringer, Cooked Pepperoni), product SUP (Salami, Uncooked Pepperoni, Chorizo, Soudjuk), and product MS (Meat Sticks) together account for >50% of the overall risk. However, under scenarios 2, 3, 4 and 5 these products account for <2% of the total. In contrast in the base case products CTND (Cooked Turkey (non-Deli)), product CCND (Cooked Chicken (Nuggets, Tenders, non-Deli)) product CPD (Cooked Poultry Deli Meat) and product CCP (Cooked Chicken Patties) collectively account for ~30% of the risk, however under scenarios 2, 3, 4 and 5 they account for 90% of the total risk estimate. Note that scenarios 3, 4 and 5 do not alter the relative contribution of each of the product categories to the overall estimate of risk because the level of contamination is reduced by the same proportion across the products under each scenario. For example, under scenario 4 the level of contamination for all products is reduced by 2 logs, and in scenario 5 the level of contamination for all products is reduced by 4 logs, maintaining the relative magnitude of the level of contamination between products.

	Base Case	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
RBCB	<0.01%	0.02%	<0.01%	0.06%	0.06%	0.06%
FCBP	<0.01%	<0.01%	0.01%	0.01%	0.01%	0.01%
CPCH	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%
CTND	0.57%	0.57%	1.59%	1.59%	1.59%	1.59%
CCND	18.53%	18.52%	51.78%	51.74%	51.74%	51.74%
CPD	12.35%	12.35%	34.52%	34.49%	34.49%	34.49%
CCP	1.61%	1.61%	4.50%	4.50%	4.50%	4.50%
BPF	0.37%	0.37%	1.03%	1.03%	1.03%	1.03%
BPB	0.23%	0.23%	0.65%	0.65%	0.65%	0.65%
PF	1.48%	1.48%	4.15%	4.14%	4.14%	4.14%
SSCP	22.69%	22.68%	0.63%	0.63%	0.63%	0.63%
SUP	21.54%	21.53%	0.60%	0.60%	0.60%	0.60%
MS	14.03%	14.03%	0.39%	0.39%	0.39%	0.39%
BJ	6.60%	6.60%	0.18%	0.18%	0.18%	0.18%
UCH	0.01%	0.01%	<0.01%	<0.01%	<0.01%	<0.01%
РСРВ	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%

Table 8-8: The percentage contribution of each of the products to the estimate of risk (number of cases of salmonellosis per year) under the base case and each of the 5 TPSF scenarios (shading indicates the top 5 contributing products in each scenario).

8.5 Sensitivity of Model Results to the Estimation of the Reheating Factor

To incorporate reheating, products are assigned a reheating pattern of never reheated, rarely reheated, usually reheated or always reheated. To test the impact of this assignment, model results were obtained for the following scenarios:

- 1. Products assigned to the always reheated category were assigned to usually reheated (applies to fully cooked beef patties, cooked turkey and cooked chicken).
- 2. All products assigned to usually reheated
- 3. All products assigned to rarely reheated

The risk estimates relative to the base model are presented in the following table. These findings indicate that scenario 1 and scenario 3 result in an increase in the risk estimate of up to two-fold. However, assigning all product to the 'usually reheated' category (scenario 2) increases the risk under the 'all log 5' lethality scenario, but for the 'split' and 'all 6.5/7' scenarios the risk is reduced relative to the base case as products *that* are assigned rarely and never reheated are now undergoing an increased lethality as a result of reheating.

Table 8-9: The change in the total estimate of risk (number of cases of salmonellosis per year) under each lethality scenario in line with the test scenarios for reheating. In each case the risk is relative to the baseline for each lethality scenario.

Scenario	Description	Lethality Scenario (Risk Relative to Baseline Scenari		•
		all log 5	split	all 6.5/7
Baseline		1	1	1
Scenario 1	Always reheated products assigned to Usually reheated	1.25	1.08	1.12
Scenario 2	All products Usually reheated	1.15	0.53	0.71
Scenario 3	All products rarely reheated	1.75	1.21	1.35

When the profile of risk across the products is investigated under the three reheating scenarios investigated (shown in the following table) the profile does not significantly change. Under each scenario, product CCND (Cooked Chicken (Nuggets, Tenders, non-Deli)), product SSCP (Summer Sausage, Thuringer, Cooked Pepperoni), product SUP (Salami, Uncooked Pepperoni, Chorizo, Soudjuk) and product MS (Meat Sticks) are amongst the top 5 products contributing to the total estimate of risk.

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		Base Case	Scenario 1	Scenario 2	Scenario 3
RBCB	Roast Beef, Corned Beef	<0.01%	<0.01%	<0.01%	<0.01%
FCBP	Fully Cooked Beef Patties	0.01%	<0.01%	0.01%	0.01%
CPCH	Cooked Pork (Cooked Ham, Pork BBQ)	<0.01%	<0.01%	<0.01%	<0.01%
CTND	Cooked Turkey (non-Deli)	0.66%	0.72%	1.47%	0.95%
CCND	Cooked Chicken (Nuggets, Tenders, non-Deli)	21.54%	23.53%	47.93%	31.06%
CPD	Cooked Poultry Deli Meat	8.18%	11.48%	15.75%	10.21%
CCP	Cooked Chicken Patties	1.87%	2.05%	4.17%	2.70%
BPF	Beef / Pork Frankfurters	0.43%	0.34%	0.70%	0.58%
BPB	Beef / Pork Bologna	0.27%	0.22%	0.23%	0.19%
PF	Poultry Frankfurters	1.73%	1.38%	2.81%	2.35%
SSCP	Summer Sausage, Thuringer, Cooked Pepperoni	12.92%	21.09%	9.73%	18.75%
SUP	Salami, Uncooked Pepperoni, Chorizo, Soudjuk	19.59%	20.02%	9.24%	17.80%
MS	Meat Sticks	19.74%	13.04%	5.42%	10.44%
BJ	Beef Jerky	13.04%	6.14%	2.55%	4.91%
UCH	Uncooked Country Ham	0.01%	0.01%	0.02%	0.03%
PCPB	Prosciutto, cappicola, pancetta, basturma	0.01%	<0.01%	<0.01%	<0.01%

Table 8-10: Percentage contribution of product classes to the total estimate of risk under the reheating scenarios

8.6 Sensitivity to Assignment of Products to Material Source

For each product, the make up of the product is specified as consisting of ground or intact meat. However, some products may be produced in a variety of ways. One such product is beef jerky, *that* may be produced either from intact of ground beef. For the main estimates provided, beef jerky is assigned as 100% ground beef. To test the impact of this assumption, results were obtained assuming beef jerky is produced from 50% ground and 50% intact beef, and 100% intact beef. The results are presented in Table 8-11. It can be seen that assuming beef jerky is produced from 100% ground beef is the most conservative assumption, resulting in a greater risk estimate than assuming 50% ground and 50% intact beef, or 100% intact beef.

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Table 8-11: The effect of the assignment of products to raw material source for the split scenario

	100% ground	50% ground & 50% intact	100% intact
Predicted cases from beef jerky	208	105	1
Total number of cases from all products	3,153	3,050	2,946

8.7 Sensitivity to Assumption That Low Growth Rate is Half Normal Growth

The assumption is made that for low growth products the growth rate used to predict the extent of population increase in contaminated servings is half that used for growth situations. To investigate the importance of this assumption in the findings of the model, the growth rate for low growth was set to 20%, 40% 60% 80% and 100% of the nominal growth rate. The results are shown in the Figure 8-4. It can be seen that as the fraction of the growth rate assumed for low growth increases so do the overall estimates of risk. However, even when the low growth rate is assumed to be 100% of growth, essentially assuming the most conservative assumption that all low-growth products behave as normal products, the increase in overall estimates of risk is less than 10% under all lethality scenarios.

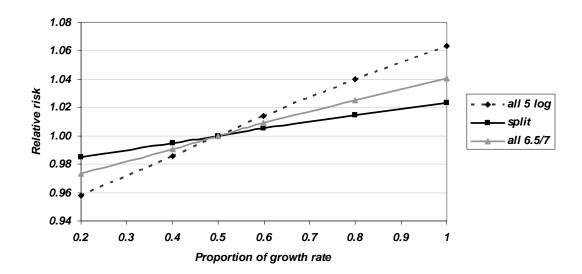


Figure 8-4: The impact of the growth rate assumption

8.8 Sensitivity to Consumption Volume Estimates

The estimation of consumption volumes of each of the RTE products considered is associated with varying degrees of uncertainty dependent upon the extent of information and data available for each of the products. Based on a qualitative assessment of the data available, the production volumes of the following products are associated with the greatest degree of uncertainty:

- Fully Cooked Beef Patties (FCBP)
- Beef / Pork Bologna (BPB)
- Poultry Frankfurters (PF)
- Summer Sausage, Thuringer, Cooked Pepperoni (SSCP)
- Salami, Uncooked Pepperoni, Chorizo, Soudjuk (SUP)
- Meat Sticks (MS)
- Beef Jerky (BJ)
- Uncooked Country Ham (UCH)

A number of these products are also associated with high risk estimates per MKg of product, in particular Meat Sticks, Salami, Uncooked Pepperoni, Chorizo, Soudjuk, Beef Jerky and Poultry Frankfurters. To illustrate the impact of this uncertainty, the consumption mass for the products with most uncertainty associated with consumption were multiplied by 0.5 to 1.5 in increments of 0.1 and estimates of the number of predicted cases of salmonellosis per year obtained. Figure 8-5 and Figure 8-6 show the results for the lethality scenarios 'all log 5' and 'split' respectively.

Results indicate that under the 'all log 5' lethality scenario, of the products tested the uncertainty associated with the level of product PF (Poultry Frankfurters) has the greatest influence on estimates of the number of cases of salmonellosis. This is because this product has a comparatively large (albeit uncertain) estimate of the consumption mass. Under the split scenario, the uncertainty associated with products SUP (Salami, Uncooked Pepperoni, Chorizo, Soudjuk) and MS (Meat Sticks), which overlap on the figure, has the greatest potential impact upon the magnitude of the estimates of risk.

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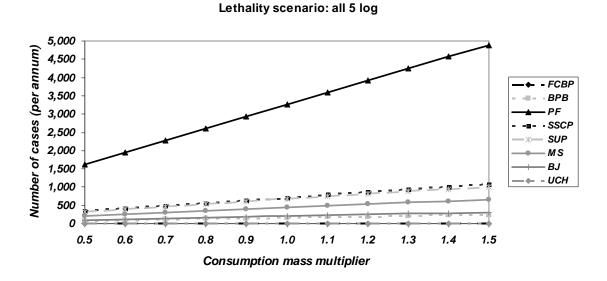


Figure 8-5: Effect of consumption volume on the number of cases of salmonellosis per year under the "all log 5" lethality scenario

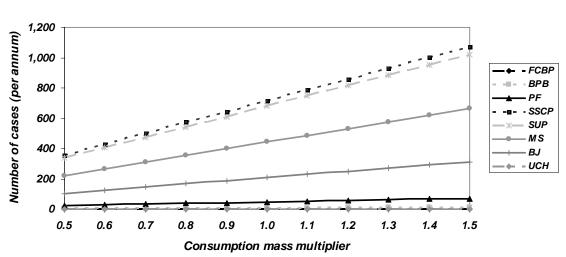


Figure 8-6: Effect of consumption volume on the number of cases of salmonellosis per year under the "Split" lethality scenario

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Lethality scenario: Split

9 Limitations and Uncertainties in the Assessment

The risk estimates generated in this assessment should be considered to fall within wide bounds of uncertainty. The calculations carried out attempt to capture variability and uncertainty.

Processes that inactivate pathogens as well as the growth of pathogen populations include variability that is best described on a logarithmic scale. This means that variations around central estimates may span multiple factors of 10 in either direction. As an example, a process that produces a 6-log reduction may have inherent variability over a range from 5-logs to 7-logs. This implies that the proportion of pathogens surviving the process will differ by a factor of 100 across this range. This is not an extreme example of the type of variability that is inherent in these systems. Growth scenarios are similarly variable, where the population size will generally span multiple orders of magnitude.

In addition to variability in processes, there is considerable uncertainty in a number of important variables that can also span multiple factors of 10. As an example, an estimate of the mean concentration of pathogens in raw materials may be 1 organism per gram. In this case, if the estimate is based on data acquired before significant changes in the industry, it might be quite reasonable to assume that the current mean concentration is only 1 organisms per 10 grams. Similarly, consideration of uncertainty in the sampling process (for example, the sensitivity of the detection process) might suggest that the mean concentration is actually closer to 10 organisms per gram.

In addition to this type of scientific uncertainty, the risk estimates may be very sensitive to uncertainty in the *extent of variability*. For microbiological risks, estimates of risk at the population level, particularly in the presence of logarithmic variability, will often be dominated by the higher-risk extremes (or 'tails') of variable processes. If the extent of these higher-risk extremes is uncertain, then the population risk estimates will be correspondingly uncertain.

9.1 Dominant Sources of Uncertainty

Categorization – to make the analysis compatible with policy analysis, with 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. A more in-depth analysis of certain types of products might further break down the categories, resulting in more refined estimates.

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Pathogen Burden in Raw Materials – the risk associated with surviving pathogens is generally proportional to the number of organisms in the raw materials. The need to know the numbers of organisms present requires the use of the FSIS Microbiological Baseline Surveys of meat and poultry products. These surveys are approximately a decade old and pre-date what may be significant changes in the processing industry that would affect the number of organisms in raw materials. Various technical issues (e.g., associated with the sampling process) add further uncertainty to the estimation of the pathogen burden in raw materials.

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*. There are numerous potential reasons for this adjustment. Examples include:

- the very high expected lethality achieved throughout a mass of cooked product in order to heat the interior part of the product adequately;
- the location of the organisms on or near the surface of the product such that they experience very high combinations of time and temperature during the heating of the product; and
- the use of very resistant strains of *Salmonella enterica* (for example serovar Senftenberg) in validating processes resulting in significantly higher lethalities than would be required in the absence of such strains.

At the level of a well-defined individual product and process, it is possible to simulate the impact of such factors on the overall effective lethality. However, it is not feasible to carry out this level of analysis when considering the entire industry producing a category of products. In addition, as discussed above, all else being equal, the risk estimate will be heavily influence by those processes where the thermal process safety factor is at its higher-risk extreme. As a result this important factor remains the most uncertain element in the assessment.

Storage and Growth – Uncertainty in the extent of growth is partially due to the crude characterization of the product categories and the fact that formulations and final product categories are proprietary and variable. The impact of storage and growth also derives uncertainty from the duration and conditions of storage and scientific assumptions regarding the maximum population density that would be achieved in a product that is stored under conditions that would allow significant growth.

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. The risk estimate is quite sensitive to the proportion of consumers *that* do not reheat or

reheat with minimal lethality. The impact of uncertainty in this factor is productspecific, as there are some products *that* are not expected to be reheated at all.

Dose-Response Relationship – there remains considerable uncertainty in the risk associated with very low 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 a contaminated serving will be a single organism. It is now generally recognized that it is possible to become ill from a single organism, however the probability of this illness is quite uncertain. This uncertainty is further complicated by the lack of information about specific serovars *that* may be important in determining pathogenicity.

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. The uncertainty is considered to be greatest for certain RTE products (e.g., fully cooked beef patties, fermented sausages).

9.1.1 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, the relative ranking (or attribution of total risk) among products should is also associated with a high degree of uncertainty, although to a lesser degree than the absolute estimates of risk.

The risk assessment, and more specifically, the risk assessment model allows the implications of a broad range of factors throughout the process to be considered quantitatively and transparently. The impact of alternate assumptions and alternate scenarios of *required lethality* can be measured in a systematic fashion.

10 References

Audits International. 1999. 1999 U.S. Cold Temperature Evaluation Design and Study Summary, available at <u>http://www.foodriskclearinghouse.umd.edu/Audits-FDA_temp_study.htm</u>

CDC, 2003. Multistate Outbreak of *Salmonella* Serotype Typhimurium Infections Associated with Drinking Unpasteurized Milk --- Illinois, Indiana, Ohio, and Tennessee, 2002—2003, Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR July 4, 2003 / 52(26);613-615

CDC, 2004. Outbreak of *Salmonella* Serotype Enteritidis Infections Associated with Raw Almonds --- United States and Canada, 2003—2004, Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR June 11, 2004 / 53(22);484-487

CDC, 1994. Outbreak of *Salmonella enteritidis* Associated with Homemade Ice Cream--Florida, 1993. Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR 43(36):1994 Sep 16

CDC, 1995. Outbreak of *Salmonella* Serotype Typhimurium Infection Associated with Eating Raw Ground Beef--Wisconsin, 1994. Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR 44(49):1995 Dec 15;

CDC, 1995a. Outbreak of Salmonellosis Associated With Beef Jerky--New Mexico, 1995 Morbidity and Mortality Weekly Report Centers for Disease Control and prevention MMWR 44(42):1995 Oct 27

CDC, 2001. Outbreak of *Salmonella* serotype Kottbus Infections Associated with Eating Alfalfa Sprouts --- Arizona, California, Colorado, and New Mexico, February--April 2001; Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR January 11, 2002 / 51(01);7-9)

CDC, 2002. Multistate Outbreaks of *Salmonella* Serotype Poona Infections Associated with Eating Cantaloupe from Mexico --- United States and Canada, 2000—2002, Morbidity and Mortality Weekly Report Centers for Disease Control and Prevention MMWR, November 22, 2002 / 51(46);1044-1047;

CDC 2000. *Salmonella* surveillance: Annual summary, 1976 to 1999. U.S. Department of Health and Human Services. Atlanta.

D'Aoust JY, 1991. Pathogenicity of foodborne *Salmonella*. Int J Food Microbiol;12(1):17-40.

Dibb-Fuller MP, Allen-Vercoe E, Thorns CJ, Woodward MJ, 1999. Fimbriae- and

flagella mediated association with and invasion of cultured epithelial cells by *Salmonella enteritidis*. Microbiology;145 (Pt 5):1023-31.

Environ Corporation, 2004. EDEA. Software to perform dietary exposure assessment.

FDA-FSIS (2003). Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. Available at http://www.foodsafety.gov/~dms/lmr2-toc.html

Frenzen P, Riggs T, Buzby J, Breuer T, Roberts T, Voetsch D, et al.1999 Salmonella cost estimate updated using FoodNet data. Food Review;22:10-5.

FSIS 1994. Nationwide Beef Microbiological Baseline Data Collection Program: Steers and Heifers (October 1992 - September 1993). Accessed at: <u>http://www.fsis.usda.gov/OPHS/baseline/steer1.pdf</u>

FSIS 1996a. Nationwide Broiler Chicken Microbiological Baseline Data Collection Program , (July 1994 - June 1995). Accessed at: <u>http://www.fsis.usda.gov/OPHS/baseline/broiler1.pdf</u>

FSIS 1996b. Nationwide Federal Plant Raw Ground Beef Microbiological Survey (August 1993 - March 1994). Accessed at: http://www.fsis.usda.gov/OPHS/baseline/rwgrbeef.pdf

FSIS 1996c. Nationwide Pork Microbiological Baseline Data Collection Program: Market Hogs (April 1995 - March 1996). Accessed at: <u>http://www.fsis.usda.gov/OPHS/baseline/markhog1.pdf</u>

FSIS (1996d). Nationwide Raw Ground Chicken Microbiological Survey (March - May and September - November 1995). Accessed at: http://www.fsis.usda.gov/OPHS/baseline/rwgrchck.pdf

FSIS 1996e. Nationwide Raw Ground Chicken Microbiological Survey (March - May and September - November 1995). Accessed at: http://www.fsis.usda.gov/OPHS/baseline/rwgrchck.pdf

FSIS 1996f. Nationwide Raw Ground Turkey Microbiological Survey (January - March, September - November 1995). Accessed at: http://www.fsis.usda.gov/OPHS/baseline/rwgrturk.pdf

FSIS 1996g. Nationwide Beef Microbiological Baseline Data Collection Program: Cows and Bulls (December 1993 - November 1994). Accessed at: <u>http://www.fsis.usda.gov/OPHS/baseline/cows1.pdf</u>

FSIS 1998. Nationwide Young Turkey Microbiological Baseline Data Collection Program (August 1996 - July 1997). Accessed at: <u>http://www.fsis.usda.gov/OPHS/baseline/yngturk.pdf</u>

FSIS, 1996. The Final Rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems. NTIS PB96-177613.

Mermin, J. Hutwagner, M.J., Vugia D, Shallow S, Daily P, Bender J, Koehler J, Marcus R, Angulo FJ; Emerging Infections Program FoodNet Working Group . 2004. Reptiles, amphibians, and human *Salmonella* infection: a populationbased, case-control study. Clin Infect Dis. 38 Suppl 3:S253-61.

ICMSF (The International Commission on Microbiological Specifications for Foods), 1996. *Salmonella*. In Microorganisms in Foods 5 Microbiological Specifications of Food Pathogens, pp 217-264. Blackie Academic and Professional, London.

Levine P, Rose B, Green S, Ransom G, Hill W. 2001. "Pathogen testing of readyto-eat meat and poultry products collected at federally inspected establishments in the United States, 1990 to 1999." J Food Prot. 64(8):1188-93.

Lumina Decision Systems 2004. Analytica® Enterprise version 3.0 (Software). Los Gatos, CA, USA.

Mead PS, Slutsker L, Dietz V, McCaig LF, Bresee JS, Shapiro C, et al. 1999. Food-related illness and death in the United States. Emerg Infect Dis 5(5):607-25.

Oscar, T.P. 2000. Variation of lag time and specific growth rate of 11 strains of *Salmonella* inoculated onto sterile ground chicken breast burgers and incubated at 25C. J. Food Safety 20, 225-236.

RTI 2005. Data Collection and Economic Analysis for the Rule: Performance Standards for the Production of Processed Meat and Poultry Products. RTI International, Research Triangle Park, NC.

Scott, J and Weddig, L, 1998. Principles of Integrated Time-Temperature Processing, Presented at the 1998 Meat Industry Research Conference, Philadelphia, PA.

Tamplin ML. 2002. Growth of *Escherichia coli* O157:H7 in raw ground beef stored at 10 degrees C and the influence of competitive bacterial flora, strain variation, and fat level. J Food Prot. 65(10):1535-40.

US Census Bureau, 1999a. *Poultry Processing, 1997 Economic Census*. EC97M-3116D.

September 2005

US Census Bureau, 1999b. *Meat Processed From Carcasses, 1997 Economic Census.* EC97M-3116B.

U.S. Department of Agriculture, Agricultural Research Service (ARS). 1998. 1994-96 Continuing Survey of Food Intakes by Individuals and 1994-96 Diet and Health Knowledge Survey and technical support databases. National Technical Information Service, Springfield, VA.

WHO/FAO, 2002. *Risk Assessment of Salmonella in eggs and broiler chickens*. Rome and Geneva.

WHO/FAO, 2003. Hazard Characterization for Pathogens in Food and Water, Microbiological Risk Assessment Series, No. 3, available at <u>http://www.who.int/foodsafety/publications/micro/pathogen/en/</u>

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11 Appendix 1: List of Model Variables and Associated Values Used in the Risk Assessment

Parameter	Assumption	Source
Parameters associated with Microbiological baseline data (eg number of samples, number of samples positive, mean MPN,		
)		
Chicken	Based on	FSIS (1996a). Nationwide Broiler Chicken Microbiological Baseline Data Collection
	summary data	Program, (July 1994 - June 1995). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/broiler1.pdf
Ground chicken	Based on	FSIS (1996d). Nationwide Raw Ground Chicken Microbiological Survey (March - May
	summary data	and September - November 1995). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/rwgrchck.pdf
Turkey	Based on	FSIS (1998). Nationwide Young Turkey Microbiological Baseline Data Collection
	summary data	Program (August 1996 - July 1997). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/yngturk.pdf
Ground Turkey	Based on	FSIS (1996f). Nationwide Raw Ground Turkey Microbiological Survey (January - March,
	sample data	September - November 1995). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/rwgrturk.pdf
Beef	Based on	FSIS (1996g). Nationwide Beef Microbiological Baseline Data Collection Program:
	sample data	Cows and Bulls (December 1993 - November 1994). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/cows1.pdf
		FSIS (1994). Nationwide Beef Microbiological Baseline Data Collection Program: Steers
		and Heifers (October 1992 - September 1993). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/steer1.pdf
Ground Beef	Based on	FSIS (1996b). Nationwide Federal Plant Raw Ground Beef Microbiological Survey
	sample data	(August 1993 - March 1994). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/rwgrbeef.pdf
Pork	Based on	FSIS (1996c). Nationwide Pork Microbiological Baseline Data Collection Program:
	sample data	Market Hogs (April 1995 - March 1996). Accessed at:
		http://www.fsis.usda.gov/OPHS/baseline/markhog1.pdf
		Individual MPN data provided by FSIS (H. Marks, Personal Communication)

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Ground pork	Based on	Data provided by FSIS (H. Marks, Personal Communication)	
	sample data on		
	summary data		
Extrapolation from sur		MPN/cm2 and rinse sample values (MPN/ml) to whole carcasses	
Extrapolation factor –	10,000cm ²	The extent of the microbial contamination of a carcass is not generally known. The	
cattle carcass		degree to which the sampled areas in the FSIS Microbiological Baseline Study are representative of the broader carcass area is also not known.	
		Total surface areas for cattle carcasses are on the order of 30,000 cm ² . This value	
		(10,000 cm ² or 1m ²) is assumed as a rough estimate of the extent of surface area that	
	2 500 2	would be contaminated on a positive carcass at the level that was found in the samples.	
Extrapolation factor –	2,500cm ²	Given the approximately 4:1 ratio of weights between cattle and pig carcasses	
pig carcass		(assumed below), this value is chosen for consistency to be 1/4 th of the extrapolation factor for cattle.	
Rinse fluid volume	400 ml	FSIS (1996a). Nationwide Broiler Chicken Microbiological Baseline Data Collection	
chicken		Program, (July 1994 - June 1995). Accessed at:	
		http://www.fsis.usda.gov/OPHS/baseline/broiler1.pdf	
Rinse fluid volume	600 ml	FSIS (1998). Nationwide Young Turkey Microbiological Baseline Data Collection	
Turkey		Program (August 1996 - July 1997). Accessed at:	
		http://www.fsis.usda.gov/OPHS/baseline/yngturk.pdf	
Weights of carcasses			
Chicken	1.36 kg	A broiler is defined as having an eviscerated weight between 2.5 and 4.5 pounds (1.1 to 2kg), a value of 3 lbs (1.36 Kg) is assumed.	
		http://www.fsis.usda.gov/Fact_Sheets/Chicken_Food_Safety_Focus/index.asp	
Turkey	4.77 kg	Turkey carcasses vary considerably in weight. This estimate is based on a nominal value of 10.5 lbs (4.77 kg) for a young turkey carcass.	
Cows and bulls	350 kg	http://usda.mannlib.cornell.edu/reports/	
Steers and heifers	350 kg	http://usda.mannlib.cornell.edu/reports/	
pork	86 kg	http://usda.mannlib.cornell.edu/reports/	
Mean MPN for positives that were not enumerated			
Beef	0.04	Assumption based on examination of minimum recorded data point	
Chicken	0.4	Assumption based on examination of minimum recorded data point	

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0.4	Assumption based on examination of minimum resorded data point
	Assumption based on examination of minimum recorded data point
	Assumption based on examination of minimum recorded data point
See Table 5-6	Assumptions based upon consideration of the product categories
See Table 5-8	Assumption based on consideration of the risk factors associated with each category
See Table 5-9	Based upon expert survey (RTI (2005). Data Collection and Economic Analysis for the
	Rule: Performance Standards for the Production of Processed Meat and Poultry
	Products. RTI International, Research Triangle Park, NC.)
See Table 5-13	Assumption based upon consideration of the form of the product (for example intact,
	comminuted etc), product quality considerations and application of lethality.
See Table 5-16	Assignment based upon product category
See Table 5-17	Assignment based upon product category
riables	
8.5 logs per day	Oscar, T.P. (2000). Variation of lag time and specific growth rate of 11 strains of
0, ,	Salmonella inoculated onto sterile ground chicken breast burgers and incubated at 25C.
	J. Food Safety 20, 225-236.
8.5 logs per	Assumption based upon analogous research for <i>E. coli</i> in ground beef (see section
serving	5.7.2 for details).
U	
7°C	ICMSF (The International Commission on Microbiological Specifications for Foods),
-	1996. Salmonella. In Micro-organisms in Foods 5 Microbiological Specifications of Food
	Pathogens, pp 217-264. Blackie Academic and Professional, London.
Probability	Audits International. 1999. 1999 U.S. Cold Temperature Evaluation Design and Study
distribution	Summary, available at http://www.foodriskclearinghouse.umd.edu/Audits-
	FDA_temp_study.htm
Probability	Assumptions – compatible with assumptions made regarding the consumer storage of
distribution	frankfurters and deli meats in the FDA-FSIS risk assessment for Listeria
	monocytogenes in RTE foods which were based on available data (FDA-FSIS,2003)
	Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria
	monocytogenes Among Selected Categories of Ready-to-Eat Foods. Available at
	See Table 5-13 See Table 5-16 See Table 5-17 riables 8.5 logs per day 8.5 logs per serving 7°C Probability distribution Probability

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		http://www.foodsafety.gov/~dms/lmr2-toc.html)
Consumption mass		
Volume of consumption	See Table 6-10	Based on Economic Census, CSFII or alternative source as discussed in Table 6-10.
Dose response		
Dose response parameter α	0.1324	WHO/FAO, 2002. <i>Risk Assessment of Salmonella in eggs and broiler chickens</i> . Rome and Geneva.
Dose response parameter β	51.45	WHO/FAO, 2002. <i>Risk Assessment of Salmonella in eggs and broiler chickens</i> . Rome and Geneva.

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12 Appendix 2: Food Codes from the CSFII Dataset Used to Estimate the Annual Level of Consumption

Roast Beef		
Food Code	Description	
25240310-0	roast beef spread	
27513010-0	roast beef sandwich	
27513010-200171	roast beef sandwich w/ hard white roll	
27513010-202146	roast beef sandwich w/ whole wheat bread, other than 100% or ns as to 100%	
27513020-0	roast beef sandwich, w/ gravy	
27513040-0	roast beef sub, roll,lettuce,tom & sprea	
27513050-0	roast beef sandwich w/ cheese	
27513050-202501	roast beef sandwich with cheese w/ cheddar or american type cheese, ns as to natural or processed	
27513060-0	roast beef sandwich w/ bacon & cheese sauce	
27513070-0	roast beef submarine sandwich, on roll, au jus	

Corned Beef

Cornea Beet	
Food Code	Description
21416000-0	corned beef, cooked, ns as to fat
21416110-0	corned beef, cooked, lean & fat
21416120-0	corned beef, cooked, lean only
27214500-0	corned beef patty
27510950-0	reuben(corn beef w/ sauerkraut & cheese) w/ spread

Fully Cooked Beef Patties		
Food Code	Description	
21500100-0	ground beef or patty	
21500200-202539	ground beef or patty, breaded, cooked w/ lean ground beef	
21500200-203350	ground beef or patty, breaded, cooked w/ extra lean ground beef	
27510210-0	cheeseburger, plain, on bun	
27510210-100404	cheeseburger, plain, on bun removed 1/2 bun	
27510220-0	cheeseburger, w/ mayo, on bun	

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Fully Cooked Beef Patties			
Food Code	Description		
27510220-204306	cheeseburger, with mayonnaise or salad dressing, on bun removed pickles		
27510230-0	cheeseburger, w/ mayo & tomato, on bun		
27510230-200064	cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun removed pickles		
27510230-201178	cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes		
27510230-203172	cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun removed onions		
27510230-203269	cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes, lettuce and pickles		
27510230-204527	cheeseburger, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce, tomatoes, and onions		
27510240-0	cheeseburger, 1/4 lb meat, plain, on bun		
27510250-0	cheeseburger, 1/4 lb meat, w/ mayo, on bun		
27510250-204382	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun removed onions		
27510260-0	cheeseburger, 1/4 lb, w/ mushroom sauce, on bun		
27510270-0	double cheeseburger, plain, on bun		
27510280-0	double cheeseburger, w/ mayo, on bun		
27510300-0	double cheeseburger, w/mayo, on double-decker bun		
27510300-100349	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed cheese		
27510300-200142	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed pickles		
27510300-200337	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed mayonnaise, onions, lettuce and pickles		
27510300-201846	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed lettuce		
27510300-202375	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed lettuce, pickles, and onions		
27510300-203317	double cheeseburger (2 patties), with mayonnaise or salad dressing, on double-decker bun removed pickles and onions		
27510310-0	cheeseburger w/ tomato & or catsup, on bun		
27510310-100542	cheeseburger with tomato and/or catsup, on bun removed		

Fully Cooked Beef	Patties
Food Code	Description
	1/2 bun
27510310-101186	cheeseburger with tomato and/or catsup, on bun removed onions and mustard
27510310-101243	cheeseburger with tomato and/or catsup, on bun removed bun and pickles
27510310-200411	cheeseburger with tomato and/or catsup, on bun removed pickles
27510310-200572	cheeseburger with tomato and/or catsup, on bun removed pickles and onions
27510310-201599	cheeseburger with tomato and/or catsup, on bun removed onions
27510310-201648	cheeseburger with tomato and/or catsup, on bun removed pickles and mustard
27510310-201692	cheeseburger with tomato and/or catsup, on bun removed onions, mustard, and pickles
27510310-202273	cheeseburger with tomato and/or catsup, on bun removed bun
27510310-202292	cheeseburger with tomato and/or catsup, on bun removed pickles and 1/4 of bun
27510310-202312	cheeseburger with tomato and/or catsup, on bun removed pickles, mustard, and catsup
27510310-203548	cheeseburger with tomato and/or catsup, on bun removed mustard
27510310-203916	cheeseburger with tomato and/or catsup, on bun removed pickles and catsup
27510311-0	cheeseburger, 1 oz meat, plain, on mini bun
27510320-0	cheeseburger, 1/4 lb meat,w/ tomato/catsup, bun
27510320-200198	cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun removed pickles and onions
27510320-200489	cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun removed pickles
27510320-202772	cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun removed onions
27510320-203692	cheeseburger, 1/4 lb meat, with tomato and/or catsup, on bun removed mustard, catsup, pickles and onions
27510330-0	double cheeseburger w/tomato & or catsup, on bun
27510330-100523	double cheeseburger (2 patties), with tomato and/or catsup, on bun removed lettuce and onions

Fully Cooked Beef	Patties
Food Code	Description
27510330-200436	double cheeseburger (2 patties), with tomato and/or catsup, on bun removed pickles
27510330-201838	double cheeseburger (2 patties), with tomato and/or catsup, on bun removed onions
27510330-203197	double cheeseburger (2 patties), with tomato and/or catsup, on bun removed onions and pickles
27510330-203290	double cheeseburger (2 patties), with tomato and/or catsup, on bun removed pickles, lettuce, and onions
27510340-0	double cheeseburger, w/ mayo & tomato, on bun
27510340-100447	double cheeseburger (2 patties), with mayonnaise or salad dressing and tomatoes, on bun removed onions and 1/2 bun
27510350-0	cheeseburger, 1/4 lb meat, w/ mayo & tomato, on bun
27510350-100316	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes and onions
27510350-101092	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce and pickles
27510350-200759	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed onions
27510350-202527	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce, pickles and onions
27510350-202719	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed pickles and onions
27510350-202884	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed pickles
27510350-203268	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed mayonnaise
27510350-203412	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes
27510350-203718	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes, pickles and onions
27510350-203778	cheeseburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun w/ swiss cheese
27510360-0	cheeseburger w/ mayo, tomato & bacon, on bun

Fully Cooked Beef	Patties
Food Code	Description
27510360-100151	cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun w/ swiss cheese and w/ sour dough bun
27510360-100195	cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun removed tomatoes
27510360-203318	cheeseburger with mayonnaise or salad dressing, tomato and bacon, on bun removed pickles
27510370-0	double cheeseburger w/ mayonnaise, on bun
27510370-100490	double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun removed pickles
27510370-101007	double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun removed onions
27510370-101080	double cheeseburger (2 patties, 1/4 lb meat each), with mayonnaise or salad dressing, on bun removed lettuce and onions
27510380-0	triple cheeseburger w/ mayo, tomato, on bun
27510390-0	double bacon cheeseburger, on bun
27510390-100933	double bacon cheeseburger (2 patties, 1/4 lb meat each), on bun removed pickles
27510400-0	bacon cheeseburger, 1/4 lb meat, w/ tomato, on bun
27510430-0	double bacon cheeseburger, w/ mayo, tomato, on bun
27510440-0	bacon cheeseburger, 1/4 lb, w/ mayo & tomato, on bun
27510480-0	cheeseburger, w/ onions, on rye bun
27510500-0	hamburger, plain, on bun
27510500-201669	hamburger, plain, on bun w/ lean ground beef
27510510-0	hamburger, w/ tomato & or catsup, on bun
27510510-100502	hamburger, with tomato and/or catsup, on bun removed 1/2 bun
27510510-200092	hamburger, with tomato and/or catsup, on bun removed pickles
27510510-200549	hamburger, with tomato and/or catsup, on bun removed pickles and onions
27510510-200932	hamburger, with tomato and/or catsup, on bun removed bun
27510510-201567	hamburger, with tomato and/or catsup, on bun removed onions
27510510-201974	hamburger, with tomato and/or catsup, on bun removed lettuce and onions

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Fully Cooked Beef	Patties
Food Code	Description
27510510-203685	hamburger, with tomato and/or catsup, on bun removed catsup and pickles
27510510-204079	hamburger, with tomato and/or catsup, on bun removed catsup
27510510-204529	hamburger, with tomato and/or catsup, on bun removed 1/2 bun and pickles
27510520-0	hamburger, w/ mayo & tomato, on bun
27510520-100799	hamburger, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes, pickles and onions
27510520-200402	hamburger, with mayonnaise or salad dressing and tomatoes, on bun removed pickles
27510520-200799	hamburger, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce
27510520-202542	hamburger, with mayonnaise or salad dressing and tomatoes, on bun removed onions
27510520-203580	hamburger, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce, tomatoes and onions
27510530-0	hamburger, 1/4 lb meat, plain, on bun
27510540-0	double hamburger w/tomato & or catsup, on bun
27510550-0	double hamburger w/ mayo & tomato, dbl-decker bun
27510560-0	hamburger, 1/4 lb meat w/ mayo & tomato, on bun
27510560-100981	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce and onions
27510560-200398	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed onions
27510560-201014	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed pickles
27510560-201704	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes
27510560-201711	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes and onions
27510560-202472	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed mayonnaise, pickles, and onions
27510560-203043	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed tomatoes and

Fully Cooked Beef Patties	
Food Code	Description
	pickles
27510560-203079	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed pickles and onions
27510560-203179	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed mayonnaise and tomatoes
27510560-203260	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce and tomatoes
27510560-203384	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed mayonnaise and onions
27510560-203415	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed mayonnaise
27510560-203531	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce, tomatoes and onions
27510560-204715	hamburger, 1/4 lb meat, with mayonnaise or salad dressing and tomatoes, on bun removed lettuce
27510590-0	hamburger, w/ mayo, on bun
27510600-0	hamburger, 1 oz meat,plain, on miniature bun
27510610-0	hamburger, 1 oz meat, tomato, on miniature bun
27510620-0	hamburger, 1/4 lb meat, w/ tomato & or catsup, bun
27510620-100770	hamburger, 1/4 lb meat, with tomato and/or catsup, on bun removed pickles
27510620-202372	hamburger, 1/4 lb meat, with tomato and/or catsup, on bun removed lettuce, pickles and onions
27510620-202847	hamburger, 1/4 lb meat, with tomato and/or catsup, on bun removed onions
27510620-203371	hamburger, 1/4 lb meat, with tomato and/or catsup, on bun removed pickles and onions
27510630-0	hamburger, 1/4 lb meat, w/ mayo, on bun
27510630-200722	hamburger, 1/4 lb meat, with mayonnaise or salad dressing, on bun removed onions
27510640-0	hamburger,1/4 lb meat(modfd fat) w/ tomato, on bun
27510670-0	double hamburger, w/ mayo & tomato, on bun
27510680-0	double hamburger (1/2 lb meat), w/ tom/catsup, bun

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Fully Cooked Beef Patties	
Food Code	Description
27510680-100791	double hamburger (2 patties, 1/4 lb meat each), with tomato and/or catsup, on bun removed pickles
27510690-0	double hamburger,1/2 lb meat,w/mayo&tom/catsup,bun

Cooked Ham	
Food Code	Description
22300120-0	ham, fried, ns as to fat
22300120-203503	ham, fried, ns as to fat eaten w/ soybean oil
22300130-0	ham, fried, lean & fat
22300130-203500	ham, fried, lean and fat eaten w/ soybean oil
22300140-0	ham, fried, lean only
22300140-203506	ham, fried, lean only eaten w/ soybean oil
22300150-0	ham, breaded, fried, ns as to fat
22300160-0	ham, breaded, fried, lean & fat
22300170-0	ham, breaded, fried, lean only
22311000-0	ham, smoked or cured, cooked, ns as to fat
22311010-0	ham, smoked or cured, cooked, lean & fat
22311020-0	ham, smoked or cured, cooked, lean only
22311200-0	ham, smoked or cured, low na, ns as to fat
22311210-0	ham, smoked or cured, low na, lean & fat
22311220-0	ham, smoked or cured, low na, lean only
22311450-0	ham, prosciutto
22321110-0	ham, smoked or cured, ground patty
22810010-0	ham, baby, strained
25230210-0	ham, sliced, prepackaged or deli, luncheon meat
25230220-0	ham, sliced, low salt, prepackaged/deli, lunch meat
25230230-0	ham, sliced, extra lean, prepackaged/deli
25230410-0	ham loaf, luncheon meat
25230430-0	ham & cheese loaf
25230510-0	ham,lunch meat,chop,minced,pressd,minced,not canned
25230520-0	ham, luncheon meat, chopped, spiced,lowfat, not can
25240210-0	ham, deviled or potted
25240220-0	ham salad spread
27120020-0	ham/pork w/ gravy (mixture)

Cooked Ham	
Food Code	Description
27120030-0	ham/pork w/ barbecue sauce
27120030-100394	ham or pork with barbecue sauce (mixture) w/ pork and w/ smoked pork sausage
27120090-0	ham/pork w/ (mushroom) soup-base sauce (mixture)
27120100-0	ham/pork w/ tomato-based sauce (mixture)
27120150-0	pork or ham w/ soy-based sauce (mixture)
27220010-0	meat loaf made w/ ham (not luncheon meat)
27220020-0	ham & noodles w/ cream or white sauce (mixture)
27220050-0	ham or pork w/ stuffing
27220080-0	ham croquette
27220080-203758	ham croquette w/ vegetable oil, nfs (include oil, nfs)
27220210-0	ham & noodles, no sauce (mixture)
27220210-204684	ham and noodles, no sauce (mixture) w/o fat
27220310-0	ham & rice, no sauce (mixture)
27220310-100231	ham or pork and rice, no sauce (mixture) w/ corn oil
27220310-100543	ham or pork and rice, no sauce (mixture) w/ vegetable oil, nfs (include oil, nfs)
27220310-202971	ham or pork and rice, no sauce (mixture) w/ lard
27220310-204143	ham or pork and rice, no sauce (mixture) w/o fat
27220310-204649	ham or pork and rice, no sauce (mixture) w/ pork fat
27220510-0	ham/pork & potatoes w/ gravy (mixture)
27320020-0	ham pot pie
27320030-0	ham/pork, noodles & veg (no car/dk gr), cheese sce
27320030-204979	ham or pork, noodles and vegetables (excluding carrots, broccoli, and dark-green leafy), cheese sauce (mixture) w/ evaporated whole milk, ns as to dilution, and w/ butter, nfs
27320450-0	ham, potatoes & veg (w/ carrots/dk green), no sauce
27420010-0	cabbage w/ ham hocks (mixture)
27420020-0	ham or pork salad
27420020-100503	ham or pork salad w/ creamy dressing made with sour cream and/or buttermilk and oil (include ranch dressing)
27420020-101050	ham or pork salad w/ reduced calorie or diet, cholesterol- free mayonnaise (include best foods cholesterol free reduced calorie)
27420020-200771	ham or pork salad w/ mayonnaise-type salad dressing (include miracle whip)

Cooked Ham	
Food Code	Description
27420020-201390	ham or pork salad w/ low calorie or diet mayonnaise-type salad dressing (include miracle whip light)
27420080-0	greens w/ ham or pork (mixture)
27420270-0	ham & veg (no carrot/dk green, no potato), no sauce
27460490-204243	julienne salad (meat, cheese, eggs, vegetables), no dressing w/ all ham and removed egg
27460510-0	antipasto w/ ham, fish, cheese, vegetables
27520250-0	ham on biscuit
27520300-0	ham sandwich w/ spread
27520320-0	ham & cheese sandwich, w/ lettuce & spread
27520320-202147	ham and cheese sandwich, with lettuce and spread w/ pita bread
27520340-0	ham salad sandwich
27520350-0	ham & cheese sandwich w/ spread, grilled
27520350-100249	ham and cheese sandwich, with spread, grilled w/ 2 slices cheese
27520350-200775	ham and cheese sandwich, with spread, grilled w/ sour dough bread and w/ 1 slice ham
27520350-201037	ham and cheese sandwich, with spread, grilled w/ 100% whole wheat bread, w/ canadian bacon, w/ 2 slices nonfat or fat free processed american or cheddar type cheese and w/o fat or w/ nonstick spray (include pam)
27520350-201190	ham and cheese sandwich, with spread, grilled w/ 1 slice ham
27520350-204596	ham and cheese sandwich, with spread, grilled w/ mozzarella cheese
27520360-0	ham & cheese sandwich on bun w/ lettuce & spread
27520360-204609	ham and cheese sandwich, on bun, with lettuce and spread w/ processed swiss cheese
27520370-0	hot ham & cheese sandwich, on bun
27520380-0	ham & cheese on english muffin
27520390-0	ham & cheese sub,multigr roll, w/ let, tom & spread
27520540-0	ham & tomato club sand, w/ spread
28320130-0	ham, rice, & potato soup, p.r.
32105030-0	egg omelet or scrambled egg, w/ ham or bacon
32105030-100122	egg omelet or scrambled egg, with ham or bacon w/o fat or w/ nonstick spray (include pam)

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Cooked Ham	
Food Code	Description
32105030-100179	egg omelet or scrambled egg, with ham or bacon w/o milk
32105030-100643	egg omelet or scrambled egg, with ham or bacon w/o milk and w/o fat or w/ nonstick spray (include pam)
32105030-101000	egg omelet or scrambled egg, with ham or bacon w/ corn oil (include mazola corn oil; mazola oil, nfs)
32105030-101029	egg omelet or scrambled egg, with ham or bacon w/ 2% milk and w/ butter, nfs
32105030-200324	egg omelet or scrambled egg, with ham or bacon w/ vegetable oil, nfs (include oil, nfs)
32105030-200327	egg omelet or scrambled egg, with ham or bacon w/ butter, nfs
32105030-202112	egg omelet or scrambled egg, with ham or bacon w/ skim milk
32105030-202907	egg omelet or scrambled egg, with ham or bacon w/o milk and w/ vegetable oil, nfs
32105030-203002	egg omelet or scrambled egg, with ham or bacon w/ canola oil
32105030-204950	egg omelet or scrambled egg, with ham or bacon w/o milk and w/ butter, nfs
32105060-0	egg omelet or scrambled egg, w/peppers, onion & ham
32105060-100221	egg omelet or scrambled egg, with peppers, onion, and ham w/o milk and w/o fat or w/ nonstick spray (include pam)
32105060-100422	egg omelet or scrambled egg, with peppers, onion, and ham w/o milk and w/ bacon grease
32105060-100511	egg omelet or scrambled egg, with peppers, onion, and ham w/ butter, nfs
32105060-100719	egg omelet or scrambled egg, with peppers, onion, and ham w/ 2% milk and w/o fat or w/ nonstick spray (include pam)
32105060-202591	egg omelet or scrambled egg, with peppers, onion, and ham w/o milk
32105060-203602	egg omelet or scrambled egg, with peppers, onion, and ham w/0 milk and w/ butter, nfs
32105060-204108	egg omelet or scrambled egg, with peppers, onion, and ham w/0 milk and w/ oil, nfs
32105080-0	egg omelet or scrambled egg,w/cheese & ham or bacon
32105080-100307	egg omelet or scrambled egg, with cheese and ham or

Cooked Ham	
Food Code	Description
	bacon w/ bacon grease
32105080-100325	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk
32105080-100353	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ butter, nfs
32105080-100363	egg omelet or scrambled egg, with cheese and ham or bacon w/ american cheese and mozzarella cheese, nfs and w/o milk
32105080-100706	egg omelet or scrambled egg, with cheese and ham or bacon w/o fat or w/ nonstick spray (include pam)
32105080-100940	egg omelet or scrambled egg, with cheese and ham or bacon w/ vegetable oil, nfs (include oil, nfs)
32105080-100945	egg omelet or scrambled egg, with cheese and ham or bacon w/ monterey jack cheese
32105080-200711	egg omelet or scrambled egg, with cheese and ham or bacon w/ butter, nfs
32105080-201197	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/o fat or w/ nonstick spray (include pam)
32105080-201264	egg omelet or scrambled egg, with cheese and ham or bacon w/ processed american and swiss cheese blend, w/o milk, and w/o fat or w/ nonstick spray (include pam)
32105080-201633	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ canola, soybean and sunflower oil
32105080-202030	egg omelet or scrambled egg, with cheese and ham or bacon w/ american or cheddar cheese based cheese spread (include velveeta) and w/o fat or w/ nonstick spray (include pam)
32105080-202237	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ turkey bacon
32105080-202650	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ bacon grease
32105080-202671	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ olive oil
32105080-203286	egg omelet or scrambled egg, with cheese and ham or bacon w/o milk and w/ vegetable oil, nfs (include oil, nfs)
32105080-203724	egg omelet or scrambled egg, with cheese and ham or bacon w/ 2% milk and w/ butter, nfs
32105080-203736	egg omelet or scrambled egg, with cheese and ham or

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Cooked Ham	
Food Code	Description
	bacon w/o milk and w/ soybean oil (includes wesson oil, nfs)
32105085-0	egg omelet or scrambled egg,w/cheese, ham or bacon, & tomato
32202010-0	egg,cheese&ham on english muffin(incl egg mcmuffin)
32202010-100685	egg, cheese, and ham on english muffin removed egg
32202010-100864	egg, cheese, and ham on english muffin removed ham
32202010-203025	egg, cheese, and ham on english muffin removed cheese
32202020-0	egg, cheese, & ham on biscuit
32202110-0	egg & ham on biscuit
41210150-0	stewed pink beans w/ viandas & ham, p.r.
41210150-201880	stewed pink beans with viandas, ham, puerto rican style w/o fat
41601110-0	bean & ham soup, chunky style (incl campbells old
41601180-0	bean & ham soup, home recipe
41602010-0	chunky pea & ham soup
41602030-0	split pea & ham soup
58100560-0	enchilada w/ ham & cheese, w/o beans
58108010-100987	calzone, with meat and cheese w/ pepperoni and ham
58112110-0	dim sum, meat filled (incl shrimp, pork, ham)
58127210-0	croissant, filled w/ ham & cheese
58127310-0	croissant w/ ham, egg, & cheese
71305110-0	white potato, scalloped, w/ ham

Pork BBQ	
Food Code	Description
27520510-0	pork barbecue or sloppy joe, on bun
27520520-0	pork sandwich

Cooked Chicken (non-Deli, non patty)	
Food Code	Description
24198700-0	chicken patty/fillet/tenders, breaded, cooked
24198740-0	chicken nuggets
28140720-100535	chicken patty, or nuggets, boneless, breaded, potatoes, vegetable (frozen meal) removed potatoes

Cooked Chicken Patties	
Food Code	Description
24198710-0	chicken patty w/ cheese, breaded, cooked
25230900-0	turkey or chicken breast, pkgd/deli, luncheon meat
27520130-202565	bacon, chicken, and tomato club sandwich, with lettuce and spread removed spread
27540110-0	chicken sandwich, w/ spread
27540110-100565	chicken sandwich, with spread w/ low calorie or diet mayonnaise
27540110-200312	chicken sandwich, with spread w/ margarine, tub, salted
27540130-0	chicken barbecue sandwich
27540140-0	chicken fillet (breaded, fried) sandwich
27540150-203229	chicken fillet (breaded, fried) sandwich with lettuce, tomato and spread removed lettuce and tomatoes
27540170-0	chicken patty sandwich, mini, w/ spread
27540180-0	chicken patty sandwich on biscuit
27540190-0	chicken patty sandwich w/ lettuce & spread
27540190-202563	chicken patty sandwich, with lettuce and spread w/ mayonnaise- type salad dressing (include miracle whip)
27540200-0	fajita-style chicken sandwich w/ cheese, lettuc,tom
27540260-100498	chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread removed tomatoes and spread
27540260-202137	chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread removed tomatoes
27540260-203422	chicken fillet, broiled, sandwich, on oat bran bun, with lettuce, tomato, spread removed spread
27540270-0	chicken fillet,sandwich,w/lett,tom,&non-mayo spread
27540270-202837	chicken fillet, broiled, sandwich, with lettuce, tomato, and non- mayonnaise type spread removed tomatoes
27540280-0	chicken fillet,broiled,sandwich,w/cheese,on bun
27540280-100906	chicken fillet, broiled, sandwich with cheese, on bun, with lettuce, tomato and spread removed lettuce

Beef/Pork Frankfurters		
Food Code	Description	
25210110-0	frankfurter, wiener or hot dog, nfs	
25210150-0	frankfurter or hot dog, cheese-filled	
25210210-0	frankfurter or hot dog, beef	

Beef/Pork Frankfurters	
Food Code Description	
25210220-0	frankfurter or hot dog, beef & pork
25210230-0	frankfurter or hot dog, beef and pork, lowfat
25210250-0	frankfurter or hot dog, meat & poultry, fat free
25210280-0	frankfurter or hot dog, meat & poultry
25210310-0	frankfurter or hot dog, chicken
25210410-0	frankfurter or hot dog, turkey
25210510-0	frankfurter or hot dog, low salt
25210610-0	frankfurter or hot dog, beef, lowfat
25210700-0	frankfurter or hot dog, meat & poultry, lowfat
27120210-0	frankfurter /hot dog,w/chili,no bun (incl chili dog,no bun)
27120250-0	frankfurters/hot dogs w/ tom-based sce (mixture)
27120250-101012	frankfurters or hot dogs with tomato-based sauce (mixture) w/ chicken frankfurters
27120250-203275	frankfurters or hot dogs with tomato-based sauce (mixture) w/ beef frankfurter
27420040-0	frankfurters or hot dogs & sauerkraut (mixture)
27420040-202191	frankfurters or hot dogs and sauerkraut (mixture) w/ beef hot dog
27560300-0	corn dog (frankfurter/hot dog w/ cornbread coating)
27560300-100193	corn dog (frankfurter or hot dog with cornbread coating) w/ chicken hot dog
27560300-100354	corn dog (frankfurter or hot dog with cornbread coating) w/ meat and poultry hot dog
27560300-202924	corn dog (frankfurter or hot dog with cornbread coating) w/ turkey hot dog
27560320-0	frankfurter or hot dog, plain, on bun
27560320-201784	frankfurter or hot dog, plain, on bun w/ beef hot dog
27560330-0	frankfurter or hot dog, w/ cheese, plain, on bun
27560340-0	frankfurter/hot dog, w/ catsup &/ mustard, on bun
27560340-200005	frankfurter or hot dog, with catsup and/or mustard, on bun w/ beef hot dog
27560350-0	pig in a blanket (frankfurter or hot dog wrapped in dough)
27560350-100121	pig in a blanket (frankfurter or hot dog wrapped in dough) w/ turkey hot dog
27560350-100228	pig in a blanket (frankfurter or hot dog wrapped in dough) w/ beef hot dog
27560360-0	frankfurter/hot dog ,w/ chili, on bun (incl chili dog)
27560360-100293	frankfurter or hot dog, with chili, on bun w/ beef hot dog
27560360-201231	frankfurter or hot dog, with chili, on bun w/ chicken hot dog

Beef/Pork Frankfurters	
Food Code	Description
27560360-202523	frankfurter or hot dog, with chili, on bun w/ meat and poultry hot dog
27560370-0	frankfurter /dog chili & cheese,bun (chili cheese dog)
27560400-0	chicken frankfurter or hot dog, plain, on bun
41206030-0	beans & franks
41811400-0	frankfurter or hot dog, meatless
58132710-0	spaghetti w/ tomato sauce & frankfurters/hot dog
58132713-0	pasta w/ tomato sauce & frankfurters/hot dogs, canned
58145160-0	macaroni/noodles w/ cheese & frankfurter/hot dog
58145160-200679	macaroni or noodles with cheese and frankfurters or hot dogs w/ cheddar or american type cheese, ns as to natural or processed and w/ beef hot dog
58145160-203877	macaroni or noodles with cheese and frankfurters or hot dogs w/ american or cheddar cheese based cheese spread (include velveeta) and w/ beef frankfurter or hot dog
58145160-204941	macaroni or noodles with cheese and frankfurters or hot dogs w/ whole milk and w/ chicken frankfurter or hot dog

Bologna, Liverwurst, Polish Sausage, other Cooked Sausages	
Food Code	Description
25220390-0	bologna, beef, low fat
25220400-0	bologna, pork and beef
25220410-0	bologna, nfs
25220420-0	bologna, lebanon
25220430-0	bologna, beef
25220440-0	bologna, turkey
25220450-0	bologna ring, smoked
25220460-0	bologna, pork
25220470-0	bologna, beef, lower sodium
25220480-0	bologna, chicken, beef, & pork
25220500-0	bologna, beef & pork, lowfat
27560110-0	bologna sandwich, w/ spread
27560120-0	bologna & cheese sandwich w/ spread
27560120-200186	bologna and cheese sandwich, with spread w/ mayonnaise-type salad dressing (include miracle whip)
27560120-200653	bologna and cheese sandwich, with spread w/ beef bologna

Beef Jerky

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Food Code	Description
21602100-0	Beef jerky
25220120-0	Beef sausage, smoked, stick (include beef jerky)

Prosciutto, Cappicola, Pancetta, Basturma		
Food Code	Description	
22311450-0	ham, prosciutto	

This information has been peer-reviewed under applicable information quality guidelines.