FSIS Response to Public Comments

for

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

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by

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FSIS Response to Public Comments on the FSIS-contracted Risk Assessment for *C. perfringens* in RTE and Partially Cooked Meat and Poultry Products [Docket No. 04-001N]

On March 24, 2005, FSIS held a public meeting to present the draft risk assessment for *Clostridium perfringens* in ready-to-eat (RTE) and partially cooked meat and poultry products, including the model, data, and underlying assumptions. At this meeting, the Agency announced that it would like to receive additional public input and information through Docket No. 04–001N. The official comment period was originally scheduled to close on May 9th, 2005, but was extended to July 11, 2005. FSIS received several comments on the FSIS *Clostridium perfringens* risk assessment from industry groups (addressed below) and none from other stakeholders.

Comments are grouped by topic and are given verbatim, although not necessarily in the order or in the context provided by the commenters. Following every paragraph of particular or grouped comments a response is provided. FSIS has attempted to respond correctly to the context of the comment, even if that context is not given in full here. Comments that clearly indicate support or agreement, or that reiterate or restate the results of the risk assessment, and that require no response are omitted. All comments and responses are numbered but are not otherwise labeled. References to page numbers, table numbers, figure numbers, and section numbers correspond to the draft risk assessment for public comment provided in Portable Document Format (PDF) on the FSIS web site.

1 AUTHOR CORRECTIONS

This section lists errors (not located by either peer reviewers or other commenters) discovered and corrected by the authors during the review process, together with other major changes in the document.

Substantive

Page 87, Section 3.11.5.2. The effect of nitrite on growth rate is discussed and evaluated. However, the implementation (the computer program) omitted the effect of nitrite in Category 1 foods (only Category 1 foods are modeled to be affected). Incorporating this change, and the other changes discussed in this document, reduces the total estimated number of illnesses by about 1/3.

Page 168, Section 6.6.2. This section incorrectly referenced Equation 6.2 for the parameters a and b of Equation 6.5. The correct reference should have been to Equation 6.1. The correct numerical values (from Equation 6.1) were used in the subsequent calculation, but the fraction f was incorrectly given as 0.6, where to a good approximation $f = 0.37$ (0.32 with the other corrections incorporated here). The correct references and values now been incorporated and used. The corrected sensitivity to the mean fraction of spores germinating in RTE production is about 0.025 to 0.04 between growths of 1-$\log_{10}$ and 3-$\log_{10}$ (rather than the range of 0.04 to 0.06 given in the draft risk assessment for growths of 1-$\log_{10}$ to 2-$\log_{10}$). The explanation of this section has been expanded to clarify the methodology used.

Page 170, Section 6.6.7. The estimated sensitivity to the fraction of Category 1 foods that are consumed cold was overestimated. The analysis failed to take account that Category 1 foods that are not consumed cold must be consumed hot. This resulted in overestimation of the sensitivity of this parameter. The correct value using the methods and data of the draft risk assessment was about 0.082. However, (see Response 17) commenters pointed out that data from an American Meat Institute sponsored survey are available that measure fraction of hot dogs eaten cold, and these data have been incorporated in the modeling. Consequently this parameter now applies to many fewer servings (now labeled Category 1b), and the sensitivity to its value is now 0.019.

Typographical and explanatory

Pages 12 through 17. The Executive Summary has been replaced.

Page 21, Section 2.2. The cross-reference to Section 2.2 should be to Section 2.4.

Page 152, Section 6.1.1. Mead *et al.*'s extrapolation was by a factor 380, not 38.

Page 188, Sections A.2 and A.3. The text indicates 1,627 food codes were abstracted by the procedure described. However, Appendix B lists only 1,625, and Figure A.1 only mentions 1,625. Food codes 71401000 and 71401030 (respectively French fried potatoes not specified as to fresh or frozen, and prepared from frozen) were originally selected by

the procedure described because they may contain beef fat. However, any fat in these foods would have been subject to temperatures that would destroy both vegetative cells and spores of *C. perfringens*, so these two food codes were omitted from further consideration. This information has been added just before Table A.2.

Appendix B. The table has been resorted first by exclusion or category codes, then by food code.

Appendix D. Four ingredients (codes 7067, 13058, 4114, 11945) were inadvertently omitted from the table (but this had no effect on the calculations). Four soup ingredients (codes 6008, 6013, 6016, 6413) have been reclassified as containing no meat that could supply vegetative cells or spores (see Response 22).

2 SCOPE AND MANDATE

Comment 1

Per the risk management questions posed, the risk assessment focuses on addressing the risk of human illness from allowing a specific log growth of *C. perfringens* during cooling of ready-to-eat (RTE) or partially cooked meat and poultry products at a manufacturing facility. Nevertheless, a "farm to fork" risk assessment might have been more informative in putting the risk in the context of all *C. perfringens* illnesses from meat and poultry products (those prepared from raw meat and poultry at retail, foodservice and in the home, as well as from RTE products that are mishandled). This would have allowed the risk estimate for number of illnesses annually to be compared to the number of annual illnesses due to *C. perfringens* derived by Mead *et al.* in 1999.

Response 1

The *C. perfringens* risk assessment was designed to specifically respond to the risk management questions posed. These questions centered on the effect of growth of *C. perfringens* at processing plants for RTE. Responding to those questions required the construction of a model incorporating many effects, including for example the effects of consumer refrigeration and hot-holding. However, the response to those questions did not require a "farm" component, nor evaluation of the use of raw meat and poultry. Such an extended evaluation would have required significantly more resources than were available. The commenter provides no scientific evidence that the value of the comparison suggested would justify the additional resources, such evidence being particularly required since Mead *et al.*'s approach is an extrapolation with unstated uncertainties that may well be as large or larger than those evaluated and discussed in the risk assessment. In addition, Mead's estimates of illnesses caused by *C. perfringens* are based on all foods from outbreak data. The risk assessment estimates illnesses caused by *C. perfringens* contaminated RTE and partially cooked meat and poultry products only and is therefore not directly comparable.

Comment 2

This would also demonstrate even more clearly that the risk of illness from *C. perfringens* due to improper cooling at FSIS-inspected establishments is so low that there is no reason to focus resources on this issue.

Response 2

The evaluation of resources that should be devoted to any particular risk is a policy issue that is not discussed in nor appropriate for the risk assessment.

Comment 3

Even without a farm-to-fork risk assessment, it is clear that the problem of foodborne illness due to *C. perfringens* is due to mishandling by foodservice establishments and consumers, not due to cooling problems at FSIS-inspected facilities.

Response 3

The risk assessment indicates that illnesses caused by *C. perfringens* in RTE foods could largely be avoided by proper handling and heat treatment, including cooling at the plant. The risk assessment evaluates the magnitude of risks due to various effects, but the importance attached to them is a policy matter that is not evaluated in the risk assessment.

Comment 4

If the points listed in question three ["Were the assumption made regarding the input data fair and proper?"] would have been considered, the scope of the assessment could have been narrowed. The effect of *Clostridium botulinum* should not have been within the scope of this assessment. Reporting on the effect of *Clostridium botulinum* serves to confuse issues.

Response 4

Information on *Clostridium botulinum* was included in the risk management questions; the scope of the assessment requested was a policy decision that is not evaluated in the risk assessment. The discussion of *Clostridium botulinum* in the risk assessment is limited and very specific. It is not clear from the comment in what other (if any) ways the risk assessment could have been narrowed in scope; the points mentioned ("in question three," see specific responses to those points below) were on the lack of distinctions between species (pork, poultry, beef), between whole muscle and comminuted product, between cured and uncured meats, and between product which has no nitrite and a product that is "hot held" in a gravy. Introducing distinctions (where they were not already present, see responses below) would not have narrowed the scope of the assessment.

3 HAZARD IDENTIFICATION FOR C. *PERFRINGENS*

Comment 5

This section would benefit from more discussion on the food items associated with the illnesses and the location of the outbreaks with respect to FSIS-inspected facilities.

Response 5

Outbreaks are expected to constitute the minority of illnesses, so such observations would not necessarily be helpful and might be misleading.

Comment 6

The risk assessment states that "only one [outbreak] has been confirmed as having been caused by a Ready-to-Eat (RTE) product, turkey loaf (CDC, 2000; DeWaal *et al*., 2001)." The first reference provides no specific information on this outbreak, nor were we able to find the information on the CDC website listings of outbreaks. The second reference is no longer available.

Response 6

The CDC, 2000 reference is a summary of all outbreaks reported by the CDC between the years of 1993 to 1997. The outbreak information is included; however, very few details are provided. Slightly more information is provided by the CDC at the following URL, http://www.cdc.gov/foodborneoutbreaks/us_outb/fbo1997/bacterial97.htm.

Organism	State	Month	Year	Number ill	Vehicle	Location
Clostridium perfringens	NY	10	97	18	Turkey	Fire department

and this 1997 listing is also available in PDF format at http://www.cdc.gov/foodborneoutbreaks/us_outbpdf/fbofinal1997.pdf. However, specific details that would allow identification of this outbreak as being caused by an RTE product are not available in either of the references cited in the risk assessment. This information comes from the more detailed information submitted to CDC by a NY State Department of Health, Bureau of Community Sanitation and Food Protection representative during a personal communication on August 13th, 2002. The risk assessment has been modified to indicate these additional sources.

The internet reference given in the risk assessment for De Waal *et al*. 2001 is correct. The original report was available at the date referenced, and was also available on 7/21/2005 after receipt of these comments, together with the update to 2002 mentioned in the reference list; and an update to 2004 was also present on 7/21/2005 at the same location (the reports are not adjacent on the web page, so can easily be missed; the update to 2004 has been added to the reference list). This reference should not have been given as a primary reference, as it merely cites CDC, 2000. The risk assessment has accordingly been modified to remove this reference at this point.

Comment 7

The updated 2004 version contains only one reference to turkey loaf, and that is a *Salmonella* outbreak. The implication of this statement in the risk assessment is that the outbreak could be related to manufacturing of the RTE product; however, it is impossible to determine the relevance of the product being RTE to the outbreak from the information provided. The risk assessors should provide clarification of this statement.

Response 7

The commenters are correct that there is not enough information to determine if the outbreak could be related to manufacturing of the RTE product, abuse of the RTE product subsequent to leaving the manufacturer, or any other possibility. No further clarification is needed, however, since no inference of responsibility for the outbreak is implied, and the information is not used further in the risk assessment.

Comment 8

The following statements were made in this risk assessment, yet were not accounted for in the assessment:

· Poultry luncheon meat is the only RTE food confirmed as a food vehicle in a *C. perfringens* outbreak since 1992 and

· Beef with gravy is the most commonly implicated food in *C. perfringens* outbreaks when "hot held."

Response 8

The statements reflect anecdotal observations on those outbreaks for which the food vector was identified. However, reported outbreaks include only a minority of all illnesses due to *C. perfringens*. Very little is known about the foods implicated even in reported outbreaks, and none at all on the great majority of illnesses that are not so reported (Mead *et al*., 1999 estimate that there are 380 times as many *C. perfringens* illnesses as are reported in outbreaks, see also Author corrections, above). Thus these anecdotes cannot be incorporated in any correct accounting, so are correctly ignored in the risk assessment.

4 EXPOSURE ASSESSMENT

4.1 Model structure

Comment 9

The flow chart for modeling survival and growth of *C. perfringens* addresses retail and home, but does not address the significant number of RTE products that go to foodservice operations. Much of what is modeled for retail applies to foodservice (*e.g.*, reheating and hot-holding), but foodservice could include additional cooling, cold storage and reheating steps.

Response 9

The food service sector is not excluded by the flow chart. Initial consideration was given to treating foodservice operations separately, but there were insufficient data distinguishing this sector from retail and home, and none providing information on further cooling, cold storage, and reheating steps. Information to this effect has been added to the risk assessment. The commenters provide no data that could be used in the risk assessment to allow separate modeling of foodservice operations.

4.2 Consumption and food categories

Comment 10

The risk assessment's attempt to predict consumption of RTE and partially cooked meat and poultry products is admirable. However, the consumption data of 1994 through 1996, supplemented with a 1998 children's survey, are likely not accurate in today's environment. New products based on technologies such as case-ready production and packaging, heat and serve delivery, and antimicrobial processing have altered shelf life, preparation practices, and food safety. All of these changes need to be understood if the risk assessment is to be an accurate predictor of risk.

Response 10

No data were available on changes in consumption since the 1994 through 1998 survey. The primary use of these data were to first classify food servings as being potentially RTE or partially cooked, then as being capable or incapable of supporting growth of *C. perfringens*, then to obtain food serving sizes, meat or poultry content, salt content, and spice content. It is not clear to what extent changes in packaging or processing would affect such parameters, and the commenters provide no data on any changes that may be used in the risk assessment.

Comment 11

The sorting exercise for consumption data provided in Appendix A was logical with respect to meat and poultry items to be included or excluded from the risk assessment. However, the limitations of the categorization are evident by looking at the contents of the four categories of foods listed in Appendix B used in the risk assessment. There is inconsistency in the way foods are assigned to the four categories. For example, category 1 (which is supposed to be foods containing nitrite likely to be reheated before consumption) includes ham and cheese sandwiches with lettuce and spread, but ham and tomato club sandwiches with lettuce and spread are in category 2 (foods unlikely to be reheated before consumption); turkey bologna is in category 1, but bologna and cheese sandwiches are in category 2.

Response 11

Category 1 foods are defined as "Foods likely to be reheated before consumption" and containing 2.2-3% NaCl in the presence of nitrite (see Table 3.1). Food code 27520320 (ham and cheese sandwich, with lettuce and spread) was estimated to contain 2.38% NaCl and likely nitrite. Additionally, because "ham and cheese sandwiches" are often

grilled, in part, to melt the cheese, this food code was placed in Food Category 1. Food code 27520540 (ham and tomato club sandwich, with lettuce and spread) is more likely to be prepared cold because it is described as a "club sandwich." Additionally, Appendix B indicates this food code contains 2.10% NaCl, so this food code contains less than 2.2% NaCl, making it ineligible for Food Category 1.

Food code 25220440 (bologna, turkey) was estimated to contain 2.23% NaCl and likely nitrites. Because of the limited food description, this product may have been reheated or eaten without reheating. The product was estimated to be less likely to allow growth of *C. perfringens* due to the high NaCl concentration and nitrites. This food code was therefore placed in Food Category 1. Food code 27560120 (bologna and cheese sandwich, with spread) was placed in Food Category 2 because it contained 2.13% NaCl (lower than the cutoff adopted for Category 1) and it was deemed that bologna is less likely to be reheated than other meats when prepared in a sandwich.

There are indeed limitations on the categorization of foods induced by the lack of complete information on individual servings. However, the categorization is used only to a limited extent in the risk assessment; the most important requirement is to obtain an approximate total quantity of RTE and partially cooked meat in the various categories. Mis-categorization of individual servings could only have a substantial effect if one particular serving type was both mis-categorized and also constituted a major use of meat in RTE or partially cooked foods.

Comment 12

It does not appear that the foods in Appendix B were cross-referenced with foods known to have caused illnesses related to *C. perfringens*, nor cross-checked for obvious foods that should be excluded.

Response 12

As mentioned in Response 8, illnesses occurring in reported outbreaks with an identified food vector are a small fraction of the total number of illnesses predicted, so that the reports are anecdotal; they do not provide any basis for characterization of the foods evaluated in the risk assessment. In addition, as the majority of *C. perfringens* outbreaks are considered to be the result of consumption of meat and poultry prepared from raw or unknown, outbreak data would not necessarily be comparable to RTE and partially cooked foods which were prepared in a processing plant.

Appendix A details the methodology adopted to exclude obvious food ingredients from the risk assessment. In general, ingredients were excluded if they were likely raw, or if their manufacturing process guaranteed that *C. perfringens* would be absent or would not be able to germinate or grow in the final food serving.

Comment 13

For example, pizza and pizza toppings receive a lethal cook and are highly unlikely to contribute to the exposure to *C. perfringens*. Bacon, including "Pork bacon, smoked or cured, lower salt" and the bacon in sandwiches, is usually cooked thoroughly, resulting in a product that will not support the growth of *C. perfringens*. A seven-layer salad,

assuming the RTE meat product of concern is bacon, is very unlikely to contribute to *C. perfringens* food poisoning because of pieces of cooked bacon. (In fact, there are no meat ingredients listed for seven-layer salad on p. 249 – it is described as lettuce salad made with a combination of onion, celery, green pepper, peas, mayonnaise.) "Baked beans," and "Baked beans, with pork and sweet sauce" would be highly unlikely to contribute to *C. perfringens* food poisoning related to RTE or partially cooked meat and poultry products. It is not clear why "pork and beans" is not excluded as a shelf stable (canned) product, although "burrito with pork and beans" is correctly included. "Canned ham" is listed in "Appendix C, Foods commonly hot-held," although canned hams have not been linked to *C. perfringens* food poisoning. Many of the Chinese dishes listed (*e.g.*, General Tso's Chicken, Moo Shu Pork) are most likely restaurant-prepared from raw meat and poultry rather than processed in an FSIS-inspected establishment and should not be included.

Response 13

The meat components of RTE pizza and pizza toppings should certainly receive a "lethal" cook during manufacture, but that is precisely what might activate *C. perfringens* spores to germinate in the meat components. The possibility of a subsequent lethal cooking (at home, for example) is taken into account in the risk assessment. The same is true for the lower salt bacon that is included in the risk assessment; cured high salt bacon is excluded from the risk assessment if the salt level is considered high enough to inhibit *C. perfringens* growth (see Appendix A and the multiple excluded bacon entries in Appendix B; see also Response 18).

The seven layer salad mentioned by the commenter (food code 75145000) does indeed contain meat (2.6%) according to the CSFII recipe information that is used as the basis for the calculations. Unfortunately, the shortened descriptor omitted the meat component, which is indeed bacon. The full ingredient list may be obtained from the recipe for this food code in the CSFII documentation, a copy of which is included in the FSIS Docket.

"Boston baked beans" and "baked beans, with pork and sweet sauce" were included because their recipes (in the CSFII) indicate that they contain meat products that might contribute *C. perfringens* spores that could be activated to germinate by the lethality step applied during manufacture.

The food code with description "pork and beans" is not excluded as a shelf stable (canned) product because this food code has a recipe that includes canned beans with un-canned pork (beans, baked, canned, with pork and tomato sauce).

Canned ham, though listed in Appendix C, was not used directly in the risk assessment. As indicated in Appendix C, "The following list of foods was supplied by US Foodservice, and used to assist selection of foods in CSFII that should be placed in Category 4" (emphasis added). All canned ham food codes were excluded from the analysis and listed in Appendix B as shelf stable canned/jarred.

It is agreed that that "Many of the Chinese dishes listed… are most likely restaurant-prepared from raw meat and poultry", however, no data were located to indicate what fraction of these products were RTE or partially cooked and what fraction was sold as

raw, and the commenters provide none. The food codes are therefore included in the analysis.

Comment 14

It is assumed that 80 % of the servings selected from the CSFII represent RTE or partially cooked foods, and this is applied to all categories (p. 119). This implies that only 20% of servings of the products included in the risk assessment are prepared from raw ingredients cooked in the home or foodservice.

Response 14

This comment may arise from a misconception on the part of the commenter. The risk assessment does evaluate any foods considered to be prepared from raw; it is solely concerned with RTE and partially cooked foods. The servings within CSFII that were consistent with being meat or poultry containing and RTE or partially cooked were first identified based on their descriptions, specifically omitting all those that contained meat ingredients stated to be (in CSFII descriptions) or considered to be prepared from raw (see in particular Appendix A.3.7). All these servings were assumed representative of how RTE and partially cooked foods are consumed, and tracked through the risk assessment. For the purpose of estimating the annual consumption of RTE and partially cooked servings, 80% of the total estimated U.S. consumption of servings represented (in the CSFII survey) by those identified in the risk assessment as potentially RTE or partially cooked were assumed to actually be RTE or partially cooked. Thus the meat in 20% of the total US consumption of such servings was assumed to be prepared from raw, but the consumption of such prepared-from-raw servings are not included in the risk assessment results.

Comment 15

There is no attempt to justify this number. Expert elicitation should be used to examine each of the listed foods and estimate the percentage of each that might be prepared from raw ingredients versus those manufactured as RTE or partially cooked products.

Response 15

The commenter is correct, and this is explicitly pointed out in the risk assessment (Sections 3.15.2 and 6.6.14). It is not clear that expert elicitations would provide estimates of any higher accuracy, and the approach suggested would be extremely resource intensive. Better approaches might be surveys, or matching the CSFII information with total production statistics from industry. However, the required information was not available, and the commenter has provided none.

Comment 16

It is assumed that 20% of category 1 servings (foods containing nitrite likely to be reheated prior to consumption, such as hot dogs) are eaten without reheating. This number should be adjusted based on the listing of products in the category and the number of servings of these products. For example, the descriptors applied to many of the products are clear indicators of whether the servings should be assigned to a

"reheated" category or not (*e.g.*, ham croquettes would be reheated, ham in sandwiches would not). It should be assumed that frankfurters on a bun and pigs in a blanket would be eaten hot.

Response 16

The available descriptors do not provide sufficient information to make the assignments suggested by the commenter; and the basis for the suggested adjustments is not provided in the comment. For example, while the majority of ham croquettes might be reheated, some fraction likely would not, and the commenter provides no methodology for making an estimate. Similarly, most frankfurters on a bun might indeed be eaten hot, but this is not necessarily true. In the absence of adequate information, a single estimate was applied to all servings, and the sensitivity to this estimate is relatively low (see Section 6.6.7 and the Author corrections above). A commenter has pointed out that there are data available to estimate the fraction of hot dogs that are eaten raw; this information has been incorporated in the risk assessment (see Response 17). However, extrapolation of the fraction known for hot dogs to the remainder of Category 1 (this remainder is now called Category 1b) was not considered valid, so the fraction for Category 1b remains unknown and is again set to 20%. The sensitivity to this fraction (which now applies to fewer servings) is now smaller, at 0.019.

Comment 17

The FDA/FSIS risk assessment for *Listeria monocytogenes* assumed that 1 to 10% of frankfurters are consumed without reheating; this should be applied to the frankfurter servings.

Response 17

The commenter is correct, and the information used in the *Listeria monocytogenes* risk assessment was erroneously overlooked. This information is included in The American Meat Institute (AMI) survey of 1000 persons (American Meat Institute, 2001, as already cited in the risk assessment). The relevant survey information has now been analyzed using methods similar to those used on other data, and the risk assessment has been updated to account for this information. Foods in Category 1 have been divided into two categories, 1a and 1b, the former consisting of all those with descriptor including the words "hot dog" or "frankfurter" (all such descriptors include both terms), the latter consisting of all remaining foods in Category 1. The fraction of Category 1a foods that are eaten cold is now represented by a lognormal uncertainty distribution with median 0.0670 (6.70%) and geometric standard deviation 1.120, as obtained by assuming that the AMI survey is representative of hot dog consumption. This representativeness assumption has been added to the others listed in Section 4.1. The fraction of foods in Category 1b that are eaten cold is not known, but is considered to probably exceed the fraction of frankfurters eaten cold. It is assigned the value 0.2 (20%), and a sensitivity analysis has been performed to evaluate the sensitivity of results to this value.

Comment 18

As noted above, bacon should be removed from the category entirely, since in its RTE form it will not support growth of *C. perfringens*.

Response 18

There are many codes that include bacon as an ingredient among those listed in Appendix B (searching for "bacon" in Appendix B gives 42, but there are more food codes, e.g. 75145000, see Response 13, that contain bacon as too minor an ingredient to have been included in the abbreviated listings given in that appendix). Most of those food codes (37 can be found by searching on "bacon" in Appendix B) have been excluded based on shelf stability, prepared from raw, or containing nitrites with >3% NaCl. Twelve food codes containing bacon (5 searchable in Appendix B) remained in the analysis, including in Category 1. The one apparent in Appendix B, food code 22602010 (pork bacon, smoked or cured, lower sodium), is estimated to contain 2.62% NaCl. This level of NaCl with nitrites, based on the available data, will not inhibit the growth of *C. perfringens* given permissive time and temperature conditions and was therefore included in the analysis. Similarly for any food codes containing bacon but not apparent in Appendix B. The NaCl and nitrite content is taken into account in the growth rate modeling in the risk assessment (see Section 3.11.5.2; but see also Author corrections, above).

Comment 19

Appendix D has significant limitations. This Appendix is intended to determine the fraction of meat associated with meat or poultry containing food servings (*e.g.*, the amount of ham in a ham sandwich). However, the list appears to contain "ingredients" that are composite products (*e.g.*, biscuit with egg and ham). It is stated that because there are insufficient data, the meat content of any item classified as a meat ingredient is considered to be 100% meat.

Response 19

The limitations of Appendix D are noted in the header to that appendix.

Comment 20

However, there are many items listed in Appendix D that are plainly not 100% meat, *e.g.*, fat, poultry skin, soup with listed ingredients, gravy, cheeseburgers, smoked link sausages with listed ingredients, biscuit sandwiches, English muffin sandwiches, pasta dishes containing meat, chili products containing meat, stroganoff, chimichangas, and dumplings.

Response 20

Some approach was necessary that was within the resources available, and that chosen is documented in Appendix D. The object was to obtain an estimate of the mass of meat within a food serving that could contribute spores (or vegetative cells). The description given by the commenter is misleading, since for every entry the food contains a substantial fraction of meat. Taking the list given in order:

Fat: It is not known whether fats, as commercially used, contain spores or vegetative cells. Fat was not distinguished from meat in the risk assessment. See also Response 21.

Poultry skin: The descriptor "skin" associated with poultry occurs only as part of an ingredient that is 100% poultry meat that contains skin.

Soup with listed ingredients: There are eight ingredients included as meat or poultry containing and listed as soup. In each case the soup is listed as beef broth, chicken broth, or cream of chicken, with various modifications. However, in response to other comments (see Comment 22 and Response 22), canned and/or commercial soups are now considered not to provide any source of spores or vegetative cells.

Gravy: All the listed meat or poultry containing gravies indeed contain meat. Gravies are also included as part of other meat or poultry containing ingredients (*e.g.* Salisbury steak with gravy).

Cheeseburgers: There is no cheeseburger listed as a meat ingredient. There is a "Cheesefurter, beef and pork" that is the sole ingredient for food servings described as "cheese-filled frankfurter or hot dog."

Smoked link sausages with listed ingredients: The only ingredient matching this description is "smoked link sausage, pork and beef, with flour and non fat dairy milk" (abbreviations have been expanded in this descriptor).

Biscuit sandwiches: The meat or poultry containing biscuit ingredients are listed as with ham, with sausage, with egg and ham, or with egg and sausage.

English muffin sandwiches: The one meat or poultry containing English muffin is listed as "with cheese and sausage."

Pasta dishes containing meat: This appears to be a reference to the entries "Healthy Choice spaghetti bolognese, frozen entree" and "Healthy Choice beef macaroni, frozen entree," both of which likely contain a substantial meat fraction.

Chili products containing meat: The "chili con carne, with beans" and "chili con carne, not stated as to beans" should also contain a large meat fraction.

Stroganoff: This is beef stroganoff, with beef being the primary ingredient.

Chimichangas: The meat or poultry containing ingredients listed are with beef or chicken, the meat component probably constituting most of the weight.

Dumplings: The meat or poultry containing ingredients are dumplings filled with meat or seafood, so that most of the weight would probably be meat or seafood (meat versus seafood is not distinguished in CSFII, so cannot be distinguished in the risk assessment).

In most cases (including some of those cited), the mass of the ingredient would be largely be the mass of the meat or poultry component(s).

Comment 21

Unless there are data that show that *C. perfringens* cells or spores are found in beef or poultry fat, it is unclear why these "fat" ingredients would be considered as meat ingredients in Appendix D.

Response 21

No data were located that would allow distinguishing the vegetative cell or spore content of different meat components. Contamination with vegetative cells and spores is presumably due to contact with contaminated materials, so that different meat components may be contaminated similarly. In view of the lack of distinguishing data, and the potential commonality of mechanisms of contamination, all meat components were treated similarly. See also Response 20.

Comment 22

It appears that soups are included as meat ingredients as well, without clarification as to whether these are canned products that would very likely be free of *C. perfringens* (*e.g.*, we would assume that "soup, chick broth, cond, comm" is condensed, canned chicken broth).

Response 22

Canned soup servings are omitted from the risk assessment (see Appendix A). Soups were, however, considered to be meat ingredients when they were part of the recipe of other servings. The commenter is correct to point out (and Appendix A also indicates) that commercial canned soups would be very likely free of *C. perfringens* (both vegetative cells and spores). The risk assessment should, therefore, exclude the meat soup component of servings (from canned, and/or commercial meat soups, ingredient codes 6008, 6013, 6016, 6413) as a potential source of spores. This change has been incorporated, and results in 21 servings (of the 26,548 servings included) with no source of spores (the meat and spice fractions are all entered as zero). These servings have been left in the input files, and cause no problems in the calculations (since they have no meat or spice component, they are treated as not containing any *C. perfringens*). The change due to this modification is too small to be measurable.

Comment 23

As stated in the risk assessment, these errors are all conservative errors that, when added atop one another throughout the model, leads to conservative estimates of exposure, and ultimately very conservative predictions of foodborne illnesses.

Response 23

The conservatism induced by the failure to take account of the meat fraction of the ingredients listed by the commenter are small, since they represent a relatively small fraction of the total mass of meat consumed in RTE and partially cooked foods. The meat ingredients contributing to servings constituting the majority of meat consumed in RTE and partially cooked foods are 100% meat. These particular errors are indeed conservative, and in several places the risk assessment has probably been conservative in selection of certain assumptions. The overall conservatism of the model is unknown, however, and it cannot be stated with any certainty that the foodborne illness predictions are conservative.

Comment 24

A more detailed analysis of the foods listed as potential sources of *C. perfringens* would improve the value of the risk assessment.

Response 24

Such a detailed analysis was not possible with the resources available. So far as the authors know the required data do not exist or are not publicly available. A more detailed analysis would require substantial information from food manufacturers. No analysis has been performed to evaluate the value of further such information; and such an analysis would require policy input and judgments that are not part of this risk assessment.

Comment 25

In Table 3.1, "RTE and partially cooked foods that could support the growth of *C. perfringens*," the reasoning for Food Category 1 states that hot dogs are "made via the highest risk process." It is unclear what is meant by this phrase, especially in the context of a *C. perfringens* risk assessment. It can be argued that hot dog production is in fact a very low risk process relative to food safety because of automation, intervention strategies and cold chain management.

Response 25

This remark has been removed.

Comment 26

Category 1 foods are also discussed in terms of secondary heat shock inducing germination of spores with the potential for growth during subsequent hot-holding at temperatures allowing growth (p. 40); yet this simply has not proven to be the case for hot dogs and frankfurters that comprise the majority of products in this category that would be held hot. There are no data to support this as a proven risk for hot dogs and franks.

Response 26

There are similarly no data to disprove it. The individual franks/hot dogs that would be contaminated would not be able to cross-contaminate other servings. The likelihood of having two or more servings contaminated in the same batch that is adversely hot-held is low (~1% for 100 g servings, see Section 3.5.5, assuming that contamination occurs independently in each serving). Illnesses caused by this source would therefore be sporadic and unlikely to involve more than single persons, so would simply not be observable in outbreak data (an outbreak by definition requires two or more people to be ill). There is no reporting mechanism for such sporadic illnesses, so the lack of such reports tells us nothing.

Comment 27

The sensitivity analysis (6.6, p. 166) indicates that, for those parameters for which the variability distributions are not well defined or for which the model was simplified to use

a single value, the fraction of selected CSFII foods that are RTE and partially cooked is one of the parameters having the biggest impact on the risk assessment. The risk assessors note that there is no scientific basis for the fraction (0.80) of servings that are RTE or partially cooked.

Response 27

That is correct (see also Response 28).

Comment 28

We believe it is unrealistic to assume that only 20% of meat and poultry servings are prepared from raw meat and poultry cooked at retail, foodservice and in the home.

Response 28

The comment reflects a misunderstanding of what was done. The risk assessment does not examine raw meat at all (except for the purpose of excluding it), and there is no assumption or implication that only 20% of meat and poultry servings are prepared from raw meat. The 80% assumption is applied only to the number of food servings already selected as potentially being RTE or partially cooked, with all servings considered to be prepared from raw meat previously omitted from the risk assessment — see Appendix A.3 for details, and in particular A.3.7. Only 26,548 of the 598,829 servings in the CSFII database were considered to be potentially representative of meat or poultry containing RTE or partially cooked foods and included in the RA. These were adopted as representative of the distribution of food servings containing RTE and partially cooked foods. To estimate the number of servings, it was assumed that 80% of them were actually RTE and partially cooked.

4.3 Concentrations of *C. perfringens* in meat and poultry

Comment 29

Because the concentrations of *C. perfringens* before and after the lethality step are critical to the risk to public health (*i.e.*, high numbers are associated with illness) and the performance criterion relates to limiting growth without reference to initial or final concentrations, a much clearer understanding of initial loads and the impact of commercial lethality steps are needed to improve the usefulness of the risk assessment. The data on levels of *C. perfringens* in meat and poultry are limited. In fact, the risk assessors determined that only three studies provided useful information on the expected distribution of "*C. perfringens* vegetative cells in post heat treated RTE commodities" (3.5.3, p. 45). Since cooking will kill vegetative cells, this should refer to "vegetative cells from surviving spores in post-heat-treated RTE commodities." This appears to be what the risk assessors meant, since they state "All three studies included heat steps corresponding closely to those expected for RTE foods prior to the sampling and analysis" and "Such cooking is expected to kill vegetative cells in the raw commodity and to cause near optimum germination of spores."

Response 29

The commenters are correct, and this information is already provided in the introductory paragraph of Section 3.5 and in Section 3.5.1. Nevertheless, we have added phraseology to make this clearer at the point indicated (at the beginning of Section 3.5.3).

Comment 30

In its discussion (3.7.1, p. 52) on the concentrations of *C. perfringens* in raw meat, the risk assessment makes the case for very limited useful data when it states that while "Strong *et al*. [1963] performed their study over 30 years ago, no more recent data with fully confirmed *C. perfringens* analysis were identified." This admission makes the case for the paucity of complete data (Strong *et al*. only examined 111 relevant samples) that are considered optimal for the risk assessment. Given the significant changes in the production of raw meat since the study was conducted, especially with the application of HACCP in the production of raw meat, the data are unlikely to reflect the concentrations of *C. perfringens* in raw meat today.

Response 30

The commenters are correct about the paucity of useful data, although the more recent data of Taormina *et al*. 2003, and Foster *et al*. 1977 were also used to impose bounds on the possible *C. perfringens* concentrations. This representativeness assumption is documented in Section 4.1. Whether or not there have been significant changes in *C. perfringens* concentrations recently is unknown, and would require experimental evidence. However, no data that could be used in the risk assessment are provided by the commenters.

Comment 31

The same pertains to data for partially cooked foods where the risk assessment states up front (3.7.2, p. 55) that "the data available from the selected studies is [sic] too sparse to fully define variability distributions for *C. perfringens* concentrations in partially cooked foods." Nevertheless, a distribution is modeled (Table 3.9, p. 56). The data are significantly skewed by data from ground beef in a study by Foster *et al.* conducted in 1977. As noted above, significant changes in the production of raw meat since the study was conducted would suggest that these data may not be representative.

Response 31

The grammar will be corrected. It is not clear if anything is "skewed;" there are no more recent experimental data to provide evidence of any such skewing. The distribution shape is modeled in the same way as other concentrations, the assumptions required are documented in Section 4.2, and some of the uncertainty is incorporated through the uncertainty analysis. The commenters provide no data that demonstrate the falsity of the assumptions, or that could be used to improve the assumptions.

Comment 32

There are no verification data to support the risk assessment's assertion that "for a serving containing 100g (3.53 oz.) of meat, the prevalence of vegetative cells is 50.6% at

the maximum likelihood values of Table 3.9," or about 300 CFU/g of partially cooked meat or poultry product.

Response 32

The assertion cited is strictly a mathematical statement based on the estimates of Table 3.9. However, the commenter's sentiment is correct. All available data have been used to derive the parameter estimates in that table, and the assertion is entirely consistent with available data. Verification would require independent sampling, and the commenters provide none. The origin of the statement "or about 300 CFU/g of partially cooked meat or poultry product" is unclear, since no such statement is made in the risk assessment. The parameters of Table 3.9 correspond to a variability distribution for *C. perfringens* vegetative cell concentration in partially cooked food with a mean of 20.4 CFU/g and a standard deviation of 78.1 CFU/g (see the text below Table 3.9). It is possible the commenter is confusing the parameter *b* of Table 3.9 (which is about 300 CFU/g) with the concentration in food — the mean concentration is obtained from Table 3.9 as the product $a_s b$.

Comment 33

Clearly, if FSIS wants to focus on controlling growth of potential survivors, or germinated spores, they need to develop adequate baseline data describing *C. perfringens* in raw meat and poultry products destined for RTE or partially cooked meat and poultry products, in RTE meat and poultry products, and in partially cooked meat and poultry products.

Response 33

The focus of FSIS, the methods FSIS or others might adopt, and the adequacy of available data for FSIS or other decisions are policy matters outside the scope of the risk assessment. The risk assessment uses the available data and evaluates the uncertainties associated with such use.

Comment 34

Current available studies indicate four (4) logs is the worst case scenario for raw materials for ready-to-eat (RTE) products; USDA Baseline Study (1992-1996), Kalinewski, et. al, (2003) and Taormina, et. al, (2003)

Response 34

The comment provides insufficient basis for any evaluation of health hazards. The origin or meaning of the "four (4) logs" is not apparent, since the cited studies evaluated different measures (the USDA/FSIS baseline study evaluated CFU/cm^2 of unconfirmed vegetative cells in raw surface tissue samples, or CFU/g in ground samples; Kalinowski *et al*. measured CFU/g of confirmed germinated spores in post-cooking samples, and Taormina *et al* evaluated CFU/g unconfirmed vegetative cells in pre-cooked and CFU/g unconfirmed germinated spores in post-cooked samples, see Tables 3.2 and 3.8). The risk assessment is not solely concerned with vegetative cells on raw materials, nor just a

worst case, although both those are included through the uncertainty analysis applied. The risk assessment also evaluates the effects of spores in raw materials.

Comment 35

In the discussions related to the concentration of *C. perfringens* in heated foods (during the preparation of RTE foods) and the spore concentration for RTE foods, it is unclear whether there is a linkage between the two estimates. In the section (3.6.1, p. 52) describing the spore concentration for RTE foods, the risk assessment states that because "the heat step kills pre-existing vegetative cells, the measured vegetative cells in heat-treated meat originate from spores in the meat that are activated to germinate." This language suggests that the earlier discussions (3.5.3 – 3.5.5, p.45-51) on survival and concentration of vegetative cells in heated foods reflect the concentration of spores that are activated to germinate, and not surviving vegetative cells. The risk assessment could combine these two elements to better describe the relationship, or clarify that these are predictions of two different concentrations of *C. perfringens*, or that only outgrowth of germinating spores needs to be considered (apparently as stated, but not as done, in the risk assessment).

Response 35

Sections 3.5.3 – 3.5.5 are subsections of Section 3.5. They all deal with "vegetative cell concentration in heat-treated meat (corresponding to spore concentrations in raw meat, modified by the fraction that are activated to germinate during heat treatment)" (Section 3.5, page 41). As the commenter realizes, these are not vegetative cells surviving from vegetative cell contamination of the original meat, but arising from activation of spores in the lethality step applied to RTE meat and their subsequent germination. It was hoped that this would also be apparent from Figure 3.1, page 32, for the RTE branch. The language at the beginning of Section 3.5 has been extended (see also Response 29) to make this clearer. Section 3.6.1 evaluates the concentration of spores remaining un-activated in RTE meats, and shows the linkage with the concentration of activated spores (= vegetative cells) in Equation 3.5. Section 3.6.1 describes and Equation 3.5 precisely defines the relationship between the spore concentration and vegetative cell concentration remaining after the lethality step. Additional text has been added to Section 3.6.1 to emphasize this.

The comment "or that only outgrowth of germinating spores needs to be considered (apparently as stated, but not as done, in the risk assessment)" is unclear, since for RTE meat or poultry the risk assessment does precisely that. Spores may germinate during the lethality step at the processing plant, then any surviving spores may germinate during storage and transport, or during any subsequent heating step. Growth may then occur during cooling, during storage and transport, or during hot-holding. All are taken into account in the risk assessment. For partially cooked meat or poultry, vegetative cells on the original raw material must also be taken into account, and the risk assessment does that.

Comment 36

No attempt was made to separate pork, chicken and beef or to separate whole muscle and ground meat products or cured and uncured products with respect to concentrations of *C. perfringens* (3.5.5, p.49), since so few data points were available. Nevertheless, there should be some attempt to model whole muscle products separate from ground meat products through the heating and cooling processes. Although whole muscle cuts will be more difficult to cool internally, *C. perfringens* will be restricted to the surface, which will cool much more quickly than the interior. Moreover, the surface will see more lethality when whole muscle cuts are being cooking to achieve a specified internal temperature.

Response 36

As pointed out in the risk assessment, the available information was insufficient to make a realistic distinction between port, chicken, or beef; between whole muscle and ground meat products; or between separate cured and uncured products with respect to *C. perfringens* concentrations. It is a policy question beyond the scope of the current risk assessment as to whether further information should be obtained in order to allow such a distinction.

The commenter is correct that there may be differences in cooling rates and the location of *C. perfringens* contamination for whole and ground meat and poultry products. However, lack of data prevented any useful detailed modeling of the heating and cooling processes. Any attempt to model these processes in detail would be futile without extensive experimental data and representative information on industry practices.

Comment 37

No distinction was made for specie, i.e. pork, poultry or beef;

Response 37

With respect to *C. perfringens* concentrations, see Response 36. No distinction could be made in other parts of the risk assessment, due to lack of any distinction observed in experimental data.

Comment 38

No distinction was made between cured and uncured product.

Response 38

Cured products with sufficiently high salt content were excluded (see Appendix A.3.6). With respect to *C. perfringens* concentrations, see Response 36. Growth rates in cured (nitrite-containing) products in Category 1 were modified as described in Section 3.11.5.2 (but see also Author corrections, above). No other distinction could be made in other parts of the risk assessment, due to lack of any distinction observed in experimental data.

Comment 39

No distinction was made for product which has no nitrite and a product that is "hot held" in a gravy.

Response 39

With respect to nitrite versus non-nitrite products, see Response 38. With respect to "hot held" foods, it is not clear what distinction is intended by the commenter; "hot-held" foods were differentiated precisely because they were hot-held (see Section 3.14). Food servings containing no nitrite were placed in Categories 2, 3, and 4, while food servings that might be hot-held were included in Categories 1 and 4. However, only 1% of food servings in Categories 1 and 4 were assumed to be hot held (see Section 3.15.2). Thus distinctions were indeed drawn between products with no nitrite and hot-held foods; the latter were only a small fraction of the former.

Comment 40

The implication of not making the distinctions listed above is significant. Not making any distinctions regarding either product or process is inconsistent with the Hazard Analysis and Critical Control Point (HACCP) system, as well as being unscientific.

Response 40

As explained in Response 37 through Response 39, relevant distinctions were made where needed and where data were available to make such distinctions.

Comment 41

For example, cured whole muscle pork would have relatively low risk during stabilization and finished product storage compared with a comminuted roast beef (no nitrite), which is "hot held" in gravy and creates an anaerobic environment that is ideal for the growth of *C. perfringens.*

Response 41

It is pointed out in the risk assessment (Section 6.4.1) that illnesses from hot-holding were probably underestimated, but that the underestimation did not affect the conclusions of the risk assessment as they related to the risk management questions (the primary aim of the risk assessment being to respond to those questions). Distinctions were made where necessary and justifiable based on data (see Response 37 through Response 40).

Comment 42

Based on the USDA/FSIS study (1992-1996), it was determined that the concentrations of *C. perfringens* were less in whole muscle meats than in non-whole muscle meats. Pork (whole muscle) was equally considered in the Monte Carlo simulation when there is significant data to use a predictive model for pork minimally.

Response 42

There is insufficient published information to distinguish the concentrations in whole muscle and non-whole muscle meats. The same applies for pork versus other meat and poultry. The available data (including the USDA/FSIS study, 1992-1996) are summarized and evaluated for adequacy for the risk assessment in Section 3.5.1 and 3.7.1. Moreover, there is insufficient published information to evaluate the quantities of whole and non-whole muscle meats produced, or to distinguish the foods containing them.

Comment 43

Taormina, et. al. (2003) demonstrated that C. perfringens rarely occurred in cured whole muscle raw meats and spores were not detected. Taormina, et. al, also found that about half of cured ground and emulsified raw meats contained C. perfringens but only 5.3% of samples were positive for spores, but did not exceed 100/g. These findings support the two (2) logs growth in other published literature.

Response 43

The data in Taormina *et al* (2003), including their uncertainties, were fully taken into account in the risk assessment. Section 3.5, for example, evaluates vegetative cell concentrations in heat-treated RTE meat and poultry products, and takes account of the findings of Taormina *et al* (2003) together with other relevant studies. The commenter does not cite any literature for the claim of two logs of growth, nor is such a claim supported by the cited results of Taormina *et al* (2003) on concentrations (not growth).

4.4 Concentrations of *C. perfringens* in spices

Comment 44

The risk assessors should confirm whether or not the data on *C. perfringens* in spices used for the risk assessment (some of which are from 1975 and 1986) are relevant to spices that are used currently in U.S. meat and poultry-containing products.

Response 44

No information was located that would allow such confirmation, and the commenter provides none.

Comment 45

A primary criterion should be whether the older spice data reflect current methods of harvesting, handling, processing, pasteurization and sterilization.

Response 45

The primary criterion is the measured concentration of *C. perfringens*. The handling may affect this, but without good evidence for the effect of particular handling practices (and knowledge of source concentrations), knowledge of handling practices provides no information that would be useful in the risk assessment.

Comment 46

On the subject of "the contribution of *C. perfringens* from spices," the assessment did not consider *sterilized spices* compared with *non-sterilized spices,* nor was a distinction made.

Response 46

No information was available to distinguish spore concentrations on "sterilized" or "non-sterilized" spices, nor was any information available on the relative quantities of these items or their distribution into foods. The commenter does not provide any such information or references to such information.

Comment 47

Furthermore, the country of origin and purchasing history for imported spices are important variables to determine the suitability of any one set of data to describe likely levels of *C. perfringens* in various spices.

Response 47

Such information would be useful only if there were data that demonstrated differences in concentrations depending on country of origin or purchasing history. No such information was located, and the commenter provides none.

Comment 48

Public health data implicate spiced foods in *C. perfringens* food poisoning, pointing to the potential contribution of spices as sources of *C. perfringens* spores. The risk assessment makes what is likely a significant assumption when it treats almost all spices as the same with the same variability and uncertainty distributions, calculating estimations, in part, from data on spices imported in Australia where *C. perfringens* was not confirmed. The assumptions continue as the risk assessment states that there are "too few data available to adequately determine the shape of the variability distribution for *C. perfringens* concentration in spices;" and that all reported concentration measurements were "assumed to be accurate – too little information was generally provided to estimate the uncertainty in concentration estimates due to counting of only a small number of colonies."

Response 48

The risk assessment points out all these sources of uncertainty, and the commenter provides no useful information to reduce the uncertainties.

Comment 49

All of these unknowns become amplified as the risk assessment proceeds, *e.g.*, in estimating how concentrations of vegetative cells may be even higher considering the impact of heating of spices on spore germination and outgrowth.

Response 49

To the extent the known uncertainties (that is, those uncertainties quantified in the risk assessment) become amplified, such amplification is built into the risk assessment by its structure. That is, the effect of the uncertainty of any parameter in the risk assessment on the results of the risk assessment are accurately evaluated by the Monte Carlo procedure used in the risk assessment.

Whether an unknown uncertainty become amplified depends to some extent on how it is expressed. For example, if an (unknown) uncertainty in the concentration of *C. perfringens* spores in the input raw meat were expressed as a multiple of the currently estimated concentration, then the resultant uncertainty in the number of illnesses can be expressed as a similar multiple of the currently estimated result (modified somewhat by the relative fraction of illnesses ultimately due to meat or spices), because of the multiplicative nature of the processes involved (as modeled in the risk assessment by Equations 3.1 through 3.3). Expressed in this way, therefore, such an unknown uncertainty is not amplified (it is in fact somewhat decreased by the relative fraction of illnesses due to meat or spices). Similar comments apply to some other unknown uncertainties (and the effect on the estimated number of illnesses can be evaluated by analysis of Equations 3.1 through 3.3, together with the information provided in the risk assessment).

In other cases, the unknown uncertainties are not readily expressible — for example, the uncertainty in temperature distributions is an unknown; the measured values are assumed to be representative, and it is the representativeness that is the unknown factor. In such cases, it is difficult to know what would be meant by the uncertainty being "amplified," since how to express it in the first place is not known. However, given a method of expressing uncertainty (even for the unknown uncertainties), the methodology used in the risk assessment provides a means of evaluating any amplification, by evaluating the sensitivity of results (number of illnesses) to any particular uncertainty (although this might require modification of the risk assessment model to incorporate the additional expression of uncertainty).

Comment 50

[*The following list of articles pertaining to C. perfringens and spices was provided by a commenter following the Public Meeting*]

Pafumi, J. 1986. Assessment of the microbiological quality of spices and herbs. J. Food Prot. 49(12) 958-963.

Rodriguez-Romo, L.A., N.L., Heredia, R.G. Labbe and J.S. Garcia-Alvarado. 1998. Detection of enterotoxigenic Clostridium perfringens in spices used in Mexico by dot blotting using a DNA probe. J. Food Prot. 61(2) 201-204.

Powers, E.M., R. Lawyer and Y. Masuoka, 1975. Microbiology of processed spices. J. Milk Food Technol. 38(11) 683-687.

DeBoer, E., W.M. Spiegelenberg and F.W. Janssen. 1985. Microbiology of spices and herbs. Antonie van Leeuwenhoek, 51: 435-438.

DeBoer, E. and E.M. Boot. 1983. Comparison of methods for isolation and confirmation of Clostridium perfringens from spices and herbs. J. Food Prot. 46(6) 533-536.

Salmeron, J., R. Jordano, G. Ros and R. Pozo-Lora. 1987. Microbiological quality of pepper (Piper nigrum) II. Food poisoning bacteria. Microbiol. Aliments Nutr. 5:83-86.

Response 50

All references indicated above were previously identified except Salmeron *et al*., 1987. The others mentioned are discussed in Section 3.8. Pafumi, 1986, Rodriguez-Romo *et al*., 1998, Powers *et al*., 1975, and DeBoer *et al*., 1985 were incorporated in the risk assessment. DeBoer *et al*., 1983 was not included in the risk assessment because *C. perfringens* prevalence and enumeration data were not assigned to a particular herb or spice (the data also appear to substantially overlap those in DeBoer *et al*., 1985).

Salmeron *et al*., 1987 examined white and black ground and whole pepper, but did not confirm presumptive *C. perfringens*. For evaluation of black pepper, the risk assessment relies on the studies of Rodriguez-Romo *et al*., 1998 and Candlish *et al*., 2001, both of which are more recent and both of which confirmed *C. perfringens*. The analysis used in the risk assessment incorporated the white pepper evaluated by Candlish *et al*. 2001 with the "all other" category; however, white pepper was not identified in the CSFII servings (Table 3.12). The data of Salmeron *et al*., 1987 are therefore not included in the analysis, but this reference has been added to Table 3.11.

Salmeron *et al*., 1987 also cite two further papers with original data not evaluated in the risk assessment. Leitao *et al*., 1974 (Leitão, M.F.de F., Delazari, I., and Mazzoni, H. 1974. Microbiologia de alimentos desidratados. Coletanea do Instituto de Tecnologia de Alimentos 5:223-241) give prevalence and ranges of confirmed *C. perfringens* concentrations in dehydrated pepper and cinnamon commercially produced in Brazil. The ranges are within those used in the risk assessment, so would not change estimates of contamination significantly, and the measurements are older or less representative of the U.S. than the measurements used in the risk assessment. The data of Leitao *et al*. have therefore not been included in the analysis, but this paper has been added to Table 3.11. Krishnaswamy *et al.* 1971 (Krishnaswamy, M.A., Patel, J.D., and Parthasarathy, N. 1971. Enumeration of micro-organisms in spices and spice mixtures. J. Food Sci. Technol. 8:191–194) measured unconfirmed *C. perfringens* in samples of black pepper, turmeric, coriander, mustard, fenugreek, red chilis, cumin, and fennel collected from manufacturers and exporters in India. They provided overall ranges of the concentrations observed, but in view of the limited information provided and the remoteness of the samples in location and time, these data have not been included in the analysis. However, this paper has been added to Table 3.11.

4.5 Growth of *C. perfringens*

Comment 51

The model focuses extensively on growth rates of *C. perfringens* but there is much less discussion, due to data limitations, on "lag phase" or delay time before germinated spores enter exponential growth phase. The risk assessment model reportedly underestimated published growth rates by about a factor of 1.739; thus, all modeled growth rates were increased by this same factor to agree with the published data. If the objective of the risk assessment was to compare risk with differing expectations for allowable growth during

stabilization, it is unclear why such a factor is necessary, particularly when, as stated by the risk assessment, this factor "should be conservative, although it may not be correct."

Response 51

The risk assessment was guided by published information to the extent it was available. Therefore, the median estimate of growth rates (at fixed temperature) was adjusted from the specific conditions analyzed in detail to the more general situation of growth conditions evaluated in the literature. It is possible, perhaps likely, that growth conditions evaluated in the literature do not correspond to growth conditions in food, which is why it was stated that the factor may not be correct. However, it was judged that the many growth conditions evaluated in the literature would more likely encompass those encountered in food, and the variability due to such varying growth conditions was also incorporated in the risk assessment. Any alternative approach would require deliberate rejection of published literature information for no good reason. The objective of the risk assessment was not compromised by this approach.

Comment 52

This "correction factor" is used again to decrease the delay time before growth initiates, and thus, impacts predictions related to hot-holding, where "it may result in a conservative bias (towards overestimates of illnesses)."

Response 52

The adjustment was based on the few available observations that indicated approximate inverse correlations between delay time and maximum growth rate under certain experimental conditions. Again, any alterative choice would have required deliberate rejection of information available in published literature.

Comment 53

While multiple conservative biases generally lead to overestimates or inaccuracy of risk, and potentially to overly restrictive or misdirected policies related to restriction of growth of *C. perfringens,* in this case it appears that not applying this adjustment would reduce the number of illnesses from hot-holding, which we believe, based on epidemiology, is underestimated by this model. This itself could lead to misdirected policies. Clearly more data on growth rates are needed to more accurately predict risk from *C. perfringens* in meat and poultry products.

Response 53

The risk assessment points out (see Section 6.4.1) that it probably underestimates illnesses from hot-holding (but for other reasons), although this is irrelevant to the principal aims of the risk assessment. Whether policies are misdirected depends on policy approaches and aims, neither of which are addressed in the risk assessment. More data on growth rates might allow a more accurate risk estimate; however, evaluation of the effect of such higher accuracy was not a primary objective, and any need for higher accuracy is a policy decision that is not addressed in the risk assessment.

Comment 54

The risk assessment notes that it is reasonable to suppose that *C. perfringens* spores are capable of germinating at water activity levels below those that would allow vegetative cell growth (3.11.5.5, p.89). While this may be true, it would not impact the number of cells of *C. perfringens,* since the germinated spores could not multiply. This point about germination may be relevant if the model takes account of the increased sensitivity of germinated spores to heat, but this is not clear.

Response 54

As pointed out just before Table 3.27, literature measurements of water activities in meat foods are all in the range in which *C. perfringens* may grow, so it is irrelevant whether or not *C. perfringens* could germinate at lower water activities. Foods with water activities sufficiently low to affect *C. perfringens* growth or germination were eliminated from consideration in the risk assessment by the procedures of Appendix A. This has been clarified in the text in Sections 3.9.2 and 3.11.5.5.

Comment 55

Furthermore, *C. perfringens* is an anaerobic microorganism; however, the effect of oxygen or lack thereof was not accounted for in the risk assessment.

Response 55

The experimental evidence on germination and growth rates was taken into account. These incorporate some effect of oxygen (for example, some of the variability in growth rates likely is due to variability in oxygen availability). No further account could be taken without further experimental evidence and data on industry practices.

4.6 Differences in growth characteristics of *Clostridium botulinum* and *C. perfringens*

Comment 56

A secondary purpose of the risk assessment was to examine whether steps taken to limit the germination and outgrowth of *C. perfringens* would be adequate to protect against germination and outgrowth of *C. botulinum*. We found the risk assessors' treatment of this issue much more limited than other parts of the risk assessment.

Response 56

The commenter is correct. The treatment of *C. botulinum* was deliberately more limited, since (as it turned out) such limited treatment was adequate to respond to the stated risk management question.

Comment 57

Section 3.11 (p.75) addresses the issue of growth of *C. botulinum* in comparison to *C. perfringens*. Data for *C. perfringens* were taken from beef and chicken, as well as from broth; the *C. botulinum* data are taken from a single study in a laboratory medium. The

curves in Figure 3-4 include one for *C. perfringens* in cured beef/chicken but not one for *C. botulinum* in cured meats.

Response 57

Further detailed data on *C. botulinum* would have been plotted were it available. However, no such further data were located, and the commenter references none.

Comment 58

(We also note that the risk assessment refers to a 1999 paper by Juneja *et al.* on growth of *C. perfringens* that is not listed in the references.)

Response 58

This has been corrected. The missing reference is:

Junega, V.K., Whiting, R.C., Marks, H.M., and Snyder, O.P. (1999). Predictive model for growth of *Clostridium perfringens* at temperatures applicable to cooling of cooked meat. *Food Microbiology* 16:335–349.

Comment 59

The risk assessors conclude that measures taken to reduce or prevent growth of *C. perfringens* will not necessarily have the same effects on growth of *C. botulinum,* based on the determination that *C. botulinum* grows at temperatures below the minimum for growth of *C. perfringens* and *C. perfringens* grows at temperatures above the maximum for *C. botulinum*. We believe this is a simplistic treatment of the issue that, while it may answer the risk managers' question, does not provide adequate information to address all relevant risk management issues.

Response 59

The risk assessment was primarily concerned with responding to the risk managers' questions, primarily focused on *C. perfringens*. Resource limitations precluded addressing the multiple potential risk management issues that were not originally raised. Such issues could be addressed by further work, given the availability of relevant data.

Comment 60

Since the relationship of growth to toxin production is not fully defined, the time to toxin production by *C. botulinum* is a better predictor of risk than growth of the organism. Even at optimal growth temperatures, toxin production takes hours (or even days, depending on the food, the temperature, the number of organisms, and many other factors). Such studies have been conducted with foods inoculated at levels much higher than what might reasonably be expected in meat (ICMSF, 1996, *Microorganisms in Foods 5: Microbiological Characteristics of Food Pathogens*, Blackie Academic). *C. botulinum* is unlikely to be present in meat and poultry, and when present its numbers are very low (ranging from <0.1 spore/kg to 7 spores/kg; summarized in Tompkin, R.B., 1980, Botulism from meat and poultry products – a historical perspective, *Food Technology* 34(5): 229-36, 257 and Hauschild, A.H.W., 1989, *Clostridium botulinum*. In

Foodborne Bacterial Pathogens, M.P. Doyle, ed., Marcel Dekker). The risk assessors acknowledge in section 6.4.2 (p. 163-164) that lag time plays a role in determining growth by *C. botulinum*. If products are cooled at a rate that minimizes *C. perfringens* growth, especially through its optimum growth temperatures, once product reaches the temperatures at which *C. botulinum* grows faster than *C. perfringens*, the growth rate for *C. botulinum* will nevertheless be limited. The risk assessors point out that additional constraints on times spent at such temperatures are needed to limit potential *C. botulinum* growth, in addition to any constraints on *C. perfringens* growth. While we do not disagree with this statement, even though the growth of *C. botulinum* will be more rapid than that of *C. perfringens*, continued cooling to temperatures that prevent growth of *C. botulinum* should prevent a problem from *C. botulinum*.

Response 60

This information may well be useful in any subsequent work evaluating further risk management issues for *C. botulinum*.

4.7 Time and temperature control

Comment 61

The risk assessment would be improved if FSIS worked with industry to define the range of industry processing times and temperatures used for initial processing or final preparation of RTE and partially cooked foods.

Response 61

Data of this nature would be useful in defining a process model. For the risk assessment, data that are representative of the industry would be required. However, the commenters provide no such information along with their comments.

Comment 62

Of course, criteria used by FSIS to assess compliance with regulations can serve as the defaults, although many products are cooked to higher temperatures and many products will cool faster than these guidelines. Industry could supply actual cooking and cooling curves for representative products.

Response 62

See Response 61.

Comment 63

These data are needed, as the risk assessment states that there are insufficient data on temperature-time combinations used by industry for initial processing or final preparation of RTE and partially cooked foods to determine the fraction of spores that germinate. However, the risk assessment describes the large variation in germination rate for a single strain (and obviously, between strains) exposed to various time-temperature treatments. The risk assessment ultimately used a range of germination rates, none specifically identified as related to specific product-strain-process combinations, so ultimately, while

useful to the modeling exercise, the rates are more speculative (or mathematically useful) than fact-based.

Response 63

The rates used in the risk assessment are based on the available published information. The commenters provide no useful information that could be used to better define them. The uncertainty in the rates is specified, and that uncertainty is propagated through the entire risk assessment.

Comment 64

For the very small and small meat processing industry, the products are generally in distribution a considerably shorter period of time compared with large volume production meat establishments and therefore would have less at risk of the *C. perfringens* growth during finished product storage time.

Response 64

The industry was not subdivided in the risk assessment because no data could be located that would allow such subdivision. The commenter provides anecdotal information suggesting that subdivision by size of establishment might be a useful to account for some of the variation in distribution time, but provides no data that would allow this subdivision in the risk assessment. In view of the sensitivity of the estimate for total illnesses to the length of storage between manufacturer and retailer (Section 6.6.6), further information would be most useful.

Comment 65

Spontaneous germination of spores during storage and transport is assumed to occur. The risk assessment assumes there are favorable conditions for germination; and germination is independent of temperature, duration and other conditions of storage.

Response 65

The comment oversimplifies. The risk assessment notes that germination has been observed to occur under many conditions, including those (very cold storage, for example) that are not at all favorable to germination. There were insufficient data available to model the effects of temperature, duration, or other conditions of storage, on the fraction germinating. The sensitivity of the estimate for total illnesses to the rate of germination is very small, however (Section 6.6.5), so that adjusting for variations in storage conditions would have little effect.

Comment 66

The likelihood that germination is independent of temperature and is the same for all food matrices would appear to be very low based on all the data related to storage temperatures, strain variations and potential antimicrobial effects of food composition.

Response 66

There are insufficient data, however, to verify or deny the hypothesis. Moreover, the contribution to and sensitivity of estimates of total illnesses due to post-cooling germination are very small (Section 6.6.5), so even large uncertainties in germination rate have little effect on illness estimates.

Comment 67

The risk assessment (3.13.3) states that the "storage temperature for each product, reached at the end of the manufacturing (heating and stabilization), is assumed to be represented by temperatures observed for packaged lunch meat immediately after removal from retail display cases in the Audits International/FDA (1999) survey." While these temperatures may appropriately be used to represent temperature during storage in the retail display case, it is not appropriate to use this for the entire time from manufacture to retail. This assertion does not take into account the much higher level of control over the cold chain at manufacturers' warehouses and through their distribution network, as compared to the vast array of retail display cabinets where temperatures are higher, less frequently monitored and less controlled. When under the control of the manufacturer, perishable products such as meat and poultry are likely to be held at lower temperatures to obtain the desired product shelf life. The assumption used would lead to another overestimation of the potential for growth of *C. perfringens*. Expert elicitation from industry could be used to define more appropriate temperatures for the part of the distribution chain under the manufacturer's control (in-plant storage, company distribution warehouses and company-controlled transportation). In addition, Audits International collected temperature data for the "back room" at retail that should be used as well. It is particularly important that more accurate data be used, given that the model attributes most of the risk to long-term temperature abuse.

Response 67

The commenters are entirely correct that the temperature time profile may well be different than assumed in the risk assessment. The data used, however, are the most representative that could be located, and the commenters provide no such data nor data sources to modify the assumptions of the risk assessment. See also Response 69.

Comment 68

For storage between retail and consumption of category 1 and 2 products, storage times are based on an AMI survey for hot dogs and deli meats. This survey, however, would not be appropriate for all the products represented in these categories, especially meat and poultry salads (see next paragraph). Storage temperatures are based on data from the Audits International survey, which are appropriate in this case.

Response 68

See Response 67 and Response 69.

Comment 69

With respect to model parameters for which the variability distributions are not well defined or for which the model was simplified to use a single value, the sensitivity analysis indicates the parameter having the biggest impact on the risk assessment is the mean storage time at manufacturing and retail. The risk assessors indicate that the results of the risk assessment are relatively sensitive to the default assumption of storage time between manufacturing and retail (6.6.6, p. 169) of 10-30 days (mean of 20 days). This distribution is based on the storage time for frankfurters and luncheon meats in the FDA/FSIS *Listeria monocytogenes* risk-ranking model (p.100). It was used for all categories of foods (including long shelf life products such as hot dogs and shorter shelf life products such as salads containing meat). Clearly this default assumption is inappropriate for all these products. In fact, the same risk-ranking model used different distributions for other products, such as a minimum of 1 day and a maximum of 7 days for pâtés and meat spreads, and considered this parameter not applicable for foods in which the organism would not grow. We believe that industry data or expert elicitation would provide more appropriate assumptions for specific types of products.

Response 69

The sensitivity analysis indicates that the results are sensitive to mean storage time at manufacturing and retail; however, that does not necessarily mean that this parameter "has the biggest impact on the risk assessment" — the impact on the risk assessment results is the product of the sensitivity parameter and the relative error of the parameter.

The FDA/FSIS *Listeria monocytogenes* risk-ranking model (2003 version, as cited in the risk assessment) contains only Table III-12, page 52, to distinguish different meat products. That table distinguishes "Frankfurters", "Dry/Semi-dry Fermented Sausage", "Deli Meats", and "Pâté and Meat Spreads". The Dry/Semi-dry Fermented Sausage entry is "not applicable" in the *Listeria* document, and it is not applicable for *C. perfringens* because this food item is shelf stable, so was omitted from the risk assessment (Appendix A). Frankfurters and Deli Meats both have the 10 to 30 day storage time used as the estimate in the *C. perfringens* risk assessment. Pate and Meat spreads are assigned the 1 to 7 day storage time mentioned in the comment. No other storage time distributions are mentioned in the *Listeria* document. However, Pate and Meat spreads are not among the foods that modeled for *C. perfringens*. The only Pate in Appendix B is "Liver paste or pate, chicken" which was assumed to be prepared from raw and excluded (Appendix A). The only meat spreads are considered to be shelf-stable, canned, so were also excluded (see Appendix A). Other "spread" entries in Appendix B correspond to non-meat spreads combined with non-spread meats. The only possible exceptions are two ingredients listed as "Poultry Salad Sandwich Sprd", and "Ham Salad Sprd", corresponding to foods listed as "Chicken salad spread" and "Ham salad spread". However, there are a total of only about 11 servings of both in the servings included in the *C. perfringens* risk assessment, so they constitute a negligible fraction of the meat evaluated.

The commenters are correct that the assumption that mean storage time is equal for all foods may be inappropriate. However, no further information was located that could provide useful information on storage times for distinguishable products or categories of foods, and the commenters provide none. It would be possible to provide alternative

inputs for the various categories distinguished in the risk assessment, and to separately evaluate the sensitivity of the results to each of those inputs. This approach was considered, but rejected as providing no increase in the value of the risk assessment in the absence of reliable additional data.

Foods in which *C. perfringens* would not grow have been omitted from the risk assessment already (see Appendix A), so no extra evaluation for such foods is required. The parameter is already inapplicable to such foods.

Comment 70

It is assumed that category 3 and 4 products (foods reheated for immediate consumption, foods reheated and held hot) are sold frozen. This assumption is somewhat questionable, but it can be argued that many of these products are frozen and that the proportions of those sold refrigerated is not known. We also question the assumption that frozen retail temperature is the same as manufacturers' frozen storage temperature, but recognize this will have limited impact on the risk assessment. There were no data on storage times after manufacture and prior to preparation identified for these categories, so the times were assumed to be the same as those for categories 1 and 2. Although this is unlikely, obtaining more accurate information will have little or no impact on the risk assessment.

Response 70

See Response 67.

4.8 Laboratory data

Comment 71

One of the somewhat confusing aspects of the risk assessment is the apparent flux between accepting laboratory data (*e.g.*, growth in laboratory media to predict growth rates) and not accepting laboratory data (*e.g.*, the effect of salt and nitrite on the length of delay time, the effect of pH, the lethal effect of low temperatures). The risk assessment should clarify further why laboratory data are acceptable in some instances but not in others. Typically, the reasons for "disqualifying" data are given; however, the risk assessment would be strengthened by stating the "qualifying" differences in laboratory data when they are used in the risk assessment, and more broadly, by providing the rationale for overall decision-making for laboratory data under consideration for use in the risk assessment.

Response 71

The comments are unclear because in all cases mentioned, laboratory data are discussed, evaluated, and relevant data are used; indeed, the general methodology adopted was to identify and use all relevant laboratory data. The commenter may also have missed that the delay time affects the risk assessment only for evaluation of hot-held foods; it is assumed in other circumstances that vegetative cells are poised for exponential growth in suitable conditions (see footnote 41 on page 85, and Section 3.13.2.4). Moreover, for this reason the delay time, as incorporated in the model, has practically no effect on the evaluation of the effects of changes in growth during cooling after the lethality step (the

primary aim of the risk assessment), so was not evaluated in great detail. An explanation that the lag time affects only modeling of hot-holding has been added in relevant locations in the risk assessment.

The particular cases mentioned as "not accepting laboratory data" are largely incorrect. The effects of salt and nitrite on delay time are discussed in Section 3.11.5.3. The only information located suggested that salt concentration may interact with other modifiers of lag time (which is a parameter estimated from data that differs slightly from the delay time used in the risk assessment), but had no main effect in the published statistical analysis (Juneja *et al*., 1996b); the risk assessment has been modified to explicitly state this lack of a main effect. Nitrite concentrations were shown to have no effect on lag phase using cured and uncured turkey emulsion, and equivocal effects in laboratory media. Laboratory media were considered less relevant for lag time evaluation, since lag time is expected to depend strongly on medium (in contrast, growth rates in laboratory media can match those observed in meat media, see Figure 3-4).

The effect of pH is discussed in Section 3.11.5.4, where available information on pH was analyzed and pH was shown to have no effect on growth rate. The effect observed on lag time in laboratory media was discounted as not likely to be predictive of the effects in a food medium. The risk assessment has been modified to point out that even if an effect of pH on delay time were predictable for food media, that information could not be used in the model without further extrapolations since pH information on the food servings used in the risk assessment is lacking.

The lethal effect of low temperatures is explicitly incorporated in the modeling (Section 3.13.2). It is possible that the commenters are referring to cold shock, rather than the effects of low temperatures themselves. This is also mentioned in Section 3.13.2; however, no data were located that would allow extrapolation to the conditions of RTE and partially cooked foods.

In general, the risk assessment attempts to use all available relevant laboratory data to model all relevant effects mentioned; where laboratory data are not used, it is because they are explicitly rejected as not predictive of the conditions evaluated in the risk assessment, and the reasons are stated. The commenters provide no further data that would be usable in the risk assessment.

Comment 72

It has been well documented that salt and nitrite have a synergistic effect inhibiting the growth of *C. perfringens*;

Response 72

The effect of salt and nitrite on growth of *C. perfringens* was incorporated in the risk assessment. In particular, cured meats with sufficiently high salt content to inhibit growth were omitted (see Appendix A). For lower salt content, the effect of salt and nitrite were both modeled and the results incorporated in the risk assessment to the extent possible using available data (see Section 3.11.5.2, but see also Author corrections, above). The commenters' preferred definition of "synergistic" is not given; generally the definition depends on the mathematical form of the models used. No data were located

that allowed a simultaneous analysis of the effect of salt and nitrite concentration on *C. perfringens* growth; however, the simultaneous effect of salt and pyrophosphate was shown to be adequately fitted with independent effects when modeled using a multiplicative model for the growth rate (see Section 3.11.5.2).

Comment 73

There is a synergistic effect of salt and nitrite inhibiting *C. perfringens* vegetative cell growth during finished product storage;

Response 73

See Response 72.

Comment 74

There is a salt/nitrite inhibition of *C. perfringens* vegetative cell growth after curing (i.e. preblending), but prior to lethality treatment (thermal processing);

Response 74

Any effect on growth of the vegetative cells prior to a lethality treatment is irrelevant to the risk assessment, since the lethality step is assumed to completely kill all vegetative cells present. See also Response 72.

5 LIMITATIONS OF THE EXPOSURE MODEL

Comment 75

Section 4 clearly lays out the many assumptions and limitations of the data for development of the exposure model. The data on *C. perfringens* spore concentrations are limited (only 3 studies), and the assumption that distinct meat products (*e.g.* beef, pork, chicken, ground or whole meat) have the same distribution of spore and vegetative cell concentrations is not likely to be correct.

Response 75

As stated, the risk assessment documents the assumptions and limitations. It is probable that distinct meat products have distinct distributions of concentrations. However, the available data are inadequate to make the distinction between different meat products, and the risk assessment incorporates the uncertainties in evaluation of spore and vegetative cell concentration distributions.

Comment 76

The concentration of *C. perfringens* (when present) is much less in whole muscle than in comminuted tissue. *Note*: This was stated in risk assessment during the discussion regarding the USDA/FSIS study of 1992-1996.

Response 76

The prevalence of (unconfirmed) *C. perfringens* vegetative cells appears to be higher in comminuted tissue than in the selected samples of whole muscle in the USDA/FSIS study of 1992-1996 (this study is evaluated for the risk assessment in Sections 3.5.1 and 3.7.1). The reported concentration data in this study for comminuted tissue and whole muscle samples cannot be compared without further assumptions. However, for RTE meat, this particular study provides no useful information for the risk assessment, since what is required is information on *C. perfringens* spore concentrations in the raw material (equivalently, vegetative cell concentrations after a heat step has killed the original vegetative cell population and activated spores to germinate). For evaluation of partially cooked foods, the USDA/FSIS study results were also considered inadequate for the reasons stated in Section 3.7.1.

Comment 77

We have noted that the times and temperatures for storage of meat and poultry products are inaccurate.

Response 77

The representativeness of the data used is unknown, and this problem is documented in the risk assessment (see Section 4.1). The commenters provide no alternative estimates.

Comment 78

The assumption that vegetative cells present in RTE and partially cooked foods are ready to begin exponential growth, and start such exponential growth as soon as temperature conditions are favorable, is a conservative one that it not likely to be correct.

Response 78

This assumption is documented in Section 4.2. Its conservatism is unknown.

Comment 79

Further, given the sensitivity of this organism to cold temperatures, the assumption that cold shock has negligible effect on the concentration of vegetative cells in practical situations for cooling RTE and partially cooked foods, and similarly for freeze/thaw cycles during storage, are also conservative.

Response 79

Cold shock, a particular phenomenon that affects *C. perfringens* exponentially growing cells, is of unknown importance after the several hours of a cooling process plus a stabilization process at the manufacturing plant, but the effect is likely substantially less than on exponentially growing cells. The assumption that there is no effect in practical situations is documented in Section 4.2. No data were located that would allow any better assumption, and the commenter provides none. The risk assessment does take into account the affect of cold and freezing temperatures on *C. perfringens* vegetative cells within the limits of the available data (Section 3.13.2). Included in the analysis are data

obtained from Kalinowski *et al*., 2003. As discussed in the risk assessment, the cells in this experiment were likely in exponential phase, accounting for the relatively large rates of *C. perfringens* vegetative cell decline due to cold.

Comment 80

In addition, it is unlikely that maximum cell densities are independent of the food.

Response 80

It is indeed likely that maximum *C. perfringens* cell density varies between different food matrices, as discussed in Section 3.11.5.6. However, as stated there, no data were located that would allow distinguishing maximum cell density between various food matrices. The magnitude of the maximum cell density and the variability between food matrices were estimated based on laboratory studies in non-food matrices. A sensitivity analysis performed to evaluate the effect of the assumptions made (Section 6.6.13) indicated that the results are fairly sensitive to these assumptions. However, the commenter provides no information that would allow better estimates.

Comment 81

In many instances the assumptions were necessary, and, in most cases, each assumption by itself introduces limited "error." However, when each assumption is conservative, the result can lead to unfounded conclusions about appropriate risk management strategies. We have made suggestions for use of expert elicitation in some instances that would improve the validity and reduce the limitations of some of the assumptions.

Response 81

The suggestions are welcome; however, they provide no data that would allow modification of the assessment in any way, nor do they point out uncertainties that are not explicitly incorporated or already stated in the risk assessment.

Comment 82

However, we disagree that improper cold storage is likely to be the primary source of *C. perfringens* illnesses. The risk assessment stated that the "extent to which abusive hot-holding contributes to *C. perfringens* food poisoning cannot be accurately estimated by this risk assessment." This is unfortunate because, as stated in the risk assessment, improper holding temperature (including improper hot-holding) was cited by CDC as a contributing factor in 93% of outbreaks from 1988-1997 where a contributing factor was acknowledged. Additional data on existing industry practices with respect to product storage temperatures as noted above would result in a better prediction of where the problem lies.

Response 82

The CDC *C. perfringens* outbreak data is biased to large institutional hot-holding outbreaks easily recognized by the food surveillance system (*C. perfringens* foodborne illness is not a reportable disease and has neither an active nor passive reporting system). The outbreak data is presumably representative of all foods, of which RTE and partially

cooked foods will be a small fraction. There are no epidemiological data to estimate the fraction of *C. perfringens* illnesses resulting from RTE and partially cooked foods that were abusively hot-held. There are thus no data that could confirm or deny the commenters' opinions. The commenters provide no data that would allow incorporation of existing industry practices with respect to product storage temperatures.

Comment 83

Moreover, a more complete risk assessment that includes additional retail and foodservice practices such as reheating and cooling should be incorporated as well. This information, particularly if based on predicted numbers of *C. perfringens* spores/cells in RTE and partially cooked products leaving FSIS-inspected establishments (*i.e.*, numbers based on actual cooling practices) will more accurately identify practices likely to contribute to *C. perfringens* illness. This approach would have more impact than focusing on growth during stabilization, which has been shown to contribute negligibly to public health risks because of controls at processing establishments.

Response 83

The commenters are correct that more representative data would probably allow a more accurate risk assessment. However, the commenters do not provide any more representative data, and do not indicate any point where the uncertainty analysis and discussion of representativeness are incorrect. Whether higher accuracy or greater representativeness are needed is a policy decision that is not within the purview of the risk assessment. The risk assessment focused on growth during stabilization because that was required by the risk management questions. The risk assessment is concerned with estimating the size of effects, and does not address such policy matters as whether the results contribute "negligibly to public health risks," which determination hinges on the meaning attributed to that phrase.

6 HAZARD CHARACTERIZATION

Comment 84

We question the use of a non-threshold dose response model given that it is well recognized that large numbers of *C. perfringens* are needed to cause illness. We note that the dose response curve predicts a 1% probability of illness from ingestion of 4.8×10^7 cells. Thus one might conclude that the dose response appropriately reflects the need for high numbers to result in illness. The problem is that with a non-threshold model, there is some finite probability of illness from even low numbers; when the large number of servings (55.7 billion) is factored in, there will be illnesses associated with small numbers where a threshold model would indicate an absence of illnesses. This may in part be why the risk assessment predicts inordinately large numbers of illnesses resulting from cold holding of RTE and partially cooked products.

Response 84

The commenters are incorrect in their supposition that it is the non-threshold dose-response shape assumed in the risk assessment that causes the 1% probability of illness

from around 5×10^7 cells. A similar result would be obtained using almost any dose-response curve applied to the available data. It is more the variability between strains that leads to this result. For example, with a threshold dose-response shape for an individual strain, the value of the threshold can be expected to vary between strains. The available information on this variation indicates that some strains would have thresholds below 5×10^7 cells; and the same result would occur if around 1% of the strains had thresholds lower than this.

The commenters are also incorrect in stating that "it is well recognized that large numbers of *C. perfringens* are needed to cause illness." What is well recognized is that in laboratory experiments large numbers of the particular strains used are necessary to *reliably* cause illness (that is, in a large fraction of the subjects). That large numbers are *always* required in order to cause illness appears to be highly unlikely, based on mechanistic ideas of infection.

The commenters are also incorrect in their apparent belief that a large fraction of the modeled illnesses are due to small numbers of cells in servings. See Response 86 below.

That the numbers of illnesses predicted are "inordinately" large is also an unsupported opinion of the commenters. The numbers predicted are a logical consequence of the data and the analyses, and are entirely consistent with (admittedly very limited) epidemiological data.

Comment 85

At least seven (7) logs of vegetative cells of Type A *C. perfringens* are necessary to cause human illness;

Response 85

The commenter provides no data to support this assertion, so it is not possible to examine it in full. All available information on dose-response is discussed in the risk assessment (Section 5.3), and the dose-response curve and its uncertainty is fully elaborated in the risk assessment. No evidence was located for a strict threshold of 10^7 cells.

Comment 86

If seven (7) logs of vegetative cells of Type A C. perfringens are necessary to cause illness, then does the simulation result in Figure ES-1, make sense?

Response 86

The risk assessment did not attempt to evaluate the effect of the stated assumption (that a minimum of 10^7 vegetative cells is required for illness). Examination of the simulation results (available in the spreadsheet CP_results.xls associated with the risk assessment and available from the FSIS web site) shows that very few (~0.2% at 0.5 logs of growth during stabilization, to ~7% at 3.5 logs of growth) of the simulated illnesses were due to

vegetative cell counts lower than 10^7, so that Figure ES-1[1] would be practically unchanged by inserting such a threshold.

Comment 87

The assumptions are numerous for the dose-response modeling and are well characterized in the risk assessment (5.4). A number of these are highly unlikely to be true, *e.g.*, that the dose-response is non-threshold, there is no effect of the food matrix.

Response 87

The commenters are correct that some of the assumptions are highly unlikely to be exactly true; however, this is irrelevant to the risk assessment provided the resulting uncertainties are adequately incorporated. For example (see Response 86) if the dose-response were to be threshold-like, there would likely be very little effect on the risk assessment. The commenters, furthermore, provide no data that would allow modification of the assumptions made.

7 RISK CHARACTERIZATION

Comment 88

The data used to estimate initial spore and cell numbers, as well as post-lethality numbers, are described in depth in the risk assessment, particularly in relation to the many questions and limitations of the data. The uncertainties and assumptions result from numerous factors such as small data sets, limited product types, or use of laboratory-prepared meat samples, the decision not to separate pork, chicken and beef, or whole muscle and ground meat, or cured and uncured products, and variations in methodologies used to enumerate and confirm *C. perfringens*. The risk assessment states that these factors can lead to an overestimate or an underestimate of risk; clearly, the output of the risk assessment needs to be considered in relation to such statements. Because of this, the risk characterization values should include ranges rather than point estimates.

Response 88

The risk characterization section is designed to specifically respond to the risk management questions. It provides complete information on the uncertainty distribution for rates of illness estimated in the risk assessment. Section 6.1 is primarily concerned with evaluation of how illness rates vary with growth during stabilization, and uses median and MLE statistics for the uncertainty distributions for that purpose, while Section 6.2 then goes on to specify the complete distributions. Since the risk characterization provides complete information on the uncertainty distributions, any desired ranges may be readily obtained by the reader.

Section 6.3 provides only point estimates; these were evaluated using MLE values for uncertainty distributions; this information was inadvertently omitted, and has been added

[1] Figure ES-1 has now been removed because of the change in the Executive Summary (see Author corrections above), but Figure 6-2 is identical.

to the risk assessment. Uncertainty estimates for these values were not derived, since their evaluation was of secondary interest and not required to respond to the risk management questions posed. This explanation has also been added.

In Section 6.4, responding to the risk management questions, specified ranges of values are provided, corresponding to what was believed to be desired by the risk managers.

Sections 6.5 and 6.6 used point estimates, again based on the MLE for uncertainties, since the results (of what-if scenarios, and sensitivity analysis) were secondary in importance, they were expressed in such a way as to be largely independent of the uncertainties, and evaluation of their uncertainties would have required substantial effort.

Comment 89

The risk assessment estimates that, with all the uncertainty parameters set at the maximum likelihood estimates, there are approximately 120,000 illnesses due to *C. perfringens* (6.1.1, p.152) if 1-log growth occurs during cooling, with a range of 111,000 cases if 0.5 log growth occurs and 207,000 cases if 3.5 logs of growth occurred during cooling in FSIS-inspected establishments.

Response 89

The commenter is correct that those values specify the estimated variation in estimated number of illnesses as growth during stabilization varies from 0.5 to 3.5 $\log_{10}$, with all uncertainty estimates held at their MLEs.

Comment 90

The CDC estimate (Mead *et al.*, 1999) for cases of *C. perfringens* from all food sources is 250,000. The risk assessors indicated that the estimate of 120,000 illnesses at 1-log growth falls within the Mead estimate.

Response 90

It is mathematically true that the second value is consistent with the first. The Mead *et al.*, estimate is subject to large and unknown uncertainties, because it uses an unvalidated methodology that consists of extrapolations based on analogies with other diseases.

Comment 91

The risk assessors determined that 76% of outbreaks from 1990-1999 were associated with USDA-regulated products (2.4, p.26). Thus, one can estimate that 190,000 of the 250,000 cases would be from meat and poultry products.

Response 91

The commenters' estimate does not follow from the stated facts without significant further assumptions. The 76% fraction is for observed outbreaks in which the food vector was identified, but the fraction for such outbreaks may be considerably different from the fraction for sporadic cases, which are expected to make up the great majority of illnesses.

Comment 92

While this is consistent with the Mead *et al.* estimate, given that the model estimate does not include illnesses from products produced at retail and in the home from raw meat and poultry, the estimates seem high.

Response 92

It is quite plausible that the ML estimate may be high, and also plausible that it may be low. The estimated uncertainty is a factor of 1.93 at one standard deviation (Section 6.2.2), for the uncertainties that could be modeled, and there are other uncertainties that are not modeled. Moreover, the Mead *et al*. estimate may be high or low by an unknown factor. No information was located that could provide any estimate of the uncertainty of the Mead *et al*. estimate.

Comment 93

The risk assessors further note that the model underestimates the number of illnesses due to hot-held foods; thus the model would appear to overestimate illnesses in comparison with Mead *et al.*

Response 93

It cannot be reliably stated what the relationship is between the risk assessment estimates and the Mead *et al*. estimates, because the Mead *et al*. estimates have unknown uncertainty.

Comment 94

The risk assessment concludes that 93% of *C. perfringens* illnesses from RTE and partially cooked products are due to improper cold holding (long term temperature abuse is identified as the primary contributor) and improper hot-holding contributes to approximately 4%.

Response 94

However, it is also pointed out (Section 6.4.1) that improper hot-holding is not adequately modeled in the risk assessment, probably resulting in underestimates by a factor approximately equal to the average number of servings held hot.

Comment 95

Moreover, the fraction of illnesses by food category (6.3.2, p. 159) attributes most of the illnesses to category 1 and 2 products (*e.g.*, cured products such as hot dogs and products eaten without reheating such as luncheon meats and meat salads). This is inconsistent with existing epidemiologic data on illnesses from *C. perfringens*.

Response 95

The results are entirely consistent with epidemiologic information. As previously mentioned (see Response 8, Response 12, Response 26, and Response 82), the epidemiology is on outbreaks, which by definition involve two or more persons, and

usually many more, and which probably make a minor contribution to the total illness burden.

Comment 96

The one aspect that is consistent with epidemiologic data is that the risk assessment identifies institutions and consumers as the points of "risky behaviors." As noted previously, the risk assessment states, "the majority of poisonings do not appear to be from ready-to-eat (RTE) products produced in FSIS regulated establishments, but rather from products prepared from raw meats and poultry …prepared… in advance by consumers or in restaurants or institutions and held for extended lengths of time at temperatures that will support growth."

Response 96

No response is necessary. However, as to the representativeness of epidemiological observations, see Response 8, Response 12, Response 26, and Response 82.

Comment 97

With respect to the estimated numbers of illnesses resulting from 0.5-3.5 logs growth of *C. perfringens* during cooling processes, given the extent of the uncertainties in the risk assessment it can be argued that the numbers themselves are meaningless except for comparative purposes.

Response 97

The uncertainties that were identified but could not be adequately treated in the risk assessment are substantial, so the absolute numbers presented in the risk assessment could be larger or smaller by a substantial factor, and this factor is in addition to the already substantial uncertainty factor arising from known uncertainties (see Section 6.2.1).

Comment 98

Moreover, since the estimates are of the same order of magnitude it is difficult to argue that there are significant differences in these numbers, which differ only by a factor of 2 from 0.5 logs growth (111,000 illnesses) to 3.5 logs growth (207,000 illnesses).

Response 98

The commenters are perhaps here not making a clear distinction between uncertainty and variation. The variation with allowed growth occurs essentially independent of the uncertainties; that is, whatever the correct number of illnesses at 0.5 logs of growth, the number at 3.5 logs of growth will be about 2 times higher, as predicted by the risk assessment. This point was mentioned also at the public meeting. While the uncertainties are large at any fixed growth, those uncertainties are correlated with the uncertainties at any other fixed growth (indeed they are largely the same uncertainties). Thus, for example, the uncertainties shown on Figure 6.2 should be interpreted primarily as showing how the whole curve might be higher or lower, but the shape of the curve would remain the same.

Comment 99

The risk characterization is summarized succinctly as "most illnesses are predicted to occur as a result of what can only be described as broken refrigerators," and that "growth during stabilization has only a small overall effect." Thus, even with the large level of uncertainty associated with this risk assessment, it is clear that foods leaving manufacturing plants do not contain harmful levels of *C. perfringens* and, provided these foods are properly handled, they pose virtually no risk of causing illness. If, as stated in the risk assessment, approximately 93% of the illnesses predicted by the model occur as a result of growth of *C. perfringens* vegetative cells during storage, primarily between manufacturer and retail, with some also during home storage, then it might be assumed that 93% of illnesses could be addressed by requiring temperature monitoring and verification in transportation, storage, and food service operations.

Response 99

Whether or not foods leaving manufacturing plants "do not contain harmful levels" of *C. perfringens*, or whether they "pose virtually no risk of causing illness" are matters dependent on the meanings assigned to "harmful" and "virtually no risk," which in turn are policy decisions outside the purview of the risk assessment. The policies that might be adopted are similarly outside the purview of the risk assessment.

8 GENERAL COMMENTS

Comment 100

How realistic is the model? Does the model help us understand the real world?

I believe that the model is not realistic because the model did not account for known certainties and therefore skewed the design of this assessment.

Response 100

All known certainties are incorporated in the risk assessment. The uncertainty assessment is centered on the certainties, and is the standard scientific method for evaluating both certainty as well as uncertainty.

Comment 101

Do the results make sense? Does the model make predictions that can be tested?

Specifically, the results of the simulation show an increase in U.S. illness moving from a one-log growth of *C. perfringens* during stabilization to a two-log growth.

And, an increase in illness is shown moving from a two-log growth to a three-log growth.

Response 101

These findings certainly make sense, in that there is a logical reason for the cited increase to happen, and that logic is implemented in the risk assessment (and a very similar increase would also occur if there were a threshold dose, as hypothesized by the same commenters, see Response 86).

Comment 102

Does four logs of *C. perfringens* in the raw materials which is a worst-case scenario, allow one to assume the results of the simulation are believable?

Response 102

See Response 34 for discussion of "four logs." The experimental data on *C. perfringens* are all evaluated, and the results of that evaluation included in the risk assessment. The evaluation accounts for those experimental results, including their uncertainties, and any worst case scenario for experimental observations is incorporated in the uncertainty analysis. Thus the simulation incorporates such worst-case scenarios.

Comment 103

In summary, if the risk assessment would have taken into account the "certainties," a predictive model could have been developed. A predictive model would have more clearly reflected the reality with regard to the growth of *C. perfringens* and *C. perfringens* illness. The use of a predictive model could be used as a basis for change.

Response 103

"Certainties" as used by the commenters is just the inverse of uncertainties. As such, all the known and available "certainties" were incorporated in the risk assessment through the uncertainty assessment. Practically all predictive models contain or hide uncertainties, although the users of such models may not recognize that to be true, and the models themselves may not evaluate the size of the uncertainties. It appears the commenters are using "predictive" as meaning a model that does not recognize uncertainty; and this approach the risk assessment explicitly rejects as being arbitrary. The risk assessment is a predictive model that explicitly incorporates uncertainties (equivalently, certainties) and evaluates their size.

Comment 104

Even without a predictive model, there is sufficient information in published literature to determine that four (4) logs of C. perfringens is the "worst case" scenario for raw materials. Changes could be made from no more than a one (1) log increase during stabilization to a two (2) log increase in the Guidelines without an increase in the number of cases of C. perfringens illness.

Response 104

The statements made by the commenter are unsupported, and the risk assessment demonstrates that changes in growth during stabilization would result in corresponding changes in the number of cases of illness due to *C. perfringens*.

Comment 105

The use of the Monte Carlo simulation, disregarding available information, provides no basis for FSIS to make any changes to Guidelines, Notices or Policy.

Response 105

The commenters provide no examples where the risk assessment disregards available information. The data in every citation provided is analyzed in the risk assessment and, where appropriate, incorporated in the risk assessment, taking account of the uncertainties of those data and their interpretation. Whether there is sufficient basis to make changes to Guidelines, Notices, or Policy, is a policy matter that is not addressed by the risk assessment.

Comment 106

After review of the FSIS Risk Assessment for *Clostridium perfringens*, I believe this risk assessment should not be used to affect any change to Agency Guidelines (specifically Appendix B for Stabilization), Notices or Policy.

Response 106

The comment represents a policy conclusion that is not addressed by the risk assessment.

Comment 107

However, a predicative model should be developed along with a change in Agency Guidelines allowing for a two (2) log growth, as opposed to the current one (1) log growth during stabilization. In addition, whole muscle cured meats could be cooled under a twenty (20) hour schedule as demonstrated by Taormina, et. al. (2003)

Response 107

The risk assessment model is a predictive model (see Response 103). The other comments are policy suggestions outside the scope of the risk assessment.

Comment 108

The mathematical and statistical analyses, however, are complex and difficult to follow.

Response 108

The complexity was necessary because of the wide variety of the available data, the subject matter itself, and the many analyses required. Some of these analyses are inherently difficult, so necessarily difficult to follow. Where suggestions have been made to clarify, they have been incorporated in the risk assessment.

Comment 109

The risk assessors recognize the substantial amount of uncertainty associated with the risk assessment. The risk assessment states that "many sources of uncertainty have not been incorporated" and "the total size of the unincorporated uncertainties is unknown."

Response 109

This statement is true of most honest risk assessments. This risk assessment in particular deals with the interaction between *C. perfringens*, a living bacterium that exhibits a wide range of complex behaviors that are not entirely understood or documented, and the

technologies and habits of humans, both of which are also complex and not entirely understood or documented. A risk assessment on this subject that came to any different conclusion would have to be considered highly suspect.

Comment 110

In spite of all this uncertainty, it is clear that cooling meat and poultry products at FSIS-inspected establishments is not the source of diarrheal illness attributable to *C. perfringens*.

Response 110

The cooling practices of meat and poultry products are necessarily not a source in one sense (since they do not introduce spores or vegetative cells). However, the way in which these practices are carried out may contribute to avoidable illnesses, and the extent of those contributions are evaluated in the risk assessment.

Comment 111

A Monte Carlo simulation was used for the analysis of the assessment's data. A Monte Carol simulation is used when there is much uncertainty with the data and a prediction is trying to be made on uncertainties.

Response 111

This comment is not quite true. A Monte Carlo simulation may be used no matter the amount of uncertainty. Monte Carlo simulation is just a technique to keep track of uncertainties.

Comment 112

The model did not account for the "significant certainties" regarding *C. perfringens* illnesses and other information, which might have allowed the assessment team to look to a predictive model and/or make recommended changes on the significant amount of information already published.

Response 112

The amount of uncertainty is irrelevant. The Monte Carlo approach takes account of both certainty and uncertainty in a consistent fashion. See also Response 103.