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July 11, 2005

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04-001N
04-001N-3
AMI, FPA, NTF

[Docket No. 04-001N] Technical Meeting on Risk Assessments of *Salmonella* and of *Clostridium perfringens* in Ready-to-Eat Products; Notice of Availability and Public Meeting; 70 *FR* 15017; March 24, 2005. [*C. perfringens* Risk Assessment]

Dear Dr. Golden:

This letter responds to the Food Safety and Inspection Service (FSIS or the Agency) March 2005 request for public comment regarding "A Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat and Poultry Products" (the risk assessment). These comments are being submitted jointly by the American Meat Institute, the Food Products Association, and the National Turkey Federation.

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb and veal products and 70 percent of the turkey products in the U.S. Headquartered in Washington, DC, the Institute provides legislative, regulatory, public relations, technical, scientific and educational services to the industry. Its affiliate, the AMI Foundation, is a separate 501(c)3 organization that conducts research, education and information projects for the industry.

The Food Products Association (FPA) – formerly the National Food Processors Association – is the largest trade association serving the food and beverage industry in the United States and worldwide. FPA's laboratory centers, scientists and professional staff provide technical and regulatory assistance to member companies and represent the food industry on scientific and public policy issues involving food safety, food security, nutrition, consumer affairs and international trade.

The National Turkey Federation (NTF) is the only national trade association exclusively representing all segments of the turkey industry. NTF represents over 98 percent of all production, processing and marketing of turkeys in the United States, representing more than $8 billion dollars in sales at the retail and food service levels.

The FSIS risk assessment team and its contractors are to be complimented on the extent of the information provided and the depth of the analysis. The risk assessment clearly articulates the data used, the sources of data and their limitations. The assumptions are clearly stated, as are the uncertainties in the model. The mathematical and statistical analyses, however, are complex and difficult to follow. 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." The risk assessment concludes that the "absolute size of the risk estimates depends crucially on some of the assumptions made in the modeling. All of the results depend on the model being an accurate representation of what happens in reality, and there are many places in the modeling where what happens has not been adequately investigated (or, in some cases, investigated at all)." 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*. As stated in the risk assessment, "the majority of poisonings do not appear to be from RTE products produced in FSIS regulated establishments, but rather from products prepared from raw [emphasis added] meats and poultry and from products such as chili, tacos and enchiladas prepared from raw [emphasis added] products in advance by consumers or in restaurants or institutions and held for extended lengths of time at temperatures that will support growth."

SCOPE AND MANDATE

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. 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. 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.

HAZARD IDENTIFICATION FOR *C. PERFRINGENS*

The hazard identification is a good review of the epidemiology of *C. perfringens* foodborne illness. 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. 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. 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.

EXPOSURE ASSESSMENT

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.

Consumption and food categories

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.

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. 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. 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.

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. 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.

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

Appendix D has significant limitations. This Appendix is intended to determine the fraction of meat associated with meat-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. 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. 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. 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). 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. A more detailed analysis of the foods listed as potential sources of *C. perfringens* would improve the value of the risk assessment.

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. 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.

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. 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.

Concentrations of *C. perfringens* in meat and poultry

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."

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.

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. 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. 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.

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).

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.

Concentrations of *C. perfringens* in spices

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

Growth of *C. perfringens*

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." 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)." 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.

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.

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

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. 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. (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.) 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. 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*.

Time and temperature control

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. 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. 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.

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. 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. 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.

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.

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.

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.

Laboratory data

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.

LIMITATIONS OF THE EXPOSURE MODEL

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. We have noted that the times and temperatures for storage of meat and poultry products are inaccurate. 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. 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. In addition, it is unlikely that maximum cell densities are independent of the food. 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.

HAZARD CHARACTERIZATION

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.

RISK CHARACTERIZATION

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.

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. 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. 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. 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. 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.*

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%. 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*. 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."

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. 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).

CONCLUSIONS

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. 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. 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. 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.

We appreciate the opportunity to comment on this "Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and partially Cooked Meat and Poultry Products." If additional information is needed regarding these comments, please contact us.

Sincerely,

American Meat Institute
Food Products Association
National Turkey Federation