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July 1, 2005

Dr. Neal Golden, Risk Analyst
Risk Assessment Division
Office of Public Health Science
1400 Independence Avenue, SW
Room 333 Aerospace Center
Washington, DC 20250–3700

RE: Docket No. 04–001N
Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat & Poultry Products

Dear Dr. Golden:

On behalf of the American Association of Meat Processors (AAMP) I am pleased to submit the following comments on the Risk Assessment for *Clostridium perfringens* in Ready-to-Eat and Partially Cooked Meat & Poultry Products (March 2005).

AAMP is an international organization whose members include meat and poultry processors, slaughterers, caterers, home food service companies, wholesalers, retailers, suppliers, and consultants to the meat and poultry industry. There are 33 state, regional, and provincial associations of meat processors that are also affiliated with AAMP. Most of AAMP's members are very small, small, and medium-sized businesses, most of them family-owned and operated.

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**.

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)

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. 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.

In reviewing this risk assessment to help understand whether the model is representative, I had the following questions:

1. 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. Specifically, the following certainties were not used or considered as a basis or assumptions for this project:

- At least seven (7) logs of vegetative cells of Type A *C. perfringens* are necessary to cause human illness;
- 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)
- It has been well documented that salt and nitrite have a synergistic effect inhibiting the growth of *C. perfringens*;
- There is a synergistic effect of salt and nitrite inhibiting *C. perfringens* vegetative cell growth during finished product storage;
- There is a salt/nitrite inhibition of *C. perfringens* vegetative cell growth after curing (i.e. preblending), but prior to lethality treatment (thermal processing);
- 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.

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

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?

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.

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?

3. Were the assumption made regarding the input data fair and proper?

I believe that some of the assumptions made within the risk assessment are not fair and proper due the fact that:

1. No distinction was made for specie, i.e. pork, poultry or beef;
2. No distinction was made between whole muscle product and comminuted product;
3. No distinction was made between cured and uncured product; and
4. No distinction was made for product which has no nitrite and a product that is "hot held" in a gravy.

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. 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.*

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

4. Was the scope of the assessment too narrow or not narrow enough?

If the points listed in question three 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.

5. Why were the products and/or product types not evaluated separately?

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."

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.

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.

6. Were all the factors taken into consideration regarding specific statements?

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.

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.

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.

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

Your consideration of this data is appreciated.

Sincerely,

Mark Schad
AAMP Treasurer

cc: Steve Krut, AAMP Executive Director
Scott Cunningham, AAMP President

Reference Attached.

References:

1. Kalinowski, R.M., Tompkin, R.B., Bodnaruk, P. W. and Pruett, W.P. (2003) Impact of Cooking, Cooling and Subsequent Refrigeration on the Growth or Survival of Clostridium perfringens in Cooked Meat and Poultry Products. Journal of Food Protection, 66:1227-1232.
2. Taormina, P.J., Bartholomew, G.W. and Dorsa, W.J. (2003), Incidence of Clostridium perfringens in Commercially Produced Cured Raw Meat product Mixtures and Behavior in Cooked Meat Products During Chilling and Refrigerated Storage. Journal of Food Protection 66:72-81.
3. USDA/FSIS (1992-1996) Nationwide Microbiological Baseline Data Collection Program.