ConAgra
Foods®

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To whom it may concern:

This letter is in response to the "Draft FSIS Risk Assessment for *Listeria* in Ready-to-eat Meat and Poultry Products (February 2003)". The comments are being submitted on behalf of ConAgra Foods. ConAgra Foods is a leading producer of prepared foods, including ready-to-eat (RTE) meat and poultry products. RTE product brands produced under USDA inspection include Armour, Banquet, Butterball, Decker, Eckrich, Healthy Choice, and Hebrew National. Our company appreciates the opportunity to provide feedback on the draft risk assessment.

As part of its risk assessment, FSIS has attempted to quantitatively model the impact of *Listeria* food-contact surface (FSC) contamination on RTE product contamination, and thus, ultimately, estimate any resulting public health impacts. The risk assessment presented was designed to address three key risk management questions posed on p. 5 of the draft document.

An in-plant (Monte Carlo) model has been combined with the FDA/FSIS risk-ranking model to estimate illness or death from listeriosis. Due to its status as the RTE meat product with the highest risk ranking, the deli-meat category was selected as the initial test product from which model calculations were generated. Because of the lack of available data and information, several assumptions were made in developing the model and calculating its outputs. The main output of the in-plant model was the level of *L. monocytogenes* in retail RTE meat and poultry products. These data were then coupled with the FDA/FSIS risk ranking model information to ascertain the public health impact.

FSIS should be commended for its extensive work in creating a model for providing quantitative answers to important risk management questions. However, the limited availability of applicable data and the complexity of *Listeria* environmental contamination severely handicap this effort. Because of the quality of data, and the uncertain and very conservative nature of many of the assumptions used as input, the quantitative outputs generated by this model may provide an inaccurate assessment of the true risk of listeriosis in RTE meat and poultry products. Without more meaningful and representative data to include in the model, the existing outputs are very weak and may be misleading. The model's current information and assumptions appear to significantly overestimate the risk of listeriosis

Some of our main concerns or issues with the model assumptions and/or outputs are stated as follows:

ξ   The apparent assumption that all packaging lines (FCS's) in an operation are contaminated with *Listeria* is incorrect. In 2002, only 99 of 239 RTE meat-packaging lines included in ConAgra Refrigerated Group's *Listeria* control program (weekly testing frequency with multiple sites per week) had one or more sites that were positive for *Listeria*-like organisms. Most of these lines had only one or two positive results for the entire year. No *Listeria*-like positives were reported for FCS sites of the remaining 140 packaging lines in the program. Therefore, *Listeria* was not detected on most (58.5%) of these RTE packaging lines. Furthermore, some of the plants within the program did not even have one FCS positive finding for any of their packaging lines in 2002.

ξ   The assumption that *Listeria* cells are evenly distributed across FCS's and in product is inaccurate. Relative to the distribution of microorganisms, it is well established (with the possible exception of fluid foods) that pathogenic bacterial contamination occurs heterogeneously and, in most cases, sporadically. A high concentration of *Listeria* cells being uniformly spread across FCS's is highly unlikely, particularly in operations that have any measure of sanitary control. Therefore, the overall model assumption that 72% of *Listeria* cells (mean log transfer coefficient of -0.14) would be transferred from a FCS to a product is likely overestimated.

ξ   The assumption that all deli meat items are high risk is quite conservative. A number of these products have been demonstrated not to support the growth of *Listeria* (e.g., sliced salami) or will contain additives (e.g., lactate/diacetate) to partially or completely suppress the growth of *Listeria*. Also, when estimating microbial growth, it is not always a certainty that a given pathogen will always grow (or grow as well) in a product that will *theoretically* support its growth. Due to a number of possible reasons, microbial growth kinetics determined with inoculated (artificially contaminated) samples versus those estimated with naturally (inherently) contaminated samples may be significantly different[1]. As an example, introduction of high initial levels of artificial contamination and the better physiological (healthier) state of such cells could lead to overestimation of pathogen's growth potential, and thus, the consumer risk. Previous work has demonstrated that factors such as inoculum level and physiological state can significantly affect the ability of *L. monocytogenes* to initiate growth under various salt and pH levels[2].

ξ   Another significant stretch in the model is the attempt to estimate *Listeria* FSC and product concentrations from prevalence data (Tompkin, 1992 and 2002). This is not a valid assumption. Relative to better determining the ratio of *L. monocytogenes* to *Listeria* sp., the model developers could draw upon another substantial data source to strengthen the estimated value. FSIS could utilize the results from its own *L. monocytogenes* monitoring program for the eight RTE meat product categories that have been historically evaluated.

ξ   For those wishing to offer comments or review the model, it is important that all data sources and references be made available and properly referenced (Hynes, 2000; Mead 1999b; Midelet and Carpentier, 2002). In addition, the current model should be accessible for data entry, allowing any interested reviewers to further assess its reliability. This would make the draft risk assessment more transparent to all reviewers.

Although a properly developed model may give some insight into the potential risks associated with *Listeria* from FCS's, control and understanding of environmental contamination patterns is far from an "exact science" and is difficult, if not impossible, to statistically or quantitatively define. Therefore, the model should never be considered a substitute for plant-specific information, experiences, or data.
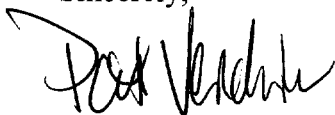
Intimate knowledge of a plant's process, equipment pieces (e.g., potential harborage sites), equipment layout, product flow, and line employee practices is required to understand potential contamination points and risks. The qualitative outputs of the model presented on page 26 (for the most part) are self-evident and do not require statistical or mathematical calculations to conclude. Currently, quantitative outputs derived using the model will be misleading because they overstate the likelihood of product contamination and risk to public health. In general, the model fails to adequately address the three questions posed by the FSIS risk managers, and should not be used as a basis for food safety policy decisions.

As has been previously stated by ConAgra Foods, the best way to address the risk of listeriosis from RTE meat and poultry products is for each establishment to execute its own scientifically-based, environmental verification and control program. The Directive "Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program (10,240.3)" currently allows establishments to employ environmental control programs that address the risk of *Listeria* contamination specific to their RTE operations. Continuing to refine the policies outlined in this Directive, based on evidence of its effectiveness, is a much better alternative for understanding and minimizing public health risks than relying on quantitative model outputs.

The industry's progress in reducing listeriosis can be assessed using the annual disease surveillance data from CDC. This is a conservative estimate of progress since illness surveillance capabilities and methodologies are always improving (e.g., expansion of PulseNet laboratories). Caution must be taken in how these data are used to measure any improvements made by industry in controlling *Listeria*. Industry practices and interventions could actually be decreasing the incidence of *L. monocytogenes* without these efforts being accurately reflected in the number of reported illnesses

Thank you for considering our comments. ConAgra Foods, Inc. would welcome any opportunity to further discuss our thoughts with the Agency.

Sincerely,

Pat Verduin, Ph.D.

Senior Vice President of Food Safety
ConAgra Foods, Inc.

[1] ConAgra Refrigerated Foods Group studies (e.g., Growth of *Listeria innocua* in a naturally contaminated head cheese product, February 28, 2001)

[2] The effect of inoculum size and sublethal injury on the ability of *Listeria monocytogenes* to initiate growth under suboptimal conditions. 2001. Pascual et al. Letters in Appl. Microbio. 33:357-361.