SEP 13 2005

The Alliance for Listeriosis Prevention
c/o American Frozen Food Institute
2000 Corporate Ridge, Suite 1000
McLean, VA 22102

Dear Sir/Madam:

This is in further response to your May 31, 2005, petition for a rulemaking to establish a regulatory limit of 100 colony-forming units (cfu)/gram of *Listeria monocytogenes* in certain ready-to-eat (RTE) meat and poultry products (as defined in 9 CFR 430.1) that do not support growth of the pathogen. Products to which the limit would apply, i.e., that you assert do not support growth of *L. monocytogenes*, include those that are held or stored at or below -1 °C, those with pH values less than 4.4 or water activity (a_w) less than 0.92, and those meeting certain other criteria, including products to which microbial inhibitors have been added to prevent growth.

We have evaluated the petition in relation to our regulatory policies and Food Safety and Inspection Service (FSIS) responsibilities for administering an effective food inspection program under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and ensuring science-based public health protection for consumers of meat and poultry products. We think the concept of a quantitative pathogen limit for certain products under carefully defined circumstances may have merit. We are concerned, however, about the limitations of available sampling and testing methods and the gaps in knowledge about the survival and growth of *L. monocytogenes* on products and its infectious dose for humans. We also are concerned about the implications of the changes you propose for the maintenance of sanitary operations in meat and poultry establishments and for the efficient and effective administration of our inspection program.

Accordingly, before we can proceed further in our evaluation of the petition, we would need additional information. We are therefore denying your petition, without prejudice to its revision and resubmission at a later date.

Current regulatory policy on *L. monocytogenes*

During the past two decades, FSIS has carried out a consistent regulatory policy aimed at preventing the occurrence of *L. monocytogenes* and other pathogens in processed meat and poultry products, and especially in RTE products. In announcing our *L. monocytogenes* testing policy in 1987, revised in 1989, we were especially concerned about possible contamination of RTE products because consumers were unlikely to further cook the products to destroy bacteria that may be present. Hence, we considered a positive test for *L. monocytogenes* on any RTE meat or poultry product to mean that the product is adulterated and subject to seizure, condemnation, or other appropriate action.

(52 FR 7464, March 11, 1987; 54 FR 22345, May 23, 1989.) Eventually, we also came to regard a positive test for *L. monocytogenes* on a food contact surface as meaning that products that contacted the surface were adulterated.

We reiterated this zero-tolerance policy in the proposed rule "Pathogen Reduction; Hazard Analysis and Critical Control Point Systems; Pathogen Reduction Performance Standards (PR/HACCP)" (60 FR 6774; February 3, 1995). As you note, in the 1995 PR/HACCP proposal, we considered regulating pathogenic microorganisms in meat and poultry slaughter operations on the basis of risk assessments and determining the levels of specific pathogens on raw meat and poultry products that do not pose a significant risk of illness. (60 FR 6798-6799; February 3, 1995.) However, in that proposal, we specifically excluded the possibility of setting a tolerance for pathogens in processed, RTE products (60 FR 6798). Even for raw products, the Agency found a tolerance for pathogens transmitted primarily through cross-contamination to be without adequate scientific support (60 FR 6799).

Our proposed performance standards for processed meat and poultry products (66 FR 12590; February 27, 2001) and our subsequent interim final rule "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products" (68 FR 34208; June 6, 2003) presuppose the destruction of *L. monocytogenes* during the initial lethality process and require effective measures to prevent post-lethality contamination of RTE products. The interim final rule was based on a risk assessment that demonstrated the importance of incorporating a combination of interventions in establishment food safety systems to ensure that RTE products were not contaminated with *L. monocytogenes*.

In the interim final rule, FSIS took into account the fact that products that do not support outgrowth of *L. monocytogenes* theoretically present less risk to the public than products that do support growth of the pathogen during their shelf life. Under the rule, post-lethality exposed RTE products in which an antimicrobial agent is used or that have been subject to a process that suppresses or limits growth of *L. monocytogenes* are likely to be sampled less frequently than other products.

We are concerned that a tolerance for a limited class of RTE products would affect the operation and efficacy of an establishment's food safety system and its components – the HACCP system, sanitation standard operating procedures, and prerequisite programs. Can you provide data showing that such a change would not have a negative effect on the safety of these systems? Clarification is particularly needed with respect to establishments that produce products that do and do not support the growth of *L. monocytogenes*. We are especially concerned that RTE meat and poultry products that are subject to the regulatory limit could, at retail deli establishments and in consumer households, cross-contaminate products that support growth of the pathogen.

A further difficulty arises from the fact that small establishments have registered their objections to the cost of testing they now perform to comply with the current *L.*

monocytogenes control requirements. Since significant testing would be required under your proposal, we would request your views on testing methodologies that are economical and effective, and that could be available to address this issue.

Harmonization with international standards

We agree that any regulatory limit we might consider should harmonize with international standards and reflect international scientific consensus on the intrinsic properties of food products that do not support *L. monocytogenes* growth. FSIS is aware that some national and international food safety authorities have proposed or adopted regulatory limits on *L. monocytogenes* in RTE products that are applied under various conditions. For example, in Canada's "tiered" approach to controlling the pathogen, which you note, RTE foods that do not support its growth are in the lowest tier in terms of risk to public health. It is important to note, however, that for such foods, applicable good manufacturing practices must be maintained and that products destined for consumption by neonates, the elderly, pregnant women, and immuno-compromised individuals are treated as posing a higher risk to public health. With this in mind, if a regulatory limit were proposed, should an exception to the limit be made for products to be consumed by vulnerable members of the population? Also, in some countries, the limit on *L. monocytogenes* for certain products is a sampling criterion (e.g., no more than 1 sample in 5 positive for *L. monocytogenes* at less than 100 cfu/gram). This raises the issue of whether a regulatory limit should incorporate sampling criteria sufficient to provide high confidence that the limit is not exceeded, and what the sampling criteria should be. We would request your views and any data you can provide addressing these issues.

Microbiological methods

FSIS would also need to consider how microbiological laboratory methodology would be applied to determine that a regulatory limit has been exceeded, and how that method might also inform FSIS of an emerging problem within an establishment that may not be demonstrated by less sensitive methods typically used for non-zero tolerance testing in other countries.

It is clear that an enumeration method such as most-probable-number (MPN), which FSIS uses when there is a need to accurately quantify low levels of bacteria, as in a baseline study, does not lend itself to use in a regular testing program to ensure that product complies with a quantitative regulatory limit. The resources required for analysis using an MPN method are excessive for routine use by Government and industry.

Some countries use direct plating methods that are designed to provide quantitative positive results only when the regulatory limit is exceeded in a given test portion. While it remains to be demonstrated that the brief resuscitation periods prescribed by these methods could recover a high percentage of injured or dormant *L. monocytogenes*, they

are simpler than the current routine qualitative method used by FSIS and far simpler than a quantitative MPN. Alternatively, a similar "threshold" method could be applied to the Agency's qualitative enrichment-based method.

The current testing of 25-gram analytical units provides a theoretical limit of detection of 0.04 cfu/gram, which is 2,500-fold lower than the theoretical limit of detection for a "100 cfu/gram" threshold method. The low limit of detection and resuscitation potential for the current FSIS methodology provides an additional safety margin for each portion that is tested. If FSIS and the industry, as in other countries, chose to test product in a manner that allowed detection of *L. monocytogenes* only when the tolerance is exceeded, we would not know when lower levels of contamination are present. If product testing were designed in a manner that does not allow detection of *L. monocytogenes* at levels less than 100 cfu/gram, FSIS and the industry would not detect and therefore be able to prevent on-going contamination problems before they became a public health problem. This is an issue that clearly needs to be addressed.

The possibility that sub-lethally injured organisms could escape detection under rapid product testing raises a further question about the conditions of sanitation under which the product was processed. Under such circumstances, how would FSIS, or the establishment, determine whether there is a serious sanitation problem? Harborages on equipment and facilities may exist; RTE product could have become contaminated; and illnesses could be occurring as a result. It is important, in our view, to resolve this issue and consider, for example, whether sampling of food contact surfaces would provide an appropriate resolution.

As you indirectly acknowledge in your petition (in "Availability of better quantitative data for foods"), there is a need for inexpensive, rapid, and accurate methods for quantitative analysis of *L. monocytogenes* in foods. It is important that new methods be developed and be made widely available. FSIS is also interested in the methodology for quantifying the level of contamination on food-contact surfaces that directly touch the exposed RTE food. In this connection and in the interest of efficient regulation, it may be necessary for both industry and FSIS to rely on one standard method for the quantitative analysis of *L. monocytogenes*. A common method would facilitate verification of results. FSIS believes that this issue must be addressed before we could act on your petition.

Effective sampling

FSIS also has reservations about the effect of a tolerance level for certain products on sampling efficacy. Given the heterogeneous nature of *L. monocytogenes* contamination patterns, FSIS needs to know how verification sampling and a high-throughput testing program could be statistically designed to provide high confidence that harmful product would not be released to the public. Careful consideration must be given to the test protocols used and their sensitivity, the number of samples to be taken, and the number of positive samples to be allowed before lot rejection. FSIS would also need to determine

how quantitative data from sampling can be used to determine the relationship between food contact surface contamination and product contamination. We also need considerably more detailed information regarding the sampling that industry would conduct and verification sampling that would be accomplished by FSIS under your proposal.

Sanitation requirements

When considered in relation to the possibility of undetected RTE product contamination, a zero tolerance policy has the advantage of providing a margin of safety that enables the Agency to detect a contamination problem before it becomes serious. Under your proposal, what new sanitation requirements should be adopted for establishments in the proposed non-zero tolerance category? The potential for non-zero tolerance foods to cross-contaminate other RTE products that lack the requisite listeriostatic properties is a serious concern. Physical segregation of zero-tolerance and non-zero tolerance products -- assuming this to be an option -- may prove to be a burden for small and very small establishments. FSIS would also need more detailed information regarding safeguards for deli and retail environments to prevent the cross-contamination of products that do support *L. monocytogenes* outgrowth?

If a tolerance were to be established, we would need to consider issues regarding a consumer education, particularly since products with a tolerance for *L. monocytogenes* may be stored in home refrigerators along with products that support rapid growth. Perhaps consideration should be given to sale of individual servings rather than bulk servings to reduce the likelihood of cross-contamination in the home. Any revised proposal should also address whether products should bear labeling focused on the needs of immuno-compromised individuals.

RTE product characteristics

Another potential difficulty to be faced involves product formulation. Our experience with the interim final rule on *L. monocytogenes* control indicates that a lack of validation exists showing that product formulations containing antimicrobials are effective in limiting growth of the pathogen during product shelf life, with the exception of freezing below -0.4 °C, pH below 4.39, and a_w below 0.92. You should therefore also provide information regarding the factors that should be taken into consideration when defining the difference between growth suppression (i.e., limiting or slowing growth) versus growth inhibition, when using antimicrobial treatments, particularly in light of current modeling programs for *L. monocytogenes* in which "zero growth" may mean that there may be up to 1-log growth. What characteristics, other than those that you have indicated, would allow foods to be excluded from the zero-tolerance requirements? What measures should be taken to validate outgrowth inhibition claims by individual establishments?

Small business and other economic impacts

Assuming the technical questions concerning a regulatory limit and its implementation can be answered satisfactorily, regulatory burden issues must be addressed. Processing establishments – especially small and very small ones – insist that routine testing of food-contact surfaces and product is an excessive burden. It is our view, however, that a regulatory limit such as you request in your petition would require considerable testing by establishments to demonstrate that contamination of food-contact surfaces does not create a problem and that the prescribed limit in products is not exceeded. We would therefore expect you to address these issues if you revise, augment, and resubmit the petition.

Conclusion

Based on the foregoing, we are denying your petition, without prejudice to its revision and resubmission in accordance with this letter.

Sincerely,

Philip S. Derfler
Assistant Administrator
Office of Policy, Program,
and Employee Development