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My name is John Drozd. I am the Quality Control Manager for Babcia Food Corp. We specialize in the production of Polish and Eastern European style sausage and other ready-to-eat meats. This facility is a small plant that is licensed and inspected by the Illinois Department of Agriculture. I have several questions and comments regarding the proposed changes addressed in Federal Register Docket 97-013P.

1. FSIS is proposing to eliminate the trichina treatment requirements of section 318.10. Part of the reasoning for this change is described in the following section from page 12608 of the proposal. *The Agency prescribes trichina treatment for certain not-RTE products that may be eaten rare or undercooked because of their appearance. These products may appear to have been cooked because they contain ingredients such as wine, paprika, or curing agents. Significantly, however, packages of raw meat and poultry products must bear the safe handling label. The safe handling instructions regulations (9 CFR 317.2(l) and 381.125(b)) require that all meat and poultry products that are not RTE bear safe handling instructions on the label. By following the ``cook thoroughly'' portion of the safe handling instructions, the consumer should eliminate possible bacterial contaminants and any trichina present in the product.*

I am uncomfortable with the notion that putting a Safe Handling sticker on a package of meat should insure public safety. I work for a company in Chicago that is owned and operated by a Polish refugee. This company employs about 250 people and includes three grocery stores, a restaurant, a bakery and an import business. I am the only person in this company for whom English is the first language. Chicago has the second largest Polish population in the world (behind Warsaw). Many of our employees have been in this country for years, but have never had to learn the language because there are so many businesses, newspapers, radio and TV outlets, etc. that cater to the Polish community. Chicago's Hispanic community is so large that there are more Latino children than African-American children in Chicago Public Schools. The Archdiocese of Chicago has asked some of its parish priests to learn Spanish in order to minister to the Hispanic Community. Add the non-English speaking immigrants from the rest of the world who settle here plus the alarming number of Americans who are functionally illiterate and one has to wonder about the efficacy of handling statements written in English.

On 1-2-92 USDA issued FSIS notice 1-92 notifying plant management and inspection personnel that the use of binders and extenders need only be listed in the ingredients statement and that no additional qualifiers are necessary. The final rule, published 8-21-91,

removed section 317.8 (b) (16) so that it was no longer necessary to prominently highlight the use of binders and extenders in the product name of any standardized sausage. However, section 316.11 (b) still requires that sausage with binders and extenders contain a qualifying statement. FSIS Directive 7221.1 (Amend. 1) from 1996 does away with prior approval for labels and clearly states that transferring of approved labels between official establishments is the responsibility of plant management. 9 CFR 317.13 addresses the shipment of labels between official establishments and specifically describes the need for notification and prior approval of the plant's IIC, before transferring labels between Official Establishments. My point here is that the cancellation of a regulation should include all references in order to avoid confusion. If section 318.10 is removed, all references to the use of certified pork for certain products (Directives 7310.7, 7320.1 etc.) should also be removed.

2. FSIS is proposing to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food contact surfaces for Listeria spp., after lethality treatment and before final product packaging, unless they have identified L. monocytogenes as a hazard reasonably likely to occur and so have incorporated into their HACCP systems one or more controls validated to eliminate it from their products. This testing will verify that an establishment's Sanitation Standard Operating Procedures (Sanitation SOPs) are preventing direct product contamination by L. monocytogenes after the lethality treatment, thus addressing the risk assessment assertion that RTE foods often are recontaminated by L. monocytogenes after lethality is applied.

I don't understand how an official establishment can identify L. monocytogenes as a hazard reasonably likely to occur or incorporate into their HACCP systems one or more controls validated to eliminate it from their products. I am not a microbiologist, but it is my understanding that Listeria monocytogenes is an environmental bacteria that can be controlled through good sanitation practices. Page 12598 of the Federal Register Docket 97-013P says *L. monocytogenes is a problem more often because of inadequate sanitation than inadequate processing.* The proposed changes for listeria testing say that the testing will verify that an establishment's Sanitation Standard Operating Procedures (Sanitation SOPs) are preventing direct product contamination by L. monocytogenes. Section 416.12 (a) (Development of Sanitation SOP's) says *The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).* Section 416.4 (a) says *All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.* If an official establishment identifies L. monocytogenes as reasonably likely to adulterate RTE products after lethality, aren't they also saying that the SSOP doesn't work?

If an establishment incorporates a validated post-packaging control into its HACCP plan, can that control be implemented off-site? As an example, a facility wants to use a post-process pasteurization system but it is impractical to purchase the pasteurization equipment due to economic or work space constraints. If the product can be shipped for further processing, how would the requirements of section 417.4 (a) (2) (ii) and 417.5 (a) (3) (c) be met. Can product produced under a state inspection program be shipped out of state to achieve post-process pasteurization?

The proposed rules talk about post-lethality product contact zones. Our processing procedures include smoking and fully cooking meat and poultry products. Some products are placed on screens or looped over stainless steel sticks and enter the cooking medium on rolling cages. After the cooking cycle, these items are chilled without ever being removed from the cages. These items are bulk packed directly from the sticks and screens on which they were cooked. Are the food contact surfaces that receive the lethality treatment along with the RTE product subject to the environmental testing requirements? Would food-contact surfaces of utensils and equipment used in handling products under a hot shipping program (products shipped at +160*F for catering trucks or hot school lunches) be subject to the environmental testing requirements? Is the manufacturer of private label product imported from another country subject to the proposed rule? Does FSIS foresee any exemptions to the proposed rules?

3. The proposed Regulation defines ready-to-eat product as a meat or poultry product that can be safely consumed without cooking or application of some other lethality treatment to destroy pathogens.

Our processing procedures include smoking and fully cooking cured meat and poultry parts (ham hocks, pork neck bones, turkey tails etc.) These products are usually boiled for flavoring in stews, soups, or vegetables by the end user. We cook these products to 160*F and they can be safely consumed right out of the smokehouse but they are nearly unpalatable and need to be boiled because of the salt content. A stewing chicken that is baked to an internal temperature of 165*F meets the log reduction requirements for pathogen control, but it is certainly too tough to be considered ready-to-eat. Will FSIS consider all products that meet the proposed definition to be RTE products?

4. FSIS has determined that post-lethality, pre-packaging contamination of RTE products with L. Monocytogenes is reasonably likely to occur.

In the FSIS publication *FSIS PRE-HACCP SANITATION STANDARD OPERATING PROCEDURES (SSOP) REFERENCE MATERIAL - 1997* (Revised April 1997) page 146 describes prescriptive measures USDA personnel implemented to control plant sanitation, including leading "bucket brigades" through pre-operational clean up. This publication goes on to say that *Sanitation SOP's make it clear that responsibility for identifying and conducting procedures needed to maintain sanitary conditions rests with the establishment, not with FSIS.* The HACCP Regulation states that ***every official establishment*** *shall conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls* ***because it historically has occurred,*** *or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.*

It is my understanding that HACCP plans are to be plant specific. That is, each plant should make its own determination about food safety hazards based partly on the plant's prior performance history. If FSIS has determined that post-lethality, pre-packaging contamination

of RTE products with L. Monocytogenes is reasonably likely to occur, have they abandoned the concepts of industry management taking responsibility for plant sanitation and the products they produce?

5. The proposed regulation will require small plants that produce one or more ready-to-eat meat or poultry products, to test food contact surfaces, on which product is handled after lethality treatment but before final packaging, for Listeria spp. The proposal calls for at least two tests, per line of ready-to-eat product, per month. The test results must be made available to inspection personnel to verify that the plant's SSOP is effective. In the event of a positive test result, establishments must take corrective actions under 9 CFR 416.15(a) and (b) that include procedures to determine and demonstrate that the affected lot or lots of product are not adulterated with L. monocytogenes. (The proposed requirements for controlling L. monocytogenes after testing positive for Listeria spp. says that corrective actions must include product testing.) FSIS requests comment on whether it should allow establishments that find listeria spp. on a food contact surface to determine if the positive sample is in fact listeria monocytogenes before having to initiate product testing.

FSIS does not except end product testing as validation for a HACCP process or procedure that differs from established performance standards. Why would FSIS accept end product tests to determine if RTE product is contaminated with L. monocytogenes? FSIS should allow establishments that find listeria spp. on a food contact surface to determine if the positive sample is in fact l. monocytogenes before having to initiate product testing. Tests that are positive for Listeria spp but not L monocytogenes are indicators that sanitation procedures should be monitored more closely or re-evaluated. (Changing soap, sanitizer or sanitizer strength may be indicated). Plant management should have the opportunity to control the product and take corrective actions and preventive measures based on the requirements of their SSOP if the tests proved positive.

What would be the role of FSIS in the event a test proved positive for Listeria spp? Will FSIS have the authority to take control of product and facilities? Will test results be subject to the Freedom of Information Act or be made public even if there is no threat to public health? Is it reasonable to assume that the media or the public understands the difference between Listeria spp. and Listeria Monocytogenes?

6. FSIS specifically solicits information on the appropriate timing of the test (pre-start-up or post-start up). Positive test results on food-contact areas will indicate a need to thoroughly clean the immediate working areas and equipment and re-test.

It doesn't matter what time of day FSIS mandates that the tests should be taken. If a plant wants to falsify reports or tests, that is what is going to happen. If positive tests indicate a need to thoroughly clean the immediate working area, why wouldn't sanitation crews use products that are specifically designed to destroy Listeria spp. prior to testing? Sanitation schedules can be manipulated so that negative results are assured. These tests will neither validate SSOP procedures nor guarantee continuous product safety. This will be an exercise in futility as FSIS attempts to reinstate some form of Command and Control.

Does plant history not count for something? If a plant has no his ory of product adulteration and the FSIS sampling program has consistently returned negati /e results for Listeria spp., why should twice monthly testing be implemented? FSIS has his torically implemented tougher standards for facilities which have proved to be out of compliance during boneless meat reinspection, failed net weight checks, or exceeded fat and adde I water limitations in cooked sausage. Why not implement the testing procedures for plants w ith a history of producing adulterated product, but retain the status quo for facilities which h ave continuously shown compliance?

I am not suggesting that sampling is a bad idea. I have been cor ducting environmental, equipment contact zone, and finished product testing since Augu st of 1999. I use it as a tool to check and adjust sanitation procedures. My inspected proces ing plant and products have always had negative results on tests that were done by us or by p rogram employees. I am saying that government mandated testing is a bad idea. Regula ions 416 & 417 are clear in the requirements to prevent product adulteration and contaminati on. Another regulation invites falsification of records to impress inspection personnel. Th e requirements of this regulation are vague enough to allow subjective enforcement wit little continuity, causing much confusion within the industry. This proposal seems like a k nee jerk reaction, by USDA, to negative publicity about this year's media hot button, Listeria.

Respectfully submitted,

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