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Docket Clerk
Food Safety and Inspection Service
U.S. Department of Agriculture
Room 112, Cotton Annex Building
300 12th Street, SW
Washington D.C. 20250-3700

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Mike Luczynski

RE: Docket No. 0583-AC46

The Agency has requested comments on various elements of the proposed rule regarding performance standards for the production of processed meat and poultry products. There are numerous assumptions and conclusions the Agency admits are not supported by scientific data, and these must be researched before an effective rule, or the cost ramifications of a rule, can be developed.

FSIS is proposing a testing frequency based on number of employees in an establishment while admitting they have not been able to correlate risk of product contamination with production volume or establishment size. The document responds by assuming a large insanitary establishment would be more likely to contaminate more products and thus pose more risk to public health. Later in the document FSIS states: "FSIS believes, based on the numerous recalls involving small quantities of RTE meat and poultry products and the fact that the majority of the recalls are initiated in small and very small establishments, that members of the meat and poultry product industry are not effectively ensuring that products are not adulterated.". The Agency is using two opposing arguments in the same document to support aspects of the proposed rule.

FSIS is requesting comments on the current state of knowledge about the relationship between *Listeria spp.* on food contact surfaces and *L. monocytogenes* on the product; the appropriate timing of the test (pre-start up or post-start up), seasonality and other risk based considerations that might be important in creating effective test protocols. The issue of the test protocol, especially the appropriate timing of the test, has to be decided before any type of cost analysis of the rule is begun. As FSIS mentions, testing product contact surfaces during production should involve holding all potentially affected product until the test results have been obtained. The additional transportation, storage, and distribution costs to industry and consumers would be tremendous if enough storage space even exists. Later in the document the FSIS asks for comments on the costs.

The rule requires that a positive *Listeria spp.* result on a prodi ct contact surface leads to product testing and further asks if it should establish more spe ific requirements regarding product sampling and testing. The protocol for produc t sampling and testing must also be established before any type of cost analysis is begu . Later FSIS requests "data regarding the relationship between *Listeria spp.* and *L. moi ocytogenes* and how the relationship should affect any required testing provisions; For ex mple, does a food contact surface positive for *Listeria spp.* scientifically necessitat product testings and what would negative product test results mean?" The amount of finished product that must be tested to demonstrate that the affected lot is safe will ha e a tremendous impact on the costs of testing. These are fundamental issues that must b e answered before any aspect of the proposed rule can be analyzed.

In the summary to the proposed rule FSIS states "Further, pro cessing must be validated to maintain the lethality and stabilization performance standards throughout the product shelf life under the conditions in which the product is st red, distributed and held". This statement in itself implies a drastic change in respor sibility to the entire meat and poultry industry and needs to be clarified. There is always a potential for a distributor, retailer, or consumer to subject a product to tempera ure or other abuse; and this potential cannot possibly be addressed through lethality and stabilization performance standards. This issue is later restated under the cor ment request for the consideration to require "use-by" date labels on certain RTE me t and poultry products. FSIS asks, "(2) What assumptions should be used about retailer nd consumer behavior in determining a use-by date? Should the use-by date be determ ned under the assumption that retailers and consumers will follow any handlin g instructions contained in the labeling? Or, should the use-by date determination be bas ed on a "worst case" assumption that the products will be mishandled or temperature abused?" These are also fundamental issues that could not only profoundly change the e tire food manufacturing and distribution industries, but would also have a huge economi impact on all consumers.

Under the cost estimates for the mandatory product contact t sting, the Agency states, "Large establishments are expected to meet this requirement by either having or incorporating a CCP addressing *Listeria* in their HACCP plan a t a cost of $5000". The proposed rule vaguely alludes to ways to comply with this requi rement but later states, "Obviously, however, since most of the needed technologies are not yet available or not yet approved, establishments would have a limited number of tr atments to choose from and some may not be appropriate or useable in every processing system. Further, mandating the use of any specific technology would be counter to the Agency's goal of granting establishments maximum flexibility to innovate and de sign customized processes capable of producing safe meat and poultry products. And, initially many of these new technologies may be prohibitively expensive as they become available, especially for small businesses". The cost estimate of $5000 co ld be off by several hundred thousand dollars for each large plant if a post processi g pasteurization treatment is required to meet the standards. Using current pricing, we've stimated it will cost our company approximately seven million dollars to purchase paste rization equipment for four plants. Our studies have found that post-packaging pasteu ization technologies give very mixed results due to product shape variabilities. Recent re search suggests that *Listeria monocytogenes* gains resistance to heat due to exposur to other stresses that are

commonly found in processing environments. Pasteurization tim es and temperatures may not be adequate to greatly reduce *Listeria* contamination of products. Again it's impossible to even begin a cost estimate until these requirements for the CCP are also finalized.

Under the projected industry costs "FSIS estimates that the pe rcentage of the large establishments, excluding canners, that have a CCP addressing *L. monocytogenes* in their HACCP plans will increase from 50 to 100 percent (from 67 esta blishments to 133 establishments) as a result of the proposed rule". As mentioned above, until acceptable standards for a CCP to address post-cooking contamination are f nalized, this assumption is completely arbitrary. No post processing technology either ex sts or is approved that can guarantee elimination of *L. monocytogenes* from RTE foods It may very well turn out that under the final rule, no establishment has an acceptable CCP to eliminate *L. monocytogenes*, and all establishments are required to conduct te sting. Until standards for compliance are established, any type of cost estimate is impo ssible.

Under the consideration to require "use-by" date labels on ce tain RTE meat and poultry products, FSIS states, "Food contact surface testing does not address (1) the physical inability of current testing devices to detect miniscule a nounts of *L. monocytogenes* in some finished RTE meat and poultry product after their manufacture and (2) the capability of *L. monocytogenes* to grow-out in certai products, even while being kept under refrigerated temperatures". FSIS decided to co nsider, rather than propose mandatory sell-by dating by asking, "For example, will smaller operations benefit from a "use-by" date more than large operations who mu st rely on larger sales areas which require longer product shelf to penetrate the entire r arketing area". The Agency is trying to reduce the economic impact of testing on sm all businesses by reducing their required frequency of testing, and decided agains proposing mandatory sell-by dating because of potential economic impact on large pr cessors. The Agency is diluting their stated goal of reducing risk to the consumer based on potential economic impact to processors, again without any supporting data.

The performance standards are a good starting point to begin developing research projects on possible ways to reduce risk associated with certain RTE meat and poultry products. Once these projects have been completed and data is generated for review, performance standards for RTE meat and poultry products can b e developed.

Respectfully submitted,

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cc: Anne Venneman