NATIONAL TURKEY FEDERATION

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Food Safety and Inspection Service
United States Department of Agriculture
Room 102, Cotton Annex Building
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-013P-2703
97-013P
David L. Meeker

2703

Re: Performance Standards for the Production of Processed Meat and Poultry Products

Dear Sir or Madam:

The National Turkey Federation (NTF) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Proposed Rule on performance standards for the production of ready-to-eat meat and poultry products. NTF is the only national trade association representing the turkey industry exclusively. NTF represents more than 95 percent of the United States turkey industry, including processors, growers, breeders, hatchery owners, and allied industry. Many of its members produce ready-to-eat products and are thus affected by this proposed rule.

NTF is concerned with the manner by which the agency is addressing this issue and in the comments that follow we question the scientific basis and assumptions of the proposed rule. We wish to make clear at the start, the NTF and its members are strongly committed to food safety. We, as an industry, understand the importance of food safety and agree with efforts to improve the safety of products based on scientific facts and data. We ardently believe that for any food safety initiative to be successful, it must be based on sound science. Unfortunately, the agency's proposed efforts in this proposal fall short of regulating the safety of processed meat and poultry products in a scientific manner.

These comments will address three (3) pertinent sections of the proposed rule: 1) Proposed lethality performance standards, 2) Proposed stabilization performance standards and 3) Mandatory *Listeria* testing.

Proposed Lethality Performance Standards For RTE Products

NTF is in General Support of the Principles for Establishing Proposed Lethality Performance Standards for Ready-to-Eat Products

Proposed section 9 C.F.R. 430.2 mandates certain lethality performance standards for ready-to-eat (RTE) products be either based on achieving probabilities of no greater than a certain level of surviving Salmonella per 100 grams of finished product or be based on achieving a certain log-10 reduction of Salmonella throughout the finished product. As will be discussed in greater

SUITE 400 ▪ 1225 NEW YORK AVENUE, NW ▪ WASHINGTON, DC 20005 ▪ TEL: (202)898-0100 ▪ FAX: (202)898-0203

detail below, while NTF generally recognizes the importance of let ıality performance standards, the scientific basis and assumptions used to derive the standards an l their "one standard fits all" application for all RTE products is of concern.

Proposed Performance Standards Based on Old Data

As articulated in the preamble to the proposed rule, the basis for th : proposed standards have been determined using "hypothetical" "worst cases" scenarios deri ed from FSIS's Nationwide Microbiological Baseline Data Collection Program surveys conduc ed at least 5 years ago and well prior to the implementation of the Pathogen Reduction/HACC ? regulations. Since the implementation of those regulations and the application of multiple intervention strategies in both the turkey and red meat industries to reduce the levels of pathogens on raw product, levels of pathogens on raw product, by FSIS's own accounting, have been d amatically reduced. Thus, using outdated and somewhat questionable data to base new perfor nance standards does not account for the achievements realized by the industry.

Validation of Lethality Performance Standards Based On Prob abilities

It is recognized that each processor must validate processes to achi ve either the proposed decimal reductions of pathogens or one of the stated probabilities t ıat only a small number of reference organisms would remain viable in a worst-case scenario. In the latter case, and as stated in the preamble to the proposal, it will be necessary for the p ocessor to define, using associated statistical criteria, the expected characteristics of the tre ted product after processing, assuming certain product conditions before processing. The proced ures, conditions studied and amounts of data, etc. necessary to validate such processes are, how ver, ill defined and could be subject to much interruption by FSIS regarding the adequacy of da a necessary to be maintained by an establishment as part of its HACCP plan. Thus, NTF recom ıends that consideration be given to the development of a protocol that would address, in more detail, the methods, procedures and the like necessary to validate processes designed to achieve one of the probability performance standards.

In further discussion of the derivation of the proposed probability l thality performance standards, reference is made on page 12595 to " The derived worst case levels are hypothetical constructs meant to represent upper limits of possibilities for raw p oduct produced under appropriate, normal manufacturing conditions. These conditions i clude maintaining the raw product at or below temperatures known to prevent growth of Salm onella and most other pathogenic organisms (e.g., at or below 40 degrees Fahrenheit)." N TF would point out that the pathogens of concern in raw product would almost never reach a l vel to challenge the adequacy of a process without a corresponding rapid growth of non-pathoge ic microorganisms that will spoil the raw product making it unusable.

Response to Specific FSIS Questions

In the preamble to the proposed regulation, FSIS posed certain spe ific questions. The questions and our responses are as follows:

Question: Whether additional lethality performance standards for ther pathogens and toxins that can pose hazards should be enumerated in the regulations.

NTF believes that until such time as there is scientific evidence and data that there are more heat resistant, vegetative pathogens than Salmonella, there is no further need to promulgate additional lethality performance standards.

Question: Whether FSIS should apply the E.coli O157:H7 performance standard to RTE fermented poultry products that do not contain beef.

NTF believes that there is insufficient scientific data and epidemiological data to support the extension of the E. coli O157:H7 performance standard to fermented poultry products.

Draft Compliance Guidelines for Ready-to-Eat Meat and Poultry Products

NTF applauds the efforts of FSIS to compile the subject guidelines as a resource (i.e., safe harbor) for the meat and poultry industry. NTF would, however, request that all available validation data, scientific studies, literature, etc. to support the various processes delineated in the guidelines be made available as a reference. In addition, it is suggested that any "conditions of use" applicable to the safe harbors be clearly defined to ensure that the processes are adequately applied for a particular processing condition and product.

NTF further suggests that the guidelines for Thermally-Processed, Commercially Sterile Meat and Poultry Products be removed from the draft guidelines and continue to be retained as part of the canned meat and poultry regulations. This would ensure consistency in regulatory requirements between FSIS and the U.S. Food and Drug Administration.

Proposed Stabilization Performance Standards

The NTF strongly disagrees with the proposed requirement that the current stabilization performance standards be expanded to include all ready-to-eat products as well as heat-treated, not fully cooked products. FSIS has provided no scientific or epidemiological data in support of its position that expansion of the performance standards is necessary to protect the public health. To the contrary, there is little to no data that would support this expansion to the standards. In fact, data even brings into question the validity of the current requirements. Please consider the following factors that support NTF's position:

1. There appears to be no data linking *Clostridium botulinum* or *Clostridium perfringens* to a food outbreak that implicated further processed meat or poultry product. Data from the Centers for Disease Control (CDC), "Surveillance for Foodborne-Disease Outbreaks – United States, 1988-1992", identifies several instances where outbreaks have been linked to raw meat and poultry products as well as uncooked products which were apparently held for extended periods of time. Recently, a frozen chili product has been identified as 'potentially' containing *C. botulinum toxin*. At this time, there is no confirmation that the product contains the toxin, nor has a 'source' for the potential toxin been identified.

2. None of the 39 foodborne outbreaks associated with *Clostridium perfringens* since 1990 and listed by the Center for Science in the Public Interest have been traced to a cooling defect in any state or federally inspected facility.

3. The Agency's baseline data, which FSIS has used to define its existing stabilization performance standard of no more than one log growth of C. perfringens, is flawed for the following reasons:

a) The baseline study the Agency conducted did not look for he number of *C. perfringens* spores which would represent the population that may germina e post lethality;
b) The agency assumed the "*C. perfringens* vegetative counts ' reported in the baseline studies for raw meat and poultry also would apply after lethalit y.

4. The baseline data the Agency collected and founded the existin; stabilization performance standard on suggests that there is an expected beginning level f *C. perfringens* of 10^4. Industry generated data on fully cooked product presented at th e public meetings on May 9th indicates levels significantly lower than the Agency has predic ed the starting level to be. In a controlled study of ground turkey that was cooked to 160°F, ll 154 samples tested for the presence of and levels of *C. perfringens* spores in product indi ated < 3 spores/g. Additional data from 53 lots of product that had not met the existing stabil ization performance standard were tested for *C. perfringens*. A total of 340 analysis were co npleted, of these, 336 samples were at <10cfu's per gram; 2 samples 11-100/g; and 2 samples 110-140/g.

5. Published microbiological studies demonstrate that *C. perfring ens* die during refrigeration storage. There is a 1 log reduction within 24 hours and > 2 log reduction within 7 days.

6. Nitrite has been shown to interfere with the germination rate of *C. perfringens* and salt with its growth rate. The stabilization performance standard does not t ıke into account product formulations.

FSIS has provided no scientific evidence or documentation to s ıbstantiate the need to apply the current stabilization performance standard to heat-treated not fully cooked product. Additionally, there is no objective evidence that would suggest hat either *C. perfringens* or *C. botulinum* are a hazard reasonably likely to occur.

Based on the above information, NTF believes there has b en insufficient scientific or epidemiological data presented by FSIS that warrants the ap olication of the stabilization performance standards to all ready-to-eat and heat treated, not full cooked products at this time. In fact, data supports, and NTF recommends, that the scientific bas is for the current requirements be reexamined. During this reassessment, should the Agency con inue to believe a stabilization performance standard is necessary, consider a requirement that would consider a ranking on relative risk relating to product formulations, which provide hur lles. Additionally, instead of defining a maximum log increase *C. perfringens*; consider a maxin um level at the time product is released for shipment.

Proposed Mandatory *Listeria* Testi g

NTF Opposes the Mandatory *Listeria* Testing for Establishmer ts Producing RTE Products

Proposed section 9 C.F.R. § 430.4 would mandate testing of foo l contact surfaces for *Listeria* species (*L. spp.*) at establishments that have not addressed post l thality contamination in their HACCP plans. As discussed in greater detail below, NTF **strongly opposes** this proposal. It will not advance the public health; rather, it represents a major step bac kwards in FSIS' transition to a regulatory public health agency.

As an initial matter, NTF always has supported aggressive *Lister a* control. NTF served on the Industry Task Force that developed the *Listeria* Guidelines for Inc ıstry and continues to provide counsel to its members. In turn, NTF members have develo ed and implemented control programs designed to detect and eliminate *Listeria* in the plant en vironment. Great strides have been made by NTF and other associations/companies. We recogr ize there is always more to do

to address this ubiquitous organism. Therefore, we wish to make clear, we do support *Listeria* control measures; it is only the controls the agency wishes to mandate that we oppose.

A Risk Analysis Does Not Support the Proposed Action

We are troubled by the apparent inconsistency between the proposed mandatory testing provision and the agency's intent to remold itself as a regulatory public health agency. At the public meeting in June, FSIS discussed how it would use risk analysis as the centerpiece of such a transition. Yet, the instant proposal is inconsistent with a risk analysis approach: it does not reflect a consideration of the severity and likelihood of risk among products (risk assessment); it does not take into account any assessment of risk or of technical/policy considerations (risk management); and it is not based on the open exchange of information (risk communication).

In lieu of proceeding at this time with any regulatory change, we strongly encourage FSIS to continue with its current *Listeria* testing policy incorporated in Directive 10,240.2. This course of action will allow establishments to conduct voluntary testing, which may include environmental/product contact testing. The results from such programs and the other changes discussed below could then be used by FSIS to develop a sound regulatory framework to effectively address *L.m.*

A. Risk Assessment

Currently, FSIS is working with the Food and Drug Administration to complete a risk assessment/risk management report on *L.m* in RTE foods (hereinafter Joint Report). We believe this report should be the starting point for a sound *Listeria* policy.

It recognizes that not all RTE products pose the same degree of risk. According to the Joint Report, five factors affect *L.m* consumer risk at time of consumption:

- The amount and frequency of consumption;
- The frequency and levels of *L.m* in the RTE food;
- The potential to support growth of *L.m* during refrigeration;
- The refrigerated storage temperature; and
- The duration of refrigerated storage before consumption.

These factors are cumulative, in that the presence of more than one factor increases risk.

Moreover, the Joint Report notes that there is a variation in the virulence of different *L.m* isolates and that the relative risk from low exposures is smaller than previously thought.

Given the importance of such findings to a sound policy, we would recommend delaying any policy decision until the risk assessment is completed, or at the very least, factor the draft findings into any regulatory policy.

In addition to our recommended use of the Joint Report in developing a regulatory policy, we wish to oppose the implication in the proposed regulation that *L.m* risk is based, in part, on the size of the plant.[1] During the public meeting, FSIS officials conceded that there are no data to justify this implication. Not only is there an absence of a scientific basis, the amount of RTE

[1] This is the justification for the differing frequencies of the mandatory monthly tests.

product manufactured at an establishment may not, and indeed, does not always correlate to the number of employees at an establishment If the agency wishes to proceed done this road, we believe a sounder basis for differentiation should be the volume of RTE produced at the facility.

B. Risk Management

As we understand risk analysis, risk management focuses on the development of a policy to most effectively address the risk identified in the risk assessment, taking into account the relevant variables, technological feasibility, and other appropriate considerations. Beyond this, FSIS should adopt a risk management policy that actually encourages industry to study the organism and develop effective, innovative solutions to the issue. Pro-active steps by industry should be fostered, not viewed as potential evidence for a regulatory enforcement action.

1. Addressing the Variables Affecting Risk

We respectfully submit that the agencies were on the right track in the Joint Report when they considered treating products differently depending on relative risks

- There are some products which pose a significant risk and new approaches should be identified;
- For certain other products, the risk varied substantially within the type of food; thus, additional data and study is needed to address these products;
- For other products, there is a lower risk if properly handled and
- Finally, there is a group with low risk due to inherent characteristics of the food (*e.g.* frozen).

Yet, the proposed mandatory *Listeria* testing provision treats all products equally. Such action is a poor allocation of agency and industry resources. In this regard we would suggest that FSIS take action now to recognize the major variables: the fact that not all products pose a realistic risk: (1) because of their nature, *e.g.*, frozen; (2) because of the processing, *e.g.*, the addition of growth inhibitors; and (3) because the specific *L.m* on the product is not virulent.

First, address the issue of frozen products. As the Joint Report noted, such products pose a very low risk. Indeed, as far as we are aware, there have been no reported illnesses attributed to a frozen product containing meat or poultry. Currently, FSIS Directive 10,240.2, recognizes that a combination product, such as a frozen entree, may not be deemed RTE if it is properly labeled. We recommend FSIS expand this concept and establish a working definition of RTE, either in the context of this rulemaking or, preferably, as an administrative policy as soon as possible. In this regard, we respectfully direct the agency's attention to the definition of RTE found in the Model Food Code. Adoption of this definition will have the additional benefit of providing a more uniform policy across all food products. The definition provides that:

> "Ready-to-eat food" means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form."

This definition would resolve the status of frozen products as a n ɔt RTE product, provided the products bear the sort of labeling currently outlined in the Directive

In our view, there is no scientific data of which we are aware ' vhich would justify different treatment depending on the location of a positive food contact ɛ urface. This being said, we respectfully submit that FSIS not treat food contact positives differe ntly depending on location.

Second, address the issue of processing technologies to reduce th Listeriosis risk. There are a variety of processing aids on the market that will prevent the growt ı of *Listeria* on RTE products even under refrigerated conditions. Three of the five risk factors vith *Listeria* identified above are related to storage and handling after packaging. If the establish ıent takes proactive measures to prevent growth, this, in turn, reduces risk. As a result, the regulatory handling of such establishments and their products should take into account the low er risk. Indeed, to the extent that FSIS provides incentives for the development and use of new technologies that reduce *L.m* risk, it can act as a force for change in enhancing the safety of the f od supply.

Third, address the issue of Listeria virulence. Not all *L.m* poses th same public health risk. We understand that FSIS has data on the PFGE profiles of product that have tested positive in agency samples. Moreover, the Centers for Disease Control has da a on those strains of *L.m* that have been implicated in illnesses. At the public meeting on this p oposal, FSIS indicated that it would share PFGE results with the affected establishment, a well as working with the establishment if it uses ribotyping. This is a sound first step. However, as part of its risk management activities (or as part of the risk communication), FSI should make available to all interested parties, the PFGE results of its samples and the PFGE p ofiles of those strains of *L.m* that have been implicated in illnesses. Obviously, we would urge th at FSIS not identify either the establishment or the patient. This sharing of information will give all establishments wishing to investigate potential harborages vital information. Moreover, ov r time, such a database will provide the documentation needed for determinations as to the ap ɔropriate regulatory response based on the virulence of the pathogen.

2. Addressing Technological Feasibility

Proposed § 430.4 would provide that if an establishment has "iden ified *Listeria monocytogenes* as a hazard reasonably likely to occur within the HACCP plan fo its ready-to-eat product and consequently established one or more controls for L. monocytog nes to be implemented after lethality treatment is complete," the establishment is exempted fron the mandatory testing.

However, under the current FSIS HACCP regulations, a finding tha a hazard is reasonably likely to occur has the affect of mandating a CCP. Unfortunately, for mar y products, there simply is no intervention that can be used to prevent or eliminate *Listeria* with 1)0% certainty. In other words there is no current technology that an establishment can employ as CCP.

If there is no technologically feasible CCP, establishments are face with a dilemma:

> Should an establishment decide to amend its HACCP plan o avoid the mandatory testing (or, as is more likely the case, the mandatory product testi ıg after even a single contact positive), this decision could have adverse, unintended c nsequences. Without a true CCP, there will be repetitive *L.*m findings. Such findings can result in FSIS ruling that the HACCP system is inadequate and cause FSIS to initiat an enforcement action, even though the system cannot prevent the finding.

Alternatively, if an establishment does not find *Listeria* to be a hazard reasonably likely to occur, then it must conduct the mandated food contact testing (and hold product). Not only is this option undesirable, it may be short term. It appears from the preamble that once an establishment has a positive product finding, FSIS would likely deem *Listeria* to be a food safety hazard reasonably likely to occur at the establishment and mandate a *Listeria* CCP.

To avoid this dilemma, many establishments have adopted a *Listeria* testing program to maintain control. However, testing is not a CCP and cannot be tied into a CCP. Accordingly, establishments have treated these programs as prerequisite programs or as an on-going hazard analyses. FSIS recognizes such programs exist in the preamble, but notes that establishments may not always be willing to share the results. Rather than mandate a CCP where no technologically feasible intervention exists, FSIS should use the same approach as that taken with Directive 10,240.2 -- allow an establishment to use a prerequisite in lieu of a CCP as required in the proposed regulations. This would best be done, if FSIS actually proceeds to finalize the proposal, by clarifying language to include the phrase "or program" immediately after the word "controls."

3. Addressing Other Concerns

The proposal mandates that whenever there is even a single food contact positive for *L. spp.*, the establishment must conduct finished product testing of product manufactured the same day the contact sample was taken. For large companies, this means holding product, which has significant costs, especially if there is uncertainty as to the scope of product implicated, *e.g.*, multiple lines. For smaller companies, who currently may not even be holding product after an FSIS finished product sample, this could mean recall.

In response to the request made by agency officials at the Public Meeting on the proposal, we are providing the follow cost estimates of holding product whenever a single food contact surface is sampled for L. spp. (attached).

Given *Listeria* is ubiquitous, an aggressive plan must be followed. However, if there are immediate and adverse regulatory implications for every finding, the establishment is being punished for being aggressive. This is bad public policy -- a company should be encouraged to be proactive. The regulatory event should not be the finding of *Listeria* -- it should be what the company does after finding it.

In this regard, we note that the one to one ratio of product contact positive to finished product testing is a dramatic reversal of existing agency policy. In the May 1999 FSIS Guidance on *Listeria*, "Attachment 1: Examples of Environmental Monitoring Programs," sets forth several acceptable programs which may be employed by establishments. In none of these examples did FSIS indicate product testing must be initiated after a single contact positive. Indeed, product testing was only recommended after several positive contact findings. Likewise, in Directive 10,240.2, FSIS defers to the establishment's determination as to the appropriate number of positive contact findings before product is implicated. Indeed, the FSIS Draft Guidance material prepared in connection with the instant proposal and posted on the agency's web site is inconsistent with the language of the proposed regulation.[2] Under the draft Guidance, FSIS is

[2] On an unrelated manner, we note that the agency in the Draft Guidance appears to use the phrases "environmental sampling" and "food contact sampling" interchangeably. Since these

willing to allow an establishment to select the number of positives before mandating product testing under its HACCP plans.

We are confused as to why FSIS would ignore the above precedent and mandate immediate *L.m* testing of finished product with a single contact positive in the proposed regulation, especially given the total absence of any justification for the change. Rather than changing policy, the current policy should be even more clearly articulated -- that isolated contact positives for *L. spp.* do not implicate product. Additional instructions to the field will help allay industry concerns that field inspection personnel may misinterpret the meaning of such findings -- concerns which have created a reluctance of the part of many in industry to share data.

4. Alternative Management Approach

As we stated at the outset, NTF is strongly committed to effective *L.m* control measures. Unfortunately, we do not believe the proposed mandatory program is the most effective use of resources. As discussed above, we respectfully suggest the agency

- Complete the Joint Risk Assessment;
- Continue with Directive 10,240.2 which will enable FSIS and the industry to develop data and experience with *Listeria* testing programs;
- Reaffirm guidelines on the regulatory consequences of isolated *L. spp.* findings;
- Develop a policy on RTE products;
- Recognize the use of growth inhibitors in allocating sampling resources; and
- Share PFGE and other data on *L.m.*

Such an approach will allocate resources to risk and take into account risk variables and technological feasibility so as to encourage establishments, both large and small, to develop the control measures which work best for them.

C. Risk Communication

The third and final component of risk analysis is risk communication. As an initial matter, we do wish to commend the agency on its aggressive efforts to apprise consumers on *L.m.*

Notwithstanding the above, we understand risk communication to involve the communication, understanding and acceptance of the risk assessment and management; in other words, conveying to the stakeholders, in an open and transparent manner, the basis for the agency's decision making. Unfortunately, in the context of this proposal, we believe that FSIS could have been more open in explaining the basis for its decision to mandate *Lister a* testing.

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phrases have different meanings to different people, clarification as to the agency's meaning would be appreciated.

- On the Draft Risk Assessment, the agency has not provide[illegible] complete access to data. As expert reviewers have noted, there is a "need for a clear exp lanation of the study data and how [the agencies] interpreted and used the data."

- On the data generated by routine *Listeria* sampling, the age ncy has not made its data and findings (including PFGE files) available to all establishme nts.

- The agency has indicated it will be reviewing data relative t › repeated *Listeria* findings to ascertain any potential patterns, but it has not articulated ' vhy it proceeded to publish a proposed rule before such a relevant review is even underta cen.

- The agency has not articulated the basis for how its proj osal addresses the true risks identified by the risk assessment. For example, whether a ny consideration was paid to the risk variables discussed above.

- The agency has not articulated the basis to require produc : contact testing, followed by finished product testing in the event of even a single *L. spp.* positive finding.

- The agency has not articulated the basis for its selection of sampling frequency and how establishment size (*e.g.* as opposed to volume) relates to pu blic health risk.

Regrettably, it appears that the instant proposal has been iss ued without any supporting justification. In such event, there is not a basis for the stakehol lers to understand, let alone accept, the risk assessment and risk management decisions embodie d in the instant proposal.

Responses to Specific FSIS Questions

In the preamble to the proposed regulation, FSIS posed certain spec ific questions. The questions and our responses are as follows:

Question: Whether positives on different food contact surfaces sho uld be treated differently.

In our view, there is no scientific data of which we are aware v hich would justify different treatment depending on the location of the positive. This being sai l, we respectfully submit that FSIS not treat positives differently depending on location.

Question: Whether FSIS should impose more specific requirem :nts on product testing after contact positive.

Such requirements would be a return to "command and control," a id for that reason alone, such requirements should not be imposed. In addition, *Listeria* inciden s seldom fit into any precise pattern, each unique unto itself. Accordingly, it makes little sense :o impose some "one size fits all" approach on when or whether product testing should be require l.

That being said, we do wish to re-emphasize that FSIS clearly resta :e its current policy that there is no automatic regulatory consequence of isolated *L. spp.* findin gs on contact surfaces. This degree of flexibility is both consistent with HACCP and the policy (f encouraging establishments to seek out and eliminate *Listeria* in the processing environment.

Question: Whether FSIS should allow an establishment to confirm a contact positive as *L.m* before finished product is implicated.

Consistent with the thrust of these comments, we believe FSIS should grant an establishment the maximum flexibility, consistent with sound science, in implementing a *Listeria* control program. Accordingly, we believe FSIS should permit an establishment to confirm a contact finding as *monocytogenes*, or, if it so desires, conduct *L.m* product contact testing in lieu of *L. spp.*

Conclusion

We appreciate the opportunity to comment on this important proposal. We hope and trust that FSIS will consider the suggestions and information herein so as to work toward enacting regulations in a manner that will promote efficiency and food safety simultaneously.

Respectfully submitted,

David L. Meeker
Vice President, Scientific and Regulatory Affairs

2703

Partial Economic Impact Analysis of Proposed RTE Rule
- Cost of Environmental Test-and-Hold Provision -

I. Assumptions

A. Processing Assumptions:
1. Average of 2 packing lines per plant
2. Assume 50 domestic processing plants
3. Run time approximately 8 hours per shift; 2 shifts per plant
4. Average Line speed: 40 units/min.
5. Units/case: 2
6. Cases/pallet: 100 (pallet square- 10 case per layer; 10 layers per pallet)
7. Micro swabs per line: 5-10/shift
8. Time to confirm positive swabs: 5-7 days

Implies:
- 2400 units/ hr./line, or 1200 cases/hr./line, or 12 pallets/hr./line
- 4800 units/hr./plant, or 2400 cases/hr./plant, or 24 pallets/hr./plant
- in an 8 hour shift: 192 pallets/shift/plant; in two 8 hour shifts: 384 pallets/day/plant

B. Cost Assumptions:
1. $9-10/pallet general handling charge (includes off-loading truck at warehouse, placing product into racks for storage, and loading product back onto truck for delivery; all product must be stored since the proposal would not allow direct shipping)
2. $5/15 days storage/pallet up to $10/30 days storage/pallet depending on contract (contracts require full charge whether pallet is stored for only one hour or the entire 30 days)
3. $21-23/swab for positive confirmation

II. Cost Analysis:

A. Storage & Distribution:

Cost Per plant-

1. Handling Charge:	384 pallets/day/plant x $10/pallet = $3,840/day/plant
2. Storage Charge:	384 pallets/day/plant x $10/pallet = $3,840/day/plant
	Total $7,680/day/plant

Since it will take up to 7 days to get micro confirmation results returned, these costs will accumulate on a daily basis for the first seven days at which time they become a constant charge. (1x$7,680) + (2x$7,680) + (3x$7,680) + (4x$7,680) + (5x$7,680) + (6x$7,680) + (7x$7,680) = 28 x $7,680

Total accumulated cost to begin releasing product from HOLD: 28 x $7,680= $215,040

Cost to Industry-

1. Total Daily Cost	$7,680/day/plant x 50 plants = $384,000/day
2.Total Cost to Begin Releasing Product from HOLD	$384,000 x 50 = $19,200,000

B. Micro Testing

1. Cost Per Plant to Confirm Swabs:
   - 10 swabs/line/shift x 2 shifts/day x 2 lines/plant x $23/swab = $920/plant/day
   - Accumulated Cost Before Product can be Released from HOLD: 7 x $920 = $6440/plant
2. Cost to Industry to Confirm Swabs:
   - $920/plant/day x 50 plants = $46,000/day
   - Accumulated Cost Before Product can be Released from HOLD: 7 x $6440 = $322,000

III. Summary

Daily Cost to Individual Plants:

Storage/Handling:	$7,680
Micro Testing:	920
	$8,600

Total Cost to Individual Plants to Release Product from HOLD:

Storage/Handling:	$215,040
Micro Testing:	6,440
	$221,480

Daily Cost to Industry:

Storage/Handling:	$384,000
Micro Testing:	46,000
	$430,000

Total Cost to Industry to Release Product from HOLD:

Storage/Handling:	$19,200,000
Micro Testing:	322,000
	$19,522,000

Additional Considerations:

The availability of warehouse space needs to be considered when placing the volume of product on HOLD as suggested by the agency. Assuming each warehouse rack location is four tiers high and three pallets deep (12 pallets total):

384 pallets/day/plant x 50 plants x 28 accumulated days to release product = 537,600 pallets

537,000 pallets must be stored domestically before product release and rotation may occur. At 12 pallets per rack location, 44,800 rack locations will be tied up storing product. A typical warehouse may contain up to 3500 rack locations. Therefore, 13 new warehouses would need to be built for no other purpose but to accommodate the test and HOLD requirements of the proposed rule.