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FSIS Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102 Cotton Annex, 300 12th Street, SW
Washington, DC 20250-3700

97-068N
97-068N-23
Dean A. Danilson

RE: Docket No. 97-068N – Comments:
Beef Products Contaminated with Eschericia coli (E.coli) 0157:H7.

These comments are submitted on behalf of IBP inc., a slaughterer and processor of beef and pork products with slaughter and manufacturing operations throughout the United States and Canada. Sales of beef and pork products produced by IBP are worldwide. IBP inc. appreciates the opportunity to comment on this proposed policy change. Following are our comments pertaining to this docket.

The sudden method of this action by the Agency is severely criticized. The January 19 publication reflecting changes in Agency policy or "thought" regarding 0157:H7 in uncooked beef products, beyond the previous ground beef applications, was dropped on the industry unannounced and resulted in immediate negative reaction and potential chaos across many segments of the beef/food industry. Subsequent conversations and meetings with industry, in addition to a Q&A that was not well thought out, resulted in even greater confusion and anxiety within the industry. The Agency is commended, however, for its subsequent response in delaying implementation of any changes until after the comment period, and also for providing the forum for further discussions at a public meeting held on March 8th.

The further actions proposed by the Agency (i.e. expansion of adulteration classification to uncooked non-intact beef cuts and pre-grind trimmings) are not supported by scientific data, nor indicated as necessary by risk assessment analysis. Data from CDC reveals that in 1997 *0157:H7* accounted for less than 5% of bacterial related food-borne illnesses, and of this 5%, less than 10% of the illness/outbreak incidents were attributed to ground beef. In contrast, illnesses attributed to *Campylobacter* and *Salmonella* are off the chart in comparison to *0157:H7*. Furthermore, the CDC data shows a steady and significant decline in ground beef related *0157:H7* illnesses/outbreak incidents since 1993. Also, to our knowledge, no other country has taken similar actions in the classification of *0157:H7* as an adulterant in uncooked beef, even though thorough risk assessments have been conducted (e.g., Canada). It is pertinent to note that a top FSIS official recently made public comment in regard to *Campylobacter* contamination in fresh poultry such that *"risk assessment must be done before any rulemaking likely to have a significant impact can be undertaken"*. IBP suggests that FSIS adopt a similar practice of utilizing appropriate risk assessment analysis and valid scientific data before enacting further policy actions regarding *0157:H7*, or any pathogen for that matter, on uncooked beef products.

It is noteworthy that *0157:H7* is a much broader scope issue than just ground beef and other types of beef products. Many of the *0157:H7* illnesses/outbreak events over the past few years have been attributed to non-beef products such as lettuce, alfalfa sprouts, apple juice, other non-meat food items, as well as non-food related incidents such as swimming pools and person-to-person transmission. It is disconcerting that FSIS regulatory and policy actions applied to *0157:H7* in uncooked beef product appear to be narrowly focused on a single segment of the meat-food industry. These policy actions (including the original 1994 administrative act that classified 0157:H7 as an adulterant in uncooked ground beef) appear to be singly targeted at the beef industry, and are not consistent with FSIS policies or actions dealing with other

pathogens on fresh meats, especially *Campylobacter* in poultry. IBP urges FSIS to be consistent and equitable in its regulatory actions and policy interpretations relative to the presence of microbiological contaminants on uncooked meat-food products.

Non-Intact Beef Cuts

The proposal to classify *0157:H7* as an adulterant on non-intact, uncooked beef cuts is not supported by data or by the scientific community. We are informed that this action was not recommended nor supported by the FSIS Microbiological Advisory committee. Data presented by Kansas State University at the March 8th meeting clearly demonstrated no difference in risk between intact vs non-intact (blade tenderized) steaks, and that cooking to a rare state (~140F) was sufficient to provide a 6D kill for *0157:H7*, equally for both non-intact or intact steaks. Furthermore, to our knowledge, there is no known epidemiological data that has demonstrated, or even implicated, non-intact beef cuts with an *0157:H7* outbreak or illness. Basis these facts and events, IBP recommends the proposed actions pertaining to non-intact beef cuts be withdrawn.

Pre-Grind Beef Trimmings

The Agency proposed similar expansion of the adulteration classification to beef trimmings. This action is a further reflection of FSIS policy evolution that is not supported by appropriate risk assessment or sound science. This proposed policy, coupled with the associated compliance and enforcement actions outlined by the Q&A, provides a blueprint for disaster that will have devastating impact on many segments of the meat-food complex in the USA. This policy change could trigger over 200 national scope recall actions annually, across all segments of the meat-food industry, which potentially could reach over 2 billion pounds of beef product annually (refer to Appendix I – Recall Multiplier Effect).

Q&A Response & Analysis

Comments below are applied to each of the Q&A questions that were issued in the 2/26/99 draft.

Q1 Receiving Plant - A positive *+0157:H7* "combo or sublot" is contaminated. A negative *-0157:H7* "combo or sublot" is considered OK for raw ground beef usage. Specifically=> "only the product units that are represented by the positive sample will be considered contaminated". The written testing protocol is a key in determining exactly what is the definition of the "lot" or "sublot", relative to determining disposition or status of related raw materials. Source Plant - The Q&A specifically states that => "for practical purposes (at this time), FSIS will not consider other raw material from a "source plant" produced from the same shift, or from the same source materials, to be *0157:H7* contaminated.

We agree with the basic principals established in the 1st question in the Q&A. However, further discussions in Q6 and Q8 contradict and negate the position established in Q1. IBP suggests that FSIS adopt the language and thought process established in Q1 relative to defining the affected "lot" or "sublot" as applied to beef trimmings, and eliminate the contradicting discussions presented in Q6 and Q8.

Q2 *0157:H7* Sampling/Testing Methodology - FSIS attempts to define a preferred methodology for sampling/testing for *0157:H7* by recommending a "325g - five 65g subsample" testing methodology.

The methodology recommended by FSIS is applicable only to ground product, not to intact cuts, un-ground trimmings, or swab or sponge carcass samples. Methodologies utilizing a 25g sample size for surface tissue extracted from beef trimmings have been demonstrated to be just as sensitive in detecting presence of 0157:H7 vs a larger 375g sample of ground product. A significant dilution effect occurs with the larger sample size that results in reduction of the detection sensitivity of the larger sample size. This application does not apply to a sponge or swab sample taken from a carcass or surface tissue. Furthermore, this action will hinder development and

innovation of rapid testing technologies. Also, the effect of this methodology recommendation will have a significant negative impact on the scope and scale of laboratory resources needed to conduct the testing of this large sample size on the tens of thousands of 0157:H7 trimming or carcass samples that are being tested by industry today. Alternate - yet equally effective and sensitive sampling/testing procedures need to be allowed. FSIS should continue to rely on the existing recommendations that stipulate the testing sensitivity and the associated false positive and false negative rates.

Q3 "Lot" Identification in the Event of *+0157:H7* Test on Trim - FSIS uses a sampling scenario of "2 individual test combos" representing a grouping of 10 total combos. The scenario presented is what happens when 1 combo tests (+), and the other combo tests (-).

Actions: The (+) combo is contaminated - must be dealt with appropriately.
The (-) combo is NOT considered contaminated - can be used in raw ground beef.

Actions on remaining 8 combos => Two scenarios presented:

- If the sampling plan previously identified the remaining 8 combos as part of the "lot", then all 8 combo's would be considered contaminated and must be dealt with appropriately.
- If the testing protocol addressed only the 2 sampled combo's - and did not address the remaining 8 combo's, then all 8 of remaining combo's should be sampled/tested to determine *0157:H7* status.

Q3 narrowly focuses on only one example of a sampling plan for beef trimmings that is being used by some Quick Service Restaurant's (QSR's) today - where meat tissue is not pulled from every combo on the load. This interpretation, applied to those plans, would lead to a significant change in interpretation to dispositions of non-tested combo's. As a result, operational changes would be either a change in the sampling plan to accommodate sampling of tissue from each combo in the "lot" or total discontinuance of sampling or testing. On the other hand, the "multiple sublot" sampling plans used by some QSR grinder/processors - where tissue samples are pulled from each combo on the load or in the sublot – fit into the above scenario in terms of a negative test determines that the "tested" product is OK to use in raw ground beef. IBP does not have significant issue with this interpretation as applied to shipments of bulk beef trimmings within the industry methods utilized today. On the other hand, this interpretation establishes a significant disincentive for surveillance-type sampling that could be applied to pre-grind trimmings in a slaughter-processing facility that produces ground beef for retail and food service.

Q4 *IBP agrees with the actions described in Q4.*

Q5 *IBP agrees with the basic principals established in this question. Once again, however, discussions in Q6 and Q8 completely contradict and negate this position.*

Q6 Source Plant - Actions in Event of *+0157:H7* Trim Event - The "source plant" would be expected to:

1) review adequacy of testing protocol,
2) perform appropriate corrective actions - before reassessing HACCP plan (i.e., pathogen interventions, etc.),
3) conduct rigorous sampling and testing of the source materials (i.e., other beef manufactured on the same day and on the same production line) - if still available,
4) review documentation to ensure procedures are in place to identify distribution channels for related raw materials,
5) inform other receivers of the same source materials about the *+0157:H7* event, especially receivers who manufacture raw non-intact products.

Actions in 3 & 5 of Q6 above contradict and negate the previously described "source plant" actions from Q1. #3 is ill-defined and unmanageable. What is considered "still available"? What is impact on "same day" trim, retail ground beef from plants that also ship trimmings, or related non-intact product (either fresh or frozen) that is in distribution, storage, or commerce. Such items would be identified according to #4 as related items, and according to this interpretation - notification to affected receivers would be considered prudent or necessary. This expectation would trigger multiple nationwide "voluntary" recall actions - and create utter chaos in the meat/food industry. Such events would likely occur weekly - even daily! Actions prescribed in Q6 may well result in the complete cessation of voluntary trim and ground beef testing - as we know it today in the industry.

Q7 *Actions and thoughts laid out in Q7 are logical and are consistent with being taken today.*

Q8 Receiving Plants - Actions in Event of a "Notified" *+0157:H7* Trim Event From a Different Location

- Perform appropriate corrective actions - before reassessing HACCP plan,
- Review adequacy of the receiving plant testing protocol,
- Conduct rigorous sampling and testing of the product, if still available,
- Use product either for processing into large mass raw product (e.g., meat loaf) or RTE product.

Actions above, coupled with actions in Q6, contradict and negate the "source plant" actions described in Q1. The Q8 discussion is ambiguous and open-ended, and will result in complete confusion and chaos in many segments of the meat-food industry. Such actions would require extensive reorganization and recommitment across a diverse industry - and would take months/years to accomplish, let alone add tremendous cost to beef products and the beef industry. Actions prescribed in Q8, coupled with Q6 actions, will likely result in the complete cessation of voluntary trim and ground beef testing - as we know it today.

Q9 Labeling / Control of *+0157:H7* Trim Product - FSIS indicates that further policy actions are needed to provide specific instructions on how affected product is to be labeled or controlled during its alternate handling phase, until disposition or dispensation is completed.

Additional regulation or policy on this issue is not needed. Directive 10,010.1 already provides for FSIS control and oversight when product that is contaminated or adulterated is identified. Furthermore, if 0157:H7 contaminated product is moved to a cooking process in a different establishment requirements 9 CFR 318.23 defines procedures for product identification and processing control. Additional procedures are not necessary. This issue can be addressed by applying existing requirements and rules.

Q10 Impact on Current Directive 10,010.1 - No immediate action on current FSIS random testing programs - grinding plants or retail.

IBP contends that several modifications to Directive 10,010.1 are necessary. This Directive currently contains significant disincentives to testing and inhibits development of innovative process control mechanisms which focus on 0157:H7 prevention.

Q11 Future Actions Relative to Directive 10,010.1 - FSIS is in process of reviewing existing criteria for "exemption" from sampling at grinding plants.

- FSIS expects to add an additional option for source plants that use validated pathogen reduction interventions on carcasses.
- FSIS will clarify/expand role of inspectors at source plants, in terms of their verification actions, on plants that are participating in the "exemption" aspects of 10,010.1.
- FSIS is considering establishing similar "exemption" alternatives for Retail.

The Q11 actions regarding 10,010.1 are needed IMMEDIATELY - if the meat-food industry is going to be able to react and respond positively to the intent of the policy actions taken on January 19. Modifications to 10,010.1 must be LINKED to these policy actions to allow for progression and implementation of upstream testing programs targeted back to the carcass and slaughter process. Workable alternatives to the 6-month "penalty" program, as well as provision for "retail sampling reduction", must be adapted into 10,010.1 in order for industry to effectively respond, as well as providing incentive to industry to develop new and better food safety protection and enhancement programs.

Q12 Marinated Products - If surface of the beef is scored, the product is considered as non-intact, and would be considered adulterated if a *+0157:H7* event was related to the meat, the marinade, or related product contact surfaces.

There is no evidence or data that marinated beef products that may contain 0157:H7 do in fact represent a public health risk. There is no evidence of any illnesses attributed to such products. Such action or policy change by the Agency should not be taken until a complete risk assessment for this application is completed. This question or issue should be withdrawn until such time that a risk assessment is conducted.

Q13 Actions Necessary for Plants That Handle *+0157:H7* Product

- Trimmings for cooking or RTE - cross contamination must be controlled.
- Subprimals - example used is "Briskets with Coring Solution". Applies to subsequent usage of "intact" meat that is identified as *0157:H7* positive. FSIS indicates that some type of control - via "purchase specifications that specify that the corned briskets in their "uncooked retail-ready packaging" will be either sold in their packaging, or returned to the official establishment at the end of their use-by date.

The scenario-example of the Corned Brisket in Q13 is unclear and confusing. The Q13 response will result in widespread confusion, is impossible to enforce, and requires further clarification and detail in order to provide appropriate comment. This question should be removed from the Q&A.

Q14 Notification Requirements/Expectations for *+0157:H7* found in any livestock or poultry product
FSIS would like to have as much information as possible on the incidence of *0157:H7* contamination. FSIS encourages establishments and others to notify the Agency whenever *0157:H7* is found in regulated products so that FSIS can update its information about the occurrence and the levels of this pathogen at all points along the farm-to-table continuum – and can take appropriate action to protect the public health. Q14 states that if plants test for *0157:H7*, the following expectations would apply:

- testing protocol is written & well defined, and testing results/records are kept
- testing records should be available to FSIS inspection personnel.

Q14 is very open-ended and needs further clarification. Reporting of occurrence of positive 0157:H7 events should only be required on products for which the "adulteration" classification is assigned (i.e., ground beef), or for products or carcasses which are participating in the Directive 10,010.1 defined programs. Requiring reporting of other non-program testing is beyond existing regulatory authority. Such requirement is perceived as a significant disincentive to responsible firms that may desire to conduct research on 0157:H7, or other pathogens for furtherance of food safety risk assessment.

Pilot Program for Carcass Testing

In the March 8th public meeting a meat industry coalition, including IBP and several other meat packers, proposed a plan to implement extensive testing for *0157:H7* on beef carcasses at the slaughter plant level. The program would effectively establish a voluntary zero-tolerance performance standard for *0157:H7* on beef carcasses for those slaughter establishments that elect to participate. The program would be developed along guidelines prescribed within the existing FSIS Directive 10,010.1 (with modifications).

Such a testing program will result in a substantial increase in the number of *0157:H7* tests that are being conducted by the industry today, thus dramatically increasing slaughter house surveillance for this bacteria. The program will serve to establish *0157:H7* surveillance programs further back in the production practice, rather than at the ground beef or beef trimming stage of production. This program represents a significant step forward by applying the principles of HACCP back towards the pre-harvest source of this bacterial infection, and will both allow and stimulate the related beef industry segments to more aggressively and accurately address the *0157:H7* problem.

The industry coalition, led by the AMI, is in the process of developing a protocol and request for a FSIS sponsored pilot program that will provide validation and verification to this voluntary method of *0157:H7* surveillance testing. Development of this pilot program is in progress, but can not be completed in time to meet this public comment deadline. Furthermore, the actual testing and data accumulation phase of this pilot program will take approximately 6 months to complete. Because of the time constraints involved, IBP asks FSIS to hold in abeyance the actions and thoughts regarding intact beef trimmings as outlined in the January 19th issuance and the associated Q&A's that were issued on February 26th.

We appreciate the opportunity to comment on this docket.

Respectfully,

Dean A. Danilson

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Vice President, Fresh Meat Quality Assurance & Food Safety

Attachment 1 - RECALL MULTIPLIER EFFECT

Conditions and Constant

- A combo of beef trim (2,000 lb) tests postive for E.coli 0157:H7 at a "2nd Level"
- 20 total combo's (40,000) from the same production day and source plant associated with the tested combo.
- The beef trim in the combo is 6 days old by the time the lab result becomes final.
- Source Plant Production Conditions:

Plant Daily Slaughter & Cut -	6,250 Head/day (2 shifts; cleanup-to-cleanup)
Carcass Fabrication Output - (per head basis)	71.9 lb/head - Trimmings (Fresh & Frozen)
	86.8 lb/head - Ground Beef (Fresh)
	338 lb/head - Subprimals (domestic & export)

1st Level Effect - "Source" Plant Production (1 Day's Production)

320,000 lbs.	Trim	-- 8 truck loads [40,000 lb] shipped to 8 different "grinders". *All product is further processed before test result known.*
542,500 lbs.	GrBeef	-- 102 Customers (Ship To's); GrBeef shipped to 32 states. *(All product in distribution before test result known.* (86.8 lb/hd x 6,250 head/day)
632,813 lbs.	NonIntact Subprimal	-- Estimated that ~30% of all whole muscle subprimals are subjected to some type of injection/tenderization/pumping process before presented to the consumer. (338 lb/hd x 6,250 head/day x 30%)

1,495,313 lbs. Amount of "Related" Product from "Source" Plant

2nd Level Effect (Trim Usage by Downstream Grinder/Further Processor)

- 11 Loads of Trimmings produced by Source Plant in 1 day (40,000 lb/load).
- 8 Loads go to 8 different "raw ground beef" grinding plants (3 loads go to cooked products).
- Source plant Trim is blended with Trim from other sources for fat% adjustment.
- Typical "grinding plant" produces approximately 450,000 lb/day.
- All product from 1 day in "2nd level" grinding plant is affected (no midshift clean-up)

3,600,000 lbs. Total Affected Product from "2nd Level" Users of Trimmings (450,000 x 8 different plants)

3rd Level Effect (Manufacture & Usage of Lean Finely Textured Beef)

- Source material for LFTB is fat trimmings (XF/SL) from the affected "source" plant.
- Frozen LFTB material typically not utilized for several days after date of production, thus impact at "2nd Level" grinders would be in different days relative to the fresh trim use.

250,000 lb.	Approximate amount of LFTB produced per 1 day shift using raw materials from the "source" plant.
125,000 lb.	Assume approximately 50% of LFTB production used in hamburger products.
3 plants	Number of different "grinder" plants that will utilize the LFTB product.
3 days	Estimated number of days required for a 40,000 lb. load of LFTB to be fully utilized.

4,050,000 lb. Total Affected Product from "3rd Level" Usage of LFTB into Ground Beef products (450,000 x 3 x 3)

Attachment 1 - RECALL MULTIPLIER EFFECT

Recap =>	1,495,313 lb. - 1st Level "recall" product
	3,600,000 lb. - 2nd Level "recall" product
	4,050,000 lb. - 3rd Level "recall" product
	9,145,313 lb. - Cumulative Total Pounds Potentially Affected

Virtually every retail chain & independent grocery store, national & regional quick service restaurant, many "regular-type" restaurants (including private, national & regional chains), as well as many institutional food service establishments (i.e., schools, hospitals, military, airlines, etc.), throughout the USA, could potentially be affected by such a "recall" event.

RECALL MULTIPLIER - SCENARIO #1 => Annual Impact (Single Plant)

2,288 Number of annual "loads" of trim produced that is used in raw ground beef production. (8 loads/day @ 286 days/year).

9,152 Number of ECH7 samples that are tested for a single plant during 1 year (Each 20 combo load is subloted 4 times and tested at 4 samples/load).

0.20% Incident rate for +ECH7 (1998 USDA rate).

18 Number of +ECH7 "trim load" events that could occur for a single plant during 1 year.

167,395,800 lbs.	Total pounds of product from this single plant that could potentially be recalled in 1 year. (18 incidents/year x 9,145,313 lbs/year)

RECALL MULTIPLIER - SCENARIO #2 => Annual Impact (Industry)

27,000 Number of annual "loads" of trim produced and used in raw ground beef. (30,000,000 head x 72 lb/hd Trim / 40,000 lbs/load x 50% used in raw GrBeef)

108,000 Number of ECH7 samples that are tested (sampling plan = 4 samples/load).

0.20% Incident rate for +ECH7 (1998 USDA rate).

216 Number of +ECH7 events that could occur within the USA beef industry.

1,975,387,500 lbs.	Total pounds of product that could potentially be recalled in 1 year across the entire industry. (216 incidents/year x 9,145,313 lbs/year).

Conclusions

+ECH7 events in beef trimmings without any associated outbreak/illness linkages (using the regulatory tought-policy outlined in the Q&A), could trigger recall actions in the meat/food industry in the USA which potentially could achieve over 200 national scope recall events totalling over 2 billion pounds of beef.