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FSIS Docket Clerk
Docket 03-009N
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

Re: Using Applied Epidemiology and Other Tools to Protect the Public Health

The National Turkey Federation (NTF) respectfully submits the e comments in response to the Food Safety and Inspection Service's (FSIS) Federal Register Notice entitled "Using Applied Epidemiology and Other Tools to Protect the P ıblic Health" (April 28, 2003). NTF supports the efforts of FSIS to date in epidemiologi al investigations related to food recalls, however, we have several recommendations to st reamline the process and make it much more effective.

NTF is the only national trade association representing the tur ey industry exclusively. NTF represents nearly 100 percent of the United States tu key industry, including processors, growers, breeders, hatchery owners, and allied indu try. Since our members have been involved with FSIS epidemiological investigations, we have an interest in working cooperatively with the agency in implementing new pr ocedures that can further enhance the efficacy of epidemiological investigations.

General Reaction to Scenario Posed at Public Meeting

USDA provided the panel with questions at the beginning of the day that would be introduced during the panel discussion. Question #2 asked "Wh t is your reaction to FSIS' approach? Are there ways that we can make the inspectio more pointed so as to increase the likelihood that it will uncover as valuable evidence a s possible? Is FSIS looking at the right things? In the right way?"

NTF would agree with comments made by two of the panelists a d an audience member that, no, FSIS is not looking at the right things. What was done n the example provided at the public meeting is common to industry's experience with e idemiological investigations: The agency generates a laundry list of minor reg latory infractions, most of which have nothing to do with the cause of the outbreak. At t e end of an investigation, both government and industry are unaware of wha caused the outbreak, and therefore, the implicated company and industry in general d es not know how to

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included spikes in generic E.coli (most investigations have shown no correlation between generic E. coli and E. coli O157:H7), condensation (there is no published evidence that E. coli O157:H7 contamination of beef products has stemmed from environmental contamination/growth in the processing plant), an employee not washing their hands after returning from break (contamination of beef products from a bee plant worker has never been documented), and several cooling issues (E. coli O157:H7 does not grow at all below 46.4° F, and if present would be on the fastest-cooling external surface of the carcass, so cooling to <40° F within 24 hours, as measured internally within the inside round is a USDA requirement that is not based on any science concerning the prevention of growth of this pathogen).

To make the investigation as efficient as possible, and to get valuable evidence as to the root cause of the outbreak, investigators need to zoom in on the most likely causes of contamination. This is the only way that we can actually catch an outbreak when it is in the peak of the bell-shaped curve, rather than well after all the contaminated food has been consumed. For *L. monocytogenes* in cooked RTE products the cause of products contaminated with levels of *L.m* necessary to cause illness in susceptible populations has nearly always been a contaminated growth niche on or very near product contact surfaces in the post-cook, pre-package plant environment, combined with extended shelf life and/or temperature abuse. For E. coli O157:H7, the most likely cause of carcass contamination is cross-contamination from the hide to the de-hided carcass. Fecal contamination can also be a cause, but even this is limited, as current research suggests that E. coli O157:H7, if present in the animals gastrointestinal system, is concentrated near the rectum. Therefore, most contamination with fecal material, and certainly with rumen fluid/ingesta does not correlate to increased risk for E. coli O157:H7 contamination. Some items that were noted during the investigation could, in fact, have a bearing on the real issue (NR's for sanitary dressing procedures and use of only one antimicrobial intervention that may have been malfunctioning), but these receive very little attention.

Scientific Evidence and Laboratory Resources

Overall, NTF believes that there must be objective scientific evidence present to justify the investigation of a specific food industry or a particular establishment. Although the Federal Investigation Team may be following a lead that may implicate the industry, the investigation methodology must continue to consider all food and water as potential vectors of transmission until a confirmed source has been identified.

All decisions made in an exploratory investigation must be based on objective, statistically valid, scientific evidence and must not be influenced by unscientific external influences, such as media reports or consumer activists.

A typical USDA investigation involves the testing of only a very few samples. USDA needs to reallocate their lab testing resources to emphasize the testing of high-risk products and reserve capacity to do massive testing in emergency situations such as an outbreak. This cannot be done if their resources are completely tied up with testing routine, low-risk samples. They are moving in the right direction with the new RTE initiatives, which emphasizes increased regulatory scrutiny on true high-risk products.

Investigation Process

The investigation process should follow a defined protocol, which clearly outlines cause, scope, and identifies objectives. If the agency's objectives change during the investigation, this change should be clearly communicated to the industry. This will help establish a methodical and thorough approach to all investigations.

Also, these questions should be asked and answered at the start of every epidemiological investigation:

- What facts will the Agency share?
- How will the facts be shared?
- Who is entitled to information?
- When will information be shared?

By answering those questions, and relaying that information to the industry, cooperation will be greater and the process will be streamlined.

It is extremely important that there is a true understanding of the meaning and intention of requests. During the investigation, specific requests for information are made that, many times, are misunderstood or misinterpreted by the implicated company. The industry and the agency have different views of the situation and a different knowledge base on which to interpret statements and requests. Also, terminology and program design are unique within each company. Having a defined protocol that discusses what information would be shared and when, would provide the industry advance knowledge of the agency's expectations, which could then be incorporated into a plant's Crisis Management Plan.

Methodology

All information gathered from the industry should be used in context of the design of the program under which the information was collected. Understanding the methodology used to gather the information is important to prevent misuse or misinterpretation of the information or data.

Epidemiological questionnaires and case control studies should follow accepted practices, which have been reviewed and accepted by a cross-functional team of professionals skilled in survey methodology. In order to ensure the integrity of the process, questionnaires should not be biased or misleading to the recipien .

The protocol associated with the survey methodology employed by the CDC and other agencies in illness investigations should be shared with the industry. Epidemiological study summaries and interpretations should minimize bias and must be statistically valid. The study design should contain rules for interpretation and follow-up.

The standard protocol should provide a defined sampling plan that can be implemented and used to demonstrate that particular lots of product can be excluded from a recall.

Sample size methodology for product or environmental sampling plans must be standardized. The agency should provide guidance on what is co nsidered acceptable.

Pulsed Field Gel Electrophoresis (PFGE) Methods

It would be much more efficient if PFGE methods were standardi zed with respect to the type and number of enzymes used to prepare the DNA sample.

Government – Industry Cooperation

Government and industry cooperation and increased communicat on can shorten investigation time and promote a more accurate and timely recall announcement. All parties involved in an investigation must coordinate efforts in orc er to have an effective and accurate outcome. The primary objective must be to protect he public health and not to punish the industry.

As mentioned above, the development and use of a defined proto col will move the Federal agencies and the industry to a common starting point. Th e industry will be able to use the defined expectations in their mock recall processes so hey are able to react more quickly and accurately in critical situations.

Members of the Investigation Teams should have received traini g in principles of relationship building. The HACCP Technical Training Manual (1997), Module 11 is on building effective business relationships. Reviewing and followi ng relationship-building materials such as the '5 Principles of Relationship Building' duri ng the investigation process will help build the rapport between the Federal Investiga ion Team and industry.

The protocol should define roles and responsibilities as well as a peal protocols. In critical events such as outbreak investigations, there will be disa reements that should not be allowed to become confrontational. Disagreements are health y and are essential in identifying pertinent and factual information. The Investigation T eams work under the direction of Washington leadership. Including the staff from Wa shington in all major briefings with an establishment will bring continuity to the proc ss.

The Investigation Team should provide complete answers to que stions raised by the company, especially when answers to those questions may be pe tinent to protecting the public. Information known to the Investigation Team that may a ssist the industry in identifying a source or cause of the contamination must be share l in a timely manner.

Efficiency

The Federal Investigation Team does not always appear to be co ordinating their efforts. Coordination is imperative in order to assure an efficient, accura e and timely investigation without redundant activities. A coordinated effort s best accomplished by following a defined procedure, which has been previously share with the Industry. In critical situations such as outbreak investigations, both industry nd agency resources are spread thin. By engaging the specific industry being investigate l early, even if only through trade associations, the investigation time frame could be shortened.

Investigation Summary

Any company that is being investigated should receive a detailed report summarizing findings, even if the source of the outbreak is found elsewhere. T ıe findings should include a discussion of conclusions drawn from any data collecte l. Any company that is investigated but found not to be a source plant should be allowed to correct any deviations identified by the team under normal and routine corre(tive action procedures. Time lines should not be accelerated beyond normal practices.

The Investigation Team must be accountable and be able to supp ›rt its conclusions with scientific 'objective' facts. All conclusions must standup to scie1 .tific rigor rather than reflect reliance on the precautionary principle. All conclusions n ust be based on sound objective evidence that is not biased by outside influences such a › the media.

Conclusion

FSIS is to be complimented for its work in numerous epidemiolc gical investigations related to food recalls to date. We realize the complexity of the i ıvestigation process and know that FSIS is looking to protect public health. But, the proc ›ss can be improved. With enhanced communication between industry and FSIS and a more defined investigation process, public health could be protected further.

The turkey industry is dedicated to producing safe and wholeson e products. Whenever a turkey product is implicated in a food recall, we want to remedy he situation as fast as possible by accurately identifying and removing the unsafe prodı ct from the market. We believe the recommendations presented here are the next step in ıdvancing public health. We hope you will consider them as you look to the future.

Thank you for this opportunity to comment on "Using Applied E pidemiology and Other Tools to Protect Public Health."

Sincerely,

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Government Affairs Coordinatory