SAFE FOOD COALITION

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Safe Food Coalition Again Urges USDA Secretary Vilsack to Change Food Safety Policy

FSIS Confirms E. coli Traceback Loophole

On Tuesday, members of the Safe Food Coalition delivered a letter to Secretary of Agriculture Tom Vilsack, urging an immediate change in the Food Safety and Inspection Service's (FSIS) *E. coli* O157:H7 traceback policy. The request follows a similar letter delivered in April 2009, which recommended that the FSIS trace meat contamination back to the source, and remove all affected product from commerce. While the agency held an informational meeting regarding their process, there has been no policy response to this dangerous loophole in agency procedure.

The letter follows confirmation from FSIS officials that the agency only conducts a complete traceback when a foodborne illness outbreak indicates that *E. coli 0157:H7* adulterated product actually entered commerce. It does not take these same steps when its routine microbiological testing program for *E. coli* O157:H7 detects the pathogen in ground product at a federally inspected facility or at retail. Since FSIS's routine testing for E. coli typically finds the pathogen 40 times a year, this lack of action on behalf of the government agency misses critical opportunities to prevent illness and unnecessarily threatens public health.

Consumer groups have been urging the USDA to change its meat-tracing activities when it finds contamination in a finished product like ground beef. Because contamination starts before beef is ground into hamburger – often at a different company's facility – the agency should investigate back in the supply chain to find the original source of the problem. Without doing this, USDA fails to prevent even more contaminated product from reaching consumers.

The agency regularly does not identify the actual source of contamination unless consumers get sick or die. It is time for USDA to take the threat of contaminated ground beef seriously and update its policies.

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See attached letter and backgrounder for more information.

Members of the Safe Food Coalition who signed onto the letter include: Center for Foodborne Illness Research & Prevention, Consumer Federation of America, Consumers Union, Food & Water Watch, Government Accountability Project, National Consumers League, Safe Tables Our Priority, and United Food & Commercial Workers International Union.

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January 26, 2010

The Honorable Tom Vilsack
Secretary of Agriculture
1400 Independence Avenue
Washington, DC 20520

Dear Mr. Secretary:

The undersigned organizations are writing to repeat the request we made to you in an April 2009 letter to change the Food Safety and Inspection Service's *E. coli* O157:H7 traceback policy. We continue to believe "that it is critical for the agency to prevent human illness by tracing adulterated products back to the source and removing all affected product from commerce." While the agency did hold an informational meeting, there has been no policy response to our concerns.

FSIS officials have confirmed that the agency only conducts the full complement of steps to trace back to the source of raw materials when a foodborne illness outbreak indicates that *E. coli* O157:H7-adulterated product entered commerce. It does not take these same steps when its routine microbiological testing program for *E. coli* O157:H7 detects the pathogen in ground product at a federally-inspected facility or at retail. There is no scientific basis for following one policy when *E. coli* O157:H7 adulteration results in an illness and another when FSIS testing finds *E. coli* O157:H7 adulteration before it has had the opportunity to cause an illness. The difference in policy unnecessarily threatens public health. We believe that FSIS should follow the same procedure when it learns from its routine testing program that *E. coli* O157:H7-adulterated product entered the production or distribution chain as it does in response to *E. coli* O157:H7-related illness.

Further, under current policy, FSIS *will not* take all necessary steps even when the source of the problem is readily identifiable and officials know that additional product that must be assumed to be adulterated is in the production and distribution chain. For example, a small grinding facility may purchase and re-grind a small portion of a given slaughterhouse's production lot of beef while the rest is purchased by other facilities. FSIS testing may then reveal adulteration at the single grinding facility. Under current FSIS policy, the tested grinder is prohibited from selling any of the product. However, it must be assumed that the other meat from the same lot sold to other grinders is adulterated as well. Yet, FSIS makes no attempt to identify other firms that received portions of the original product or to inform those firms that they may have received adulterated product. With no notification from FSIS, the other grinding establishments will continue to use and sell ground beef made from the same production lot as the tested, adulterated material, needlessly exposing consumers to illness and death.

On average, FSIS' routine testing program for *E. coli* O157:H7-adulterated product in federally-inspected or retail facilities finds the pathogen 40 times every year. Current policy ensures the

USDA is passing up 40 opportunities each year to try to prevent foodborne illness tragedies. This failure to act is not consistent with a preventive, public health-based program and threatens consumers on a daily basis.

We, therefore, believe that FSIS should follow the same procedure when it learns of adulterated product in the production or distribution chain from its routine *E. coli* O157:H7 testing program as it does in response to an illness. We strongly urge you to direct the Food Safety and Inspection Service to begin immediately to trace all parts of any lot of product when a portion of the lot is found to be adulterated with *E. coli* O157:H7, and take all other necessary tracing steps at source slaughterhouses to prevent future *E. coli* adulteration, as is routinely done in response to illnesses. We have attached a memo that provides the details and identifies specific problems with the policy.

We look forward to hearing from you about how the agency can address this important public health issue. If you have any questions about this issue or letter, please contact Felicia Nestor, Senior Policy Analyst for Food & Water Watch at (201) 330-1618.

Sincerely,

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Food & Water Watch

Carol Tucker-Foreman
Founder, Safe Food Coalition

Pat Buck
Center for Foodborne Illness, Research & Prevention

Chris Waldrop
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Sally Greenberg
National Consumers League

Nancy Donley
Safe Tables Our Priority

Steven M. Powell
United Food & Commercial Workers International Union

Background Information on FSIS *E. coli* 0157:H7 Traceback Policies

Attachment to January 26, 2010 Safe Food Coalition letter to Secretary Vilsack

In April 2009, consumer organizations urged Agriculture Secretary Vilsack to change the Food Safety and Inspection Service's *E. coli* O157:H7 traceback policy to better protect the public health. While the agency did hold informational meetings on the topic, there has been no policy response to these concerns. Since April, FSIS officials have confirmed that the agency currently conducts the full complement of traceback steps *only* when a foodborne illness outbreak indicates that adulterated product entered commerce. There is no scientific basis for following one policy when *E. coli* O157:H7 adulteration results in an illness and another when FSIS testing finds the adulteration before it has had the opportunity to cause an illness. The difference in policy unnecessarily threatens public health. FSIS should follow the same procedure when it learns from its routine testing program that *E. coli* O157:H7-adulterated product entered the stream of commerce as it does in response to an *E. coli*-related illness.

In the majority of cases, the facility where FSIS finds the adulterated product is neither the source of the original adulteration nor the only location to which the original adulterated product was shipped. More than 75 percent of the facilities at which FSIS discovers adulteration are grinders and other downstream processors that are unlikely to be the originators of the adulteration because they are not slaughterhouses. Most grinders are very small plants and do not use the entire lot created and tested at the source slaughterhouse. Consequently, in most cases, FSIS would need to identify the source slaughterhouse to identify the entire original adulterated lot and trace forward to all recipients of associated, potentially adulterated product so that it could be removed from commerce.

Same problem, different policy

A positive *E. coli* 0157:H7 finding in commerce, whether discovered through the FSIS regulatory testing program or during the course of an epidemiological investigation, indicates the same potentially lethal public health threat and therefore should be met with the same response. Under current FSIS policy, however, there is only one action the agency takes in both situations: ensuring that all associated beef products located at or used by the grinding or processing facility at which the positive test was identified, will be prevented from continuing in commerce. (In the event that the grinder/processor already shipped some adulterated product, the agency also mandates a trace-forward inquiry so that it can be recalled from all subsequent purchasers).

During a foodborne illness outbreak investigation (and not after the discovery of contamination through regulatory sampling[1]) the agency takes additional important actions.[2]

1. Investigate, if necessary, to determine the actual source of the adulteration;
   e.g. test source materials, if available, at the grinder to conclusively link one slaughterhouse to the adulterated product. (*In response to a routine positive the agency identifies all possible sources - all suppliers that contributed any beef to the*

[1] FSIS Directive 10, 010.1 Rev.2 Chapter 3.
[2] As identified by FSIS officials at the FDA-FSIS Public Meeting on Traceability, December 8-10, 2009.

lot determined by FSIS to be positive - but does not seek to identify the actual source of adulteration. All follow-up testing, done by the agency at slaughterhouses that contributed supplies to the lot found to be positive, is done on current production, not the specific production lots that were incorporated into the adulterated product).

2. Investigate to determine the full extent of the original adulteration*;*
e.g. Have an Enforcement, Investigation, and Analysis Officer (EIAO), scrutinize the source slaughterhouse's food safety and testing programs to determine if they were adequate for determining the extent of original adulteration, or whether additional products produced at that location should also be considered to be adulterated (*In response to a routine positive, in-plant inspectors review the plant's self-policing records to determine if the plant followed its own food safety plans; in some cases, EIAO's review whether the plans, themselves, are valid, but no attempt is made to identify and remove additional product associated with the specific production lot that tested positive*).

3. Consider whether primals or other intact products (e.g. steaks and roasts) produced during the relevant time period should also be considered adulterated;

4. Trace forward from the source slaughterhouse, and require that all recipients of potentially adulterated products in the distribution chain recall any associated products;

Most grinders do not use the full lot (the originally-contaminated lot) produced by the slaughterhouse, so in most cases when FSIS discovers adulteration at a grinder, other grinders received additional portions of that originally contaminated lot. *(In the case of a routine positive, these additional grinders are not identified or informed they are producing potentially deadly products.*)

5. Mandate changes in the source slaughterhouse's food safety plan in order to prevent future adulteration of product.

These actions are important to protect the public health following a foodborne illness outbreak. However these same actions should be conducted to prevent illnesses from occurring in the first place, following the identification of a positive test result for *E. coli* O157:H7 during routine FSIS sampling and testing.

It should be noted that a routine positive for *E. coli* O157:H7 discovered during FSIS sampling indicates the same systemic failure as an outbreak positive: beef became contaminated with *E. coli* O157:H7 during the slaughter process, the system of slaughterhouse interventions did not eliminate the problem, and testing schemes did not prevent it from entering commerce. Waiting for an outbreak is waiting too long

FSIS has committed to take these important actions in the event of an outbreak investigation. However, the agency often cannot identify the source slaughterhouse in an outbreak situation because the trail has gone cold. Even when a grinder can be identified through an epidemiological

investigation, raw product is often no longer available at the grinder/processor for testing necessary to identify a single supplier slaughterhouse. According to FSIS' recall website, of the 30 recalls resulting from epidemiological investigations since 2004, a source slaughterhouse was identified in only six cases (20 percent). If FSIS is unable to identify the source of the adulterated product, the agency cannot conduct the important activities listed above to protect the public health.

Yet when FSIS discovers a positive for *E. coli* O157:H7 during routine testing and the agency is presented with the perfect opportunity to identify the source of the adulteration, agency policy is to not conduct these important activities that could prevent further adulterated product from reaching consumers. Under current policy, FSIS will not take all necessary steps even when officials know that additional product that must be assumed to be adulterated is in commerce and that the source of the problem is readily identifiable. The counterproductive nature of this policy is clear. On average, FSIS' testing program reveals that *E. coli* O157:H7-adulterated product is in commerce 40 times every year. That means current policy ensures there will be 40 missed opportunities to try to prevent foodborne illness tragedies. This failure to act is not consistent with a preventive, public health-based program.

Agency officials have made clear, that even in cases when the source plant is unmistakable, they will not take the full complement of actions necessary to protect the public health. But identification of, and action at, the slaughter establishment that was the source of adulteration is crucial in removing all adulterated beef from commerce before it injures consumers. This can be most easily accomplished when adulterated product is found through the agency's routine testing program and before the product enters commerce.

For example, a small grinding facility may purchase and regrind a small portion of a full, original lot of beef produced by a slaughterhouse. The rest of the lot goes to other facilities. FSIS testing may then reveal adulteration at the grinding facility. Under current FSIS policy, the tested grinder is prohibited from selling any of the product. However, it is possible and even likely that other meat from the same lot was also adulterated with *E. coli* O157:H7 and that that adulterated meat was sold to another grinder for use in ground product. FSIS makes no attempt to identify other firms that received portions of the original product, nor does the agency inform those firms that they may have received adulterated product. With no notification from FSIS, the other grinding establishments will continue to use and sell ground beef made from the same source as the adulterated material, needlessly exposing consumers to illness and death.

An unscientific assumption that threatens public health

This unscientific, bifurcated policy unnecessarily threatens public health. In fact, agency officials recently acknowledged that in 2008 and 2009, the agency's data analysis office indicated a link 23 times between a routine positive and positives found in illness outbreaks or clusters by the Centers for Disease Control and Prevention. Since the agency's analysis typically identifies all associations within 90 days before and after a routine positive, it does not indicate whether, or how many times, the failure to aggressively investigate in response to a routine positive may have resulted in human illness. However, it is reasonable to assume, at least, that this policy has unnecessarily allowed adulterated beef products to remain in commerce. In response to our

request, the agency further analyzed its database to determine whether, and in how many cases, the routine positive preceded illnesses linked to the same product. The agency would not share its analysis with consumer groups. Frankly, we are surprised that the agency had not done such analysis prior to our suggestion.

Officials confirmed that the basis for this dual policy is an assumption that the system of government and industry controls is effective in preventing "widespread" *E. coli* O157:H7 contamination. Consumer groups have been given no scientific basis for this assumption. Additionally, the mere presence of an *E. coli* O157:H7 positive is proof that this assumption did not hold true in that particular set of circumstances.

The majority of beef trim used to make ground beef is approved by FSIS based on a sampling program (N-60 sampling) that was designed by industry to "facilitate the movement of perishable product."[3] Both the agency and industry admit that this sampling method, even if scrupulously conducted, is capable of detecting only "highly contaminated" lots of product. The agency has further admitted that industry's use of N-60 is "inconsistent." For these and other reasons, Representative Rosa DeLauro requested in November of this year that USDA's Office of Inspector General review the agency's reliance on N-60 sampling as a basis for its seal of approval. It should be noted that consumer groups were neither consulted nor informed of the agency's use of this sampling program until we learned about it from whistleblowers and vigorously sought more information from agency officials.

A positive *E. coli* O157:H7 finding at a grinder is evidence that the food safety system did not prevent contamination from occurring. That finding should warrant further investigation and action by FSIS to assure that all adulterated product is removed from commerce in order to prevent illnesses from occurring. FSIS' regulatory program should not be designed to only prevent "widespread" contamination of ground beef. A truly preventive approach to public health should be focused on preventing both illness and contamination from occurring in the first place.

FSIS should change its current policy and begin immediately to trace all parts of any lot of product when a portion of it is found to be adulterated with *E. coli* O157:H7. The agency should then take the other necessary tracing steps at source slaughterhouses to prevent future *E. coli* O157:H7 adulteration, as is routinely done in response to illnesses.

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[3] Rosemary Mucklow quoted in "New investigations of school lunches and N-60 sampling sought following latest *E. coli* recall." Amber Healy. *Food Chemical News.* November 16, 2009. Vol. 51, Issue 37.