The National Council of Chain Restaurants
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FSIS Docket Clerk
Docket No. 97-068N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-068N
97-068N-55
Terrie M. Dort

Re: Docket 97-068N

Dear Sir or Madam:

These comments are submitted on behalf of the National Council of Chain Restaurants (NCCR) in response to the Food Safety and Inspection Service's (FSIS) Notice entitled "Beef Products Contaminated with Escherichia Coli O157:H7."

NCCR represents virtually all quick service restaurant chains. Taken as a whole, our members are the largest purchaser of ground beef in the United States. Moreover, we serve literally millions of hamburgers and similar products to our customers every day. Thus, there is no more interested stakeholder in the safety of these products. In this regard, we support the FSIS clarification concerning the legal status of beef trimmings contaminated with E. coli O157:H7 (hereinafter O157:H7).

However, we respectfully submit that the clarification, by itself, is only a partial response to this pathogen. To better enhance food safety, many of our members are now actively supporting a proactive plan focusing on carcass testing as a verification of slaughter intervention technologies. This plan, presented by representatives of the packing and grinding industry at the March 8, 1999 public hearing, is designed to better identify and control the pathogen before grinding.

We understand that the protocol for a pilot testing program will be submitted to the agency shortly and that the pilot can be completed in approximately 180 days. We hope that FSIS will work closely with the industry on this pilot test.

Based on our understanding of the carcass testing plan, we are confident that a carcass testing approach will be at least as effective, if not better than, any current regulatory approach. If that proves to be the case, we request that FSIS revise its Directive on O157:H7 testing (Directive 10,101.1) to expressly recognize a carcass testing program in lieu of random agency testing of products further downstream in the distribution chain.

In the meantime, we strongly request that the current status quo regarding testing of trimmings be maintained.

As we understand the agency's position, a positive finding of O157:H7 would render adulterated both ground beef and product intended for use in ground beef -- beef trimmings -- unless the product is further processed (presumably under inspection) to destroy the pathogen.[1] The single most important practical question raised by this legal determination is what product is implicated by a positive finding for O157:H7 in beef trimmings.

Traditionally, FSIS has left the answer to the company conducting the sampling to determine the scope of product that sample represented. This was reaffirmed in both the original and revised draft Question and Answer (Q & A) documents. In the Federal Register Notice, FSIS expressly asked for comments on its sampling program and the scope of products deemed adulterated. For the reasons discussed below, we respectfully submit that FSIS should officially recognize that the company doing the sampling would determine the extent of product represented by the sample.

A. <u>NCCR Members' Dedication to Viable Testing</u>

As noted above, NCCR members are committed to a sound, scientifically based food safety program, which includes controls for O157:H7. However, this organism represents a challenge because it is infrequently found. Indeed, in the four plus years which the agency has conducted tests for the organism in ground beef, it has been discovered in only a handful of the literally thousands of agency samples of ground beef.

In light of the above, simple testing for the organism in ground product cannot provide adequate assurance that the pathogen is not present. As FSIS stated in its Guidance for Beef Grinders: "Results from microbiological testing can provide only a limited measure

of assurance that the pathogen is not present. Total reliance upon sampling is inadequate because <u>E. coli</u> O157:H7, if present, is present sporadically and at extremely low levels."

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[1] We note that the agency would also deem injected beef and other non-intact products as adulterated if they test positive for O157:H7. We respectfully question whether there is adequate data at this time to support such a conclusion. We concur with the recommendation of the National Advisory Committee on Microbiological Criteria for Foods that a risk assessment should be performed and completed before ruling on these products.

B. Benefits of Testing Trimmings versus Finished Product

Given the infrequency with which O157:H7 appears, simple testing of product is not a "silver bullet." Thus, testing only represents one component of a total program; a component which should be used in a manner to achieve the maximum possible benefit.

In this regard, the majority of our members require their supplier grinders to conduct a sampling program for the raw materials of ground beef -- the trimmings -- rather than finished product. This is because of the greater benefits achieved.

First, it provides a high degree of testing per pound of production. Although our members have different sampling programs for their suppliers, the general rule is to take at least one sample per 2,000 pound combo bin of trimmings received (which are then composited by sub-lot). Since a large grinder would run approximately 20,000 pounds (10 combos) per hour, one sample per bin equates to one sample per six minutes of ground beef production -- as good as or better than the most rigorous finished product sampling program.

Second, it is more practical to perform. Some of our members require fresh hamburgers. Since it takes two days to run a sample to presumptive and several days after that to confirm, testing finished product is simply not viable. Whereas, it is possible for a grinder to retain a load of trimmings for several days and still provide fresh finished product.

Third, it provides valuable information not only to the grinder but to the slaughterer. By testing units before they are commingled, the grinder knows the source of the trimmings and can provide the analytical results to the slaughterer for feedback to improve its system.

Fourth, it minimizes the economic consequences of a positive finding. Although food safety should never be compromised for economic reasons, if two systems are equally effective and one is less costly, it only makes sense that the less costly system be used. As noted above, we submit that testing of trimmings is at least as effective as testing finished product. Moreover, it has the benefit of limiting the amount of product at issue. Therefore, it is the better approach.

C. Agency Treatment of Trimmings

As an initial matter, we wish to note that FSIS has recognized the value of testing trimmings in lieu of finished product testing. Under FSIS Directive 10,010.1, one of the

approved ways an establishment may "opt out" of the FSIS random testing program for finished product is to test incoming ingredients, i.e., trimmings, for O157:H7. In its

Guidance for Grinders, FSIS again supports the use of a microbiological testing program for trimmings. See Section II, Receiving Meat. Moreover, we always understood that the establishment is free to define the "lot" that the sample represented.

When the agency first published the Notice, there was confusion within the industry as to whether the clarification somehow changed the agency's treatment of the scope of product covered by the sample. We were grateful when the agency promptly issued its draft Q & A documents mentioned above to clarify that its treatment had not changed -- that establishments are free to designate what product is represented by the sample. Indeed, continuation of this policy is essential to improve food safety.

D. Scientific Evidence in Support of Agency's Treatment

As discussed above, testing of trimmings represents a practical means of testing product. Moreover, the current lotting scheme is consistent with public health.

In the past several years, our members have conducted thousands of analyses on trimmings. To the best of our knowledge, there is no statistical correlation between a positive finding in one combo and a positive finding in another -- even if taken from the same load. Moreover, we understand the agency will be receiving data from two companies regarding finished product testing. These data will show that a positive finding in one sublot of combos did not result in any contaminated finished product when the remainder of the load was used. Admittedly, such data may not be statistically significant. Nevertheless, the absence of contamination is persuasive; especially when one set of data represents finished product sampling at the rate of one sample every fifteen minutes.

E. Sound Public Policy Supports Current Treatment

As shown above, analyzing trimmings is a valid means to detect O157:H7 before it is incorporated into ground beef. Moreover, it is an economically feasible approach. Thus, we strongly encourage FSIS to continue its policy concerning what product is represented by a sample.

There initially was some concern, by those outside the agency, that FSIS intended to expand the product covered by a single sample, up to and including all product produced at the slaughtering facility from clean-up to clean-up. In light of those concerns, we would briefly like to comment on why such an expansion would prove a disservice to food safety and industry initiatives.

Sampling combos of trimmings is at least as good as sampling finished product in terms of the amount of product actually sampled. But testing of trimmings is better for the other benefits it provides: the identification of source; the control prior to production and distribution; and the limitation on the amount involved. Expansion of the amount of the product represented by a single sample systematically negates each one of these benefits.

Identification of source would not be used for improving slaughter controls but for regulatory action, principally recalls. Control prior to distribution would be lost since not all trimmings

would be tested at the same time, thereby making it possible for the last test performed by one customer to dictate a recall of all product, even product that previously had tested negative by every other customer. Finally, the limitation on the economic consequences of a single positive would be shattered. A large slaughterer's single day's production, especially when blended with other product at its customers, could represent literally tens of millions of pounds. Such a consequence is simply insupportable by the scientific data summarized above.

In short, expansion would not only negate the benefits, it would make sampling of trimmings the least viable alternative and thereby eliminate its use. It simply is not sound public policy to discourage a viable sampling scheme for O157:H7, especially here, when there is no scientific evidence to justify such agency action.

Conclusion

NCCR appreciates the opportunity to express its views on this important issue. We will be continuing our support of pro-active measures. Meanwhile, we stand ready to provide any assistance the agency may desire to further enhance and improve food safety.

Respectfully submitted,

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President