(3)

00-022N
00-022N-3
Dr. Patricia Verduin

December 6, 2002

FSIS DOCKET CLERK
Docket No. 00-022N
U.S. Department of Agriculture FSIS
Room 102, Cotton Annex
300 12th Street, SW
Washington, D.C. 20250-3700

RE: *E.coli* O157:H7 Contamination of Beef Products [Docket No. 00-022N]; Comments to Federal Register notice, October 7, 2002

ConAgra Foods, Inc. is a food company with approximately $20 billion in sales, and over 67,000 employees. ConAgra Foods is deeply interested in the above-referenced Federal Register notice regarding *E.coli* O157:H7 Contamination of Beef Products, and appreciates the opportunity to comment.

UNILATERAL RULEMAKING

ConAgra Foods agrees with USDA that *E.coli* O157:H7 needs to be eradicated. However, we are concerned that the approach taken by USDA in this document will not assist in achieving that goal.

FSIS indicates in the opening paragraph of the above-referenced Notice that the purpose of the Notice is to inform beef manufacturers of its views regarding HACCP, CCP's and *E.coli* (hereinafter "Views"). FSIS bases its Views on "new scientific data". Based on this alleged "new scientific data", FSIS is attempting to implement another unilateral policy with respect to *E.coli* O157:H7. In this document, FSIS takes the position that "[n]ew information regarding the fact that *E.coli* O157:H7 is more prevalent than was previously thought is ... a change ..." which would trigger a reassessment of a plant's HACCP plan. [Fed.Reg. Vol.67, No.194, 10/7/02, pg 62326] However, FSIS fails in this document to support the hypothesis that *E.coli* is more prevalent than previously thought, and fails to give a rational explanation as to the reason, even if the presumption is true, that this "new thinking" should trigger regulatory activity.

In the past ten years, the USDA has issued two other unilateral policies with respect to *E.coli* O157:H7, neither of which went through proper administrative procedures in order to become law. The first, as the USDA indicates in its current Views, is that "[i]n 1994, FSIS notified the public that raw ground beef contaminated with *E.coli* O157:H7 is adulterated under the FMIA unless the ground beef is further processed to destroy this pathogen." [Ibid.]

Again, in January of 1999, FSIS published another "policy statement" that "explained the Agency's policy governing beef products that contain *E.coli* O157:H7." [Ibid.] Regardless of all of the verbiage that was used in that unilateral policy statement, the bottom line is that the USDA took the position that "trimmings", and any other intact cuts of muscle that were further processed into non-intact product, were considered *a priori* adulterated if *E.coli* O157:H7 was found in those products.

USDA's Views go on for several paragraphs to discuss the public hearings and documents related to the above-referenced unilateral policies. What the USDA fails to mention, however, are the extensive discussions between the USDA and industry in 1999 in an attempt to come to a practical consensus on how best to protect the public health. There is no doubt that *E.coli* O157:H7 needs to be eradicated, and the public needs to be protected against this particular pathogen. However, when the January 1999 policy was issued, USDA, through discussions with industry, realized that what it was asking was not practically possible, and that industry was very willing to work with the government to minimize the *E.coli* risk. A series of Questions and Answers were drafted by USDA and adopted by Industry. Policies were put into place to better handle this issue. However, the current View ignores the consensus and the work done at that time, and, in fact, pretends it never happened.

A HIGHER *E.COLI* PRESENCE OR MORE SENSITIVE TESTING?

ConAgra Foods does not argue with the USDA's position that *E.coli* is a serious, life-threatening problem. Moreover, ConAgra Foods does not disagree with FSIS when it states that current estimates of illnesses show that previous CDC estimates for illnesses associated with *E.coli* O157:H7 were low compared to the actual incident rate.

However, what the USDA fails to tell the public is that *E.coli* O157:H7 is also prevalent in several common mediums, including fresh produce and water. In fact, CDC illness reports indicate a decline in *E.coli* O157:H7 illnesses due to beef consumption between 2000 and 2001, years for which the most recent numbers are available. According to CDC's Website, in 2000 there were 1564 total *E.coli* O157:H7 illnesses, 971 of which were attributable to beef. In 2001 the total was a little more than half of the previous year's, at 925, with beef illnesses down to almost 10 % of the previous year's, or 127. These numbers demonstrate that the prevalence of the bug is decreasing in beef, not increasing. In addition, illness caused by other sources of the bug are largely ignored by the government as these industries are not nearly as regulated as the beef industry with respect to eliminating this bug. And *E.coli* O157:H7 on produce is more dangerous than

in beef because the produce is normally not heated to 160°, nor does washing eliminate the bug.

Moreover, the USDA indicates in these Views that FSIS began using a new testing method for *E.coli* O157:H7 in September of 1999. The USDA indicates that this method is approximately four times more sensitive than previous methods. [Id. at 62326-27] Yet, even with the new testing methods, the prevalence of *E.coli* O157:H7 in raw ground beef samples tested was still less than 1%. According to the USDA the increase in prevalence is from .149% using the old method, to .797% with the new method. Incredibly, however, the USDA states this increase in test results indicates an increase of *E.coli* prevalence even though the USDA states in the same paragraph that "the low rate of positive findings in the past may have had more to do with the sensitivity of the method and size of the sample being used than with the rarity of the pathogen". [Id. at 62327] Clearly the USDA does not even agree with the hypothesis underpinning these Views that *E.coli* prevalence is higher now.

Interestingly enough, the USDA sidesteps its new test method results in favor of anecdotal information from its inspection program personnel, and IDV reviews. Based on this anecdotal evidence, "FSIS believes that most establishments have not taken the data discussed above into account in their HACCP analysis...." [Id. at 62328] Therefore, the Agency has issued this notice "informing the public of its views concerning the implications of *E.coli* O157:H7 data discussed above." Again – these are simply the USDA's ***views***, not a policy based on sound science, or a proposed regulation based on fact.

Cattle Studies

The USDA discusses several studies of various types of cattle in various phases of production with respect to *E.coli*. The USDA states that three "multi-state studies reported that the *apparent* prevalence of feedlots containing one or more infected cattle. Even if one animal in a herd was found positive for *E.coli* O157:H7, the herd was considered positive for *E.coli* O157:H7." [Id. at 62327] Is considering an entire herd positive for *E.coli* if only one positive is found an accurate, scientific measure of prevalence of the bug?

Furthermore, the statistics should not surprise anyone. It has been common knowledge for years that *E.coli* bacteria live in the intestinal tract of mammals. The fact that a specific strain of *E.coli*, particularly O157:H7, would also be found in the intestinal tracts in cattle in feedlots would be a logical conclusion. Moreover, the USDA states that "these studies did not find many animals within a specific herd to be positive for *E.coli* O157:H7", [Ibid.], which suggests that *E.coli* prevalence may not, in fact, be very high today.

There is no mystery here – *E.coli* has been and probably will continue to be found in the intestines of mammals. Special strains that mutate, like O157:H7, need to be controlled, and consumers of products that potentially contain *E.coli* O157:H7 need to be

diligent and alert, but this does not mean that animals that carry this bug, or the meat they produce, are illegal.

While the USDA cites several studies that have been performed in the last two or three years, they do not compare these results to studies that were done in the early 1990's to test the hypothesis that *E.coli* O157:H7 has truly increased in the beef population. As noted above, FSIS stated that new testing methods indicate the low incidence of *E.coli* was due to inferior test methods, not necessarily due to better processing techniques. In addition, when discussing the public meeting of February 29, 2000, and the preliminary results of the draft risk assessment, all FSIS can do is give their "best estimates" of the prevalence of *E.coli* O157:H7. [Ibid.]

However, instead of focusing on the question of prevalence of *E.coli* O157:H7, the USDA should instead be working on the prevention of *E.coli* in the feedlots and farms, where the *E.coli* is spread. USDA's continued focus on slaughter and grinding operations is an attempt to cure the patient once he is already sick, instead of trying to prevent the illness to begin with, which will never eradicate the problem.

Log Reductions

The USDA admits that it does not have information about the level of log reduction for *E.coli* O157:H7 in specific slaughter plants. [Ibid.] USDA indicates that if validated interventions being used result in more than a 1.5 log10 reduction, **then the actual prevalence of *E.coli* O157:H7 will be lower than what USDA has indicated in the preliminary risk assessment**. FSIS indicates that it is still reviewing the draft risk assessment, and may further modify its assessments in the future. [Id. at 52328] What this means is that the USDA is basing its Views, and proposing regulatory action, when it still does not have a good handle on how prevalent *E.coli* O157:H7 really is.

FSIS does discuss some studies done in the early 1990's as a basis for its *belief* that the prevalence of *E.coli* O157:H7 has increased. FSIS indicates that in a 1992-93 baseline survey, .2% of carcasses tested positive with *E.coli* O157:H7 (which is coincidentally very close to the .149% of *E.coli* O157:H7 positive test results found prior to the new testing method being implemented in 1999). But not only were the testing methods ineffective compared to modern testing methods, prior to the Jack-in-the-Box deaths due to *E.coli* O157:H7 in 1994, the USDA was not focusing on *E.coli* O157:H7 at all. Rather, the testing was part of an overall pathogen testing regime that was being done as a perfunctory analysis, and not pursuant to HACCP (which had not even been implemented yet), nor any kind of organized and validated testing procedures.

Consequently, the statement by FSIS that "*E.coli* O157:H7 testing programs since FSIS has begin using its new testing method in certain research studies discussed above provide evidence that *E.coli* O157:H7 is more prevalent than was thought before these data became available" is absolutely false. Furthermore, because USDA bases its statement, "this pathogen may be a hazard that is reasonably likely to occur at all stages of handling raw beef products" on that falsehood, it is equally unsupportable. For FSIS

to go on to conclude that the above discussed information requires an establishment to reassess their HACCP plans is equally unsupported. *E.coli* O157:H7 has not been proven to be more prevalent than was thought before this View was published.

REQUESTED INDUSTRY ACTIONS

FSIS indicates that "[t]his document addresses only the need for HACCP plan reassessment." [Id. at 62329] However, FSIS clearly indicates in the pages before this statement, and the pages after, that it views *E.coli* O157:H7 as a hazard reasonably likely to occur in any production plant manufacturing most types of beef products. Furthermore, those facilities are at risk of being shutdown if they have not reassessed their HACCP plans to make it clear that *E.coli* O157:H7 is a hazard reasonably likely to occur, and has CCP's place to deal with the issue. [Id. at 62331] This position taken by FSIS has no basis in law or fact.

FSIS sets up a Catch-22 with respect to HACCP and *E.coli* O157:H7. FSIS indicates that companies should build into their HACCP plans CCP's that are validated and designed to eliminate or reduce the risk of *E.coli* O157:H7. FSIS goes on to say that "if such establishments have controls in place to address *E.coli* O157:H7 specifically, they cannot conclude that the pathogen is not a hazard reasonably likely to occur in the absence of these controls." [Id. at 62329] This is the proverbial "rock and a hard place" dilemma for industry: FSIS says a company will be violating the law if it does not put these CCP's in place, and on the other hand says that if CCP's are in place then the company is implicitly admitting that *E.coli* is a hazard reasonably likely to occur, which triggers the statutory requirement that CCP's must be in place!

Furthermore, the USDA seems to be implying in this View that *E.coli* O157:H7 be introduced into the plant environment in order to prove that the validation measures put into place actually work. For example, FSIS states that "[u]ntil establishments demonstrate that the CCP achieves the anticipated effect under actual in-plant conditions, effectiveness of the CCP is theoretical and the plant is not validated." [Ibid.] However, without actually introducing *E.coli* O157:H7 into the environment, how can "actual" tests be achieved?

Moreover, FSIS discusses the "fact" that there are several intervention measures that plants can take to eliminate, or greatly reduce, the risk of *E.coli* O157:H7 in finished raw products. However, what the FSIS fails to mention is that FSIS required ConAgra Foods to put into place a few of these interventions on a test basis after the recall this summer, and two of those interventions failed. Therefore, ConAgra Foods respectfully requests that FSIS be more specific about the kinds of interventions that it requires, and also provide the validation that FSIS has done to validate that these techniques actually work to reduce *E.coli* O157:H7.

These intervention techniques are particularly important for ConAgra Foods in their grinding operations, and, again, FSIS indicates that there are interventions available to grinders, but fails to mention any of these interventions. The Guidance document

referenced in the Notice is about process flow and record keeping and contains little real guidance on preventive techniques. Yet these are really what industry needs.

The USDA seems to indicate that grinders will be held to the same standards as slaughterers with respect to *E.coli* issues. However, as a practical matter, grinders must rely on slaughterers to provide them with true and accurate test results with respect to *E.coli* O157:H7, and cannot be expected to implement expensive, and untested procedures to reduce the risk of *E.coli* O157:H7 in product that is received from slaughterers who are already required by law to minimize pathogens. While FSIS pays lip service to prerequisite programs of this type, FSIS goes on to say that grinders need to "ensure their effectiveness and should take appropriate corrective actions when they determine that the prerequisite programs have failed to prevent contamination or adulteration of product." [Id. at 62330] Moreover, USDA states that it is the combination of the sanitation SOP's, HACCP Plans and prerequisite programs that will satisfy USDA, not just the prerequisite programs. [Ibid.]

As far as the grinders are concerned, *E.coli* O157:H7 is a hazard ***not*** reasonably likely to occur in their facilities because they expect the slaughterers to control the problem at the source (this assumption, of course, begs the question of whether the slaughterhouse should assume that the feedlot has controlled the problem at its source, which is where the problem actually begins). The bottom line is that FSIS is trying to spread the risk of *E.coli* contamination to grinders who have no way to control the input of the pathogen.

The most obvious example of the View's failure to adequately address *E.coli* elimination is with respect to further processing establishments. Some such plants receive intact muscle products and those products are "blade tenderized" and marinated prior to sale. *E.coli* O157:H7 does not reside in buildings, it resides in the intestinal tracts of cows and other mammals. Therefore, unless it comes in through meat or people, there is no *E.coli* in a further processing plant. However, according to the USDA, should *E.coli* O157:H7 present itself in finished product after it has been through the tenderizing process at one of the those facilities, such facilities will be deemed to have adulterated the product, even though the product had to have come into it with *E.coli* O157:H7, or have been exposed to it from another beef product. This is not only an unfair interpretation of the law, it is not based on science, and could effectively shutdown the beef industry if pushed to its illogical conclusion.

QUESTIONS AND SUGGESTIONS

In addition to the general issues discussed above, we have the following suggestions and questions:

- The Notice is unclear with regard to its application to beef establishments that process raw beef, other than grinding. Our specific concern is related to our further processing plants that receive intact muscle product which they then "blade tenderize" and marinate.

- It is impractical to assume that grinders will be able to segregate suppliers used in a given finished product on a consistent basis.
- The Notice calls for grinders to require suppliers to have trace-back to the farm. Most suppliers will only be able to trace-back to feedlots.
- FSIS suggests that when they sample finished product, the establishment should hold product and release when testing is completed. Many of our products ship directly (no plant storage), and even if they do not, the plants are not configured to hold that much product. There are also serious shelf life issues with waiting for those tests.
- FSIS suggests that either an incoming testing protocol for trim "or" product specifications be incorporated into the HAACP or SSOP. Verification testing is then required on the finished product. We respectfully suggest that finished product destined for QSR establishments, where a strict lethality step is monitored, be exempt from this verification testing. Ground products destined for "other uses" would be subjected to finished product O157:H7 verification testing.
- The Notice indicates that the grinding establishments should employ interventions (i.e., irradiation, acidified sodium chlorite or lactic acid). Our customers have not permitted the use of these materials in their products. Without these, there are no employed interventions.
- The USDA seems to suggest that there should be two different HACCP/SSOP's to reflect the higher incident of *E.coli* O157:H7 from April through September. Is this what USDA really means?
- If finished product testing for O157:H7 is required, will a negative test result serve as a boundary for a recall versus the current cleanup to cleanup boundaries (ala Jack-in-the-Box)?
- There is some confusion over when the FSIS considers a delivery of meat received into a facility. We would like the opportunity to define this in our HACCP plans so that the incoming testing program for O157:H7 is easily executed.

While we appreciate the work USDA is attempting with this Notice, it is really the consuming public that is in the best position to protect itself from this particular foodborne problem. Certain undercooked beef products can be dangerous – just like a car when not handled properly can be dangerous. Consumers had to be taught that cars become less dangerous if seat belts are worn and yet, even though we now know seat belts save lives, it took years and years, and finally state and local laws, before people accepted seat belts as a fact of life. Some people still assume the risk by not wearing a belt. It is their choice.

More headway would be made against foodborne illness if the money spent on testing, which will never "cure" *E.coli* O157:H7, was instead spent on educating the public regarding proper cooking and handling of beef products. As the USDA states in this Notice, the only way to truly kill *E.coli* is to cook it or irradiate it, and irradiation has not been universally accepted nor even thoroughly tested. ConAgra Foods has already

partnered with ADA to educate consumers re: safe handling through websites, pamphlets and conferences, and more of these kinds of activities would be efficacious.

We appreciate the opportunity to comment on these Views, and would be pleased to provide any additional information to USDA to assist in its attempts to increase food safety.

Respectfully submitted,

Dr. Patricia Verduin
Senior Vice President
Office of Product Q&D