EXCEL

June 10, 2002

Mr. Phil Derfler
Deputy Administrator
U.S. Department of Agriculture
Food Safety and Inspections Service
1400 Independence Avenue, SW, Room 350
Washington, DC 20250

Dear Mr. Derfler:

It is my understanding that USDA-FSIS intends to re-visit, revise and re-write Directive 10,010.1. Excel strongly supports doing this since considerable new scientific knowledge about E. coli O157:H7 has been gained since the original Directive was issued. Sampling and testing methodology has improved, as has the sensitivity of test equipment. New microbial interventions have been developed and implemented and industry practices altered since the original Directive was issued. The stated USDA-FSIS intent has been to encourage industries *to* do more self-testing and to add microbial interventions into their processes. A new or revised Directive would hopefully be written and structured in such a way to meet the goal of encouraging industry self-testing and not discourage or penalize those who do.

Directive Revisions:

Directive 10,010.1could be improved to give guidance and aid the industry in further reducing the incidence of E. coli O157:H7 in beef products. Areas that could be improved includes those parts of the Directive that:

1) Requires six months of negative test results.
2) Does not recognize differences in sampling and testing frequencies required dependent upon microbial intervention effectiveness.
3) Does not differentiate sampling and testing frequency dependent upon product being tested.
4) Does not spell out clearly how establishments can provide certification to their customers for products produced that meet the guidelines of the Directive in situations where the customers intent is to do no further processing of those products.

It is our sincere hope that any new or revised Directive would take the above points into consideration and that every effort be made to improve them. 'There are scientifically recognized differences in log reduction capabilities of different microbial interventions. It is also generally recognized that multiple interventions are more effective than single interventions. Scientists and statisticians acknowledge that when levels of pathogens like E. coli O157:H7 are relatively low, a greater frequency of product sampling and testing must be done:to identify and find it, if present. It is also generally accepted that the more homogenous the product being tested, the greater the probability of finding E. coli O157:H7 if it is present. Sampling plans of homogenous products that call for serial sampling through the lot with subsequent compositing of those samples into one are more apt to identify the presence of an organism than sampling plans where a single sample is collected at a point in time. Attachment A provides data supporting t h e statements. None of the above points are adequately addressed currently in Directive 10,010.1, but will hopefully be addressed in any new or revised Directive.

Suggested Directive 10,010.1 Revisions:

Based on research studies and industry experience, a suggested approach to revising Directive 10,010.1 might include the following concepts:

1. **Intervention Effectiveness:**
   Mandate sampling frequency for intervention effectiveness based on scientific evidence of log reductions of the interventions used. Establishments should be allowed to use log reduction numbers that have been previously published in the scientific literature rather than requiring each establishment to prove the reduction in each plant. No one in a commercial food plant wants to deliberately introduce pathogens into their plants in order to probe intervention effectiveness.

2. **Sampling Plans by Product:**
   The probability of finding E. coli O157:H7 increases as the product being sampled becomes blended and more homogenous. This principle would dictate that carcasses would need to be sampled more frequently than trim and trim more frequently than ground beef to reach the same level of statistical verification of a process. Thus, the product being sampled should influence sampling frequency and protocol for lot sampling in any new or revised Directive.

3. **Recall/Lot Holding Provisions:**
   Hopefully a new Directive will include the provisions for allowing a plant that has **a** sampling plan and is testing ground beef products to minimize the amounts of product implicated for potential recall by a positive lot. The amount should be dependent upon the plants sampling plan and data. This is currently allowed by USDA, but it is not widely known and/or understood. A clear Directive on this might provide encouragement for plants to self-test.

4. **Labeling Provision:**
   A new Directive should provide a means to identify ground beef products that have been subjected to a testing program for E. coli O157:H7. The Directive should also spell out that any product so tested is eligible for "reduced testing" by USDA personnel much like the current Directive 10,010.1 provides for in some cases. A labeling provision should be included whereas any ground beef product that has been "sampled and the sample tested and found negative for E. coli O157:H7" could be labeled as such either on the primary package or on a retail ready package. This labeling could serve as a guide to inspectors to point them towards sampling ground beef products that were not tested in lieu of that which had been subjected to self-testing by industry. In this type program, it should be identified that FSIS personnel at the plant doing the self-testing have the right and responsibility to review both the sampling protocol arid test results on a routine basis.

It is our belief that a carefully written revised Directive 10,010.1 could provide a powerful incentive to the beef industry to improve and do more self-testing to verify their production processes. It is our hope that some of the ideas included in this letter may be of value as suggestions to FSIS as they consider revising Directive 10,010.1.

Labeling Request:

Excel is currently testing all ground beef produced in their two Texas plants. Each lot is serial sampled and those samples cornposited for a test sample. This provides for a more representative.

lot sample to be tested. Each lot is identified with plant identity, date of production and individual lot number. Our packaging system in each of these plants are chub packaging and each chub is identified with plant identity, a marked use/freeze by date identifying date of production, lot number and time of production to the minute. All chubs are packed into boxes which are also marked with plant identity, product codes, names, date of production, lot number and each box has an individual box identity sequence number which provides us with tracking capability on all production.

Excel would like *to* extend this ground beef testing program to all of our North American plants where we manufacture ground beef. Currently, under the existing Directive 10,010.1, there is limited incentive for us to do this. Excel would like to label the ground beef that has been sampled, tested and the sample found negative for E. coli O157:H7. The preferred wording would be; **"Product sampled and sample tested and found** negative for E. coli O157:H7." We would encourage FSIS to provide for previously tested and labeled ground beef to be eligible for "reduced FSIS testing" at retail and/or food service as is currently done in production plants under the current Directive 10,010.1. It would be our hope that a new or revised FSIS Directive would provide the details for how a retail store or food service operator could qualify for reduced testing when utilizing previously tested ground beef. Such a provision in the Directive would provide a great incentive for self-testing of ground beef at the production level for the industry.

Sincerely,

Dr. Dell M. Allen
Vice President Technical Services and Food Safety
Excel Corporation

cc. Mr. Bill Smith
Deputy Administrator, Field Operations, FSIS-USDA

Attachment

Attachment A :

E. coli O157:H7 Testing Data

Homogeneity of Products Tested: The data in Table 1 shows test results collected from September 1, 2001 through May 31, 2002. The products being tested are listed in the table with results coming from multiple plants. It should be noted that testing protocols were the same in ail plants as was test equipment, etc. This information indicates that *E. coli* O157:H7 is found in carcass testing at the least frequency, followed by ground beef and then tissue. Offal tested includes red meat items removed from the head of the animal that do not go through any type microbial intervention. Of these products, the most homogenous is the tissue since it is actually ground, blended and then put through a low-temperature rendering system which in a sense, acts as an incubator in growing and spreading any contaminant more uniformly through the product. Next most homogenous is ground beef with carcasses being the least homogenous. Data reflect the fact that the greater the homogeneity of the product, the greater the incidence level and the greater frequency of detecting it's presence.

Table 1: Summary of Products Tested, Multiple Plants: September 1,2001 through May 31, 2002.

Product Tested	No. Tests	No. Positive Tests	% Positive Tests
Carcasses	3607	3	0.08
Tissue	3835	81	2.10
Offal	5624	40	0.71
Ground Beef	3447	7	0.21
Total Tests	16513	130	0.79

Serial Sampling of Products: Figures 1 and 2 show data supporting the fact that products should be serially sampled across lots with those being then cornposited *into one* sample for analysis in order to maximize the probability of identifying a positive lot for *E. coli* O157:H7. In reviewing these figures of when the positives occurred within the lots obviously indicate that serial samples are preferred in lieu of pulling a one-time sample at a point in time of the Iots production. Both ground beef and tissue represented by figures 1 and 2 were serially sampled across their respective lots with those then being composited into one sample for analysis. It was after determining that the lots were positives that individual samples by time across the lots were analyzed to determine the times within the lots that *E. coli* O157:H7 was present in h e product. These charts also show that both the ground beef and the tissue process tend to cleanse themselves thus providing logic to the approach o frequiring only the positive lot being retained plus some part of the pre- and post lots as an added precaution.

Figure 1: Individual Samples By Time Across a Ground Beef Lot Found Positive for *E. coli* O157:H7. (Samples showing on 5 axis are positive, all others negative.)

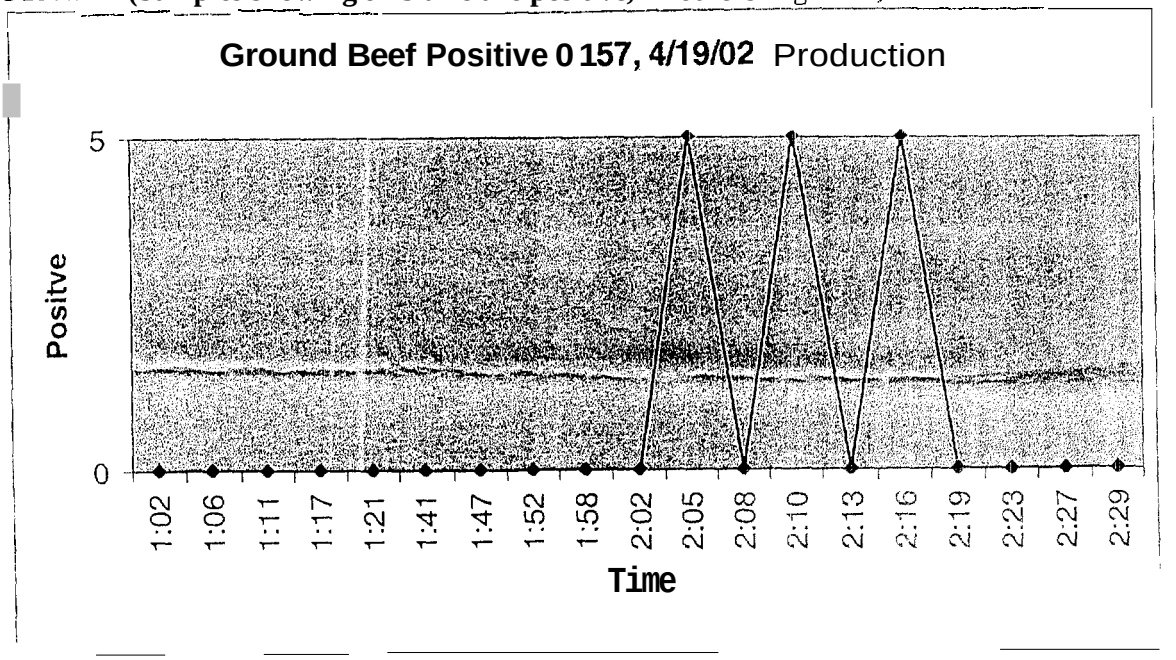
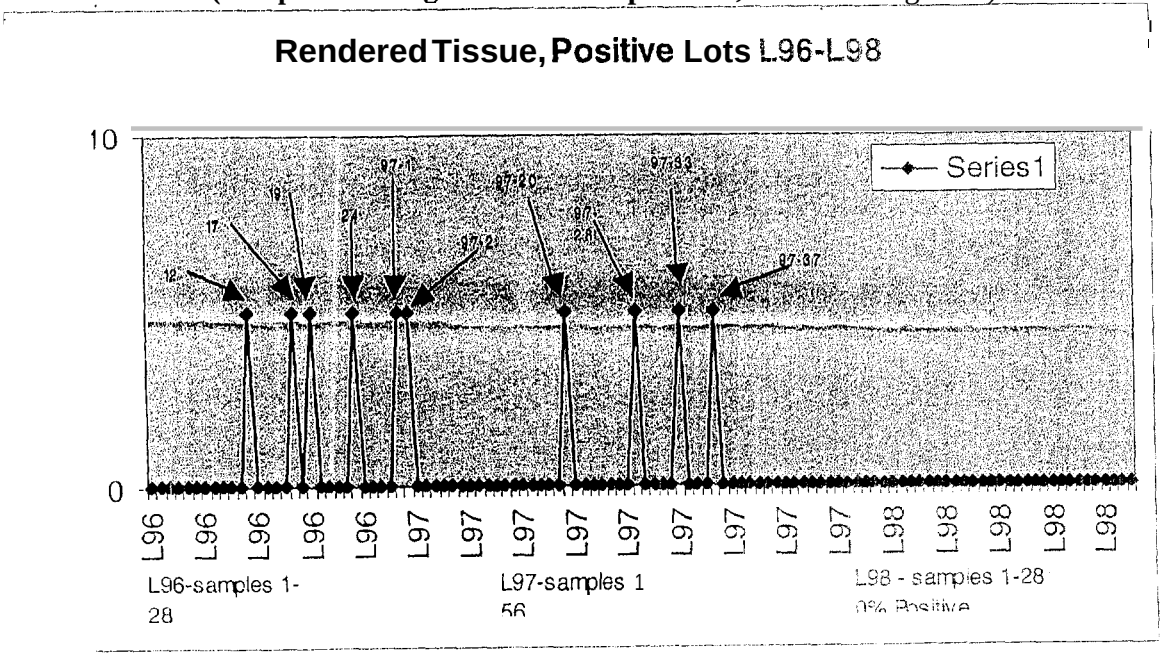


Figure 2: Individual Samples By Time Across Lots of Rendered Tissue Found Positive for *E. coli* O157:H7. (Samples showing on 10 axis are positives, all others negative.)



Summary: This data is presented in support of the concepts of frequency of sampling required based upon homogeneity of the product being sampled and *the* importance of sampling serially across the time of production of any given lot of homogenous product. The data in Figures 1 and 3 also support the fact that contamination occurs within a lot but that the process cleanses itself over time dependent upon the extent of contamination present.