Evaluation Report - Feedback on FSIS Directive on Microbial Sampling of Ready-To-Eat (RTE) Products, Revision 1 and Amendment 1

Final Report *06/15/01*

Introduction

This brief report summarizes the comments of field inspection personnel regarding the FSIS Directive on Microbial Sampling of Ready-To-Eat (RTE) Products, Revision 1 (10,240.2) and Amendment 1 (issued on 12/00, followed by the Amendment issued 2/01). These comments were gleaned from a telephone survey of a sample of 47 IICs in plants producing RTE products supplemented with a sample of 8 directors of state cooperative programs. Also analyzed were questions on this Directive received by the Technical Service Center and Headquarters staff. Results are reported as follows: key findings, clarity concerns for the main content sections of the Directive, the questions and answers section, the table, obtaining help for clarification, and distribution problems. The results for the Amendment are included with the appropriate sections of the Directive. The responses from both federal and state inspectors are similar unless noted.

Key Findings

Overall, respondents felt the Directive and Amendment were sufficiently clear. Hands-on experience with a positive test result helped inspectors to understand the Directive better, as did unit meeting discussions. Releasing the Amendment shortly after the Directive succeeded in clarifying some difficult topic areas.

Nevertheless, respondents raised questions about the appropriateness of sampling and testing procedures for very small plants that produce small and intermittent amounts of product.

Inspectors would like additional detail on the definition of RTE products, along with specific examples. The Amendment clarified some issues of definition regarding products such as lard and pork popped skins, but a number of questions remain.

Inspectors remain uneasy with plants that add a label requiring cooking in a perceived effort to avoid RTE microbiological testing requirements.

Inspectors requested more detailed definitions of sample, weight, size and clarification of intact and non-intact samples. Definitions should be the same as those required by labs, to ensure submitted samples are not rejected.

Inspectors understand that they determine the sampling plan, but some remain uncomfortable with that role and would request that the District Office provide them with the necessary sampling specifications. This was a particular concern of the state inspection programs.

Inspectors suggested format changes: highlighting important items, including definitions for abbreviations, providing copies of forms referenced and issuing a combined Directive and Amendment with changes marked rather than a separate Amendment to insert.

Key Recommendations

- Clarify the definition of RTE vs. NRTE, with more specific examples of products.
- Clarify the explanatory table with definitions and specific examples of types of products.
- Further define what constitutes an acceptable scientific basis for production and sampling, and what the HACCP plan must address.

- Standardize procedures and requirements and improve communication between labs and inspectors over sample and sampled lot size, bagged samples, and providing materials in timely fashion.

- Clarify the role of the District Office versus an individual inspector in determining sampling plans.

- Provide more complete instructions for the completion of forms on the forms themselves.

- Provide two copies of the sample request one for the lab and one for the plant, and provide the sample results to inspectors when they are sent to the District Manager.

- Issue new directives with amendment included and changes highlighted.

Clarity of Main Sections of Directive

Respondents rated most sections as relatively clear. However, some questions remain about individual sections that are discussed in the order they appear in the directive.

Sections I-IV - p .1

Virtually all respondents rated these sections as clear.

Section V. Terminology
Ready-to-Eat Product - p. 2

A quarter of the respondents identified problems understanding product definitions. Inspectors would prefer a clearer distinction between Ready-to-eat (RTE) and Not-Ready-to-eat (NRTE) products, and a more detailed listing of such products. Both categories appear to be applicable to many products, such as pre-cooked, refrigerated or frozen items that need to be heated; smoked sausages; items heat-treated shelf stable; and items fully cooked not self-stable. Inspectors would like to share this list with the plants to aid in their enforcement of regulations.

Inspectors would also like clarification regarding the impact of revised labels now requiring cooking on product categorization and testing. Inspectors expressed concern with plants "labeling out" of RTE testing by merely adding a label requiring cooking -- thereby categorizing their product as NRTE and thus becoming exempt from testing. This issue was previously raised in the May 2000 *Evaluation Report - Listeria Reassessment*, and continues to be a concern for some inspectors.

Sample - p. 2

Nearly a fifth of the respondents said this section was unclear.

- Clarify the sampling plan for plants with large numbers of products, but a small quantity of each.

- Determine if sampling procedures and the term "lot" are appropriate for very small plants. Very small plants often have difficulty trying to apply these procedures.

- Clearly define weight, size of sample, slack-fill, and "intact/ non intact" samples.

- Institute consistent policy and practices for sampling across plants and labs. A respondent stated that "every time they send a sample, it's in a bag. When it gets to the lab, it's not intact so the lab discards it. They have even tried packaging as they would the final product, and sending that to the lab in a bag. However, because it is still in the bag, the lab discards it."

Sampled Lot - p. 2

Over a fifth of the respondents found this section unclear.

- Clarify the difference between the two possible definitions for sampled lot (the plant HACCP plan and the determination by FSIS in the Directive). Which has priority and how to resolve the differences?

- Clarify the term "clean-up to clean-up." Is it the normal daily clean-up between products or shifts or a more or less extensive clean-up?

Section VI. Policy - p. 3

Although most respondents rated this section clear, a state program respondent expressed concern over the cost of testing for both Listeria and Salmonella as described in the Policy section on the Unified Sampling Form. In that five-year old state program, there has never been a positive test result for Salmonella. Therefore, the state would prefer to focus resources on Listeria testing.

Section VII. Sampling - p. 3-4

Most found this section to be clear, but offered the following suggestions.

- Include all the necessary information on the form so the inspector does not have to refer to the Directive when completing it.

- Improve instructions for completion of the form. Labs reject forms when deemed incomplete, incorrect, or missing information not indicated by the form instructions. Suggest requiring information rather than leaving blank.

- Provide inspectors two copies of the sample request – one for the lab and one for plant.

State programs advise inspectors not to pull samples on Thursday as well as Friday unless they can guarantee delivery to the lab to avoid holding a sample for more than three days.

Section VIII. Verification of Establishment Testing - p. 4-5

Respondents found this section to be relatively clear with only comments on the Note.

- Provide guidelines, or a paper, on what constitutes scientific evidence, how to determine adequacy, and who should make the determination.

Section IX. FSIS Test Results - p. 6-7

Most respondents found Section IX to be clear. The specific issues raised included:

- Clarify what is adulterated, how it is to be determined, and who will make the determination.

- Provide guidelines on how long to hold product while waiting for test results.

- Recommend that the inspector be informed of test results at the same time as the District Manager to prevent possible delays in actions due to district office absences.

- Clarify who will notify the Recall Management Division if a recall is required.

Inspectors expressed concern that "product that had been tested for microbial contamination could be gone and consumed by the public since establishments are not obligated to hold the sampled lot. The first sentence of this section indicates that upon receiving a positive test result, the inspector should write an NR after first contacting the District Office. Therefore, it could be hours or days before the paperwork is completed and processed and action taken."

Another respondent noted that, "Although it is clear per the first sentence of this section that plants must take corrective and preventive measures when a positive test result occurs, there are reported cases when inspectors have

been subject to disciplinary action as a result of waiting for the plant to take corrective action as per their HACCP plan. This leaves inspectors torn between sampling the old way (pre-HACCP) or trying to enforce the HACCP approach. Inspectors expressed concern that this makes it very difficult to do their job sometimes, especially in the case of obtaining samples when they are at the discretion of the establishment to hold the lot."

Section X. FSIS Follow-up Sampling - p. 7-8

Over one third of the respondents posed questions. How to determine the number of follow-up samples? Who should determine the number, and the procedure to determine the number of samples? Inspectors would like written guidelines on the suggested number of samples they should take.

Even those who understood the Directive to say that the inspector could determine the sampling plan, felt the District Office should determine sampling plan. Many state respondents said they would not allow inspectors to determine the sampling plan without supervision.

In fact, a typical comment noted that "It was the District Office that first notified the inspector a sample was positive for contamination. The District Office then told the inspector what the frequency of the follow-up sampling should be. In most cases, the District manager will ultimately determine the sampling plan."

Respondents suggested wording be changed regarding plant responsibilities from "may" to "need to/ should" if the tests are positive for microbial contamination.

Attachment 1: Questions and Answers - p. 9-11

Some inspectors expressed concern about Question and Answer 1 under "Sample Collection" which states that establishments are not obligated to hold any product when inspection program personnel collect samples. This has created problems for inspectors who have requested plants to hold a sampled lot without authority to do so.

Attachment 2: Not-Ready-To-Eat/ Ready-To-Eat Table - p. 12

A third of respondents found the original table to be unclear, and were divided on whether the changes in the Amendment helped. The main concerns were over the RTE/NRTE definitions discussed above.

Obtaining Help for Clarification

Most inspectors learned of the Directive and the Amendment first by reading them individually. More than half then sought additional help to clarify the Directive and Amendment from other colleagues, the Tech Service Center and other sources such as district and supervisory meetings. The previous *Evaluation Report – Feedback on Sanitation Directive (*11000.1*)* in April of 2000 recommended the strengthening of these supervisory meetings, and they continue to be an important source of clarification for inspectors. Topics for which they requested assistance included RTE definition and classification, sample size, labeling and certification of plants.

Of those who sought help, two-thirds said their questions were answered. However, some respondents reported contacting the Technical Service Center and other sources and receiving conflicting responses. Better communication is needed among Technical Service Center, District offices, and labs in interpreting the Directive and providing information to field.

Directive Format

Respondents made several suggestions to improve the format for the Directive and Amendment to increase the readability of the document including:

- Bold more items to facilitate readability.

- Include definitions of abbreviations.

- Include copies of forms referenced and other directive definitions or guidelines.

Respondents (almost 4 to 1) preferred to receive a combined Directive with Amendment over a separate Amendment to insert, particularly with the use of computer-accessed documents.

They also expressed support for use of change or other symbols to indicate where changes occurred, and to label new tables as "new".

Distribution Problems

Inspectors prefer to receive issuances by regular mail and email (rather than by fax or Internet). The most common way respondents received the Directive and Amendment were regular mail and email with a number reporting receiving it both ways.

Most inspectors reported receiving the Directive and Amendment in a timely fashion. Half of them reported receiving the Directive and Amendment within three weeks of the issuance date, a somewhat lower number than in previous evaluations. However, a large number of the remaining respondents did not recall how long it took to receive the Directive or Amendment due to the time lapse from the release date until this survey.

Problems with regular mailing included delays in mailing, problems with noting correct addresses, and receiving an inappropriate numbers of copies. Per the latter concern, an inspector noted that "There should be consistency in procedures for distribution to plants, i.e., if FSIS sends extra copies to Headquarters plants for delivery to smaller plants, then always do that rather than occasionally sending directly to the smaller plants. "

The *Evaluation Update –Feedback on Export Directive 9000.1* in February 2000 identified some similar issues in the delivery of Directives and suggested changes. Among the problems identified that might delay the mailing of a directive were:

- Lack of back-up personnel to coordinate the contract mailing process.

- Database problems such as incorrect and incomplete listing of existing establishments.

- Poor matches with appropriate directives to appropriate plants.

In response to suggestions in the *Evaluation Update – Feedback on Export Directive 9000.1*, changes had been made in the responsibility for updating addresses and for a back-up for the staff responsible for timely mailing.

When asked if they had not received an issuance during the past year, one fifth of respondents reported knowledge of at least one. Most did not know why they had not received an issuance. This response was lower than in a previous survey and may indicate improvement in the process. Some respondents did volunteer that they received directives in a more timely fashion than in previous years, and felt the situation was improving.

Identified problems with email or computer access included:

- Inability to find all directives on the Public Folder.

- Slightly differing page spacing on computer printed and mailed versions.

- A number of inspectors who still do not have access to computers.