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MEMORANDUM

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FSIS Revised Directive On Microbial Sampling of RTE Products

We will be forwarding by telecopy the Food Safety and Inspection Service's (FSIS) Revised Directive 10,240.2, Revision 1 (12/1/2000) dealing with micro-testing of ready-to-eat (RTE) products, such as testing for *Listeria monocytogenes* (*L.m*). FSIS considers such testing to be a verification of the establishment's HACCP plan. We will also forward the FSIS press release and change transmittal sheet specifying the new procedures for the inspectors to follow in drawing samples under Directive 10,210.1 Amend. 2.

At the industry briefing where the Directive was distributed, the FSIS officials stated that this Directive as an interim step in its *L.m* initiative. As regards the other components of the initiative, the *L.m* Risk Assessment will likely issue in approximately one month, to be followed by the FSIS proposed regulation to mandate environmental *Listeria* testing.

As discussed in greater detail below, the Directive clarifies how the FSIS in-plant inspector is to draw samples and how FSIS will respond to positive findings of pathogens in RTE product. In addition, the Directive recognizes establishment microbial testing of finished products (with or without environmental testing) in lieu of agency testing. This Directive will become effective on December 1, 2000.

Sample Selection

FSIS will now be sampling all RTE products. As to what constitutes an RTE product, FSIS will continue to follow the decision-making classifications previously issued and included as a table in the revised Directive.

Moreover, FSIS will now test products for all pathogens of concern, rather than merely testing for one pathogen. For example, a frankfurter sample will now be tested for both *Salmonella* and *L.m*.

The in-plant inspector **must** provide the establishment with meaningful notice of the sample collection so as to provide the establishment sufficient time to hold the sampled lot. Moreover, only current day's production which has completed the pre-shipment

HACCP records review will be sampled. Finally, samples will only be taken of intact packages, the precise number will be dictated by package size. For example, for final packages weighing more than one pound but less than three pounds, two units are collected, whereas for packages weighing three pounds or more, only one unit is collected. For shipping size packages, the establishment may short-weight/slack-fill the container.

Regarding the lot represented by the sample, the establishment in the first instance will define the lot on a scientific basis. If not, the agency will revert to the lot representing "clean-up to clean-up."

Responding to Positive Agency Findings

The agency would respond to a positive pathogen finding in finished product as follows:

- The inspector, upon instruction from the District Office, will issue a NR.
- The inspector will perform an O2 procedure and review the HACCP and SSOP plans and records from the relevant date to the present. If the inspector concludes the establishment has not stopped producing and shipping adulterated product, a withholding action would be taken and the general HACCP enforcement procedures will be followed.
- The inspector will verify the establishment is taking necessary corrective and preventive actions. With a *L.m* positive, the establishment must incorporate *L.m* controls in the HACCP plan, "absent substantial, scientifically supportable reasons."
- The District will determine whether any additional enforcement action is necessary.
- The establishment will be subject to targeted FSIS sampling after it implements its corrective/preventive actions -- there is no "magic number;" rather the number of samples will be determined by the IIC in light of the establishment's corrective and preventive actions.

Plant Testing

The Directive provides the rules applicable to establishment testing in lieu of agency testing. It also provides an insight into the anticipated proposed regulation to mandate establishment environmental testing for *Listeria*.

Under the Directive, an inspector is not to draw an agency sample (without the express approval of the Circuit Supervisor or District enforcement personnel) if the establishment is either:

Testing one RTE product per HACCP plan every month; or

Testing one RTE product per HACCP plan every three months as part of an environmental program which includes product contact zone and non-product contact zone testing for indicator organisms, such as *Listeria spp.*, and targeted product testing for *L.m* when there are positive product contact findings.

Finished product testing must be incorporated in the "validated HACCP plan" as a verification activity; the environmental testing protocol may be in either the SSOP or HACCP plan.

Regarding plants with multiple HACCP plans, the FSIS officials indicated that these establishments may "opt out" of FSIS testing for some plans and still have FSIS testing for other plans since the testing protocols are on a per HACCP plan basis.

The Directive's requirement relating to product testing for *L.m* following a positive product contact result for *Listeria spp.*, is inartistically worded. As written, it would appear the Directive would require finished product testing after every single positive contact surface finding. FSIS Administrator, Mr. Billy, and Deputy Administrator for Policy, Mr. Derfler, both stated at the industry briefing that there is **not** a one-to-one requirement. The frequency of such targeted testing is to be determined by the establishment. Thus, it remains our understanding that an occasional positive for an indicator organism, even on product contact surfaces, will not automatically implicate product.

Under both this program and generally, FSIS will not issue an NR in response to a positive finding by the establishment (or its customer). However, the establishment must take appropriate corrective/preventive actions in light of the finding. This may include a recall and/or reassessment of the HACCP plan. Failure to undertake such action could result in an NR.

Hopefully this has proved useful. If you have any questions, please contact us.

DRJ:drj
Attachment