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MEMORANDUM

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RE: OIG Audits of FSIS -- HACCP, Compliance, Laboratory, and Imports

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Yesterday, the U.S. Department of Agriculture's Office of Inspector General (OIG) issued four audit reports that it prepared on various Food Safety and Inspection Service (FSIS) programs. The four audits covered: FSIS' implementation of HACCP; FSIS' traditional compliance activities; FSIS Laboratories; and FSIS' handling of imported meat and poultry. The discussion below is a general overview of each report. The four reports (totaling 427 pages) are posted on the OIG web site at [www.usda.gov/oig](http://www.usda.gov/oig) if you wish to read the report or its Executive Summary.

Overall, the OIG audit reports were not complementary to FSIS. In all areas, OIG recommended that FSIS institute better documentation procedures and management controls.

However, it is the HACCP audit which will likely receive the most attention. Indeed, the bulk of the OIG Press release announcing the audit reports addressed the HACCP findings. The press release is at [www.usda.gov/oig/2000/oig54.html](http://www.usda.gov/oig/2000/oig54.html).

**HACCP**

To understand the OIG HACCP audit report, it is important to recognize that the OIG auditors are not HACCP experts. Although they received the same three day training session that FSIS inspectors receive and were provided with the FSIS Model HACCP plans developed by the agency, such training is hardly sufficient to provide adequate expertise in HACCP, especially HACCP as developed and disseminated by the National Advisory Committee on Microbiological Criteria for Foods. Thus, the auditors approached their review from a "command and control, regulatory" HACCP approach.

The OIG auditors see HACCP as a replacement of the old inspection system. Under the "new" system, the auditors reported that FSIS had ceded much of its oversight authority so that establishments, in effect, were monitoring themselves. The auditors alleged that plants were deliberately reducing the number of CCPs so as to minimize agency oversight. In part, this allegation was based on the difference in the number of CCPs in the FSIS Model HACCP plans versus the number of CCPs actually developed by plants.

Moreover, the auditors were concerned that establishments were failing to provide non-HACCP plant test results. In two cases, OIG sent FSIS "management alerts" where the auditors believed the plants' testing showed potential product adulteration. As evidence of the auditors' lack of scientific background, they apparently were very concerned that establishments would not conduct finished product testing based on screening tests; for example, not testing for *E. coli* O157:H7 if a product tested positive for generic *E. coli*.

The auditors found numerous "problems" during their review of the HACCP plans at the 15 establishments visited. These included incomplete hazard analyses, lack of "necessary" CCPs, and inadequate data to support critical limits. In addition, there were incidents of open noncompliance reports and the failure of the establishment to take corrective/preventive action. In short, the clear tone is that FSIS has handed over its food safety functions to establishments and the establishments are using HACCP to avoid regulatory oversight.

OIG called for FSIS to take a more active role in overseeing HACCP. First, FSIS should undertake a more detailed review of plant HACCP plans and "command" establishments to follow regulatory requirements as well as adding additional CCPs. Second, FSIS should require the greater sharing of plant microbial test records (as well as increasing agency testing for all pathogens, such as *Campylobacter*). Third, FSIS should recast the granting of inspection as a "contract," subject to periodic renewal, which would dictate the obligations and responsibilities of the establishment as a condition of receiving inspection.

In response, FSIS agreed that it should take a more in-depth look at the establishments' plans. In this regard, the agency will be undertaking In-Depth Verification reviews of establishments. In addition, FSIS is continuing to train its supervisory field personnel on HACCP verification. With regard to the "contract," the Department lawyers are reviewing this possibility, though it is our view that such "contractual obligations" cannot statutorily be included in a grant of inspection.

One concluding point, the OIG did indicate its overall support of the HACCP approach (as it interprets HACCP), in light of the overall reduction in pathogens and in reduced foodborne illnesses.

## **Compliance**

The second audit reviewed FSIS compliance activities. The focus was on compliance outside of official establishments and thus did not include any HACCP-related compliance activities.

Overall, the auditors recommended that the management of the program be improved in order to increase its efficiency. They called upon FSIS to: (1) establish procedures to identify and review high risk, non-inspected facilities; (2) create inspection checklists for all types of facilities subject to compliance inspection (only warehouse inspections currently have such a checklist); (3) direct more resources to high risk facilities and larger

population centers; (4) develop a more comprehensive system for handling consumer complaints; (5) improve training; (6) develop timelines for tracking the progress of enforcement cases; and (7) seek civil penalty authority.

FSIS indicated that the review was conducted at a time when the agency was shifting to the HACCP system and the creation of the District Offices. However, FSIS will seek to implement the recommendations as resources permit.

## **Laboratories**

The third audit investigated the FSIS laboratories. The audit report was complimentary regarding the accuracy of the laboratories in detecting pathogens. This was based on the fact that the laboratories correctly detected *Salmonella* and *E. coli* O157:H7 in the 180 "spiked" samples submitted by OIG. Moreover, OIG reported that the laboratory was following AOAC methods.

However, the audit did detect certain deficiencies. First, the laboratories had not identified all establishments which should be subject to monitoring tests. Second, not all samples were being submitted by the in-plant inspector. Third, late delivery/improper shipment resulted in samples being discarded. Fourth, the FSIS laboratory quality assurance visits should be conducted more frequently and the QA observations of such visits should be communicated to the laboratory. Fifth, the agency was using a *Salmonella* screening kit which did not meet contract specifications (it would permit approximately 4% more false negatives than that specified -- the kit has since been replaced). Finally, the laboratories were not always documenting all activities, such as each step in an analysis or equipment maintenance.

FSIS responded, in part, by noting that the auditors were using ISO standards, which the laboratories have not yet implemented. However, the laboratories will be seeking ISO certification in the future. Otherwise, FSIS intends to improve documentation as recommended.

## **Imports**

Other than the HACCP audit, the audit report dealing with imports was the least complementary to FSIS. The auditors found that FSIS was not, in OIG's view, managing the program adequately. The auditors noted that FSIS was **not**: (1) adequately documenting equivalency determinations of exporting countries; (2) obtaining expertise as needed to make HACCP equivalency determinations; (3) mandating exporting countries provide annual certifications and residue test plans as required by regulation; and (4) maintaining all records so that they could be readily accessible.

In addition, the audit uncovered that product was being exported from certain foreign plants during the time the plants were delisted. However, further investigation showed that the imported products were indeed produced at a time that the plant was eligible.

FSIS agreed that it needed to improve documentation overall but disagreed as to the auditors' conclusion that the program was not being adequately managed. The agency also pointed out that the audit did not document any instance of unsafe product being imported.

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Hopefully, this has proven useful. If you have any questions or desire further information, please do not hesitate to contact us.

OFW:drj