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January 5, 2001

United States Department of Agriculture
FSIS Docket Room
Room 102 Cotton Annex
300 12th St., SW
Washington, DC 20250-3700

**Re: FSIS: The Next Steps;
Notice; Docket No. 00-047N;
65 Fed. Reg. 76210 (Dec. 6, 2000)**

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food Safety and Inspection Service's (FSIS) plans to improve the quality and effectiveness of its programs, as well as the performance of the meat and poultry industry under the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) regulations. CSPI is a non-profit consumer organization that focuses primarily on food safety and nutrition issues and represents over eight hundred thousand members in the U.S. and Canada.

Summary:

As a result of the FSIS Pathogen Reduction; HACCP rule, consumers throughout the nation are enjoying the benefits of a safer meat and poultry supply. More must be done, however, to realize the full benefits of this new system. Therefore, CSPI urges FSIS to take the following steps: expand the pathogen testing program, establish more performance standards, exercise more oversight--including enforcement--of HACCP implementation, strengthen the import and the drug residue control programs, continue the HIMP pilot project and the in-distribution strategies, and support the creation of a single food-safety agency.

CSPI has been a strong supporter of FSIS's HACCP program since its inception. In the comments submitted by CSPI and several members of the Safe Food Coalition (CSPI/SFC), we stated that it "represents a tremendous step forward for the agency in improving the safety of these [meat and poultry] products."¹ However, we recognized that the system would deserve consumer confidence only to the extent that it was subject to strict government oversight and ongoing government verification.²

To work effectively to improve food safety, HACCP systems must be implemented as one component within a larger regulatory framework. This framework must:

- Extend from the farm to the table in order to capture the multitude of potential hazards.
- Include inspections by federal regulators to ensure that the HACCP plans are being implemented properly.
- Give regulators effective enforcement tools so that they can take prompt action against processors that violate their HACCP plans and send contaminated food into the market.
- Mandate that processors utilize end-product sampling to demonstrate that their HACCP plans actually work to minimize food hazards and for ongoing verification.³
- [D]efine product-specific performance standards for other human pathogens in addition to *Salmonella*.⁴

Since the time that those comments were submitted, the agency has achieved significant success in reducing pathogens in various meat and poultry products through its HACCP program.

¹ Center for Science in the Public Interest, Comment on the Proposed Rule on Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, (July 5, 1995), p. 1 [*hereinafter cited as CSPI Comments*]. Several members of the Safe Food Coalition signed on to these comments: American Public Health Association, Consumer Federation of America, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy and United Food and Commercial Workers International Union. *Id.* at 1-2.

² *Id.* at 3-4.

³ *Id.*

⁴ *Id.* at 25.

After two years of product testing in large plants, *Salmonella* contamination has been cut in half in chicken and pork products and has declined substantially in ground beef and ground turkey as well.⁵ HACCP performance in small plants has been equally impressive. After one year of testing in small meat and poultry plants, *Salmonella* contamination in ground beef has been reduced by more than 40 percent, and contamination in chicken by nearly 20 percent.⁶

Despite these impressive results, more work remains. In June 2000, the U.S. Department of Agriculture's (USDA) Office of Inspector General (OIG) released a report of its audit of the agency's implementation of the HACCP program.⁷ The report concluded:

“ . . . for HACCP to reach its full potential, FSIS must assert its authorities under the program to ensure that the intent of the program is met. Because FSIS was uncertain of its HACCP authorities and had not established needed procedures, it had reduced its oversight beyond what was prudent and necessary for the protection of the consumer.⁸

The OIG advised FSIS to strengthen its management controls to provide greater oversight of HACCP program implementation, pathogen testing, and independent reviews of plant and inspection activities in plants.⁹ CSPI strongly supports this recommendation.

⁵ Food Safety and Inspection Service, “FSIS Reports Continued Decline of *Salmonella*,” News Release, (March 21, 2000).

⁶ *Id.* The only exception to the downward trend in *Salmonella* contamination was the performance of small swine plants. *Id.*

⁷ U.S. Department of Agriculture, Office of Inspector General, *Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System*, (June 2000) [hereinafter cited as OIG Report].

⁸ *Id.* at Sec. I, p. ii.

⁹ *Id.* at Sec. I, p. v.

A. FSIS Needs to Place Greater Emphasis on Pathogen Testing.

It is a well-known management concept that “you manage what you measure.” For this reason, in CSPI/SFC’s comments on the proposed HACCP rule, we noted:

Only mandatory and frequent end product microbial sampling will prove that HACCP systems work and give consumers confidence that they are a proven technology for food safety. Without the benefit of end product sampling, reliance on HACCP systems is based on blind faith rather than hard facts.¹⁰

The OIG investigative report made a similar observation: “One of the keys to the success of HACCP is microbial testing, and sound management practices dictate that known harmful pathogens should be monitored through an effective testing program.”¹¹ The OIG recommended that FSIS expand pathogen testing in order to increase food-safety protections offered by the HACCP rule. We agree.

The Centers for Disease Control and Prevention (CDC) has reported that *Campylobacter* is the primary pathogen causing foodborne illnesses, and *Listeria monocytogenes* and *Salmonella* cause the most foodborne-illness-related deaths.¹² FSIS’s own baseline studies, conducted prior to HACCP implementation, found significant levels of *Campylobacter* and *L. monocytogenes* in certain products.¹³ This year, CSPI petitioned FSIS to require ready-to-eat processed meat products to be tested for *L. monocytogenes* and also urged the agency to require slaughterhouses to test beef carcasses for the harmful *E. coli* O157:H7.¹⁴ President Clinton promised that his administration

¹⁰ CSPI Comments at 10.

¹¹ OIG Report at Sec. I, p. 32.

¹² *Id.* at Sec. I, p. 34.

¹³ *Id.*

¹⁴ Center for Science in the Public Interest, “Petition for Regulatory Action to Require Microbial Testing By Industry for *Listeria monocytogenes* in Ready-To-Eat Meat and Poultry Products,” January 13, 2000; Center for Science in the Public Interest, Comments on Recent Developments Regarding Beef Products Contaminated With *Escherichia coli* O157:H7; Public Meeting (Docket No. 99-060N), (April 11, 2000). The OIG also recommended

would issue a proposed rule to require testing for *L. monocytogenes* in processing plants.¹⁵ To date the only action we have seen is the release of an FSIS Directive that encourages producers of ready-to-eat meat and poultry products to conduct their own product testing and environmental sampling in lieu of the government sampling program.¹⁶ The opportunity to fulfill the President's promise soon will lapse, but CSPI strongly urges the agency to press on with issuing its proposed rulemaking on *L. monocytogenes*.

In addition, we believe that FSIS should establish a performance standard for *Campylobacter* in poultry products. The agency should not stop there, however. It should identify pathogens that represent the greatest public health threat associated with other classes of product and establish performance standards and testing regimes for those as well. The OIG stated:

We believe that FSIS is not fully addressing the danger posed by known and other new or emerging foodborne pathogens. FSIS may be placing undue reliance on plants that may be unable or unwilling to take necessary action in the face of repeated tests showing the presence of potentially harmful microbes.¹⁷

It is clear that consumers would benefit from additional performance standards and increased testing by both the industry and the government to monitor for food-safety hazards. Moreover, the results will demonstrate the HACCP program's ability to reduce food safety hazards beyond *Salmonella* or, alternatively, areas to improve.

that FSIS "[d]evelop and implement procedures . . . to require HACCP plans to include pathogen testing of product environment, contact surfaces, and final products, particularly if a plant has a history of positive test results for microbes such as *Listeria*." OIG Report at Sec. I, p. 35.

¹⁵ William J. Clinton, *Radio Address By the President to the Nation*, The White House, (May 6, 2000).

¹⁶ Food Safety and Inspection Service, Directive 10,240.2, Rev. 1, (Dec. 1, 2000).

¹⁷ OIG Report at Sec. I, p. 35. See also, CSPI Comments at 15 ("Microbial sampling of meat and poultry products might play an important role in identifying emerging pathogenic bacteria before they become a public health threat.").

B. FSIS Needs Better Methods To Ensure the Adequacy of HACCP Plans.

From the time of the proposed rule, CSPI has been concerned about FSIS's limited oversight of HACCP plans:

We oppose the absence of specific government oversight of crucial components of HACCP systems, like the HACCP plan. . . . We strongly disagree with USDA's decision not to require that HACCP plans be submitted to the Agency, as well as reviewed and retained by it.¹⁸

Five years later, the Department's Inspector General criticized FSIS for severely limiting its inspectors' oversight of HACCP plans, such that inspectors only verify controls that are declared in firms' HACCP plans. The OIG auditors concluded that all too frequently various elements of the HACCP plans were inadequate.¹⁹ For example, in 14 of the 15 plants visited, the auditor found at least one HACCP plan that was incomplete; that is, it did not identify all critical control points (CCP's) and frequently used Good Manufacturing Programs (GMP's) or other non-HACCP measures in lieu of establishing CCP's for identified hazards.²⁰ The Government Accounting Office (GAO) found similar problems in an investigation it conducted in 1999. The GAO determined that the practice of relying on non-HACCP programs to control food safety hazards "limits the consistent implementation of the HACCP system nationwide as well as USDA's oversight of food safety at these plants."²¹

¹⁸ CSPI Comments at 44-45.

¹⁹ OIG Report at Sec. I, pp. 16-30.

²⁰ *Id.* at Sec. I, p. 9.

²¹ Government Accounting Office, *Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System*, (Dec. 1999), p 19.

To address this problem, the OIG recommended that FSIS implement a system of oversight to review and approve each HACCP plan, including proposed changes, to verify that the plant has properly identified critical control points (CCP's),²² critical limits and corrective actions,²³ and has performed adequate hazard analyses.²⁴ CSPI agrees that HACCP approval assures consumers the greatest degree of protection. In the 1995 CSPI/SFC comment, we suggested that the agency deploy a specially trained group of HACCP specialists to review and approve plans.²⁵ CSPI believes that the FSIS teams currently conducting In-Depth Verification (IDV) reviews of HACCP plans should be authorized to approve HACCP plans, including the CCP's selected. IDV will be of limited benefit if the agency is reduced to verifying plans that fail to include all of the food safety hazards present.

We also suggest that the agency look to FDA's activities in on-site review of seafood HACCP plans as a model for FSIS's on-site verifications. FDA has a more rigorous HACCP plan review than FSIS currently does, so adopting similar measures would no doubt strengthen FSIS's oversight of HACCP plans in meat and poultry establishments.

²² OIG Report at Sec. I, pp. 16-17. OIG further recommended that FSIS personnel be authorized to require additional CCP's. *Id.*

²³ *Id.* at Sec. I, p. 23.

²⁴ *Id.* at Sec. I, p. 28.

²⁵ CSPI Comments at 46, n. 51.

C. FSIS Needs to Define Its Oversight Role and More Vigorously Enforce the HACCP Rule.

While many plants are doing a good job in implementing the HACCP rule, quite clearly FSIS needs to strengthen its oversight of plants that are failing to meet the program's requirements. The OIG stated:

Because the HACCP concept limits FSIS monitoring to only those controls declared in the HACCP plan, plants can distinguish between the controls available to Federal scrutiny and those in actual operation. In some cases, plants have even declared their HACCP plans proprietary documents and do not allow FSIS to copy them or release their contents.²⁶

The auditors concluded that FSIS did not enforce greater disclosure in the HACCP plans because it was unsure of its authorities.²⁷ The OIG recommended that FSIS clarify the HACCP plan requirements and provide its field personnel "clear authority to enforce this mandate."²⁸

The OIG also found that FSIS has failed to adequately respond to establishments with repetitive noncompliance deficiencies, for example, by requiring permanent corrective actions or initiating enforcement actions.²⁹

FSIS . . . is reluctant to challenge plants that have taken measures to limit Federal oversight. We concluded that FSIS needed to define its oversight role in HACCP and ensure that industry understands the nature of its presence: to ensure that HACCP is operating as intended and that the expectations of HACCP--sanitary environment, identification and elimination of harmful bacteria on foods--are met. . . . Plant inspectors are currently unsure when to declare a plant's corrective actions unworkable. Some plants have received numerous notices of noncompliance for the same deficiency, but the inspectors had no understanding of what number, frequency

²⁶ OIG Report at Sec. I, p. 10.

²⁷ *Id.*

²⁸ *Id.* at Sec. I, p. 11.

²⁹ *Id.* at Sec. I, p. 64.

or nature of deficiencies would constitute a breakdown in the system.³⁰

The auditors recommended that FSIS establish procedures for repetitive deficiencies, including timeframes for responding to Noncompliance Records and initiating planned corrective actions.

CSPI agrees with the OIG conclusions that FSIS should vigorously enforce the requirement to have adequate HACCP plans, as well as to prosecute plants that repeatedly fail to address their plant sanitation or process control systems deficiencies.

D. FSIS Needs to Strengthen Its Import Controls.

Although FSIS has improved its regulatory program for U.S. meat and poultry plants, it has been too lax in its requirements for foreign plants. The OIG audit found that FSIS failed to develop a comprehensive detailed plan to ensure that controls are maintained over import inspection operations. The investigators concluded: “The absence of a strong internal control structure does not provide reasonable assurance that objectives of the import inspection program are being achieved.”³¹ Specifically, the OIG found that FSIS failed to prevent delisted establishments from exporting product to the U.S., enforce the requirements for foreign governments to file annual certifications and residue test plans, and demonstrate that it judged the equivalency of foreign food safety standards of exporting countries according to U.S. standards.³² In response to the OIG report, FSIS committed to implementing the agreed-upon recommendations by March 2002. We urge the

³⁰ *Id.* at Sec. I, p. 47.

³¹ U.S. Department of Agriculture, Office of Inspector General, *Food Safety and Inspection Service: Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-Hy, (June 2000), Sec. III, p. ii [hereinafter cited as OIG Import Report].

³² *Id.* at Sec. III, pp. ii-iii.

agency to promptly address these matters and suggest that the agency may wish to consider holding a public meeting this year to discuss the status of improvements in the import program.

E. FSIS Needs to Effectively Control Antibiotic Residues.

Antibiotic resistance stemming from drug use on the farm is another food-safety related public health concern. CSPI has been working for years to encourage producers and the government to take strong action to help preserve the effectiveness of antibiotics for human use.³³ Although the FDA has primary authority over the practice of treating animals with antibiotics, drug residues could clearly be the focus of an on-farm HACCP program, using records and residue testing for verification.

We see the theoretical value of incorporating FSIS's residue testing program into the HACCP system. Chemical hazards such as drug residues are food safety hazards that should already be addressed in an establishment's HACCP plan. We strongly recommend that plants be required to do verification testing for drug residues. This would place more responsibility on the processing industry to ensure that meat does not violate residue limits. We look forward to future public meetings and agency publications that will provide more detail of the FSIS's plans in this regard.

F. FSIS Should Continue Its Pilot Program on Inspection Models.

At the time of the proposed rule, CSPI and members of the SFC that endorsed our comment strongly believed that before any changes were made in inspection mandates, FSIS should conduct

³³ To hamper the development of antibiotic resistant bacteria, CSPI has petitioned the Food and Drug Administration (FDA) to ban all subtherapeutic uses of antimicrobial agents that (a) are used in human medicine or (b) that might select for cross resistance to antimicrobials used in human medicine. We have been joined in this effort by 52 scientists and health officials. For example, CSPI called upon the FDA to revoke its approvals for subtherapeutic use of penicillin and tetracyclines.

pilot programs to determine the appropriate role of federal inspectors in a HACCP environment.³⁴

We concluded:

Once operating HACCP systems are demonstrated to be more effective than the existing system, the inspection frequency can be adjusted as appropriate to fit the new system.³⁵

CSPI has continued to support the creation of the HACCP-based Inspection Models Project (HIMP).

Recently, questions were raised about early data from the HIMP project--related to the performance on one OCP category of one shift at the first HIMP plant. After close examination, we have concluded that the measures taken by FSIS since the time that the data were collected, including setting a performance standard for the OCP category at issue, are adequate to address any concerns the data may have raised. We continue to believe, as we stated in a comment filed earlier this year:

Based on the limited data currently available, the FSIS's HACCP-based Inspection Model Program (HIMP) shows promise in helping the agency to realign its inspection activities on both food safety and other consumer protections (OCP) in poultry plants. We support the continuation and completion of the HIMP study to determine the effectiveness of this inspection model. Only by examining performance measured over time will the HIMP project prove itself successful.³⁶

G. FSIS Should Continue to Pursue In-Distribution Activities.

Food safety experts almost unanimously agree that a farm-to-table approach is needed to achieve the maximum level of food safety possible. In 1985, the National Academy of Sciences (NAS) stated: "An ideal meat and poultry inspection system will ensure that adequate public

³⁴ CSPI Comments at 9.

³⁵ *Id.*

³⁶ Center for Science in the Public Interest, Comments on Other Consumer Protection Activities-Proposed Rule, (June 30, 2000), p. 4.

protection measures are located throughout the food system, from animal production to the final sale of the food product.”³⁷ CSPI believes that food safety strategies implemented throughout the continuum of production through distribution and sale of products offers the highest degree of protection to consumers from foodborne illnesses.³⁸ FSIS’s in-distribution activities can, with adequate planning and monitoring, add a valuable component to the food safety system in the United States. Therefore, we urge FSIS to continue to pursue in-distribution strategies.

H. FSIS Should Support the Creation of a Single Food-Safety Agency.

For the past thirty years, policymakers ranging from congressional committees to White House councils have advocated for the creation of a single, independent food-safety agency. Most recently a National Academy of Sciences (NAS) committee determined that the “current fragmented regulatory structure is not well equipped to meet the current challenges.”³⁹ In its report, the NAS found glaring disparities that result from the multiple agency system of food safety regulation and concluded that:

[A]n identifiable, high-ranking, presidentially-appointed head [is needed], who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety efforts;

³⁷ National Research Council, Commission on Life Sciences, Food and Nutrition Board, *Meat and Poultry Inspection: The Scientific Basis of the Nation’s Program*, (Washington, D.C.: National Academy Press, 1985), p. 153.

³⁸ The Center for Science in the Public Interest (CSPI) strongly advocates for the use of on-farm controls as the first line of defense against contamination. See, e.g., CSPI, Comment on Egg Safety; Current Thinking Papers on Egg Safety National Standards; Notice of Availability; Public Meeting (Docket No. 98-045N4), (Aug. 14, 2000). See also, Caroline Smith DeWaal, Remarks Before the Animal Protection Food Safety Conference, St. Louis, MO, (Sept. 6, 2000).

³⁹ National Research Council, Institute of Medicine, Committee to Ensure Safe Food from Production to Consumption, *Ensuring Safe Food From Production to Consumption*, (Washington, D.C.: National Academy Press, 1998), p. 12.

[and] the structure should have a firm foundation in statute Many members of the committee are of the view that the most viable means of achieving these goals would be to create a single unified agency headed by a single administrator -- an agency that would incorporate the several relevant functions now dispersed . . . among three departments and a department level agency.⁴⁰

Many stakeholders agree that a single food-safety agency makes good sense, including the National Cattleman's Beef Association, S.T.O.P., Consumer Federation of America, American Society for Microbiology, Institute for Food Technologists, American Meat Institute and the Food Marketing Institute. We encourage FSIS to support the creation of a single food safety agency to achieve a more rational system of food safety regulation.


Conclusion

CSPI applauds FSIS for its tremendous efforts in implementing the Pathogen Reduction; HACCP rule. As a result of those efforts, we believe that consumers are enjoying the benefits of a safer meat and poultry supply. The agency's work is not done, however. FSIS must continue to improve its HACCP program. We believe that the agency should focus its attention on some key areas: more pathogen testing, more oversight and enforcement of HACCP implementation and better

⁴⁰ *Id.*, p. 13.

import controls. Strengthening these aspects of the program will help to ensure that consumer confidence in FSIS's HACCP program is justified.

Sincerely,

Handwritten signature of Charlotte Christin in black ink.

Charlotte Christin
Food Safety Attorney

Handwritten signature of Caroline Smith DeWaal in black ink.

Caroline Smith DeWaal
Food Safety Director