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

**Re: Announcement of and Request for Comment Regarding Industry Petition on
Hazard Analysis and Critical Control Point (HACCP) Inspection
Notice; Opportunity to Comment
Docket No. 00-014N
65 Fed. Reg. 30,952 (May 15, 2000)**

Dear Sir or Madam:

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the industry petition on the Food Safety and Inspection Service's (FSIS) Hazard Analysis and Critical Control Point (HACCP) regulations. CSPI is a non-profit consumer organization representing over eight hundred thousand members in the U.S. and Canada that focuses primarily on food safety and nutrition issues. We submit these comments on behalf of ourselves and the following members of the Safe Food Coalition: American Public Health Association, Consumer Federation of America, National Consumers League and Safe Tables Our Priority.

We support FSIS's efforts in developing and rigorously enforcing a strong, standards-based HACCP program. We are concerned, however, by a recent Office of Inspector General report contending that the agency has "reduced its oversight short of what is prudent and necessary for the protection of the consumer."¹ The OIG recommended, among other things, that FSIS further strengthen its HACCP program by expanding the pathogen-testing requirements.² We strongly agree. With an estimated 76 million illnesses and 5,000 deaths each year in the United States from foodborne illnesses, we urge the agency to implement testing requirements for pathogens in addition

¹ U.S. Department of Agriculture Office of Inspector General, "Food Safety and Inspection Service: Implementation of the Hazard Analysis and Critical Control Point System," Sec. I, p. ii (June 2000) [hereinafter cited as *OIG report*].

² *Id.* at Sec. I, p. I - vi, 31.

to *Salmonella* that cause illness in humans and to require plants to provide inspectors with microbial test results for both generic microbes and pathogens.³

In this comment, we will first address the petitioners' main arguments and then the specific questions raised by FSIS in its Federal Register notice.

HACCP Plans Must Be Self-Contained Documents

Prerequisite programs are a supplement to, but no substitute for, stand-alone HACCP plans addressing food-safety hazards. The requirement of self-contained HACCP plans is critical to FSIS's ability to verify that critical limits are being met and that corrective actions are effective when those limits are exceeded.

Two recent government reports raise significant concerns about the use of prerequisite programs to manage food-safety hazards in meat and poultry plants. A Government Accounting Office (GAO) report issued last December cautioned that FSIS inspectors have only limited oversight of non-HACCP programs and the use of non-HACCP programs to control food-safety hazards prevents the HACCP rule from being consistently applied.⁴ Similarly, the recent OIG report rejected the use of prerequisite programs to manage food safety hazards on several grounds:

1. FSIS has no assurances that prerequisite programs have been adequately developed and implemented.
2. Prerequisite programs do not require documentation to show that they will prevent a specific hazard in the production process.
3. FSIS's oversight is limited by the scope of the plant's HACCP, because inspectors review only HACCP records and not other operational records.⁵

³ OIG report at Sec. I, p. 31.

⁴ Government Accounting Office, "Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System," 19 (Dec. 1999) [hereinafter cited as *GAO*]. GAO analysts found that 13 of 28 HACCP plans they reviewed used good manufacturing practices (GMP's) as justification for excluding food safety hazards from HACCP plans. *Id.* at 8. ("One manager told us that his plant had originally included several critical control points in its HACCP plan, but because USDA inspectors were finding too many instances of noncompliance, the control points were moved to the plant's overall quality control program.")

⁵ OIG report at Sec. I, pp. 14 - 15. The OIG report found that, contrary to FSIS regulations, 9 of the 15 plants the OIG monitored used prerequisite programs or USDA inspection activities in lieu of establishing Critical Control Points (CCPs) in their HACCP plans. *Id.* at 14. We support the agency's efforts to address this problem by developing the In-Depth Verification system of HACCP oversight and by supplemental training of its Circuit Supervisors. See, OIG report at Sec. I, pp. 17-18. However, we agree with the OIG that FSIS must begin to approve CCPs and to require notification of proposed HACCP plan changes. OIG report at Sec. I, pp. 16-17. We also call upon the agency to provide additional training on inspection verification methods and regulatory authority to its on-site inspectors.

Petitioners rely on the 1997 National Advisory Committee on Microbiological Criteria for Foods (NACMCF) guidelines in calling for FSIS recognition of prerequisite programs. However, the NACMCF guidelines are premised on the existence of rigorous prerequisite programs that are “documented and regularly audited.”⁶ The GAO and OIG reports amply demonstrate that non-HACCP prerequisite programs are inadequate to control food-safety hazards in meat and poultry plants. Even industry representatives conceded to GAO investigators that food safety can be jeopardized under the NACMCF approach in facilities with poorly managed or nonexistent prerequisite programs.⁷

Clearly, FSIS should not allow food-safety controls to be relegated to practices and procedures over which its inspectors have little effective oversight. Agency regulations on stand-alone HACCP plans should not be amended as petitioners request, because prerequisite programs are insufficient to manage food-safety concerns.

The Proposed Revisions to the Hazard-Analysis Regulations Are Inadequate to Protect Food Safety

CSPI strongly opposes the petitioners’ requested revisions to the hazard-analysis regulations and offers the GAO and OIG reports in support of its opposition.

Both government reports criticized the very practice that petitioners are now urging the FSIS to adopt: the use of non-HACCP programs to control food-safety hazards that are reasonably likely to occur. “This practice limits the consistent implementation of the HACCP system nationwide, as well as USDA’s oversight of food safety at these plants,” the GAO stated.⁸ The June 2000 OIG report agreed: “Using prerequisite programs such as GMP’s, SSOP’s, and plant operating procedures outside HACCP as justification for determining that a food safety hazard is not likely to occur (not a significant hazard) is not acceptable.”⁹ The OIG explained that when a plant analysis fails to document all food safety hazards, there is reduced assurance that the plant has properly identified and selected preventive measures that, in turn, increases the possibility of contaminated or adulterated products entering the market place.¹⁰ The risk is compounded because of the agency’s inability to verify programs outside the HACCP plan.

⁶ NACMCF, “Hazard Analysis and Critical Control Point Principles and Application Guidelines,” 10 (Aug. 14, 1997).

⁷ *Id.* at 9.

⁸ GAO at 19.

⁹ OIG report at Sec. I, p. 15.

¹⁰ OIG report at Sec. I, p. 26

Even if FSIS were to begin to verify non-HACCP programs, the language in petitioners' suggested amendments to the hazard analysis regulations is too vague to be instructive to either industry or agency inspectors. Among the flaws we see are the following:

- ▶ The term “prerequisite program” is undefined by petitioners. Thus, the scope of acceptable programs that could remove a hazard from analysis under § 417.2(a)(1) would be seemingly limitless.¹¹
- ▶ The requirement in § 417.2(a)(1) to “identify the preventive measures the establishment can apply to control those hazards [that are reasonably likely to occur]” is removed. This step is necessary to help the HACCP team identify which points in the process are Critical Control Points (CCPs).¹²
- ▶ The requirement in § 417.2(a)(1) to consider hazards that occur “before, during, and after entry into the establishment” is removed and weaker language is inserted.¹³ The existing language is important in reinforcing the establishment’s duty not to serve as a pass through for contaminated products.
- ▶ References to “likely occurrence” in § 417.2(a)(1) are removed, together with the references to hazards that have “historically” occurred or have a “reasonable possibility” of occurring. “Likely occurrence” is a critical factor in hazard analysis according to the NACMCF¹⁴ and the FDA seafood HACCP and proposed juice HACCP rules.¹⁵ Moreover, the NACMCF states: “A knowledge of any adverse health-related events historically associated with the product will be of value in this exercise.”¹⁶
- ▶ The new term “significance” is used without a definition or an adequate list of factors to be considered in determining “significance.” Without such guidance, it would be difficult for a plant to conduct a thorough hazard analysis.

The proposed changes to the hazard analysis provision would produce flawed HACCP plans. The NACMCF warned: “If the hazard analysis is not done correctly and the hazards warranting control

¹¹ The NACMCF defined “prerequisite program” as “[p]rocedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.” NACMCF at 7.

¹² NACMCF at 14-15.

¹³ Petitioners instead would insert the following language: “The hazard analysis shall consider the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the customer.”

¹⁴ NACMCF at 13-14.

¹⁵ 63 Fed. Reg. 20450, 20482-83 (April 24, 1998).

¹⁶ NACMCF at 13.

within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.”¹⁷

Without question, the current provisions on hazard analysis must be retained to assist the plants in conducting full hazard analyses and to allow the agency to verify that plants are identifying and controlling food-safety hazards in their establishments.

The Regulations Should Be Amended To Allow The HACCP Plan To Function Fully

CSPI supports petitioners’ new definition of “shipped,” as well as the amendments to §§ 417.3(b)(3) and 417.6(e), because they provide needed clarifications to the existing rule. We agree that a plant should not be penalized when it identifies a defect in pre-shipment review and takes corrective action, including recalling product back to the plant, before the product has left its direct or effective control.

Having said this, it is imperative that FSIS regulations and inspection activities continue to ensure that contamination problems are detected before adulterated foods reach consumers’ tables. Therefore, we oppose any efforts – from petitioners or otherwise – that would weaken FSIS’s ability fulfill its duty in this regard.

We now turn to the questions posed by the agency in its Federal Register notice of May 15, 2000:

FSIS Question 1.

Petitioners cite temperature controls as an example of quality criteria that need not be incorporated into the HACCP plan.¹⁸ We strongly disagree. Temperature is frequently both a quality control and critical control point. Prerequisite programs such as quality controls are directed at plantwide operations and do not focus on the identification and prevention of food hazards.¹⁹ The failure of a quality control does not require corrective action. By contrast, HACCP temperature CCP’s should be based on the temperature at which bacteria multiply in the product, so the failure of a HACCP temperature control necessitates corrective action. The requirement of a self-contained HACCP plan helps the establishment determine when safety has been compromised and corrective action must be taken in order to ensure food safety.

¹⁷ Id.

¹⁸ 65 Fed. Reg. 30952, 30954 (May 15, 2000).

¹⁹ For example, temperature controls in quality criteria are used to prolong shelf-life.

FSIS Question 2.

The Federal Meat Inspection Act²⁰ and Poultry Products Inspection Act²¹ were enacted to protect the health and welfare of consumers by assuring that the meat and poultry products distributed in commerce are “wholesome, not adulterated, and properly marked, labeled and packaged.”²² The agency would violate this statutory mandate if it chose to allow food safety controls to be moved outside the scope of effective agency oversight. Both the GAO and OIG reports stand as clear warnings to the agency that prerequisite programs are wholly inadequate to manage food-safety concerns.

FSIS Question 3.

The changes proposed by petitioners are unnecessary. The GAO concluded that the agency’s HACCP regulations, directives and guidance are consistent with the 1997 NACMCF guidelines.²³ Furthermore, the FDA’s proposed juice HACCP program, published in 1998 after consultation with the NACMCF, closely parallels FSIS’s existing hazard-analysis provisions.²⁴

FSIS Question 5.

Although FSIS designed its meat and poultry HACCP rule to be consistent with the FDA’s seafood HACCP regulations, the two HACCP rules will never be completely coordinated because the two agencies operate under different statutory authorities, under separate government officials, in separate Executive Departments. All told, 12 federal agencies and 35 different laws govern food safety and inspection functions, but this patchwork of laws and regulations lacks consistency, clarity and accountability. The only real solution to this bureaucratic maze is the creation of a single, independent Food Safety Administration that could promulgate and enforce regulations protecting our nation’s food supply from farm-to-table. We call upon the Administration, with the full support and guidance of the Secretary of Agriculture, to assemble a legislative package to create a Food Safety Administration that would ensure uniform food safety for American consumers.

Conclusion

In order to protect consumers and maintain public confidence in the HACCP program, we urge FSIS to reject petitioners’ suggested changes to the existing requirements for hazard analysis

²⁰ 21 U.S.C. § 601 et seq.

²¹ 21 U.S.C. § 451 et seq.

²² 21 U.S.C. §§ 451, 602.

²³ GAO at 3.

²⁴ 63 Fed. Reg. 20450 (April 24, 1998).

and self-contained HACCP plans. We support petitioners' requested revisions on shipping, so that an establishment whose HACCP plan is adequately functioning is not penalized for catching defects in products still within its control.

Respectfully submitted,



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Submitted on behalf of:

American Public Health Association
Consumer Federation of America
National Consumers League
Safe Tables Our Priority