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December 22, 2000

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);
Notice, re-opening of comment period
Docket No. 00-014R2
65 Fed. Reg. 63,229 (Oct. 23, 2000)**

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 that focuses primarily on food safety and nutrition issues and represents over eight hundred thousand members in the U.S. and Canada. We submit these comments on behalf of ourselves and the Consumer Federation of America.

CSPI, on behalf of itself, Consumer Federation of America and several other members of the Safe Food Coalition, responded to the initial comment period on this petition.¹ In this second comment CSPI will address issues relating to FSIS's statutory authority to develop and enforce a

¹ Center for Science in the Public Interest, Comment on the Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) (Docket No. 00-014N), (July 14, 2000).

strong, standards-based HACCP program and, in particular, the definition of the term “food safety hazard” and the requirement that an establishment’s HACCP plan be a standalone document.

In its petition, the meat industry uses the National Advisory Committee on Microbiological Criteria for Food’s (NACMCF) HACCP principles as the measuring stick for determining the adequacy of FSIS’s HACCP rule. Notwithstanding the important work of the NACMCF, FSIS’s duty is to effectuate the will of the Congress, as expressed in the statutes which authorize the agency to act. Anything less would violate the agency’s statutory mandates.

The Federal Meat Inspection Act (FMIA)² and the Poultry Products Inspection Act (PPIA)³ were enacted to assure that meat and poultry products distributed in commerce are “wholesome, not adulterated, and properly marked, labeled and packaged.”⁴ The agency explicitly exercised that broad authority under the FMIA and PPIA when it promulgated the meat and poultry HACCP regulations that the industry petition now seeks to change.

A. The Existing Definition of “Food Safety Hazard” Is Consistent with the Statutes and Case Law.

The petition seeks to redefine “food safety hazard” from a hazard that “may cause” a food to be unsafe, to a “hazard” that is “reasonably likely to cause” illness or injury. To adopt the

² 21 U.S.C. §§ 601 *et seq.*

³ 21 U.S.C. §§ 451 *et seq.*

⁴ 21 U.S.C. §§ 451, 602.

standard suggested by petitioners would impair FSIS's ability to prevent "adulterated" meat and poultry products from reaching consumers.⁵

Under the FMIA and PPIA, the term "adulterated" is defined to include any meat or poultry product that is "unsound, unhealthful, unwholesome, or otherwise unfit for human food."⁶ A meat or poultry product also is "adulterated" if it has been "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."⁷ It is important to note that the statutes do not require actual contamination⁸--nor do they require a showing of the likelihood of contamination--for a meat or poultry product to be considered legally adulterated.

Moreover, in construing a "may render" adulteration standard in the Food and Drugs Act of 1906, the Supreme Court stated:

It is not required that the article of food . . . must affect public health, and it is not incumbent upon the Government in order to make out a case to establish that fact . . . The word 'may' is here used in its ordinary and usual signification . . .⁹

⁵ As a practical matter we note that the definition of "food safety hazard" only goes to the question of what hazards the establishment must consider in performing its hazard analysis. An assessment of "reasonable likelihood," such as the industry is advocating here, is conducted during the hazard analysis. The concerns raised by the industry petition in this regard are amply addressed during the hazard analysis phase of HACCP plan development.

⁶ 21 U.S.C. §§ 453(g)(3), 601(m)(3).

⁷ 21 U.S.C. §§ 453(g)(4), 601(m)(4).

⁸ Actual contamination of the finished product need not be shown for the agency to find legal "adulteration." See *U.S. v. General Foods Corp.*, 446 F. Supp. 740, 752 (N.D.N.Y. 1978) (construing the comparable "adulteration" standard under the Federal Food, Drug and Cosmetic Act), citing *U.S. v. H.B. Gregory Co.*, 502 F.2d 700 (7th Cir. 1974), *cert. denied*, 422 U.S. 1007.

⁹ *United States v. Lexington Mill*, 232 U.S. 399, 411 (1914).

The Court made clear that if the food “may possibly” injure consumers, it is adulterated.¹⁰ Only if the food “cannot by any possibility” cause harm does it escape the ban on adulterated foods.¹¹

In establishing the stringent “may cause” adulteration standards in the FMIA and PPIA, Congress noted: “It is essential in the public interest that the health and welfare of consumers are protected by assuring that meat and meat food products [and poultry products] distributed to them are wholesome, [and] not adulterated . . .”¹² Removing the “may cause” standard from the HACCP definition of “food safety hazard” would frustrate Congress’s clear intent in this regard. Thus, the agency should reject the petitioners’ request to modify Section 417.1.¹³

B. The Requirement For A “Standalone” HACCP Plan Is Consistent With the Statutes.

The industry petition also seeks to limit the scope of the HACCP plan through the use of prerequisite programs that are beyond the agency’s regulatory reach. The effect of petitioners’ request, if granted, would shield important food safety critical control points and limits from agency scrutiny.

Protecting the public from meat and poultry produced under insanitary conditions is a key function of the FMIA and PPIA, and Congress has given the government very broad authority to establish new standards for sanitation. Section 608 of the FMIA specifically directs the Secretary to “prescribe the rules and regulations of sanitation under which [meat-processing plants and other

¹⁰ *Id.*

¹¹ *Id.*

¹² 21 U.S.C. §§ 451, 608.

¹³ 9 C.F.R. § 417.1.

establishments] shall be maintained.”¹⁴ The PPIA contains a similar provision, requiring poultry establishments to be operated “in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary.”¹⁵ In addition to this specific authority, both statutes give the Secretary discretion to establish regulations necessary to implement the statutes.¹⁶ For example, Section 621 of the FMIA provides that the Secretary “shall, from time to time, make such rules and regulations as are necessary for the efficient execution of the provisions of this chapter,” including rules on sanitation.¹⁷

These provisions of the FMIA and PPIA complement the definition of “adulteration” by affording the Agency broad rulemaking authority to define what constitutes sanitary and insanitary conditions in a slaughter or processing plant for the purposes of finding meat or poultry products to be adulterated. To that end, the agency’s HACCP rule requires the development and implementation of written HACCP plans to target and reduce pathogenic microorganisms on raw meat and poultry.¹⁸ The rule also mandates that HACCP plans contain certain elements, including critical control points and critical limits.

¹⁴ 21 U.S.C. § 608.

¹⁵ 21 U.S.C. § 456.

¹⁶ 21 U.S.C. §§ 463, 621.

¹⁷ 21 U.S.C. § 621.

¹⁸ 9 C.F.R. § 417.2.

After the HACCP rule was issued, FSIS published a document clarifying for industry that prerequisite programs, such as good manufacturing practices, are not a substitute for HACCP plans.¹⁹ In particular, the document stated:

[T]he function of critical control points and critical limits is to prevent, eliminate or reduce to an acceptable level one or more food safety hazards . . . To determine whether critical limits are met and, if not, prevent the distribution of adulterated food and future deviations, the regulations require plan-specific monitoring, verification, and corrective action procedures.²⁰

Since prerequisite programs are outside the scope of FSIS's HACCP regulations and are not subject to agency oversight and verification, the agency's ability to monitor the production of safe food would be limited if petitioners' request were granted. Importantly, petitioners do not propose measures that would give FSIS the additional controls it needs to ensure that food safety "critical limits" contained in prerequisite programs are being met and that corrective action is taken when those limits are exceeded.

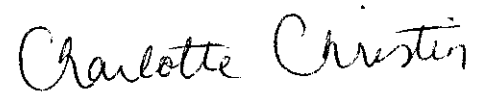
In sum, the maintenance of an adequate HACCP plan is essential to prevent meat and poultry products from becoming adulterated, and an establishment's failure to effectively implement these requirements would constitute a public health hazard. Thus, the agency clearly acted within the bounds of the broad discretion provided to it under the FMIA and PPIA to define proper plant sanitation when it required establishment HACCP plans to be standalone documents.

¹⁹ U.S. Department of Agriculture, Food Safety and Inspection Service, *Contents of HACCP Plans, Compliance with HACCP system regulations*, Vol. 63, No. 20, *Federal Register* (1998), p. 4562.

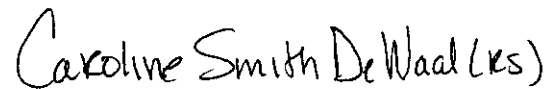
²⁰ *Id.*

For this reason, the petitioners' request to allow prerequisite programs to manage food safety controls should be denied.

Sincerely,

Handwritten signature of Charlotte Christin in black ink.

Charlotte Christin
Food Safety Attorney

Handwritten signature of Caroline Smith DeWaal (ks) in black ink.

Caroline Smith DeWaal
Food Safety Director

On behalf of:

Center for Science in the Public Interest
Consumer Federation of America