

of nonimmigrant visas to immigrate to this country.

Accordingly, no changes have been made as a result of these comments.

#### Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule will not, if promulgated, have a significant adverse economic impact on a substantial number of small entities. This rule allows certain nationals of the PRC to apply for adjustment of status; it has no effect on small entities as that term is defined in 5 U.S.C. 601(6).

#### Executive Order 12866

This rule is not considered by the Department of Justice, Immigration and Naturalization Service, to be a "significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and the Office of Management and Budget has waived its review process under section 6(a)(3)(A).

#### Executive Order 12612

The regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

#### Executive Order 12988 Civil Justice Reform

This interim rule meets the applicable standards set forth in section 3(a) and 3(b)(2) of E.O. 12988.

#### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the

private sector, of \$100 million or more in any 1 year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

#### List of Subjects in 8 CFR Part 245

Aliens, Immigration, Reporting and recordkeeping requirements.

Accordingly, the interim rule amending 8 CFR part 245 which was published at 58 FR 35832 on July 1, 1993, is adopted as a final rule with the following change:

#### PART 245—ADJUSTMENT OF STATUS TO THAT OF A PERSON ADMITTED FOR PERMANENT RESIDENCE

1. The authority citation for part 245 continues to read as follows:

**Authority:** 8 U.S.C. 1101, 1103, 1182, 1255; 8 CFR part 2.

2. In § 245.9, paragraph (m) is revised to read as follows:

#### § 245.9 Adjustment of Status of Certain Nationals of the People's Republic of China under Public Law 102-404.

\* \* \* \* \*

(m) *Effect of enactment on family members other than qualified family members.* The adjustment of status benefits and waivers provided by Public Law 102-404 do not apply to a spouse or child who is not a qualified family member as defined in paragraph (c) of this section. However, a spouse or child whose relationship to the principal alien was established prior to the approval of the principal's adjustment-of-status application may be accorded the derivative priority date and preference category of the principal alien, in accordance with the provisions of section 203(d) of the Act. The spouse or child may use the priority date and category when it becomes current, in accordance with the limitations set forth in sections 201 and 202 of the Act.

Dated: October 31, 1997.

**Doris Meissner,**

*Commissioner, Immigration and Naturalization Service.*

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## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

**9 CFR Parts 301, 307, 308, 310, 318, 381, 416, and 417**

[Docket No. 97-067N]

### Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Notice on complying with food safety standards under the HACCP system regulations.

**SUMMARY:** The Food Safety and Inspection Service is publishing this notice to assure that the owners and operators of federally inspected slaughter establishments are aware that the Agency views its "zero tolerance" for visible fecal material as a food safety standard. Fecal material is a vehicle for microbial pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process. In controlling microbiological contamination, a hazard analysis and critical control point plan for slaughter must be designed, among other things, to ensure that, by the point of post-mortem inspection of livestock carcasses or when poultry carcasses enter the chilling tank, no visible fecal material is present.

**FOR FURTHER INFORMATION CONTACT:** Patricia F. Stolf, Assistant Deputy Administrator, Regulations and Inspection Methods, Food Safety and Inspection Service, Washington, DC 20250-3700; (202) 205-0699.

**SUPPLEMENTARY INFORMATION:** The Food Safety and Inspection Service (FSIS) administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers by preventing the distribution of livestock products and poultry products that are unwholesome, adulterated, or misbranded. A livestock product or poultry product is adulterated under any of a number of circumstances, including the following: if it bears or contains any poisonous or deleterious substance which may render it injurious to health, unless when the substance is not an added substance, the quantity in or on the article does not ordinarily render it injurious to health; if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise

unfit for human food; or if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health (21 U.S.C. 453(g)(1), (g)(3), and (g)(4) and 601(m)(1), (m)(3), and (m)(4)). Both the FMIA and the PPIA include requirements for government inspection and prohibit transactions in products required to be inspected unless they have been "inspected and passed" or if they are adulterated (21 U.S.C. 458(a)(2) and 610(c)).

FSIS enforces a "zero tolerance" standard for visible fecal material on carcasses and carcass parts at inspected establishments that slaughter livestock or poultry. This standard is reflected in the Agency's regulations under the FMIA and the PPIA (9 CFR chapter III, subchapter A and subchapter C, respectively), which require (among other things) that establishments handle livestock carcasses and carcass parts to prevent contamination with fecal material and promptly remove contamination if it occurs (§ 310.18) and that establishments prevent poultry carcasses contaminated with visible fecal material from entering the chilling tank (§ 381.65(e)). When inspection program personnel observe fecal material at post-mortem livestock inspection or thereafter (*i.e.*, at or after the final rail) under the FMIA or when poultry carcasses are about to enter the chilling tank or thereafter (*i.e.*, at any point after the final pre-chiller wash) under the PPIA, they condemn affected carcasses and carcass parts unless the contamination is removed in accordance with regulatory requirements.

The Agency is publishing this notice to assure that the owners and operators of federally inspected slaughter establishments are aware that FSIS regards its zero tolerance for visible fecal material as a food safety standard under both the FMIA and the PPIA. Reiterating the Agency's position is particularly appropriate now, as federally inspected establishments prepare to comply with the hazard analysis and critical control point (HACCP) system regulations (part 417).<sup>1</sup>

<sup>1</sup> Part 417 requirements, as well as pathogen reduction performance standards for *Salmonella* in establishments that slaughter cattle, swine, chickens, or turkeys, prepare ground beef or fresh pork sausage, or process ground chicken or turkey (§§ 310.25(b) and 381.94(b)) will apply as of January 26, 1998, in establishments with 500 or more employees; January 25, 1999, in establishments with 10 or more but fewer than 500 employees

The essence of FSIS's position is that fecal material is a vehicle for microbial pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process (§ 417.2(a) and (b)). Consequently, HACCP plans must control for microbiological contamination at slaughter, and to meet the zero tolerance standard, an establishment's controls must (among other things) include limits that ensure that no visible fecal material is present by the point of post-mortem inspection of livestock carcasses or before poultry carcasses enter the chilling tank (§ 417.2(c)).

In the Pathogen Reduction-HACCP Systems final rule (61 FR 38806, July 25, 1996), FSIS explained the reasoning underlying its position on fecal contamination, and at the beginning of this year, FSIS addressed the role of its zero tolerance for visible fecal material on poultry carcasses in the final rule that codified the standard under the PPIA (62 FR 5139, February 4, 1997). Preparation for implementation of the HACCP system regulations has not changed the Agency's conclusions about the appropriateness of this standard, under the FMIA as well as the PPIA.

As the Agency stated in the Pathogen Reduction-HACCP Systems final rule (61 FR 38837):

In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens. Pathogens may reside in fecal material and ingesta, both within the gastrointestinal tract and on the exterior surfaces of animals going to slaughter. Therefore, without care being taken in handling and dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. Additionally, once introduced into the establishment environment, the organisms may be spread from carcass to carcass.

Because the microbial pathogens associated with fecal contamination are the single most likely source of potential food safety hazard in slaughter establishments, preventing and removing fecal contamination and associated bacteria are vital responsibilities of slaughter establishments. Further, because such contamination is largely preventable, controls to address it will be a critical part of any slaughter establishment's HACCP plan. Most slaughter establishments already have in place procedures designed to prevent and remove visible fecal contamination.

(unless the establishment has annual sales of less than \$2.5 million); and January 25, 2000, in establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

As noted in the zero tolerance final rule and confirmed today with respect to livestock as well as poultry, establishments that process animals must adopt controls that they can demonstrate are effective in reducing the occurrence of microbial pathogens, including controls that prevent the fecal contamination of carcasses (62 FR 5140). Under the HACCP system regulations, critical control points to eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' HACCP plans. Initial validation of a HACCP plan for slaughter and monitoring thereunder, as verified and documented in establishment records, must demonstrate the effective operation of the plan's controls on a continuing basis (§§ 417.3(a), 417.4, and 417.5).

FSIS personnel will continue to verify compliance with the zero tolerance standard in slaughter establishments that are subject to part 417 requirements. The Agency will use visual observations and other findings by FSIS personnel in evaluating the effectiveness of an establishment's preventive controls and corrective actions for fecal contamination (§§ 417.6 and 417.8). The presence of visible fecal contamination on livestock carcasses presented for post-mortem inspection or poultry carcasses entering the chilling tank will mean that establishment controls have failed; repeated failures will evidence that establishment corrective actions have failed to prevent recurrence and, thus, possible system inadequacy.

In addition to enforcing the zero tolerance for visible fecal material, FSIS will use the results of establishment testing for generic *E. coli* (*Escherichia coli* Biotype I, as already required by § 310.25(a) or § 381.94(a)) in assessing how well an establishment is controlling its slaughter and dressing processes to prevent fecal contamination. The pathogen reduction performance standards for *Salmonella* (§§ 310.25(b) and 381.94(b)), which FSIS will enforce through its own testing program, will complement the zero tolerance standard and *E. coli* testing.

Done at Washington, DC, on November 18, 1997.

**Thomas J. Billy,**

*Administrator.*

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