rule applies are: Title—Commodity Loans and Purchases; Number 10.051, as found in the Catalog of Federal Domestic Assistance.

Interim Rules

On March 5, 1987, an interim rule was published in the **Federal Register** at 52 FR 6775 which amended the Honey Price Support Regulations governing 1986–1990 crops. The interim rule amended the regulations at 7 CFR 1434.4(a) and 1434.6(b) to extend the final date in which price support loans and purchase agreements are available to producers from January 31 to March 31 of the year following the year in which the honey is produced and extracted. The extension of the price support availability period will (1) permit producers and cooperatives to take full advantage of the recent amendment to the regulations which permits honey producers to repay their price support loans at the price support level or at a lower level as determined by the Secretary and (2) minimize the quantity of honey which CCC would acquire.

On April 10, 1987, an interim rule was published in the **Federal Register** at 52 FR 11617 which amended the Honey Price Support Regulations governing 1986–1990 crops. The interim rule amended the regulations at 7 CFR 1434.1, 1434.2, 1434.7, and 1434.34 to provide: (1) That the Secretary of Agriculture shall make price support available to producers through loans, purchases or other operations as determined and announced annually by the Secretary, (2) that the honey container requirements may be waived by Commodity Credit Corporation (CCC) when producers agree to redeem, under the lower loan repayment option provision and within a period of time determined by CCC, honey pledged as collateral for price support loans, and (3) for certain other miscellaneous amendments.

The annual determination of the method by which price support would be made available will permit the Secretary to maintain the competitive relationship of honey in domestic and export markets after taking into consideration the cost of producing honey, supply and demand conditions, and world prices of honey. The waiver of honey container requirements will permit producers who agree to redeem honey pledged as collateral, to use the type of containers suitable for their own purposes rather than use the type of containers required by the regulations. The miscellaneous amendments delete certain provisions and definitions which are confusing.

Comment periods were provided with respect to both interim rules but no comments were received. Accordingly it has been determined that both interim rules should be adopted as final rules without any changes.

List of Subjects in 7 CFR Part 1434

Honey, Loan programs—agriculture, Price support programs, Warehouse.

Final Rule

Accordingly, the interim rules published at 52 FR 6775 and 52 FR 11617, which amended 7 CFR Part 1434, are hereby adopted as final rules without any change.

Authority: Sec. 4, 62 Stat. 1070, as amended (15 U.S.C. 714(b); sec. 5, 62 Stat. 1072 (15 U.S.C. 714c); secs. 201, 401, 63 Stat. 1052, 1054, as amended (7 U.S.C. 1446, 1421).

Signed at Washington, DC on December 14, 1987.

Milton Hertz,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 87–29111 Filed 12–17–87; 8:45 am]

BILLING CODE 3410–05–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 212, 214, 238, 245, 248, and 299

[INS Number: 1054–87]

Guam Visa Waiver

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule implements the visa waiver provisions provided in section 14 of the Omnibus Territories Act, Pub. L. 99–396, whereby the nonimmigrant visa requirement is waived for certain aliens applying as nonimmigrant visitors for business or pleasure solely for admission into and stay on Guam for a period not to exceed fifteen days. It facilitates travel to Guam, while insuring through limitations on periods of authorized stay, hearing rights, adjustment of status eligibility, through a carrier contract requirement and sanctions for carrier violations, that Guam is protected from an influx of immigration law violators.

EFFECTIVE DATE: December 18, 1987.

FOR FURTHER INFORMATION CONTACT: Dwight S. Faulkner, Assistant Chief Inspector, Immigration and Naturalization Service, 425 I Street, NW—Room 7123, Washington, DC 20536, Telephone: (202) 633–3995.

SUPPLEMENTARY INFORMATION: In pursuant of tourism and commercial expansion, the government of Guam has long sought relief from the requirement that all aliens entering Guam for business or pleasure be in possession of valid nonimmigrant visas. The visa requirement is applicable to Guam in that in a geographical sense, and pursuant to the terms of the Immigration and Nationality Act, Guam is a part of the United States.

The Guam visa waiver legislation stipulates that the waiver must not represent a threat to the welfare, safety, or security of the United States, its territories and commonwealths. Yet, as stated in the Senate and House Records, the Congressional intent supports an initially liberal application; in particular, countries with visa denial rates through 16% for the preceding year. Therefore, a country whose refusal rate exceeds the 16.9% limitation would only be given consideration if that country established a United States preinspection station within its territorial boundaries, as preinspection minimizes potential threats by stopping them at their source. The waiver then applies to visitors from countries within geographical proximity to Guam and who thus maintain a traditional cultural interchange. It also applies to visitors from countries which, although not geographically proximate to Guam, have a substantial volume of traffic into Guam and extend reciprocal privileges to citizens of the United States. In addition, as Congress did not intend for Guam to become an avenue for circumvention of normal refugee processing, countries deemed by the Department of State to be of special humanitarian concern are excluded from participation.

Entry under this section bars the alien from adjustment of status to temporary or permanent resident; change of nonimmigrant status; extension of stay; or the right to an exclusion or deportation hearing, other than on the basis of a request for asylum, thus paralleling the visa waiver pilot program.

The issue of carrier liability is addressed in the House Report of August 27, 1986, which states in pertinent part, "In addition to the obligations that this provision would impose on the Immigration and Naturalization Service, the program that it would establish necessarily imposes responsibilities on the airlines who must cooperate with its controls, especially with regard to preclearance." Accordingly, the carrier must be

prepared to establish that each alien it transports without a visitor's visa was prima facie eligible for the visa waiver, because the carrier is subject to fine pursuant to section 273 of the Immigration and Nationality Act for transporting any alien not in possession of an unexpired visitor's visa, as required, unless the requirement is waived pursuant to this part. The carrier contract and ticket restrictions parallel the visa waiver pilot program, thereby substantiating the intent of Congress regarding carrier responsibility.

Implementation of the terms of the visa waiver is contingent upon the establishment on Guam of an adequate arrival/departure control system and a determination that such waiver does not represent a threat to the welfare, safety or security of the United States, any threat to be dealt with on a country by country basis, resulting in the Commissioner's immediate removal of that country from the list. The Attorney General, the Secretary of State, and the Secretary of the Interior, after consultation with the Governor of Guam, shall jointly detemine that these conditions have been met.

Compliance with 5 U.S.C. as to notice of proposed rulemaking and delayed effective date is impracticable and contrary to public interest as the revision has been mandated by an amendment to the Immigration and Nationality Act by Pub. L. 99–396.

In accordance with 5 U.S.C. 605(b) the Commissioner of Immigration certifies that this rule does not have a significant economic impact on a substantial number of small entities. This is not a major rule within the meaning of section 1(b) of E.O. 12291.

The information collection requirements contained in this document have been submitted to the Office of Management and Budget for review in accordance with the provisions of the Paperwork Reduction Act.

List of Subjects

8 CFR Part 212

Administrative practice and procedure, Aliens, Passports and visas.

8 CFR Part 214

Administrative practice and procedure, Aliens.

8 CFR Part 238

Administrative practice and procedure, Aliens, Transportation lines.

8 CFR Part 245

Administrative practice and procedure, Aliens, Permanent resident status, Temporary resident status.

8 CFR Part 248

Adjustment of status, Administrative practice and procedure, Aliens.

8 CFR Part 299

Forms, Reporting and recordkeeping requirements.

Accordingly, Chapter I of Title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. The authority citation for Part 212 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1182, 1184, 1225, 1226, 1228, 1252, 8 CFR Part 2.

2. In § 212.1, existing paragraphs (e) through (j) are redesignated (f) through (k), and a new paragraph (e) is added to read as follows:

§ 212.1 Documentary requirement for nonimmigrants.

* * * * *

(e) *Aliens entering Guam pursuant to section 14 of Pub. L. 99–396, "Omnibus Territories Act."* (1) A visa is not required of an alien who is a citizen of a country enumerated in paragraph (e)(3) of this section who:

(i) Is classifiable as a vistor for business or pleasure;

(ii) Is solely entering and staying on Guam for a period not to exceed fifteen days;

(iii) Is in possession of a round-trip nonrefundable and nontransferable transportation ticket bearing a confirmed departure date not exceeding fifteen days from the date of admission to Guam;

(iv) Is in possession of a completed and signed Visa Waiver Information Form (Form I–736);

(v) Waives any right to review or appeal the immigration officer's determination of admissibility at the port of entry at Guam; and

(vi) Waives any right to contest any action for deportation, other than on the basis of a request for asylum.

(2) An alien is eligible for the waiver provision if all of the eligibility criteria in paragraph (e)(1) of this section have been met prior to embarkation and the alien is a citizen of a country that:

(i) Has a visa refusal rate of 16.9% or less, or a country whose visa refusal rate exceeds 16.9% and has an established preinspection or preclearance program, pursuant to a bilateral agreement with the United States under which its citizens traveling to Guam without a valid United States visa are inspected by the Immigration and Naturalization Service prior to departure from that country;

(ii) Is within geographical proximity to Guam, unless the country has a substantial volume of nonimmigrant admissions to Guam as determined by the Commissioner and extends reciprocal privileges to citizens of the United States;

(iii) Is not designated by the Department of State as being of special humanitarian concern; and

(iv) Poses no threat to the welfare, safety or security of the United States, its territories, or commonwealths.

Any potential threats to the welfare, safety, or security of the United States, its territories, or commonwealths will be dealt with on a country by country basis, and a determination by the Commissioner of the Immigration and Naturalization Service that a threat exists will result in the immediate deletion of that country from the listing in paragraph (e)(3) of this section.

(3) The following countries now meet the eligibility criteria as stated in paragraph (e)(2) of this section:

Australia, Brunei, Burma, Indonesia, Japan, Malaysia, Nauru, New Zealand, Papua New Guinea, Singapore, Solomon Islands, the United Kingdom (including citizens of the colony of Hong Kong), Vanuatu, and Western Samoa.

(4) Admission under this section renders an alien ineligible for:

(i) Adjustment of status to temporary or permanent resident;

(ii) Change of nonimmigrant status; or

(iii) Extension of stay.

(5) A transportation line bringing any alien to Guam pursuant to this section shall:

(i) Enter into a contract on Form I–760, made by the Commissioner of the Immigration and Naturalization Service in behalf of the government;

(ii) Transport only an alien who is a citizen and in possession of a valid passport of a country enumerated in paragraph (e)(3) of this section;

(iii) Transport only an alien in possession of a round-trip, nontransferable transportation ticket:

(A) Bearing a confirmed departure date not exceeding fifteen days from the date of admission to Guam,

(B) Valid for a period of not less than one year,

(C) Nonrefundable except in the country in which issued or in the country of the alien's nationality or residence,

(D) Issued by a carrier which has entered into an agreement described in part (5)(i) of this section, and

(E) Which the carrier will unconditionally honor when presented for return passage; and

(iv) Transport only an alien in possession of a completed and signed Visa Waiver Information Form I–736.

PART 214—NONIMMIGRANT CLASSES

3. The authority citation for Part 214 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1184, 8 CFR Part 2.

4. In § 214.2(b)(1) the following sentence is added at the end of the existing paragraph:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(b) * * *

(1) * * * Those B–1 and B–2 visitors admitted pursuant to the waiver provided at § 212.1(e) of this Chapter may be admitted to and stay on Guam for a period not to exceed fifteen days and are not eligible for extension of stay.

* * * * *

PART 238—CONTRACTS WITH TRANSPORTATION LINES

5. The authority citation for Part 238 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1228.

6. In § 238.3 paragraph (a) is revised to read as follows:

§ 238.3 Aliens in immediate and continuous transit.

(a) *Form I–246 agreements.* A transportation line bringing aliens to the United States pursuant to § 212.1(f)(1) of this chapter shall enter into an agreement on Form I–426. Such agreement shall be negotiated directly by the Central Office and the head offices of the transportation lines.

* * * * *

7. In Part 238 a new § 238.5 is added to read as follows:

§ 238.5 Aliens entering Guam pursuant to section 14 of Pub. L. 99–396, "Omnibus Territories Act".

(a) *Form I–760 agreements.* A transportation line bringing aliens to Guam under the visa waiver provisions of § 212.1(e) of this Chapter shall enter into an agreement on Form I–760. Such agreements shall be negotiated directly by the Central Office and head offices of the transportation lines.

(b) [Reserved]

PART 245—ADJUSTMENT OF STATUS TO THAT OF PERSONS ADMITTED FOR PERMANENT RESIDENCE

8. The authority citation for Part 245 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1154, 1159, 1182, 1255, 8 CFR Part 2.

9. In § 245.1(b) a new paragraph (b)(11) is added to read as follows:

§ 245.1 Eligibility.

* * * * *

(b) * * *

(11) Any alien admitted as a visitor under the visa waiver provisions of § 212.1(e) of this chapter.

* * * * *

PART 248—CHANGE OF NONIMMIGRANT CLASSIFICATION

10. The authority citation for Part 248 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1184, 1258, 8 CFR Part 2.

11. In § 248.2 a new paragraph (e) is added to read as follows:

§ 248.2 Ineligible classes.

* * * * *

(e) Any alien admitted as a visitor under the visa waiver provisions of § 212.1(e) of this chapter.

PART 299—IMMIGRATION FORMS

12. The authority citation for Part 299 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 8 CFR Part 2.

13. § 299.1 is amended by adding the following immediately before the entry "ICAO" in numerical sequence:

§ 299.1 Prescribed forms.

* * * * *

I–736 (7–23–87)—Guam Visa Waiver Information

I–760 (7–22–87)—Agreement Between Transportation Line, Operating Between Foreign Territory and Guam, and United States.

* * * * *

Dated: November 19, 1987.

Alan C. Nelson,

Commissioner, Immigration and Naturalization service.

Dated: November 4, 1987.

Joan M. Clark,

Assistant Secretary, Bureau of Consular Affairs, Department of State.

Dated: November 10, 1987.

Kittie Baier,

Principal Deputy Assistant Secretary, Territorial and International Affairs, Department of the Interior.

Dated: November 19, 1987.

Joe Ada,

Governor of Guam.

[FR Doc. 87–28963 Filed 12–17–87; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 303 and 381

[Docket No. 87–002F]

Experimentation With Procedures for Determining Intensity of Inspection Coverage in Processing Establishments; Waivers of Provisions of Regulations

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Final rule.

SUMMARY: On March 30, 1987, the Administrator, FSIS, published an interim final rule with request for comments, thereby initiating a period of experimentation as the first step in changing the Federal inspection system in establishments conducting post-slaughter preparation of meat food products and/or post-slaughter and evisceration processing of poultry products to a "discretionary inspection" (DI) system; that is, one in which the frequency and the manner of government inspection are based on consideration relevant to effective regulation of such products and protection of the public health and welfare. Such a change is called for by 1986 amendments to the Federal Meat Inspection Act (FMIA) and is authorized by the Poultry Products Inspection Act (PPIA). The object of the experimentation is to determine whether and, if so, to what extent the intensity of Federal inspection of meat food and poultry products exceeds that which FSIS should consider or deem necessary under these statutes. During the period of experimentation, the frequency of government inspection at some official establishments is being reduced. To the extent that this or other conditions and methods of inspection coverage are identified as conflicting with current provisions of the regulations, such

provisions are to be waived for the period of experimentation.

FSIS has reviewed the information, views, and arguments submitted during the comment period and is now publishing a final rule. Except for a clarification in wording, the provisions of this final rule do not differ from those of the iterim rule.

FSIS now anticipates publication of a proposal to amend the Federal meat and the poultry products inspection regulations to include the new and revised provisions needed for full implementation of a DI system in the near future. The provisions for experimentation set forth herein will be rescinded upon completion of that rulemaking, unless the experimentation period has been terminated earlier.

EFFECTIVE DATE: December 18, 1987.

FOR FURTHER INFORMATION CONTACT: Judith A. Segal, Director, Policy and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–6525.

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Effect on Small Entities

The Administrator, FSIS, has determined that this final rule is not a major rule under Executive Order 12291. It is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The Administrator also has determined that this action will not have a significant economic impact on a substantial number of small entities, in accordance with the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*).

The basis for these determinations includes the fact that waiver of certain provisions of the regulations and other aspects of this experimentation affect only a limited number of processing establishments subject to inspection under the FMIA and/or the PPIA for a limited period. Any economic benefits which might indirectly result from inclusion in pilot testing (e.g., reduction in payments for inspection program employees working overtime) are relatively small and affect only a portion of the establishments in which pilot tests are conducted, and selecting all establishments within a designated site that are found to satisfy the establishment performance criteria is further reducing the opportunity for any adverse effect on competition. Both the number of establishments selected and the length of time during which they are included in a pilot test of DI procedures is not being extended beyond that which is needed to test the program variables under consideration in establishments with different characteristics. FSIS selected only 14 establishments initially and plans to select not more than about 200 in all, or approximately 3 percent of the federally inspected establishments that will be subject to the fully implemented DI system. Moreover, the Agency is conducting pilot testing in most establishments for only 3 to 6 months, with termination of the experimentation period expected by the end of the spring of 1988. As particular pilot tests are ended, the Agency returns to pre-experimentation conditions and methods of inspection coverage until full implementation of the DI system; at that time, all establishments (including those previously selected for pilot testing) will be evaluated.

Background

The Secretary of Agriculture's duties include implementation of 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 prevent the preparation or processing and distribution of meat, meat food products, and poultry products which are adulterated or misbranded or not properly marked, labeled, and packaged (21 U.S.C. 453 (g) and (h), 457, 458, 601 (m) and (n), 607, and 610). Responsibility for exercising the functions of the Secretary contained in the FMIA and PPIA has been delegated to the Administrator, FSIS (7 CFR 2.17(g) and 2.55(a)(2)). Among those functions are administration of the inspection requirements for meat food and poultry products and sanitation practices in establishments preparing or processing such products for commerce or otherwise subject to inspection under the FMIA or PPIA (21 U.S.C. 455, 456, 605, 606, and 608) and the issuance of rules and regulations executing provisions of these Acts (21 U.S.C. 463(b) and 621).

Late last year the Congress of the United States amended the inspection requirements for meat food products in section 6 of the FMIA (21 U.S.C. 606). Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (FTA) (Pub. L. 99–641), rather than requiring the Secretary to cause inspectors appointed for that purpose to make "an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment," such examination and inspection is to be:

> conducted with such frequency and in such manner as the Secretary considers necessary, as provided in rules and regulations issued by the Secretary, taking into account such factors as the Secretary considers to be appropriate. . . [FTA, section 403(a)].

Three such factors are specified in the statute: the nature and frequency of processing operations at an establishment, the adequacy and reliability of the processing controls and sanitary procedures at an establishment, and the history of compliance with inspection requirements in effect under the FMIA by the operator of an establishment or anyone responsibly connected with the business (i.e., any partner, officer, director, holder, or owner of 10 per centum or more of its voting stock or employee in a managerial or executive capacity) that operates that establishment.

By so amending the FMIA, Congress authorized the Department, for a 6-year period.* to base the frequency with which and the manner in which meat food products are examined and inspected by program employees on considerations relevant to the effective regulation of meat food products and the protection of the public health and welfare. The legislation also reflects Congressional recognition that full implementation of a new system of government inspection of post-slaughter processing operations will take time: Title IV and the amendments made thereby became effective on the date of enactment (November 10, 1986), except that sections 6, 9, and 21 of the FMIA (21 U.S.C. 606, 609, and 621), as in effect immediately before that date, "apply with respect to establishments until the Secretary . . . first issues rules and regulations to implement the amendments made by section 403(a)" (FTA, section 408). This rulemaking has initiated implementation of those amendments; however, it is only the first step in a process intended to assure an orderly transition to the "discretionary inspection" (DI) system mandated by the recent amendments to the FMIA.

*Not later than 6 years after the date of enactment, Congress is to evaluate the operation and effects of the amendments made by section 403 of the FTA for the purpose of determining whether to extend or modify the operation of such amendments and enact such legislation as may be necessary to efficiently and effectively carry out the FMIA. (FTA section 407).

This rulemaking also has initiated changes that will result in the institution of a DI system for operations processing products from poultry carcasses that have passed post mortem inspection. The PPIA authorizes the Department to vary the frequency and the manner of government inspection in establishments conducting post-slaughter and evisceration processing of poultry products based on effective regulation and public protection considerations. In particular, section 6(b) (21 U.S.C. 455(b)) requires the Secretary to cause government inspectors to make "post mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection. . ."

The Administrator of FSIS now believes that the frequency and manner of reinspection by program employees of poultry products made from poultry previously slaughtered and eviscerated and found to be not adulterated that is "deem[ed] necessary" should be varied, taking into account the same factors as those considered appropriate under the amended FMIA. To date, however, the rules and regulations and other aspects of inspection coverage have been basically comparable to those prescribed pursuant to the narrower pre-amendment authority in the FMIA. Therefore, exercising the authority to implement a DI system of inspection presents orderly transition concerns under the PPIA as well.

The Department supported the 1986 amendments to the FMIA, as well as administering the PPIA to institute the same approach to the inspection of comparable processing operations, because it believes that the efficiency and effectiveness of the meat and poultry inspection program in utilizing available resources to maximize the level of compliance with regulatory requirements, and thus achievement of the purposes of the FMIA and PPIA (see 21 U.S.C. 451 and 602 and FTA, section 402), can be improved by adjusting the frequency and the manner of government inspection. However, before modifying the inspection system as a whole and fully implementing a DI system, rules regarding the frequency and the manner of government inspection should be tested in order to assess their adequacy and appropriateness and thereby protect the integrity and effectiveness of the inspection program.

In particular, the Administrator of FSIS concluded that procedures for determining whether and, if so, to what extent the intensity of inspection coverage in some processing establishments exceeds that which should be considered or deemed necessary under the FMIA, as amended (21 U.S.C. 606), or the PPIA (21 U.S.C. 455) and for designing the conditions and methods of inspection coverage in such establishments should be tested in a small-scale, experimental setting in order to obtain sufficient information on which to base final amendments to varous portions of the Federal meat inspection and the poultry products inspection regulations. Therefore, the first rules and regulations issued in implementing the amendments made by section 403(a) of the FTA to section 6 of the FMIA (21 U.S.C. 606) and instituting a comparable DI system under the PPIA consisted of provisions for conducting pilot tests of such DI system in establishments subject to inspection under the FMIA (9 CFR 303.2) or the PPIA (9 CFR 381.3(c)–(e)).

The Administrator also concluded that the Federal meat inspection regulations should address the waiver for limited periods of provisions of those regulations to provide for situations in which alternative courses of action are appropriate and do not conflict with either the purposes or the provisions of the statute. In particular, the Administrator determined that, despite potential or actual conflicts with provisions of the regulations, such alternative courses of action should be pursued in administering the FMIA in order to permit (1) appropriate and necessary action in the event of a public health emergency and (2) experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements. In both of these classes of cases, the waiver decision reflects a judgment that certain provisions of the regulations as applied in specific situations should be temporarily suspended in order to achieve the purposes of the FMIA and that the alternative course of action pursued during such a limited period is not inconsistent with FMIA provisions.

The inclusion of such a rule in the Federal meat inspection regulations (9 CFR 303.1(g)) specified Agency policy for carrying out its statutory responsibilities and conducting the inspection program. The poultry products inspection regulations already included such a rule (9 CFR 381.3(b)). However, the emergency situations provided for in the poultry products inspection regulations were limited to those that are "national" in scope. Since such waivers also may better enable FSIS to take appropriate and necessary action in response to an emergency in a smaller geographic area and the focus of concern here is assuring adequate public health protection, the Administrator determined that the words "public health" should be substituted for "national" in § 381.3(b) of the regulations (9 CFR 381.3(b)).

Nineteen submissions (17 written comments and 2 oral presentations) were received during the 30 days following publication of the interim final rule. (Two additional persons subsequently submitted comments that include views already expressed by others referred to herein.) Comments were submitted by 9 individuals, 3 of whom further identified themselves (1 as a concerned citizen who formerly worked in a plant that manufactured processed meat products, 1 as a consumer, and 1 as a USDA food inspector who has worked in packing plants). Comments also were submitted on behalf of food inspectors by their union representative and by a United States Senator, a State department of agriculture, and 7 industry members (1 processing company, 4 trade associations of meat packers, processors, and/or purveyors, and 2 trade associations of food processing companies).

Comments from individuals, the food inspectors union, and the Senator expressed opposition to the interim final rule, to changing the inspection system, and/or to a DI system. Comments from the State department of agriculture and industry members expressed support for the discretionary inspection concept and/or for implementation of a DI system; 7 of these commenters addressed the interim final rule, and 5 of them expressed views or concerns about features of the anticipated DI system or the implementing regulations.

FSIS wishes to point out that the March 30 notice requested comments concerning the interim final rule and stated that interested members of the public will have an opportunity to comment on the design of the DI system and specific proposed regulatory changes when the Agency proposes the regulations needed for full implementation of a DI system (52 FR 10028). Nevertheless, a number of commenters addressed issues involved in changing to a DI system, including the types of regulatory provisions and Agency decisionmaking believed to be

appropriate for full implementation of a DI system, rather than or in addition to the interim final rule. FSIS has reviewed all of the comments submitted, but its consideration of those that go beyond the question at hand—whether any changes should be made to the interim final rule (52 FR 10028)—has been limited. As indicated in the March 30 notice, FSIS is conducting pilot testing in order to obtain additional information before proposing final amendments to the Federal meat and the poultry products inspection regulations and to provide a meaningful opportunity to the public to participate in a rulemaking to consider the new and revised provisions needed for full implementation of a DI system (52 FR 10030, 10031). FSIS has not yet reached conclusions on issues such as whether or not various criteria for evaluating the performance of establishments should be further refined or supplemented before proposing their application to all establishments conducting post-slaughter preparation of meat food products and/or post-slaughter and evisceration processing of poultry products.

Of the commenters expressing opposition, only 3 addressed the interim final rule, and they also are against changing to a DI system. Two of these commenters contended that FSIS is proposing to lower the standards of inspection and will do so on a permanent basis, not just temporarily, and one of them feels the proposal to experiment with reducing the frequency of inspection of meat and poultry products will jeopardize the products' wholesomeness. Both basically view the inspection laws as addressing "Dollars versus public safety" concerns that have not changed. The third opposes suspension of the regulations because consumers will think that products bearing the inspection legend have been inspected when they have been only monitored. This commenter contended that the inspection program for poultry has become a disaster and DI will lead to the same in processing if not worse, questioned how food inspectors can insure that processing plants are using inspected meats and poultry products when they no longer get daily inspection, and called for a change of direction at the Washington level to make an effective inspection program the first priority.

Other commenters opposing changes in the system of government inspection expressed similar views and concerns. They believe that plants will not comply with sanitation or product requirements if inspectors are not present or the frequency of government inspection is reduced, that most plants cannot be trusted to take responsibility for some of their own inspection since the companies' objective is making a profit, that industry is going to be permitted to regulate itself, that FSIS is not or will not be adequately protecting consumers, and/or that an increase in foodborne illnesses may or will result from implementation of DI, with 1 predicting that DI will result in an annual economic effect of over $100 million due to increased food poisoning-related medical bills. In criticizing current FSIS enforcement and the 1986 law amending the FMIA or in questioning cutting back on inspection activities and asking that the DI system be reevaluated, two of these commenters cited figures on salmonella in poultry and annual rates of foodborne illness and deaths. One of them also referred to an assurance, given to him and another Senator by the Administrator, that passage of the bill to amend the FMIA would not result in involuntary reassignments of meat inspectors and requested information on inspector employment and steps intended to be taken under the DI system to ensure full and adequate inspection of all meat and poultry. In addition, 1 commenter took the position that DI should not interfere with inspector overtime: inspectors working over 8 hours should be compensated and plants working over 8 hours a shift should be charged.

Of the commenters favoring DI, 6 expressed support for FSIS experimentation under the interim final rule. FSIS's action was supported as a first step approach to implement a DI system, an initiative to test the procedures and protocol for implementing provisions of the 1986 law amending the FMIA, moving forward in a timely manner on the issue, or utilizing a trial period to gain some practical experience in DI so that final regulations will offer maximum protection of the food supply at a minimum burden to industry. One commenter stated general support for the interim final rule and another fully supported the procedures outlined therein, believing this to be a logical first step and information-gathering process in line with implementation of a DI program. Five of these commenters, all trade associations, indicated interest in assisting or working with FSIS during implementation of a DI system. One of them also commended FSIS for the recent finalization of comprehensive canning regulations, which it believed will serve as a very strong foundation in building a DI program for this industry segment, and encouraged the inclusion of canning establishment coverage in the current experimentation program. Another recommended including several State inspected processing operations in the pilot study and soliciting State officials' cooperation and support to make the pilot program more meaningful because of the anticipated ramifications and impact on inspection frequency determinations for such operations.

Commenters indicated that they favor DI in order to modernize the inspection program, because the processor bears the burden of complying with the Department's rules and regulations, or as permitting the utilization of inspection resources where they are most needed, more efficient and cost-decreasing usage of available inspection personnel nationwide, or Agency and industry realization of production efficiencies from sources such as expanded operating hours and a lessened need to incur overtime inspection costs. One commenter believes a DI program is feasible and cost effective for canning and freezing operations because processing operations and product safety requirements are the same whether or not products contain meat or poultry ingredients. Another believes that by reducing overtime costs a DI program should make small meat packers more cost competitive in the marketplace, thereby enabling them to modernize and improve product quality.

Aspects or provisions of the interim final rule were critiqued by 4 of the commenters favoring DI. As regards evaluation of the performance of establishments (9 CFR 303.2 (b)(1) and (c)(1) and 381.3 (d)(1) and (e)(1)), 1 commenter feels that for a corporation with multiple domestic processing establishments, the evaluation concerning compliance information and competency of those conducting the operation should be applied to the total corporation rather than to individual plant sites, and that such a change would be in direct cooperation with this company's approach to centralized Quality Assurance. This commenter also expressed the view that a company's ability to respond to and its manner of correcting noncompliance situations are more critical in evaluating an establishment's performance than the 10-year record of noncompliance criterion. Another commenter took the position that the Department seems to be placing undue emphasis on compliance history elements that may be outdated and may not necessarily portray a proper picture of existing conditions (which is what the Department should primarily evaluate)

because management changes, application of tighter controls, or correction of improper FSIS inspection procedures erroneously pointing to noncompliance could negate the validity of past records. This commenter believes that decisions concerning the frequency, type, and intensity of inspection should be based primarily on the adequacy of processing controls in the establishment to assure production of safe, wholesome, and properly labeled products and that the application of proper controls demonstrates management commitment to assure regulatory compliance.

In addition, 2 commenters characterized criteria for evaluating an establishment's performance, particularly the management competence factor and the substantial and recent noncompliance criterion (9 CFR 303.2 (b)(1)(ii) and (c)(1)(i) and 381.3 (d)(1)(ii) and (e)(1)(i)), as subjective. One of them suggested that more objective criteria, including the health risk of the operation, be used in determining "eligibility" for DI and contended that the plant's processing controls should be the most important factor in such a determination and that the adequacy of such controls should outweigh the more subjective compliance and management attitudes factors. The other requested that FSIS develop an objective profile of its intended "disqualifiers" and consider whether an official warning letter for a minor or technical FMIA violation constitutes such documented noncompliance. One commenter also noted that their initial evaluations seem to indicate the "screening process" is more complex than necessary and cautioned the Department to avoid creating an overly restrictive, cumbersome, bureaucratic maze.

As regards determinations involving the characteristics of establishments (9 CFR 303.2 (b)(2) and (c)(2)(i) and 381.3 (d)(2) and (e)(2)(i)), 1 commenter took issue with FSIS Directive 1030.2, which ranks pizza assembly as "medium" complexity when meat components are bought from sources outside the plant. This commenter feels that such a classification is unjustified, and at odds with a 1983 staff report, and suggested that pizza assembly establishments be reclassified as "simple" processing because their handling of meat is limited to slicing already inspected meat and placing it on the product and this is analogous to operations FSIS classifies as "simple".

The submissions from 3 of these commenters and 2 others favoring DI also included views and concerns about full implementation of a DI system by the Department, some of which are similar to comments on the interim final rule. To 1 commenter, a crucial concern is that decisions be made in an objective manner and be based on plant performance criteria that evolve from considering critical public health risks, uninfluenced by unrelated matters. A second hopes and expects that the final DI regulation will be more detailed than the interim final rule and is especially interested in the type of inspection to be conducted under the DI system (e.g., the types and frequency of tests and the composition of inspection teams). One commenter foresees the likelihood that initial implementing rules will require modification, urges the Department to conduct another rulemaking before full implementation, and views industry input as necessary to assure adequate program testing and review. According to this commenter, demonstrated controls are in place in plants with approved total quality control systems and other plants should be required to demonstrate their in-house control programs to the Department, with an on-site assessment, in order to be considered for "periodic inspection". According to this commenter, demonstration of processing control should be limited to items directly related to product safety, adulteration, and misbranding. Another commenter hopes that FSIS will not make total quality programs a prerequisite for a lesser degree of inspectional presence because this would result in the possibility of other plants continually incurring overtime inspection costs, despite a compliance history warranting a lesser degree of physical inspector presence, which would tend to put the smaller packer at a disadvantage.

As regards establishment evaluations, one commenter favors addressing the nature and frequency of inspection as a function of processing controls, taking the position that such controls should be adequate to meet the complexity, volume, and size of the operations. According to this commenter, plant initiated actions to correct deficiencies are part of any praoperly designed control program and isolated observations of noncompliance may not adequately describe overall conditions; the Department should clearly identify the specific criteria necessary to disqualify a plant for periodic inspection and verifiable noncompliance instances should be carefully documentd before a plant is considered "ineligible". Another commenter took the position that those establishments considered and "rejected" for DI by the Agency should be provided with a notice, since rejection may have adverse economic and/or competitive consequences, and requested that the regulations include a notice which specifies the issues on which the firm did not meet the qualifying criteria and provides an opportunity for appeal.

FSIS's consideration of the comments received indicates that the scope and purpose of the experimentation period and the anticipated changes in the Federal inspection system are not clear to some members of the public. First, the only establishments affected by this rule are ones in which meat food products and/or poultry products are made from livestock previously slaughtered and/or poultry previously slaughtered and eviscerated in official establishments (9 CFR 303.2(a) and 381.3(c)). When fully implemented, the DI system will apply to all establishments preparing or processing such products, but not to livestock slaughter or poultry slaughter and evisceration operations in packing and other official establishments. The system of ante- and post-mortem inspection is not being changed (see 21 U.S.C. 455 and 603–605).

Second, issues that concern a number of commenters have already been considered by Congress during its deliberations on the 1986 amendments to the FMIA. Those deliberations resulted in amendments to the inspection requirements for meat food products and a recognition of the Department's authority under the PPIA to institute a comparable system for poultry products processed beyond slaughter and evisceration. Congress concluded (FTA, section 402), and FSIS agrees, that the 1986 amendments further effective government regulation of processed products and protection of the health and welfare of consumers (21 U.S.C. 602).

Third, the primary change called for under the anticipated system of inspection is the exercise of greater discretion by the Department in utilizing inspection program resources (21 U.S.C. 455(b) and 606(a)(2)). The responsibility of regulated industry members to prepare or process products only in compliance with statutory requirements and not to do business in adulterated or misbranded products or products required to be inspected unless they have been inspected and passed (21 U.S.C. 458(a) and 610) is unchanged. The standards for determining if product is adulterated or misbranded (21 U.S.C. 453((g) and (h) and 601 (m) and (n)), including the requirement that products bear an inspection legend (21 U.S.C. 453(h)(12) and 601(n)(12)), also are unchanged.

Thus, the fundamental task for FSIS in implementing a DI system is to decide how best to manage available program resources to maximize compliance with sanitation and product requirements under the FMIA or the PPIA in federally inspected establishments preparing meat food products and/or processing poultry products beyond slaughter and evisceration. To date, FSIS has focused on the procedures to be used by the Agency in determining the frequency and manner of government inspection under a DI system, particularly whether and, if so, to what extent the intensity of inspection coverage exceeds that which FSIS should consider or deem necessary. Inherent in such determinations is the exercise of judgment by FSIS. The factors appropriate for consideration in a DI system, including those specified by Congress (21 U.S.C. 602(a)(2)), are not precise measures to be applied in a rote manner. The FMIA and PPIA commit determinations about the frequency and manner of government inspection of meat food products and reinspection of poultry products to the Department's discretion.

The criteria specified in the interim final rule for use during the period of experimentation indicate the types of decisions that the Agency must make under a DI system. Among other things, the provisions call for establishment-by-establishment evaluations of performance and characteristics (9 CFR 303.2(b) and 381.3(d)) because Congress has directed that the situations in particular establishments preparing meat food products be taken into account (21 U.S.C. 602(a)(2)) and because FSIS believes that the conditions and methods of its inspection coverage should reflect the particular regulatory situation at an establishment. Similarly, while FSIS believes that the procedures used in an establishment to control the production process, environment, and resulting product are an important component of the performance evaluation (9 CFR 303.2(b)(1)(iii) and 381.3(d)(1)(iii)), their adequacy and reliability depend in part on the competence of establishment management (9 CFR 303.2(b)(1)(ii) and 381.3(d)(1)(ii)). Additionally, compliance history (9 CFR 303.2(b)(1)(i) and 381.3(d)(1)(i)) is a factor that should be considered in making a predictive judgment about the probability of future noncompliance (9 CFR 303.2(c)(1) and 381.3(e)(1)). (See 21 U.S.C. 606(a)(2) (B) and (C).) Moreover, the criteria in these provisions denote the Agency's intention to consider corrective actions and other responses to establishment deficiencies and noncompliance with applicable regulatory requirements (including, but not limited to, those involving critical public health risks) by taking into account the demonstrated ability and commitment of management (9 CFR 303.2(b)(1)(ii) (B) and (C) and 381.3(d)(1)(ii) (B) and (C)) and both the nature and frequency of any documented instances of noncompliance (9 CFR 303.2(c)(1)(i) and 381.3(e)(1)(i)).

Of the establishments initially selected for pilot testing, one prepares canned products. As testing proceeds, FSIS anticipates that additional establishments with canning operations will be identified for review and, if found by the Agency to satisfy its selection criteria, included in pilot tests. While institution of a DI system of Federal inspection may well have ramifications for State inspection programs, this period of experimentation is being conducted pursuant to the Federal meat and the poultry products inspection regulations to initiate implementation of amendments to the FMIA and to exercise existing authority under the PPIA. Therefore, only federally inspected establishments have been or will be identified for review.

During the period of experimentation, FSIS is using the assessment of establishment performance in selecting establishments for inclusion in pilot tests, and a focus of that testing is reducing the frequency of inspection by meat and poultry inspection program employees. However, as indicated above, when fully implemented, the DI system will apply to all establishments preparing meat food products and/or processing poultry products beyond slaughter and evisceration. At that time, FSIS will, in accordance with criteria developed after further rulemaking, evaluate all such establishments in order to make determinations about the frequency and the manner of government inspection. Those criteria will not be used to specify classes of establishments. (I.e., FSIS will not be "reject[ing]" establishments or classifying them as "ineligible".) Instead, the objective will be to determine the conditions and methods of inspection coverage that are appropriate in the circumstances presented, and at a given establishment, such conditions and methods might include various modifications of previous inspection coverage.

As information is obtained from pilot testing and existing regulations are reviewed, FSIS is considering the range of regulatory issues presented by full implementation of a DI system. These issues include concerns of some commenters, such as compliance with the requirement that products be prepared or processed only from livestock previously slaughtered and/or poultry previously slaughtered and eviscerated in official establishments and the appropriate categorization of processing operations by complexity. FSIS has concluded, however, that except for the clarification in wording discussed below, the provisions of the interim final rule should not be changed. The Agency encourages these commenters and other interested members of the public to participate in the upcoming rulemaking on the new and revised provisions needed for full implementation of DI system.

Provisions of the Final Rule

The provisions in this final rule include the factors that appear appropriate for consideration in assessing the performance of an establishment to determine whether the intensity of inspection coverage can be reduced while continuing to assure effective regulation of products and protection of the public health and welfare (9 CFR 303.2(b)(1) and 381.3(d)(1)), as well as the factors that appear appropriate for consideration in assessing the characteristics of an establishment on which to base the level of Federal inspection and other conditions and methods of government inspection during such experimentation (9 CFR 303.2(b)(2) and 381.3(d)(2)). For purposes of both meat food product and poultry product inspection, criteria are specified to take into account the factors included in section 6(a)(2) of the amended FMIA (21 U.S.C. 606(a)(2); section 403(a) of the FTA): Nature and frequency of processing operations (9 CFR 303.2(b)(2) and 381.3(d)(2)), adequacy and reliability of processing controls and sanitary procedures (9 CFR 303.2(b)(1) (ii) and (iii) and 381.3(d)(1) (ii) and (iii)), and history of compliance with inspection requirements (9 CFR 303.2(b)(1)(i) and 381.3(d)(1)(i)).

FSIS is using the information being obtained during the experimentation period to decide whether the criteria set forth in these provisions should be further refined or supplemented before their application to all establishments conducting post-slaughter preparation of meat food products and/or post-slaughter and evisceration processing of poultry products is proposed as part of the upcoming rulemaking on a proposal to amend the Federal meat inspection regulations and the poultry products inspection regulations to include the new and revised provisions needed for full implementation of a DI system. FSIS

currently anticipates completion of that rulemaking by the end of the spring of 1988. The final rule so amending the regulations also will rescind the provisions for experimentation with DI procedures set forth herein, unless such experimentation period has been terminated earlier.

FSIS is selecting establishments for inclusion in a pilot test from those the Administrator identifies for review (9 CFR 303.2(a) and 381.3(c)). The Agency expects that the number of establishments selected for pilot tests may increase from the initial group of 14 to as many as 200 as groups of establishments in new, limited geographical sites are phased in over the course of the experimentation period. Such sites are being designated on the basis of their suitability for generating information to satisfy evaluation needs. The length of time during which establishments are included in a pilot test is being varied depending on the testing involved and is not expected to exceed 3 to 6 months in most establishments.

An establishment so identified may be selected for inclusion in the pilot testing of procedures for reducing the intensity of inspection coverage if, and only if, evaluation of the performance of the establishment (1) reveals, in records compiled no earlier than 10 years before, no documented instances of substantial and recent noncompliance with applicable regulatory requirements and (2) evidences the competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements (9 CFR 303.2(c)(1) and 381.3(e)(1)). The "substantial and recent" criterion is intended to assure that in assessing compliance history (9 CFR 303.2(b)(1)(i) and 381.3(d)(1)(i)), both the nature and frequency of noncompliance with process, environment, and/or product requirements are taken into account for an appropriate length of time. Thus, noncompliance is regarded as substantial when, for example, it involves the preparation of adulterated product that could pose a serious public health threat if distributed to consumers or recurring failures that could be considered indicative of a lack of regard for the public health or welfare; and, within the 10-year time limit on record documentation, the more substantial the violation, the longer it is to be regarded as sufficiently recent for consideration. The second performance evaluation criterion reflects the assessment of both management's knowledge of appropriate manufacturing practices and applicable regulatory requirements, demonstrated ability to apply that knowledge in a timely and consistent manner, and commitment to correcting deficiencies noted by inspection program employees and otherwise assuring compliance with applicable regulatory requirements (9 CFR 303.2(b)(1)(ii) and 381.3(d)(1)(ii)) and the procedures used to control the production process, environment, and resulting product in order to assure and monitor compliance with requirements of the FMIA or PPIA and rules and regulations promulgated thereunder (9 CFR 303.2(b)(1)(iii) and 381.3(d)(1)(iii)). The objective is to include an establishment in pilot testing only if there are adequate indications that the probability of future noncompliance at such establishment is low.

In any establishment included in such a pilot test, during experimentation the conditions and methods of inspection coverage of operations other than the slaughter of livestock or the slaughter and evisceration of poultry, including the frequency of government inspection, are being determined by the inspection program based on (1) an evaluation of the characteristics of the particular establishment, (2) the significance of potential health consequences of noncompliance, and (3) the availability of meat and poultry inspection program employees (referred to as "Program" and "Inspection Service" employees in the Federal meat inspection and the poultry products inspection regulations, respectively) (9 CFR 303.2(c)(2)(i) and 381.3(e)(2)(i)). Drawing upon its experience in regulating a broad range of establishments with differing characteristics and allocating inspection program resources, FSIS developed tentative guidelines for use in making these determinations during pilot testing. Thus, for example, in assessing processing operation complexity (9 CFR 303.2(b)(2)(i) and 381.3(d)(2)(i)), FSIS is categorizing operations as involving product preparation or processing that is "simple", "medium", or "complex" by applying Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85, which is available for public inspection and copying in the Policy Office). FSIS also is utilizing a three category approach in assessing certain other establishment characteristics (9 CFR 303.2(b)(2) (iii), (iv), and (vi) and 381.3(d)(2) (iii), (iv), and (vi)): production volume (highest total product volume during any quarter within the preceding year as less than 60,000; 60,000 to 1,000,000; or more than 1,000,000 pounds), establishment size (less than 12,000; 12,000 to 80,000; or more than 80,000 square feet), and the scope of any livestock slaughter or poultry slaughter and evisceration operations (none, part time, or full time) also being conducted (but to which the DI system will not apply) at an establishment which makes meat food products and/or makes poultry products that are processed further (i.e., a "combination" establishment).

The Federal meat inspection regulations (9 CFR Chapter III, Subchapter A) and the poultry products inspection regulations (9 CFR Part 381) will continue to apply to establishments in which FSIS is pilot testing except to the extent that the frequency of Federal inspection or other conditions and methods of inspection coverage determined to be appropriate for the period of experimentation are identified as conflicting with provisions of the regulations (9 CFR 303.2(c)(2)(ii) and 381.3(e)(2)(ii)). To that extent, the Administrator will waive such provisions for the period of experimentation, in accordance with §§ 303.1(g) and 381.3(b) of the regulations (9 CFR 303.1(g) and 381.3(b)), which set forth Agency policy as to when the temporary suspension of provisions of the regulations comports with its responsibilities in administering the FMIA and the PPIA. Consistent with that policy, any such waivers permit the testing of new procedures that are expected to facilitate definite improvements and do not conflict with statutory purposes or provisions.

Finally, FSIS is repeating the words "frequency of" before the second reference to "Federal inspection" in §§ 303.2(c)(2)(i) and 381.3(e)(2)(i) of the regulations (9 CFR 303.2(c)(2)(i) and 381.3(e)(2)(i)), consistent with the opening phrase of these provisions. FSIS has concluded that this minor clarification should be made to avoid an inadvertent and potentially confusing shorthand.

As already discussed, this final rule has been in effect for several months on an interim basis. The Agency has determined that it should continue in effect, with the minor change in wording now included for clarification. Therefore, the action taken today is effective upon publication.

List of Subjects

9 CFR Part 303

Meat inspection.

9 CFR Part 381

Poultry products inspection.

On the basis of the foregoing, the Federal meat inspection regulations (Part 303) and the poultry products

inspection regulations (Part 381) are amended as follows:

PART 303—[AMENDED]

1. The authority citation for Part 303 is added to read as follows and the authority citation following § 303.1 is removed:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438 (21 U.S.C. 71 *et seq.*, 601 *et seq.*, Pub. L. 99–641, Title IV, 100 Stat. 3556, 3567–72, 33 U.S.C. 466–466k); Pub. L. 96–511; 94 Stat. 2812 (44 U.S.C. 3501 *et seq.*).

2. Section 303.1(g) is revised to read as follows:

§ 303.1 Exemptions.

* * * * *

(g) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.

3. Part 303 is further amended by adding a new § 303.2 to read as follows:

§ 303.2 Experimentation: Intensity of inspection coverage.

(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99–641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, is so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as "responsibly connected" is defined in section 401(g) of the Act,

(ii) the competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowlege in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and

(vi) The size of such establishment.

(c)(1) For the period of experimentation described in paragraph (a) of this section, the frequency of inspection by Program employees of operations other than slaughter may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (b)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2) (i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (b)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Program employees.

(ii) To the extent that such frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this subchapter, the Administrator will waive such provisions for the period of experimentation, in accordance with § 303.1(g) of this subchapter.

PART 381—[AMENDED]

4. The authority citation for Part 381 continues to read as follows:

Authority: 71 Stat. 441, 82 Stat. 791, as amended, 21 U.S.C. 451 *et seq.*; 76 Stat. 663 (7 U.S.C. 450 *et seq.*), unless otherwise noted.

5. Section 381.3(b) is amended by removing the word "national" and inserting, in its place, the words "public health".

6. Section 381.3 is further amended by adding new paragraphs (c) through (e) to read as follows:

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[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

§ 381.3 Administration.

* * * * *

(c) Pursuant to section 6 of the Act, the Administrator believes that, in establishments processing poultry products at which inspection under the Act and regulations is required, the frequency with which and the manner in which poultry products made from poultry previously slaughtered and eviscerated in official establishments are reinspected by Inspection Service employees should be based on considerations relevant to effective regulation of poultry products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be deemed necessary pursuant to section 6 of the Act, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Inspection Service employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(d) The determinations referred to in paragraph (c) of this section shall be made by the Inspection Service and shall reflect evaluations of the performance and the characteristics of such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person operating such establishment or by anyone responsibly connected with the business operating such establishment, as "responsibly connected" is defined in section 18(a) of the Act,

(ii) The competence of the person operating such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Inspection Service employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter and evisceration operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Federal Meat Inspection Act also are processed at such establishment, and

(vi) The size of such establishment.

(e)(1) For the period of experimentation described in paragraph (c) of this section, the frequency of inspection by Inspection Service employees of operations other than slaughter and evisceration may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (d)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (d)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Inspection Service employees.

(ii) To the extent that frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this part, the Administrator will waive such provisions for the period of experimentation, in accordance with paragraph (b) of this section.

Done at Washington, DC, on December 14, 1987.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

[FR Doc. 87-29007 Filed 12-17-87; 8:45 am]

BILLING CODE 3410-DM-M

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40 and 70

Domestic Licensing of Byproduct, Source, and Special Nuclear Material; Revision of List of Non-Agreement States in Region III

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations pertaining to non-Agreement States in Region III to reflect the removal of Illinois and Iowa from its list of non-Agreement States because they have become Agreement States. The amendments are being made to inform affected licensees and members of the public of the change in status of these two States.

EFFECTIVE DATE: December 18, 1987.

FOR FURTHER INFORMATION CONTACT: Donnie H. Grimsley, Director, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-7211.

SUPPLEMENTARY INFORMATION: In January 1986, Iowa became an Agreement State and in July 1987, Illinois became the NRC's most recent Agreement State. Inadvertently overlooked when the two States became Agreement States were several places in the NRC's regulations that continued to refer to Illinois and Iowa as non-