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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 220

[FNS–2008–0033]

RIN 0584–AD65

School Food Safety Program Based on Hazard Analysis and Critical Control Point Principles

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Final rule.

SUMMARY: This final rule implements a legislative provision which requires school food authorities participating in the National School Lunch Program (NSLP) or the School Breakfast Program (SBP) to develop a school food safety program for the preparation and service of school meals served to children. The school food safety program must be based on the hazard analysis and critical control point (HACCP) system established by the Secretary of Agriculture. The food safety program will enable schools to take systematic action to prevent or minimize the risk of foodborne illness among children participating in the NSLP and SBP.

DATES: *This final rule is effective* January 14, 2010.

FOR FURTHER INFORMATION CONTACT: William Wagoner or Marisol Benesch, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service at (703) 305–2590.

SUPPLEMENTARY INFORMATION:

I. Background

Section 111 of the Child Nutrition and WIC Reauthorization Act of 2004 (Pub. L. 108–265; June 30, 2004) amended section 9(h) of the Richard B. Russell National School Lunch Act (NSLA) (42 U.S.C. 1758(h)) by adding the requirement that school food authorities

(SFAs) implement a food safety program at each food preparation and service facility participating in the NSLP or the SBP. The food safety program, which became a requirement in the school year beginning July 1, 2005, must be based on the HACCP system established by the Secretary of Agriculture. A HACCP-based food safety program should enable SFAs to identify potential food hazards, identify critical points where hazards can be controlled or minimized through control measures, and establish monitoring procedures and corrective action.

Prior to Public Law 108–265, there was no federal requirement for a HACCP-based food safety program for SFAs participating in the NSLP and SBP. Program regulations only required SFAs to follow State and local sanitation and health standards. SFAs were expected to check food temperatures per State and local regulations, but were not required to follow a systematic food safety program.

To provide guidance and help SFAs implement the required food safety program in School Year 2005–2006, FNS issued two memoranda in January 2005 and July 2006, as well as “Guidance for School Food Authorities: Developing a School Food Safety Program Based on the Process Approach to HACCP Principles” in June 2005, <http://www.fns.usda.gov/cnd/CNlabeling/Food-Safety/HACCPGuidance.pdf>. This practical guidance was followed by a proposed rule published in the **Federal Register** on August 5, 2008 (73 FR 45359). The FNS guidance and the proposed rule recommend the Process Approach because it is considered easier to implement than the traditional HACCP method. The Process Approach, developed by the Food and Drug Administration, simplifies traditional HACCP by grouping foods according to preparation process and applying the same control measures to all menu items within a group, instead of developing a HACCP plan for each item. The proposed rule also gave SFAs the option to implement traditional HACCP.

This final rule codifies the requirements set forth in the proposed rule. The statutory requirement has already been implemented by program operators with the assistance of guidance, technical assistance, and training from FNS and the National

Food Service Management Institute (NFSMI).

II. Discussion of Public Comments

The comment period for the proposed rule ended September 19, 2008 (73 FR 45359). FNS received seven public comments: one from an advocate, one from a State Agency, three from school districts, and two from individuals. The comments addressed the following areas:

Food Safety Program Based on HACCP

A program advocate would like assurances that the HACCP-based food safety programs SFAs had in place prior to this rule would be considered acceptable. The commenter asked the Department to emphasize that SFAs have discretion to follow traditional HACCP or the Process Approach to HACCP.

FNS stated in the proposed rule that SFAs may keep an existing food safety program if it reflects all the HACCP principles described in the rule. SFAs may follow traditional HACCP or the Process Approach to HACCP.

A large school district commented that the Process Approach only saved minimum time, and recommended the Department allow 18–24 months for phased-in implementation to give program operators sufficient time to design/implement the program and train the food service staff. The commenter also expressed concern about the potential cost of equipment for the food safety program and stated that it spent \$50,000 in specialized thermometers for all its SFA sites. Another commenter recommended that SFAs be allowed flexibility to develop cost-effective and unique systems that reflect the HACCP principles.

Public Law 108–265 established July 1, 2005 as the effective date for the food safety program requirement. The Department identified school year 2005–2006 as the implementation period for the food safety program, as required by statute, and provided SFAs practical guidance and training in collaboration with NFSMI. Several years have passed since the implementation date established by law; therefore, phased-in implementation is not an option. By now, SFAs should be working on reviewing and improving their established HACCP-based food safety program.

Implementation of this legislative requirement is not expected to result in major equipment expenses for program operators. SFAs operating the NSLP and SBP should already have thermometers and other basic equipment necessary to prepare, serve, and store meals safely in compliance with State and local public health standards, as previously required by the NSLP and SBP regulations.

With regard to ease of implementation and flexibility, the Department wishes to emphasize that the practical guidance and training provided to SFAs presented a simplified version of the Process Approach adapted for school food service operations. The Process Approach is less complex than traditional HACCP and is inherently flexible because it gives each SFA the ability to tailor the food safety program to each site. Furthermore, SFAs have discretion to follow either the Process Approach or traditional HACCP.

Monitoring and Recording Food Temperature Daily

A large school food authority commented that developing and monitoring the HACCP-based food safety program is time consuming. One commenter asked that schools be allowed to maintain electronic records, and another recommended the Department issue schedules for food safety inspections and temperature monitoring.

While the food safety program must reflect all HACCP principles discussed in the FNS guidance, it does not have to be elaborate or extremely time consuming. A number of resources were developed to facilitate implementation of the school food safety program. NFSMI produced templates and other materials to help SFAs implement a basic HACCP-based food safety program in School Year 2005–2006. In addition, NFSMI provided technical assistance and training to SFAs upon request from the State Agencies. These resources continue to be available to SFAs to enhance their current HACCP-based food safety program.

FNS encourages the use of technology to reduce burden when possible. This final rule allows SFAs to maintain electronic records as long as they can be retrieved. FNS does not consider it necessary to set a schedule for temperature checking and recording because HACCP already identifies the critical control points for temperature monitoring and the timing is defined by the food preparation process. The schedule for food safety inspections is determined by the State or local agency in charge of inspections. The food safety

inspection requirement is discussed in a separate rule.

Recordkeeping Period

Commenters in general recommended that recordkeeping requirements be based on the incubation period for a likely pathogen or communicable disease and not exceed 1 year. As suggested by several commenters, the proposed recordkeeping period will be changed to six months following each month's temperature records. FNS believes this recordkeeping requirement will not be an unnecessary burden on schools and will allow schools to document their efforts to comply with the food safety program requirement and to prevent foodborne illness.

Miscellaneous Comments

Commenters would like funding for training and program implementation, as well as additional guidance and training activities. A commenter requested refresher training on the Process Approach and regular updates to the FNS practical guidance. Another commenter asked FNS to explicitly state that State Administrative Expense Funds can be used for food safety purposes.

NFSMI continues to offer training to support the implementation of school food safety programs. In addition, FNS continues to serve as an information resource for SFAs and assesses the need for additional training and technical assistance resources on a regular basis.

With regard to funding, State Administrative Expense funds are available to support food safety training and technical assistance activities sponsored by the State agency.

III. Conclusion

This final rule amends 7 CFR 210.9 to incorporate the food safety program in the provisions covered by the SA agreement, 7 CFR 210.13 to add a new paragraph on the food safety program requirement based on HACCP, 7 CFR 210.15 to address the recordkeeping requirement, 7 CFR 210.18 to include the food safety program as part of the administrative reviews, and 7 CFR 220.7 to extend the food safety program requirement to the SBP.

IV. Procedural Matters

Executive Order 12866

This rule has been determined to be significant and was reviewed by the Office Management and Budget in conformance with Executive Order 12866.

Regulatory Impact Analysis

Need for Action

This action is needed to formally implement the food safety program requirement established by Public Law 108–265. More than 101,000 schools participate in the NSLP and SBP and serve over 38 million meals daily in a variety of settings. Although school meals are generally safe, it is essential that SFAs follow a systematic food safety program to safeguard the health of children.

Benefits

HACCP is considered an effective method to attain control of foodborne illness risk factors. As a result of this rule, SFAs will implement a HACCP-based food safety program in their preparation and service sites to prevent or minimize the risk of foodborne illness.

Costs

The Regulatory Impact Analysis estimates that the total cost associated with implementing a HACCP-based food safety program at \$46 million in the first year of implementation. FNS expects that the subsequent annual costs associated with this proposal would decline as one-time program development efforts are completed, with 5 year costs totaling approximately \$116 million.

Regulatory Flexibility Act

This final rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612). Implementation of this rule is not expected to impose a significant economic impact on a substantial number of small entities. Existing program regulations in § 210.13(a) require that SFAs follow proper sanitation and health standards established under State and local law. Many SFAs have Standard Operating Procedures in place to comply with State and local public health regulations, or have already implemented a food safety program as a result of the statutory requirement, subsequent FNS guidance and NFSMI training available since 2005.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, the Department generally must prepare a written statement, including a cost/

benefit analysis, for proposed and final rules with Federal mandates that may result in expenditures to State, local, or tribal governments in the aggregate, or to the private sector, of \$100 million or more in any 1 year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that impose costs on State, local, or tribal governments or to the private sector of \$100 million or more in any 1 year. Program operators already have basic equipment and standard operating procedures in place to prepare meals that comply with sanitation and health standards established under State and local law. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

The NSLP is listed in the Catalog of Federal Domestic Assistance under No. 10.555 and the SBP is listed under No. 10.553. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related Notice [48 FR 29115, June 24, 1983], these Programs are included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Since the NSLP and SBP are federally funded programs administered at the State level, FNS headquarters and regional office staff have ongoing formal and informal discussions with State and local officials regarding operational issues. This arrangement allows State and local agencies to provide feedback that forms the basis for any discretionary decisions made in this and other rules.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13132.

Prior Consultation With State and Local Officials

Shortly after passage of the Child Nutrition and WIC Reauthorization Act of 2004, FNS met with officials from State education agencies to discuss the new school food safety requirements and to hear their concerns. FNS also solicited input from the Food Safety and Inspection Service, Food and Drug Administration, National Food Service Management Institute, Centers for Disease Control and Prevention, School Nutrition Association, National Environmental Health Association, and State and local public health agencies. Furthermore, the Department published a proposed rule on August 5, 2008 to solicit public comments, which have been addressed in the preamble.

Nature of Concerns and Need To Issue This Rule

During the public comment period, some State and local officials raised concerns that school food service personnel may lack the expertise and time to properly implement a HACCP-based food safety program. Others expressed concern that the proposed requirement will increase the workload of school foodservice personnel.

This rule establishes in regulation the requirement that SFAs follow food safety procedures that are generally regarded as essential in institutional food service operations. Implementation of this requirement also supports the food safety recommendations in the 2005 Dietary Guidelines for Americans.

Extent to Which FNS Meets Those Concerns

To address the stakeholders' concerns, FNS offered the Process Approach to HACCP, which is considered an easier method than traditional HACCP. FNS adapted the Process Approach to fit the school food service operation, issued practical guidance in 2005, and worked with NFSMI to develop training materials for program operators. The guidance and training materials provide step-by-step instructions for implementing the food safety program and examples. FNS will assess the need for additional training and technical assistance resources as we continue to learn about program experience at the State and local levels.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice

Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations, or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures under § 210.18(q) or § 235.11(f) must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this final rule in accordance with the Department Regulation 4300-4, "Civil Rights Impact Analysis," to identify any major civil rights impacts the rule might have on children on the basis of age, race, color, national origin, sex or disability. After a careful review of the rule's intent and provisions, FNS has determined that this rule does not affect the participation of protected individuals in the NSLP and SBP.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. Chap. 35, *see* 5 CFR 1320) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. Once OMB approves the information collection, FNS will merge these burden hours into National School Lunch Program, OMB # 0584-0006, expiration date 5/31/2012. A 60-day notice was published in the **Federal Register** at 70 FR 45359 on August 5, 2008, which provided the public an opportunity to submit comments on the information collection burden resulting from this rule. FNS will publish a document in the **Federal Register** once these requirements have been approved. FNS is increasing the burden hours from 1,938,870, which was the total burden hours published in the proposed rule on August 5, 2008, to 2,248,284. The increase is due to the increase in program participants in school food authorities and schools. The 2,248,284 takes into account the increase from 20,710 to 20,858 school food authorities and an increase from 100,398 to 101,705 schools that participate in the NSLP and the 81,517 schools that participate in the SBP.

ESTIMATED ANNUAL BURDEN

| | Section | Number of respondents | Annual frequency | Average burden per response | Annual burden hours |
|---|--------------------------|-----------------------|------------------|-----------------------------|---------------------|
| Reporting | | | | | |
| State agency shall confirm that each school food authority has a food safety program based on HACCP principles. New Burden. | 7 CFR 210.18(h)(6) | 57 | 61 | 1 | 3,477 |
| SFA must implement a food safety program based on HACCP principles for each food preparation and service facility under its jurisdiction. New burden. | 7 CFR 210.13(c) | 20,858 | 1 | 76 | 1,585,208 |
| Total New Reporting | | | | | 1,588,685 |
| Recordkeeping | | | | | |
| Schools record and maintain NSLP records from food safety program. New Burden. | 7 CFR 210.15(b)(5) | 101,705 | 180 | .02 | 366,138 |
| Schools record and maintain SBP records from food safety program. | 7 CFR 220.7 | 81,517 | 180 | .02 | 293,461 |
| Total New Recordkeeping | | | | | 659,599 |
| Total Burden Requested | | | | | 2,248,284 |

E-Government Act Compliance

FNS is committed to complying with the E-Government Act 2002, 44 U.S.C. 3601, et seq. to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects

7 CFR Part 210

Grant programs—education, Grant programs—health, Infants and children, Nutrition, Penalties, Reporting and recordkeeping requirements, School breakfast and lunch programs, Surplus agricultural commodities.

7 CFR Part 220

Grant programs—education, Grant programs—health, Infants and children, Nutrition, Reporting and recordkeeping requirements, School breakfast and lunch programs.

Accordingly, 7 CFR parts 210 and 220 are amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. The authority citation for 7 CFR part 210 continues to read as follows:

Authority: 42 U.S.C. 1751–1760, 1779.

2. In § 210.9, revise paragraph (b)(14) to read as follows:

§ 210.9 Agreement with State agency.

* * * * *

(b) * * *

(14) Maintain, in the storage, preparation and service of food, proper sanitation and health standards in conformance with all applicable State and local laws and regulations, and comply with the food safety requirements of § 210.13;

* * * * *

3. In § 210.13, redesignate paragraph (c) as paragraph (d), and add a new paragraph (c) to read as follows:

§ 210.13 Facilities management.

* * * * *

(c) *Food safety program.* The school food authority must develop a written food safety program for each of its food preparation and service facilities that meets the requirements in paragraph (c)(1) or paragraph (c)(2) of this section.

(1) A school food authority with a food safety program based on traditional hazard analysis and critical control point (HACCP) principles must:

- (i) Perform a hazard analysis;
- (ii) Decide on critical control points;
- (iii) Determine the critical limits;
- (iv) Establish procedures to monitor critical control points;
- (v) Establish corrective actions;
- (vi) Establish verification procedures;

and

(vii) Establish a recordkeeping system.

(2) A school food authority with a food safety program based on the process approach to HACCP must ensure that its program includes:

- (i) Standard operating procedures to provide a food safety foundation;
- (ii) Menu items grouped according to process categories;

(iii) Critical control points and critical limits;

- (iv) Monitoring procedures;
- (v) Corrective action procedures;
- (vi) Recordkeeping procedures; and
- (vii) Periodic program review and revision.

* * * * *

4. In § 210.15, a. Revise the introductory text in paragraph (b); and b. Revise paragraph (b)(5).

The revisions read as follows:

§ 210.15 Reporting and recordkeeping.

* * * * *

(b) *Recordkeeping summary.* In order to participate in the Program, a school food authority or a school, as applicable, must maintain records to demonstrate compliance with Program requirements. These records include but are not limited to:

* * * * *

(5) Records from the food safety program for a period of six months following a month's temperature records to demonstrate compliance with § 210.13(c), and records from the most recent food safety inspection to demonstrate compliance with § 210.13(b).

5. In § 210.18, add a new paragraph (h)(6) to read as follows:

§ 210.18 Administrative reviews.

* * * * *

(h) * * *

(6) *Food safety.* The State Agency must examine records to confirm that each school food authority under its

jurisdiction meets the food safety requirements of § 210.13.

* * * * *

PART 220—SCHOOL BREAKFAST PROGRAM

■ 6. The authority citation for 7 CFR part 220 continues to read as follows:

Authority: 42 U.S.C. 1773, 1779, unless otherwise noted.

■ 7. In § 220.7:

■ a. Add a new paragraph (a)(3); and

■ b. Revise paragraph (e)(8).

The addition and revision read as follows:

§ 220.7 Requirements for participation.

(a) * * *

(3) A school food authority must implement a food safety program meeting the requirements of § 210.13(c) and § 210.15(b)(5) of this chapter at each of the food preparation and service facilities under its jurisdiction serving breakfasts.

* * * * *

(e) * * *

(8) Maintain, in the storage, preparation and service of food, proper sanitation and health standards in conformance with all applicable State and local laws and regulations, and comply with the food safety requirements in paragraph (a)(2) and paragraph (a)(3) of this section;

* * * * *

Dated: December 4, 2009.

Kevin W. Concannon,

Under Secretary, Food, Nutrition, and Consumer Services.

[FR Doc. E9-29799 Filed 12-14-09; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2008-0032]

RIN 0579-AC80

Importation of Cooked Pork Skins

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to allow for the importation of cooked pork skins from regions affected with foot-and-mouth disease, swine vesicular disease, African swine fever, and classical swine fever under certain conditions. We are taking this

action after preparing a risk assessment that concluded that the cooking methods examined are sufficient to inactivate the pathogens of concern. This action will relieve restrictions on the importation of cooked pork skins while continuing to protect against the introduction of those diseases of concern.

DATES: *Effective Date:* January 14, 2010.

FOR FURTHER INFORMATION CONTACT: Dr. Karen A. James-Preston, Director, Technical Trade Services-Products, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; (301) 734-8172.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) prohibit or restrict the importation of certain animals and animal products into the United States to prevent the introduction of communicable diseases of livestock and poultry. The regulations in §§ 94.4, 94.8, 94.9, and 94.12, among others, contain requirements for the importation of cured or cooked meat and pork or pork products from regions where rinderpest, foot-and-mouth disease (FMD), African swine fever (ASF), classical swine fever (CSF), and swine vesicular disease (SVD) exist.

On July 2, 2008, we published a proposed rule¹ in the **Federal Register** (73 FR 37892-37896, Docket No. APHIS-2008-0032) in which we proposed to allow for the importation of cooked pork skins from regions affected with FMD, ASF, CSF, and SVD under certain conditions. Specifically, we proposed to amend the FMD-related provisions in § 94.4, the ASF-related provisions in § 94.8, the CSF-related provisions in § 94.9, and the SVD-related provisions in § 94.12 by adding a new paragraph to each section that authorizes the importation of pork skins if they have been cooked using one of the two cooking methods described in the proposed rule.

We solicited comments on the proposed rule for 60 days ending September 2, 2008. We received six comments by that date, from State agriculture departments, a pork industry association, and a snack food manufacturer. The commenters raised several issues related to the proposed rule. These issues are discussed below.

All the commenters expressed concern that importing cooked pork

skins into the United States would increase the risk of introducing swine diseases into the United States. Some commenters expressed concern that disease could be introduced through contaminated packaging as well as through the product itself.

As we explained in the proposed rule, cooked pork skins imported into the United States must meet the other requirements of our regulations as well as the provisions of the Federal Meat Inspection Act and the regulations in 9 CFR part 327. These safeguards include requirements for pork and pork products from regions where ASF exists to be packed in clean new packaging that is clearly distinguishable from packaging used for pork or pork products not eligible for export to the United States. These safeguards have been effective in preventing the introduction of swine diseases into the United States.

One commenter stated that the cooking processes do not alter protein functionality in pork skins. The commenter expressed concern that pork skin pellets could be rehydrated to their original consistency and could therefore present a risk of spreading disease.

As we explained in the proposed rule, cooked pork skins would be fully cooked by one of two cooking processes, both of which exceed the heat inactivation requirements for the pathogens of concern. In addition, the low levels of water activity in the pellets would make it unlikely that the pathogens would survive, since viruses prefer moist conditions. Rehydrating the pellets would not reactivate the pathogens.

One commenter stated that when pork skins are cooked in accordance with the proposed processes, there would be a temperature discrepancy between the temperature of the oven or cooking oil and internal temperature of the product. The commenter was concerned that, without proper validation, the internal temperature of the product would not be held high enough for long enough to inactivate viruses.

The product in this case consists of small pieces of skin which are typically 1 to 6 centimeters in width and half a centimeter thick. Given both the size of the pieces of skin and the length of the prescribed cooking times, we are confident that the interior temperature of the product will reach a temperature that will be near that of the oven or cooking oil and that will be sufficient to inactivate all the pathogens of concern.

One commenter stated that the Animal and Plant Health Inspection Service (APHIS) underestimated the likelihood of the imported pork skins

¹ To view the proposed rule and the comments we received, go to (<http://www.regulations.gov/jdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0032>).