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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. FSIS–2009–0019]

HACCP Systems Validation

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is issuing this document to propose to clarify its requirements for validation by an official establishment of its Hazard Analysis Critical Control Point (HACCP) system, that is, validation of both the critical control points (CCPs) in the HACCP plan and any interventions or processes used to support decisions in the hazard analysis. Validation of a HACCP system involves two separate elements: The scientific or technical support for the judgments made in designing the HACCP system, and evidence derived from the execution of the HACCP plan to demonstrate that it is, in fact, achieving the critical operational parameters documented in the scientific or technical support.

The Agency is also announcing the availability of, and requesting comments on, a revised draft guidance document prepared to assist establishments in appropriately validating their HACCP systems. The Agency received and analyzed comments on the initial draft of this guidance, which the Agency posted on its Web site in March 2010. FSIS is soliciting comments on this revised guidance and will hold a public meeting to discuss the revised guidance before it issues final guidance for HACCP systems validation.

DATES: Comments on this document and the revised guidance document, ''Compliance Guidance: HACCP Systems Validation,'' must be received by July 9, 2012.

ADDRESSES: FSIS invites interested persons to submit comments on this document and the related guidance. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov*. Follow the on-line instructions at that site for submitting comments.
- *Mail, including floppy disks or CD–ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMD, Docket Unit, Patriots Plaza 3, 1400 Independence Avenue SW., Mail Stop 3782, 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2009–0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov*.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: William K. Shaw, Jr., Ph.D., Office of Policy and Program Development, FSIS, USDA, 1400 Independence Ave. SW., Patriots Plaza 3, Mailstop 3782, 8–142, Washington, DC 20250. Telephone: (301) 504–0852 Fax: (202) 245–4792. *Email: william.shaw@fsis.usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

FSIS implements the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) to protect the health and welfare of consumers by preventing the distribution in commerce of meat or poultry products that are unwholesome, adulterated, or misbranded. To reduce the risk of foodborne illness from meat or poultry products, FSIS issued regulations on July 25, 1996, that require that federally inspected establishments adopt HACCP systems (61 FR 38806). These regulations require that federally inspected establishments adopt measures to prevent or control the occurrence of food safety hazards at each stage of the production process where such hazards are reasonably likely to occur.

The HACCP regulations in 9 CFR part 417 require that each establishment conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in its production process and to identify the preventive measures the establishment can apply to control those hazards in the production of particular products (9 CFR 417.2(a)). Whenever a hazard analysis reveals one or more food safety hazards reasonably likely to occur in the production process, the HACCP regulations require that the establishment develop and implement a written HACCP plan, for each product, that includes specified measures to prevent, eliminate, or reduce to an acceptable level the effects of each hazard so identified (9 CFR 417.2(b)(1) and 9 CFR 417.2(c)). The regulations in 9 CFR 417.2(c) require, among other things, that the HACCP plan include CCPs at which such measures can be applied.

The HACCP regulations in 9 CFR part 417 also require that establishments validate the HACCP plan's adequacy to control the food safety hazards identified by the hazard analysis (9 CFR 417.4(a)). The regulations in 9 CFR 417.4(a)(1) prescribe requirements for the initial validation of an establishment's HACCP plan and require establishments to ''conduct activities designed to determine that the HACCP plan is functioning as intended.'' During this initial validation period, establishments are to ''repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions'' prescribed in their HACCP plans (9 CFR 417.4(a)(1)). The regulations state that ''[v]alidation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities'' (9 CFR 417.4(a)(1)).

After an establishment has validated its HACCP plan, the regulations require that it conduct ongoing verification activities and reassess the HACCP plan at least annually or whenever a change occurs that could affect its hazard analysis or HACCP plan (9 CFR 417.4(a)(2) and 9 CFR 417(a)(3)).

The regulations in 9 CFR 417.5 require that establishments maintain

certain records that document their HACCP plans. In addition to records associated with the HACCP plan itself, these records must include the written hazard analysis prescribed in 9 CFR 417.2(a), including supporting documentation (9 CFR 417.5(a)(1)).

HACCP System Validation

Initial validation period. Validation is the process of demonstrating that a HACCP system, if operating as designed, can adequately control identified hazards to produce a safe product. As discussed above, the regulations in 9 CFR 417.4(a)(1) provide for an initial validation period during which meat and poultry product establishments are to conduct activities to validate their HACCP systems. Official meat and poultry product establishments that were in operation when FSIS issued its HACCP regulations in part 417 were required to conduct this initial validation when they became subject to part 417.

Since FSIS issued its HACCP regulations, meat and poultry product establishments have been required to conduct a hazard analysis and develop and validate a HACCP plan in accordance with 9 CFR 417.2 and 9 CFR 417.4 as a condition for receiving Federal inspection (9 CFR 304.3(b) and 9 CFR 381.22(b)). The regulations provide for the issuance of a conditional grant of inspection for a period not to exceed 90 days during which time the establishments are to complete their initial HACCP plan validation.

In addition, if an establishment decides to produce a new product for distribution in commerce, it is required to conduct a hazard analysis and develop a HACCP plan applicable to that product before introducing it into commerce (9 CFR 304.3(c) and 381.2(c)). The establishment is required to complete the initial validation of the new HACCP plan in accordance with 9 CFR 417.4 during a period not to exceed 90 days after the date the new product is produced for distribution in commerce.

HACCP system records reviews. The regulations in 9 CFR 417.4(a) identify certain activities that an establishment is required to complete to validate its HACCP plans. These regulations state, among other things, that validation is to encompass ''reviews of the records, routinely generated by the HACCP system, in the context of the validation.'' The ''HACCP system'' is defined as ''[t]he HACCP plan in operation, including the HACCP plan itself'' (9 CFR 417.1). Thus, HACCP plan validation under 9 CFR 417.4(a)(1) requires that an establishment conduct reviews of both the records required in the HACCP plan, as well as required records generated by the HACCP plan in operation.

The operation of a HACCP plan involves all activities performed by the establishment to prevent or control food safety hazards identified in the hazard analysis. An establishment may perform these activities as part of its HACCP plan or as part of a program that contains interventions or controls that could affect the hazard analysis but that may or may not be referenced in the HACCP plan. For example, an establishment may conduct activities to address an identified hazard as part of a prerequisite program or as part of a program to comply with specifications of a business customer. Because the results obtained under these programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)).

The written hazard analysis and supporting documentation are among the records required under 9 CFR 417.5 to document the HACCP plan and, as such, are also among the records ''routinely generated by the HACCP system'' subject to review for validation under 9 CFR 417.4(a)(1). Thus, if an establishment's supporting documentation for its hazard analysis includes records associated with a prerequisite program that provides for an intervention or process designed to prevent a hazard from being likely to occur, the records required for validation under 9 CFR 417.4(a)(1) would need to cover all documents associated with the prerequisite program. An establishment must assess whether these records demonstrate that the intervention or control provided for in the program can achieve results that support decisions in the hazard analysis that a hazard is not reasonably likely to occur because of the operation of the program.

Elements of validation. Validation under 9 CFR 417.4(a)(1) requires that establishments assemble two types of data: (1) The scientific or technical support for the judgments made in designing the HACCP system, and (2) evidence derived from the HACCP plan in operation to demonstrate that the establishment is able to implement the critical operational parameters necessary to achieve the results documented in the scientific or technical support.

Establishing and documenting the scientific or technical basis for the HACCP system requires that the establishment gather scientific or technical documentation demonstrating that the measures adopted in its HACCP system are effective in controlling identified food safety hazards. Scientific or technical support for a HACCP system may consist of Agency guidance documents, documented expert advice from processing authorities, an article from a peer-reviewed journal, a documented scientific study, documented results from a pathogen modeling program, or analogous information. To be effective, the scientific documentation should identify: (1) The hazard that the measures are intended to address; (2) the expected level of hazard reduction or prevention that the measures will achieve; (3) the critical operational parameters, such as time, temperature, humidity, and pH, that must be met for the measures to be effective; (4) the processing steps necessary to achieve the specified level of hazard reduction or prevention; and (5) how the processing steps can be monitored.

For example, for scientific support of its HACCP system, an establishment that processes beef carcasses may use a published journal article that describes the use of a lactic acid spray system as an antimicrobial intervention. To meet the first element of validation, the journal article should identify *E.coli* O157:H7 and other pathogens as the hazard that the lactic acid intervention is intended to address and should specify the level of pathogen reduction that the intervention is capable of achieving. The article should identify the critical operational parameters needed for the intervention to be effective, such as the design of the spray cabinet, the concentration of the lactic acid, the pressure at which the spray is delivered, the temperature of the acid at the point of delivery, and the temperature of the carcass when the acid is applied.

Once an establishment has satisfactorily documented the scientific or technical support for its HACCP system, the regulations require that it ''repeatedly test the adequacy'' of the various components of its HACCP plan in controlling identified hazards (9 CFR 417.4(a)(1)). This element of the validation process requires that the establishment demonstrate that the system will actually perform as expected. An establishment must develop data to demonstrate that it has and can routinely meet the scientifically documented parameters in its HACCP systems under in-plant conditions, *i.e.,* with its own employees and equipment, and that its HACCP system, as implemented, is capable of achieving

the expected results. Data used to support this in-plant demonstration may include in-plant observations, measurements, microbiological test results, documentation to demonstrate that employees have been properly trained regarding the important aspects of their duties, or other information to demonstrate that the establishment can implement the preventive or control measures, as written into the HACCP system, in a manner that achieves the intended food safety objective.

For example, an establishment that has incorporated the use of a lactic acid spray intervention described in a peer-reviewed journal article into its HACCP system will need to assemble documentation to demonstrate that it is capable of following the procedures in the same manner in which they are described in the study. To conduct the in-plant demonstration, the establishment will need to measure and record the results for all critical operational parameters identified in the study, such as the concentration of the lactic acid spray, the pressure of the spray, the temperature of the lactic acid, and the temperature of the carcass at the point of delivery. The lactic acid intervention will be validated if, at the end of 90 days, the establishment has assembled data demonstrating that the establishment is consistently meeting all critical operating parameters documented in the scientific study under in-plant conditions.

As discussed above, an establishment must validate all measures that it relies upon to prevent or control the hazards that it has identified in its HACCP system, whether the measures are part of the establishment's HACCP plan itself or part of a program that includes interventions or controls that affect the hazard analysis. Under FSIS's regulations, these measures are not considered to be validated until the establishment has satisfied both elements described above.

For example, an establishment that receives, grinds, or otherwise processes ground beef may determine that *E. coli* O157:H7 is not a hazard reasonably likely to occur in its production process because it has a prerequisite program incorporating purchase specifications that require that the establishment's suppliers apply validated interventions to address *E. coli* O157:H7 on the product that they send the establishment. The establishment may reference the documentation provided by the supplier as the support for the prerequisite program. However, the prerequisite program is not validated until the receiving establishment has documentation from each supplier, such as a letter of guarantee, that assures that the supplier employs CCPs that address *E. coli* O157:H7, describes those CCPs and the method of monitoring of them and provides certificates of analysis that specify the sampling method that the supplier uses and the results of that sampling. The receiving establishment should also do its own testing or visit the supplier's establishment to confirm that the supplier is executing the purchase specifications in a consistent and effective manner to ensure that the product the supplier sends does not contain detectable levels of *E. coli* O157:H7. If the receiving establishment visits the supplier, the receiving establishment should develop and maintain records that document the findings of such visits.

As noted in the preamble to the HACCP final rule, adequate validation needs to include both supporting scientific information as well as in-plant operational data to ''* * * demonstrate not only that [the establishment's] HACCP plan is theoretically sound, but also that this establishment can implement it and make it work'' (61 FR 38806, 38826).

Initial Draft Guidance

FSIS developed an initial draft guidance document in 2010 to assist the industry, particularly small and very small establishments, in complying with the requirements for HACCP systems pursuant to 9 CFR 417.4. FSIS made this initial draft guidance available to the public in March 2010 by posting it on the FSIS Web site and announcing its availability in the Constituent Update. The Agency also mailed the guidance document to all federally-inspected meat and poultry product establishments.

The initial draft guidance described the types and sources of scientific information that establishments can use to meet the first element of the validation requirement, the scientific or technical support. It also described the types of observational data and in-plant measurements that establishments can use to meet the second element of validation, the in-plant demonstration. The guidance also explained that, in addition to gathering observational data, in-plant validation requires demonstrating that the array of interventions and process steps together in sequence are achieving the desired result. The guidance included an Appendix titled ''Validation Examples for Raw Products and Processed Products'' that provided examples on the kinds of data that establishments could use to meet the validation requirement.

With respect to the types of data that would be appropriate to demonstrate that an establishment's HACCP system was achieving the desired result, the initial draft guidance stated that:

''FSIS believes that microbiological testing that combines enumeration of indicators with the presence/absence of an identified pathogen in conjunction with monitoring critical parameters plays an important role in the initial validation of many interventions for biological food safety hazards. Microbiological testing data, where appropriate, can provide establishments information about whether the overall system of interventions can achieve the desired log reductions documented in the scientific supporting documentation. Establishments would need to provide support in instances where they believe microbiological testing data is not needed to demonstrate the effectiveness of the HACCP system in controlling biological food safety hazards. Once the operational effectiveness of each individual intervention is determined, the establishment can use microbiological testing data in conjunction with the data on the individual interventions to establish that the process as a whole results in the production of safe, unadulterated product. In this final part of step 2 initial in-plant validation, the establishment should pull together the data for each intervention and the data from microbiological testing at various points throughout the HACCP system to ensure that the multiple hurdle design of its entire HACCP system will result in the production of safe, unadulterated products. Failure to take these steps will raise questions whether the HACCP system has been adequately validated.''

Public Meeting

An array of issues were raised in comments submitted in response to the initial draft guidance, particularly with respect to the guidance on the use of microbiological testing to validate the effectiveness of HACCP systems in controlling biological hazards. To address these issues, the Agency developed, and made available on its Web site, a supplemental fact sheet to assist small and very small meat and poultry establishments obtain information to support the scientific design of their HACCP systems (*http://www.fsis.usda.gov/Science/HACCP_Validation/index.asp*).

In addition, on June 14, 2010, FSIS held a public meeting to discuss the draft HACCP validation guidance and received input from stakeholders.

The transcripts of the July 2010 public meeting are available on the FSIS Web site at: *http://www.fsis.usda.gov/PDF/Transcripts_HACCP_Validation_061410.pdf.*

Comments on the Initial Draft

FSIS received over 2000 comments on its March 2010 draft guidance on HACCP validation from consumers of organic meat and poultry, small livestock producers and family farmers, small and very small meat or poultry processors, trade associations representing meat and poultry processors, trade associations representing animal producers, State Departments of Agriculture and other local or State government officials, academics, insurance companies, and consumer advocacy organizations.

FSIS has carefully considered the comments and re-evaluated its draft guidance in light of these comments. Based on this re-evaluation, FSIS has revised the draft guidance. Following is a brief summary and discussion of the major issues raised by the comments.

1. Microbiological Testing vs. Critical Operating Parameters

Comment: FSIS received a significant number of comments on the use of microbiological testing to validate a HACCP system. The majority of these comments objected to the requirements for microbiological testing as part of the in-plant demonstration component of validation. The comments stated that the benefit of collecting microbial data is unclear and is not justified by the significant financial burden that such testing would impose.

A number of comments stated that instead of requiring microbiological testing, the focus of in-plant validation should be on critical operating parameters. The comments asserted that a scientific study is the safest and most effective method to validate a process, and that the in-plant validation should be focused on collecting data to demonstrate that the establishment is properly implementing the procedures described in the scientific support, allowing establishments to focus on meeting the established parameters.

Response: FSIS agrees and has revised the draft guidance to remove the references to the use of in-plant microbiological testing as a necessary part of the in-plant demonstration component of the HACCP validation process. FSIS has concluded that a key focus of validation should be on the establishment's ability to achieve the scientifically supported critical operating parameters under in-plant conditions. A showing that the establishment can effectively achieve these parameters will satisfy the in-plant demonstration requirements of validation and fulfill the objectives of the HACCP regulations without imposing significant costs on small businesses.

Accordingly, the in-plant demonstration of validation will be considered effective when an establishment has demonstrated that it is capable of effectively implementing the critical operational parameters identified in the establishment's scientific or technical support.

Although references to microbiological testing in the initial in-plant validation phase have been removed from the revised compliance guidance, FSIS will continue to include establishments that are conducting the initial validation in the Agency's regulatory microbiological sampling programs. FSIS would question the adequacy of an establishment's HACCP system if regulatory samples analyzed by the Agency show non-compliance with microbiological standards.

Comment: Some comments pointed out that all parameters specified in an establishment's supporting scientific and technical documentation may not in fact be needed for the intervention or control measure to be effective. The comments asserted that meeting only the critical parameters necessary to successfully implement an intervention should be required as part of the in-plant demonstration.

Response: As noted above, FSIS has revised the guidance to focus on the critical operational parameters. The critical operating parameters are those that have been shown to influence the effectiveness of an intervention when variations occur. If some of the operational parameters described in the scientific support have been found to have no impact on the effectiveness of the intervention, there would be no need to monitor those operational parameters during the initial validation period.

Comment: Some comments suggested that FSIS create safe harbors for establishments in which they can operate without concerns about the validity of their process. The comments stated that the Agency should only request in-plant information from an establishment when the validity of the process is being questioned, or if the establishment is implementing a new or unique process.

Several comments submitted by the industry stated that HACCP plans are backed by scientific studies that have been conducted by a university, trade association, or a regulatory body. The comments stated that these scientific studies validate that an establishment's HACCP plan is capable of producing a safe product.

Response: Establishments may use established processing guidelines, such as Appendix A of the final rule ''Performance Standards for the Production of Certain Meat and Poultry Products,'' for their scientific support. The parameters established in these guidelines would be considered ''safe harbors.'' However, the establishment would still need to collect in-plant data to demonstrate that is capable of achieving the critical operational parameters documented in these processing guidelines to complete the validation.

The regulations that prescribe requirements for validation require that establishments ''* * * repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions'' described in their HACCP plans (9 CFR 417.4(a)(1)). While a scientific study may demonstrate that the HACCP system is designed to effectively address the relevant hazards, additional in-plant monitoring and observation is needed to demonstrate that the system will function as designed. Thus, a scientific study on its own is not sufficient to validate an establishment's HACCP system.

Comment: One trade association asked how the Agency will work to ensure that small and very small plants have access to the scientific support mentioned in the guidance document.

Response: FSIS has posted a list of relevant journal articles by pathogen on its Web site (*http://www.fsis.usda.gov/Science/HACCP_Validation_Articles/index.asp*). The Agency is also developing a tutorial on understanding scientific and technical journal articles and identifying critical operational parameters. FSIS will post that material on the Web site when it is complete.

2. Validation and Verification

Comment: Several comments expressed concern about requiring that establishments implement regular, year-round microbiological testing, regardless of whether problems have been identified. The comments also expressed concern about the annual cost for ongoing in-plant testing.

Response: The concerns about ongoing or year-round testing expressed by the comments are related to the on-going verification that is required after the validation is complete. After an establishment completes the initial validation, it is required to conduct verification activities to demonstrate

that it continues to achieve the critical operating parameters on an on-going basis. The draft guidance does note that these on-going verification procedures may need to include microbiological testing, although establishments may use a number of measures including ongoing communication with suppliers and third party audits, to support the HACCP system is functioning as intended on an ongoing basis.

3. Improve Agency Training and Management of Communication With Field Personnel

Comment: Some comments submitted by trade associations representing meat and poultry processors stated that FSIS needs to ensure that its field personnel interpret the validation guidance in an accurate and consistent manner. The comments suggested that FSIS conduct workshops and training sessions on the validation guidance for industry and inspection personnel.

Response: FSIS will provide instructions to the field when it issues final guidance on HACCP validation. The Agency also will provide additional materials and supplemental training to ensure that the validation requirements are properly implemented.

4. Accommodating Small and Very Small Establishments

Comment: Several comments emphasized the importance of recognizing that a ''one size fits all'' approach to regulatory requirements is not the most effective approach. Some comments suggested that FSIS should establish a separate set of requirements for small processors, or perhaps exempt small processors from the HACCP validation requirements.

Response: FSIS agrees that it is important to provide small and very small establishments the flexibility they need to comply with regulatory requirements. At the same time, in order to ensure that meat and poultry products are safe, wholesome, and accurately labeled, it is essential for all establishments to effectively validate their HACCP systems. The revised draft guidance provides small and very small plants the flexibility to choose the most appropriate procedures for them to achieve the requirements for HACCP validation. In addition, FSIS will continue to assist small and very small plants in meeting the regulatory requirements for HACCP through the Agency's ongoing small and very small plant outreach activities.

5. Data Sharing

Comment: One industry commenter asked whether a company that owns more than one establishment can use the validation data gathered from one facility to validate the HACCP systems of other facilities owned by the same company.

Response: Both the initial guidance document and our revised draft guidance explain that if a company owns multiple establishments that conduct the same operations, the establishments may use the same scientific support for all establishments to satisfy the first element of validation. However, each establishment would need to conduct its own on-site study to demonstrate that it is capable of meeting the critical operational parameters in the scientific study. It is important that each establishment do so because variations exist from establishment to establishment, such as differences in equipment configurations or building structures, which could have an impact on the implementation of a measure documented in the scientific support.

Revisions Made After Consideration of Comments

After careful consideration of the comments submitted on the March 2010 initial draft guidance, the Agency revised its draft guidance on HACCP systems validation. Following is a summary of major areas that FSIS addressed when it revised the draft guidance.

Scientific Support. As part of its HACCP verification activities, in addition to the issues related to the in-plant demonstration described above, FSIS has identified instances in which an establishment's HACCP system design did not reflect the critical operational parameters documented in the scientific or technical support. Therefore, the revised draft guidance provides additional recommendations on measures that an establishment can take to ensure that its scientific or technical support is properly applied to its production process and the hazards identified in the hazard analysis. The guidance emphasizes that to be effective, the establishment's HACCP system design must relate and adhere to the specifications in the supporting documentation.

The revised draft guidance also discusses the five major types of scientific support. These include: (1) Published processing guidelines, *e.g.* Appendix A of the final rule ''Performance Standards for the Production of Certain Meat and Poultry Products'' and Appendix B, Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization); (2) a scientific article from a peer-reviewed journal; (3) a challenge or inoculated pack study that is designed to determine the lethality or stabilization of a process; (4) data gathered in-house; and (5) regulatory performance standards.

The revised draft guidance recommends that scientific support contain microbiological data that specifies the level of pathogen reduction that an intervention for a target pathogen identified in the hazard analysis will achieve. If this information is not provided, establishments will need to conduct or provide additional research to show that either the target pathogen would behave similarly to the microorganisms studied in the scientific support, or that the intervention will function as intended.

In-plant support. The revised draft guidance explains that to conduct an adequate in-plant demonstration, establishments need to identify the critical operating parameters documented in the scientific support. The draft guidance stresses that the critical operating parameters often will be in addition to the critical limit associated with the critical control points. The document provides that establishments should implement all of the critical operating parameters identified in the scientific support.

The draft document has also been revised to remove references the use of in-plant microbiological testing as a necessary part of the in-plant demonstration component of the HACCP validation process. Instead, the revised guidance emphasizes the importance of achieving the scientifically supported critical operating parameters under in-plant conditions.

Identifying critical operating parameters. The revised draft guidance contains a new Appendix, ''*Guidance to Identify Critical Operational Parameters from Supporting Documentation,''* that explains how establishments can apply journal articles to their own processes and how to identify in the journal article the essential or critical operating parameters. FSIS will post information on its Web site on how to identify critical operating parameters documented in a journal article. This Web posting will include examples of journal articles that have been broken down to identify the critical operating parameters.

FSIS shared the revised draft HACCP validation guidance with the National Advisory Committee on Meat and Poultry Inspection (NACMPI) at the committee's public meeting held on September 22–23, 2011. The draft compliance guidance that the Agency is making available through this **Federal**

Register document reflects recommendations made by the NACMPI HACCP Systems Validation Sub-Committee. Most of the revisions recommended by NACMPI were to improve the clarity of the document. For example, in response to a NACMPI recommendation, the draft compliance guidance now clearly and concisely describes the distinction between validation and verification and explains how the establishment's HACCP plan reassessment fits into the process. The draft guidance reiterates that the establishment is required to reassess its HACCP plan annually and whenever changes occur that affect the hazard analysis or HACCP plan (9 CFR 417.2(a)). The draft guidance also makes clear that that to conduct an effective reassessment, establishments should review the records generated by the entire HACCP system and analyze these records to determine how the HACCP system is performing as a whole. Pre-requisite programs are a critical part of the environment in which HACCP plans function and are therefore an important part of any HACCP plan reassessment. FSIS also updated the guidance to include guidance for validating cooking instructions for ground poultry patties.

The NACMPI report is available on the FSIS Web site at: *http://www.fsis.usda.gov/PDF/Validation_Issue_Paper_Final.pdf*.

In addition to comments on the draft guidance document, the NACMPI also made recommendations on FSIS's implementation and verification activities after the Agency issues final validation guidance. The NACMPI recommended that FSIS ''phase in'' its activities to ensure that establishments have appropriately validated HACCP systems by focusing first on those product categories that present the greatest public health risk. The NACMPI also recommended that at their next annual reassessment, existing establishments should be expected to have determined whether they need to collect additional in-plant data to complete their validation or whether the data they have collected meet the validation requirements. FSIS believes that both recommendations have merit and requests comments on them.

The revised draft guidance document is available for public viewing in the FSIS docket room and on the FSIS Web site at *http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Assistance/index.asp*. FSIS again invites comments on the revised guidance document, as well as on the issues discussed in this **Federal Register** document. The Agency will also hold a public meeting to discuss the revised draft guidance and to solicit additional input on validation requirements.

Next Steps

After considering the public input and comments it receives on the revised draft guidance document, FSIS will issue a final guidance document on HACCP system validation and publish a **Federal Register** document to announce its availability. At that time, FSIS will also announce when Agency personnel will begin to take enforcement actions if it finds that an establishment has failed to conduct and document in-plant validation.

Until then, FSIS inspection personnel will continue to issue a noncompliance record (NR) if an establishment lacks the required scientific or technical support for its HACCP system, or if the scientific or technical support is inadequate. FSIS will also continue to issue an NOIE if, taken together with other relevant findings, an establishment's scientific or technical support is inadequate, and the Agency can support a determination that the establishment's HACCP system is inadequate for any of the reasons provided in 9 CFR 417.6.

FSIS will also continue to conduct Food Safety Assessments (FSAs). If, when conducting an FSA, an EIAO finds that an establishment has not completed the in-plant demonstration, the EIAO will note this finding in the FSA and inform the establishment. Until the enforcement date, FSIS will not issue NRs or take enforcement actions based solely on a finding that an establishment lacks in-plant validation data.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this document, FSIS will announce it online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations/2012_Notices_Index/*. FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS' policies, procedures, regulations, **Federal Register** notices, public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/*. Information is available about a variety of topics including recalls, exports, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and they have the option to password protect their accounts.

Done at Washington, DC, on May 1, 2012.

Alfred V. Almanza,

Administrator.

[FR Doc. 2012–10895 Filed 5–8–12; 8:45 am]

BILLING CODE 3410–DM–P

EXPORT-IMPORT BANK OF THE UNITED STATES

12 CFR Part 404

[EXIM–OIG–2012–0010]

RIN 3048–AA02

Privacy Act of 1974: Implementation of Exemptions; Export-Import Bank of the United States Office of Inspector General—Office of Inspector General Investigative Records

AGENCY: The Export-Import Bank of the United States.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Export-Import Bank of the United States (hereafter known as ''Ex-Im Bank''), Office of Inspector General (hereafter known as ''OIG'' or ''Ex-Im Bank OIG'') is giving concurrent notice of a new system of records entitled, ''EIB–35–Office of Inspector General Investigative Records.'' In this proposed rulemaking, Ex-Im Bank proposes to exempt portions of this system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments should be received on or before July 9, 2012 to be assured of consideration.

ADDRESSES: You may submit comments, identified by Docket Number EIB–2011–0010 by one of the following methods:

- Electronically through the eRulemaking Portal at *http://www.regulations.gov*. Follow the instructions for submitting comments. Please search for EIB–2011–0010.
- *By Mail/Hand Delivery/Courier:* Alberto Rivera-Fournier, Ex-Im Bank,