in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith C. Jones, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2289.

SUPPLEMENTARY INFORMATION:

Background

On January 30, 2013, we published in the **Federal Register** (78 FR 6222–6227, Docket No. APHIS–2012–0002), a proposal [1] to amend the fruits and vegetables regulations to allow the importation of avocados from continental Spain (excluding the Balearic Islands and Canary Islands) into the United States subject to a systems approach and treatment.

Comments on the proposed rule were required to be received on or before April 1, 2013. We are reopening the comment period on Docket No. APHIS–2012–0002 for an additional 15 days. This action will allow interested persons additional time to prepare and submit comments. We will also accept comments received between April 2, 2013 (the day after the close of the original comment period) and the date of this notice.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013–12679 Filed 5–28–13; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the proposed rule, risk documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0002.*

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2011–0132]

RIN 0579–AD62

Importation of Fresh Apricots From Continental Spain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would allow the importation into the United States of fresh apricots from continental Spain. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published January 30, 2013 (78 FR 6227) is reopened. We will consider all comments that we receive on or before June 13, 2013.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0132-0001.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2011–0132, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0132* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith C. Jones, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1231; (301) 851–2289.

SUPPLEMENTARY INFORMATION: On January 30, 2013, we published in the **Federal Register** (78 FR 6227–6232, Docket No. APHIS–2011–0132) a proposal [1] to amend the regulations concerning the importation of fruits and vegetables to allow the importation of fresh apricots from continental Spain into the United States subject to a systems approach jointly agreed upon in a bilateral workplan between APHIS and the national plant protection organization of Spain.

Comments on the proposed rule were required to be received on or before April 1, 2013. We are reopening the comment period on Docket No. APHIS–2011–0132 for an additional 15 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between April 2, 2013 (the day after the close of the original comment period) and the date of this notice.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013–12685 Filed 5–28–13; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the proposed rule, risk documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0132.*

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: Notice of public meeting and request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of updated guidance for Hazard Analysis Critical Control Point (HACCP) systems validation. In addition, FSIS is announcing that it will hold a public meeting on June 25, 2013, to review changes to the guidance announced in this notice and to take comments. The public meeting will also be available by teleconference.

Following the public meeting, the Agency will accept written comments until July 25, 2013. Given the extensive opportunity for comment on the guidance, however, the Agency believes

that very few, if any, issues remain in this proceeding.

DATES: The public meeting will be held on June 25, 2013 from 8:30 a.m. to 12:30 p.m. On-site registration will begin at 8:00 a.m. Written comments may be submitted until July 25, 2013.

ADDRESSES: The public meeting will be held in the 1st Floor Auditorium of Patriots Plaza 3, 355 E Street SW., Washington, DC 20024.

FSIS will finalize the agenda by June 18, 2013 and post it on the FSIS Web page at: *http://www.fsis.usda.gov/News_&_Events/meetings_&_events/index.asp.*

Registration: Pre-registration is recommended. To pre-register, access the FSIS Web site at *http://www.fsis.usda.gov/News_&_Events/meetings_&_events/index.asp.* Call-in information will be provided via email to pre-registered participants. If you are interested in making a public comment during the teleconference, please indicate so on the registration form.

In addition to the public meeting, interested persons may submit comments using 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 CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Patriots Plaza 3, 1400 Independence Avenue SW., Mail Stop 3782, Room 8–163A, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20024.

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 Avenue SW., Patriots Plaza 3, Mailstop 3782, Room 8–142, Washington, DC 20250. *Telephone:* (301) 504–0852 Fax: (202)245–4792. *E-Mail: william.shaw@fsis.usda.gov.*

Background

FSIS administers 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, which 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.

In the May 9, 2012 **Federal Register** (77 FR 27135), FSIS issued a notice to clarify its requirements for validation by an establishment of its HACCP system and to announce the availability of the draft guidance on validation, which is discussed in more detail below. The HACCP regulations in 9 CFR part 417 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)). These regulations 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)). As FSIS explained in the May 9, 2012 **Federal Register**, 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.

The regulations also provide that ''[v]alidation . . . 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)). As FSIS explained in the May 9, 2012 **Federal Register**, 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 establishment's validation records would need to include all documents associated with the prerequisite program. Thus, validation of the HACCP system involves validation of the critical control points in the HACCP plan, as well as of any interventions or processes used to support decisions in the hazard analysis.

Initial Draft Guidance

In March 2010, FSIS posted on its Web site an initial draft guidance document to assist the industry, particularly small and very small establishments, in complying with the requirements for HACCP systems, pursuant to 9 CFR 417.4.

On June 14, 2010, FSIS held a public meeting to discuss the initial draft HACCP validation guidance and received input from stakeholders. The transcript of the June 2010 public meeting is available on the FSIS Web site at: *http://www.fsis.usda.gov/PDF/Transcripts_HACCP_Validation_061410.pdf.*

FSIS received over 2,000 comments on the initial draft guidance, particularly with respect to the use of microbiological testing to validate the effectiveness of HACCP systems in controlling biological hazards. The Agency considered the issues raised by the comments received in response to the May 2010 **Federal Register** notice and at the June 2010 public meeting and developed updated second draft compliance guidance.

On September 22–23, 2011, FSIS shared a second draft of the HACCP validation guidance with the National Advisory Committee on Meat and Poultry Inspection (NACMPI). The Committee reviewed the draft and provided comments and suggestions to FSIS on how to improve the guidance. The NACMPI report is available on the FSIS Web site at: *http://www.fsis.usda.gov/PDF/Validation_Issue_Paper_Final.pdf.* The Agency made additional revisions to the draft guidance in response to the input from NACMPI.

In a May 9, 2012 **Federal Register** notice, FSIS announced the availability of, and requested comments on, the revised draft guidance document

(*http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2009-0019.htm*). In the May 2012 **Federal Register** notice, the Agency also clarified its requirements for HACCP system validation and responded to the comments that it had received on the initial draft guidance. The May 2012 **Federal Register** notice explained that the Agency was soliciting comments on the revised draft, and that it would hold another public meeting before issuing final guidance for HACCP systems validation (77 FR 27135).

Comments on the Guidance

FSIS received fifty-one (51) comments on its May 2012 revised draft guidance on HACCP validation from small and very small meat or poultry processors, trade associations representing animal producers, small business owners, corporations, State Departments of Agriculture, and consumer advocacy organizations. FSIS has carefully considered the comments and has revised its draft guidance in light of these comments. The following is a brief summary and discussion of the major issues raised in the comments to the draft guidance document.

1. Concerns About Validation, Its Applicability, and Cost

Comment: Several commenters asked why the validation guidance or new FSIS enforcement of validation requirements is necessary, especially given the amount of time the HACCP regulations have been in place. These commenters stated that establishments should not have to ''revalidate'' their systems.

Response: The validation guidance is necessary because the Agency found that establishments have not adequately validated their systems. During the process of developing the draft guidance, FSIS added an appendix to the document that explains the need for validation and FSIS's experiences that led it to create the guidance document (*e.g.,* FSIS's findings following a 2011 Lebanon bologna outbreak that the establishment's scientific support on file did not match the process the establishment was using to make the bologna; non-O157 positives in 2012 that FSIS concluded likely occurred because of improperly designed interventions; and the chicken pot pie outbreaks in 2007 that FSIS concluded may have occurred because of improperly validated cooking instructions).

Based on findings from FSIS's data analyses and outbreak investigations, the Agency recommends that establishments use the guidance document to ensure that their HACCP systems are properly validated. On an annual basis, and whenever changes occur that affect the hazard analysis of the HACCP plan, the establishment should conduct a reassessment as required in 9 CFR 417.4(a)(3) (*i.e.,* review records generated over the course of the previous year, or during the period the change occurred, that reflect how the HACCP system is performing as a whole and analyze them to determine whether food safety goals are being met).

If the reassessment shows that the HACCP system is effective and functioning as intended, the establishment can consider continuing on with the same system and the same monitoring and verification procedures and frequencies. If reassessment shows that either their HACCP system was not set up correctly, is not being implemented consistently, or is no longer effective, the establishment would make changes to its HACCP system (*e.g.,* add another intervention) and then would, in most cases, be required to validate any changes to its HACCP system.

While most establishments have assembled the scientific or technical documentation needed to support their HACCP systems, many establishments have not gathered the necessary in-plant validation data demonstrating that their HACCP systems are functioning as intended, which is why the guidance document is necessary. As is explained below, in approximately six months from the time that FSIS issues the final validation guidance, FSIS intends to begin verifying that establishments comply with all validation requirements.

Comment: Several commenters expressed concern about the cost of validation, particularly for small establishments that have many different HACCP plans. One comment stated that if a very small establishment cannot afford to comply with validation requirements, it should have the option to return to ''conventional'' inspection instead of HACCP. Commenters were also concerned about the costs of obtaining in-plant microbial data and other costs associated with validation.

Response: HACCP was implemented in 1996 and has resulted in great improvements in food safety. The Agency is not going back to a command and control inspection approach because it would not provide establishments with the flexibility to design innovative systems that ensure food safety.

In the guidance, FSIS states that microbiological testing is needed for in-plant data in only limited circumstances and has provided low cost ways in which establishments can validate their systems in place of microbiological testing, such as ensuring that they are meeting the critical operating parameters of the interventions as defined in the scientific support. Therefore, FSIS estimates that costs associated with meeting validation requirements will be minimal.

Comment: Several commenters stated that establishments should not have to validate their prerequisite programs because 9 CFR 417.4(a)(1) does not apply to prerequisite programs. One commenter recommended that, in the absence of a CCP, prerequisite programs referenced in the flow chart should be validated, but that otherwise, establishments should not be required to validate their prerequisite programs. The same commenter also requested that FSIS begin only reviewing validation for CCPs and then, at a later date, begin reviewing validation for prerequisite programs referenced in the flow chart. One commenter stated that only prerequisite programs that contain scientifically supported critical operating parameters (*e.g.,* foreign material control, Good Manufacturing Practices, employee hygiene) should have to be validated. Several commenters stated that they needed guidance concerning how to validate pest control, employee hygiene, sanitation practices, and other processes.

Response: Validation is the process of demonstrating that the HACCP system, as designed, can adequately control identified hazards to produce a safe, unadulterated product. Prerequisite programs designed to support a decision in the hazard analysis are part of the HACCP system. When an establishment determines that a hazard is not reasonably likely to occur because the prerequisite program prevents the hazard, that prerequisite program becomes part of the HACCP system. Therefore, prerequisite programs designed to support decisions in the hazard analysis (*e.g.* Sanitation Standard Operating Procedures (Sanitation SOPs), purchase specifications, antimicrobial interventions) need to be validated to ensure that the overall system can operate effectively. Even though 9 CFR 417.4(a)(1) does not refer to Sanitation SOPs or other prerequisite programs, establishments' initial validation activities need to include employee hygiene and other similar prerequisite programs if they are used to support decisions in the hazard analysis. As explained in the guidance, in order to validate such programs, establishments

need to provide scientific documentation that supports that they will work as intended and to collect in-plant data to support that the programs can be implemented as designed.

Comment: Some commenters stated that establishments should not be required to validate cooking instructions because the cooking is performed by the consumer. One comment stated that discussion of validating the time and temperature combinations for cooking instructions should be removed from the guidance. Another commenter requested more guidance on how establishments should validate cooking instructions. Another commenter asked for confirmation that validated cooking instructions are not considered a CCP.

Response: 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 HACCP plan itself or part of a program that includes measures that affect the hazard analysis. Thus, if an establishment's HACCP system includes cooking instructions as a measure to address a potential food safety hazard after entry into the establishment, the establishment must properly validate the instructions.

As we saw in the 2007 salmonellosis outbreak associated with chicken pot pies, providing cooking instructions on a package that cannot be repeated by the consumer represents an increased risk to the consumer. Had the establishment validated the cooking instructions on the pot pies to ensure they would achieve the desired endpoint temperature under actual consumer cooking conditions, these illnesses may have been prevented (*http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm*).

If an establishment's HACCP system includes placing cooking instructions on the product's label, the instructions must be validated to ensure that consumers who follow the instructions will achieve the endpoint time/temperature needed to ensure that the product is cooked and safe to consume. While validated cooking instructions may be used as a control to address hazards that may occur after the product has left the establishment, the establishment is still required to address food safety hazards that are reasonably likely to occur in the production process and identify the measures the establishment can apply to control those hazards (9 CFR 417.2(a)(1). *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5747a3.htm*).

FSIS is in the process of developing a guidance document on validating cooking instructions for mechanically tenderized beef product. FSIS has previously recommended validated cooking instructions for product that appears to be ready-to-eat, but its meat or poultry components have not received a sufficient lethality step or some other component has not received a lethality step. *http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4/Resource_1.pdf* Resource 1 for NRTE products that appear to be RTE (*e.g.,* entrees, dinners, casseroles etc) *http://www.fsis.usda.gov/PDF/Info_on_Validation_of_Labeled_Cooking_Instructions_Raw_or_Partially_Cooked_Poultry.pdf* (validated cooking instructions) *http://www.fsis.usda.gov/PDF/Labeling_Policy_Guidance_Uncooked_Breaded_Boneless_Poultry_Products.pdf* (this link includes the background information and Q&As)

Comment: Several comments stated that establishments should not be required to collect in-plant data for more than one product in a HACCP process category. These commenters also requested guidance on how to select a product from within each HACCP category. Commenters noted that such in-plant data would include execution data for all CCPs, interventions, and prerequisite programs used to support decisions in the hazard analysis. One commenter questioned whether the establishment would need to validate the food safety system for each product if the only difference among products is a seasoning. Another commenter stated that it is possible to have in-plant data for product of one species within a HACCP category serve as in-plant data to validate the process for product from another species if there are no additional food safety concerns. Another commenter stated that FSIS's guidance should follow the NACMPI recommendations to group typical products into categories and select ''worst case products'' within the group.

Response: In the revised guidance, FSIS has clarified that establishments are not required to collect in-plant data for more than one product within a HACCP process category. The guidance now provides information concerning how establishments should select a product from within a HACCP category. The guidance also provides information on how establishments can develop a decision-making document concerning product choices for collecting in-plant data. The guidance provides examples of how to collect in-plant data to aid industry, but establishments will have the flexibility to develop their own criteria.

Comment: A few commenters requested confirmation that establishments would not have to conduct ''initial'' validation for all changes that result from reassessment. Several commenters asked whether the whole system would need to be validated or just a change following reassessment. One commenter stated that improved implementation of a HACCP system would not necessarily result in changes to the design of the system.

Response: Establishments do not need to conduct validation of the whole system for all changes that result from reassessment. Depending on the change, the establishment will likely only need to validate that the change is functioning as intended. For example, an establishment may change the thickness of a raw patty product and determine that it only needs to validate that the cooking instructions still achieve the desired endpoint temperature at the new product thickness. In this example, the establishment would not need to validate the entire HACCP system.

Comment: Several commenters stated that very small establishments that produce products infrequently cannot obtain 13 production days worth of records within 90 calendar days. One commenter suggested extending the validation period beyond 90 calendar days in order to obtain 13 days worth of records. Another commenter requested that the guidance document clarify that large establishments have the flexibility to determine whether there are a sufficient number of production days within the 90 calendar-day period to gather appropriate data.

Response: The guidance explains that for large establishments, 90 calendar days equates to approximately 60 production days. FSIS recognizes that many small and very small establishments do not operate daily. Therefore, the guidance also states that a minimum level of records from 13 production days within those initial 90 calendar days should be used to initially validate a small or very small establishment's HACCP system. The establishment should consider focusing validation activities on the product produced most frequently within each HACCP category.

In the guidance, FSIS recognizes that there are some establishments that produce products so infrequently that they would not be able to gather records from 13 production days within those 90 initial calendar days. If the establishment infrequently produces several products that are each part of a separate HACCP category, there is

inherent risk with the processes if the establishment does not have experience in producing them. Therefore, to determine whether the system is properly designed and executed, even though the regulations provide 90 days for a conditional grant of inspection (9 CFR 304.3(b)), an establishment needing more than 90 days can ask the District Office, in writing, for additional time to collect at least 13 production days of records. The guidance explains that establishments may also consider evaluating data collected for products across multiple HACCP categories that share some common steps, ingredients, or equipment, to determine whether the data together can support its ability to meet critical operational parameters.

Scientific Support

Comment: Appendix A of the final rule, ''Performance Standards for the Production of Certain Meat and Poultry Products'' (64 FR 746–748) is specific to *Salmonella* but is often used to support lethality of other pathogens, such as *E. coli* O157:H7 and *Lm.* Therefore, several commenters asked whether establishments could use Appendix A as scientific support for process controls for pathogens other than *Salmonella.*

Response: FSIS has revised the validation guidance to clarify that during slaughter, in order to be most effective, it is very important that interventions have been studied for the pathogen and product pair of interest. In addition, FSIS has clarified that for thermal processing treatments, *Salmonella* can be used as an indicator for other pathogens of concern. Therefore, Appendix A can be used as scientific justification for the process without further support that the results apply to other pathogens such as *E. coli* O157:H7 or *Lm.*

Comment: Some commenters questioned whether their scientific support must be peer-reviewed. One commenter asked whether a processing authority could be an establishment owner with knowledge of the process. The commenter also asked if it could use documents that only provide a critical limit as scientific support (for example, a University publication or a textbook with growth limits of bacteria).

Response: FSIS has revised the guidance to clarify that the Agency recommends peer-reviewed scientific data to support the process used, but does not require peer-reviewed data. An establishment may use peer-reviewed scientific data or information in addition to a scientific article from a peer-reviewed journal as scientific support for its processes. Such information would include data from a textbook on the growth limits of certain pathogens, based on a food product's water activity and pH. This information could be used as scientific support because information in scientific textbooks has generally been peer-reviewed. Peer-reviewed scientific data goes through a process of evaluation involving qualified individuals within the relevant field that ensures the integrity of the data.

Scientific data that is not peer-reviewed is less reliable than peer-reviewed data, because there could be flaws in the science that a peer review would have revealed. If an establishment uses scientific data that is not peer-reviewed, the establishment may be subject to additional scrutiny by Agency personnel performing verification activities.

An establishment may rely on a process authority to provide necessary scientific support for the establishment's process. As stated above, to meet validation requirements, the establishment is required to ensure that the scientific data and documentation provided by the processing authority supports that the process addresses the identified hazards, and meets the expectations for validation requirements.

Comment: Several commenters stated that the guidance document is still too vague in terms of how close the scientific support needs to match an actual process. For example, commenters asked whether the manufacturer of a grinder would have to be the same as the grinder used in a supporting study. Commenters also asked how significant casing size differences among the process used and support studies would need to be before the support document would no longer apply. Commenters stated that parameters are often more controlled during research than in-plant, and that it is costly for establishments to measure temperature and pounds per square inch.

Response: In the guidance, FSIS has clarified how scientific support should match an actual process. Generally, establishments should use the same critical operational parameters as those in the support documents. In some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (*e.g.,* higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. Establishments also need to ensure the levels are safe and suitable (*http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/7120.1.pdf* and 9 CFR 424.21(c)).

Comment: Several commenters stated that FSIS Notice 36–12 (*http://www.fsis.usda.gov/oppde/rdad/FSISNotices/36-12.pdf*) suggested that the challenge study establishments used in the case of the Lebanon bologna would not be adequate support because the critical operational parameters in the study did not match those used in the establishment.

Response: The FSIS notice on Lebanon bologna explained that the actual process that the establishment used did not match the scientific support. As a result, the establishment's process did not achieve adequate lethality. Establishments producing Lebanon bologna can use the guidance as scientific support; however, they need to ensure that their process meets the critical operating parameters used in the study.

FSIS recognizes that scientific support performed in a laboratory may not always match an establishment's *exact* parameters. However, significant differences, such as the permeability of the casing used or the diameter of the product, are key factors that affect lethality and therefore cannot be overlooked. For instance, if an establishment wants to use a permeable casing, the establishment cannot assume that its process will achieve the same reduction in pathogens as achieved in a study using an impermeable casing.

Comment: Some comments stated that discussion of critical operational parameters in the guidance will lead some to conclude that all parameters are critical. Several commenters requested that FSIS create a third party or consortium to help establishments identify scientific support and critical operational parameters. Another commenter requested that FSIS's guidance address validation and scientific support for additional hazards, such as viruses and protozoa.

Several commenters stated that establishments do not have the expertise to scientifically support or identify critical operational parameters. One commenter stated that establishments

do not know how to test parameters of the different processes.

Response: Critical operational parameters are the specific conditions that the intervention must operate under in order for it to be effective. The guidance document explains in detail how an establishment can identify the critical operational parameters in its scientific support. Specifically, Appendix 3, provides step-by-step guidance to establishments.

FSIS will continue to post commonly cited journal articles on its Web site in which critical operational parameters have been identified and will offer support through askFSIS to establishments trying to identify critical operational parameters.

Comment: One commenter requested that reference to Purac's modeling program be made within the guidance, and that the guidance address the use of pathogen modeling programs as scientific supporting documentation. The commenter also requested an additional example in the guidance to show how an establishment could validate the effectiveness of an antimicrobial agent through pathogen modeling.

Response: FSIS has added a reference to pathogen modeling as a type of scientific support. In addition, FSIS has added an example in Appendix 3 to show how an establishment can validate its stabilization process through pathogen modeling. FSIS does not advocate certain programs and therefore did not cite Purac in the guidance.

Comment: One commenter requested a listing of surrogate or indicator organisms that can be used for validation. Another commenter requested clarification on when establishments can use scientific support based on indicator organisms.

Response: As explained in the guidance document, establishments should not rely on scientific support containing data from indicator or surrogate organisms unless available data establishes a relationship between the presence or level of a pathogen or toxin and the indicator organism. Such data can be collected from in-laboratory studies using indicator organisms that parallel the data in a challenge study performed with the inoculated pathogen. This data could be collected in the same way in which the pathogen is being tested or in another study performed under similar conditions. If similar and consistent reduction or control can be established, then control of the indicator organisms can be reliably used to indicate expected pathogen control in actual application in-plant.

2. Validation Worksheet Examples

Comment: One commenter stated that FSIS should include an explanation of how the validation worksheet examples can be used. Another commenter recommended that the guidance state that establishments have flexibility to utilize approaches other than those in the worksheet examples. Two commenters recommended that FSIS recognize in the guidance that not all critical operational parameters identified in the Appendix will apply to all processes.

Another commenter requested more detail be provided in the worksheet examples in terms of formatting and the types of data that establishments should collect.

One comment stated that establishments' environmental monitoring verifies that the Sanitation SOPs are working as intended, but does not validate them.

Response: In the guidance document, FSIS has added numerous validation worksheet examples to illustrate how an establishment may want to display its own in-plant validation data. As FSIS explains in the guidance, the validation worksheet examples are for illustration purposes only and are included to help establishments to understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements.

With regard to the comment on the Sanitation SOP monitoring, FSIS included this data in the guidance as an example of data collected during the initial 90 days of the set-up of a new program. Scientific support is needed to support the frequency of testing (which would address the factors used to determine the frequency). In-plant validation data is needed to support that the testing is adequate.

3. Microbiological Testing

Comment: One comment asked for clarification as to whether samples need to be collected for each and every process, product, or species, and whether establishments would need to collect 13 samples for every product produced, as in the regulations that require establishments to conduct testing for generic *E. coli* (9 CFR 310.25 and 381.94)

Response: If an establishment's scientific support contains microbiological data showing the efficacy of the intervention against the identified food safety hazard, then the in-plant data does not need to include sampling. In that case, the in-plant data should support that the establishment follows the critical operational parameters from the study.

Agency Training and Implementation

Comment: Commenters stated that FSIS should ensure that inspection program personnel consistently verify and enforce validation requirements. One commenter stated that FSIS should share training for FSIS personnel with industry.

A commenter also recommended that FSIS hold regional sessions to communicate the policy to establishments, and that the Agency engage cooperative extension programs in its communication strategy. One commenter recommended that the Agency create a tutorial on understanding scientific articles and on identifying critical operational parameters. Commenters also requested that FSIS issue a notice or directive explaining how inspectors should use the validation guideline.

A few commenters requested that FSIS phase-in verification of validation requirements based on risk or product categories, rather than establishment size. One commenter requested an additional six months to gather validation documents before FSIS begins new verification activities related to validation.

Response: The guidance is meant for establishments. FSIS will ensure inspection program personnel understand validation requirements and will issue necessary instructions to field personnel so that they are aware of the final guidance and share it with establishments. FSIS will also issue necessary instructions to field personnel for them to verify that establishments meet all validation requirements.

FSIS will implement its new verification activities by phasing them in based on establishment size. For large establishments, the agency plans to wait approximately six months from the date that the final guidance is issued to start verifying and enforcing the second element of validation (initial in-plant validation). Thus, large establishments will have six months from the date that the final guidance is issued to gather all necessary in-plant demonstration documents.

FSIS intends to begin verifying that small and very small establishments meet all validation requirements nine months from the date the final guidance is issued. Therefore, these establishments will have approximately nine months from the date the final guidance is issued to gather all necessary in-plant demonstration documents before FSIS will verify and

enforce the second element of validation.

Other Changes to Validation Guidance

Examples: The guidance contains additional examples of food safety problems linked to inadequate validation and recommendations to aid establishments in meeting initial validation requirements. These examples demonstrate the need for validation and provide support for recommendations made within the guidance.

Scientific Support Documents. FSIS has added a section to the guidance that explains to establishments how to determine whether scientific support documents are sufficiently related to the process, product, and hazard identified in the hazard analysis to constitute appropriate validation. The guidance explains that the supporting documentation should identify the hazard (biological, physical, and chemical), the expected level of hazard reduction or prevention to be achieved, all critical operational parameters or conditions necessary to address the hazard, the processing steps that will achieve the specified reduction or prevention, and how these processing steps can be monitored. FSIS has also included information on how establishments can identify supporting documentation that adequately addresses the expected level of hazard or reduction or prevention to be achieved. FSIS provided examples for biological, physical, and chemical hazards that should aid establishments in ensuring that the scientific support closely matches the hazard being controlled. FSIS has also clarified when establishments may use scientific support containing data from indicator or surrogate organisms.

Critical Operational Parameters. The guidance continues to state that critical operational parameters are those necessary for interventions to be effective and explains how an establishment can identify the critical operational parameters in its scientific support. As discussed above in response to comments, establishments generally should use the same critical operational parameters as those in the support documents. However, in some circumstances, establishments may be able to support using critical operational parameters that are different from those in the support documents (*e.g.,* higher concentrations of antimicrobials or higher thermal processing temperatures). In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the support documents.

FSIS has added an additional Appendix (Appendix 2) to provide an example of a decision-making document an establishment could develop when it uses different levels of a critical operational parameter than the parameters in the support document. An establishment may use the decision-making document to explain the scientific rationale for why it is using critical operational parameters that are different from those in the support documents.

In-plant data. The guidance recommends that establishments collect in-plant validation data for a wide variety of products and worst case scenarios. Appendix 4 of the guidance contains validation worksheet examples that establishments may reference to help them understand the types of scientific support and in-plant documentation that are needed to comply with the validation requirements.

Initial validation vs. on-going verification. The guidance explains the differences between initial validation and on-going verification and the relationship between the activities performed to provide initial validation as opposed to on-going verification. The revised guidance also clarifies when changes that result from reassessment would not require validation. For example, an establishment may need to reassess its HACCP system following a change in supplier of a raw material, but the change would not require validation if the establishment determines that the composition of the raw material and microbiological profile are not significantly different from the material provided by the previous supplier. In other cases, changes that result from the reassessment would not require additional scientific support but would require additional in-plant demonstration data. For example, an establishment may find through reassessment that the design of an intervention was adequate, but that its employees are not implementing the intervention correctly. In that case, the establishment would only need to collect in-plant data to demonstrate that the intervention could be implemented appropriately. Depending on the change, the establishment would likely only need to validate that the change is functioning as intended and not the entire HACCP system. The current draft of the compliance guide is available for public viewing in the FSIS docket room and on the FSIS Web site at *http://www.fsis.usda.gov/Significant_Guidance/index.asp*.

Public Meeting

On June 25, 2013, the Agency will hold a public meeting to review the information presented in this document and accept comments.

Next Steps

Following the public meeting, the Agency will accept public comment for 30 days. Given the extensive opportunity for public comment on the compliance guide, it is likely that there are very few, if any, remaining issues. Therefore, FSIS does not foresee granting an extension to this final 30 day comment period. As soon as possible after the comment period ends, the Agency will issue a **Federal Register** notice announcing the final guidance and will post the final guidance to its Web page. FSIS will implement its new verification activities phased in by establishment size. As stated above, for large establishments, the Agency plans to delay verification of the second element of validation as part of its inspection activities for approximately six months from the date the final guidance is posted. For small and very small establishments, the Agency plans to delay implementation for approximately nine months from the date the final guidance is posted.

Until FSIS begins enforcing all validation requirements, FSIS inspection personnel will continue to issue noncompliance records (NRs) 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 continue to issue a Notice of Intended Enforcement 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.

Moreover, if, in conducting a Food Safety Assessment (FSA), an Enforcement, Investigations, and Analysis Officer (EIAO) finds that an establishment has not collected in-plant data to demonstrate that its HACCP process works as intended, the EIAO will note this finding in the FSA and inform the establishment. Until FSIS begins enforcing the in-plant data requirements, 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

FSIS will announce this notice online through the FSIS Web page located at

http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

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, FSIS 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. In addition, FSIS offers an electronic mail 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_&_Events/Email_Subscription/.* Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done at Washington, DC on May 23, 2013.

Alfred V. Almanza,

Administrator.

[FR Doc. 2013–12763 Filed 5–24–13; 8:45 am]

BILLING CODE 3410–DM–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 703, 715, and 741

RIN 3133–AD90

Derivatives

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed Rule.

SUMMARY: This proposed rule permits credit unions to engage in limited derivatives activities for the purpose of mitigating interest rate risk. This proposed rule applies to federal credit unions and any federally insured, state-chartered credit unions that are permitted under applicable state law to engage in derivatives transactions. It requires any credit union seeking derivatives authority to submit an application for one of two levels of authority. Level I and Level II authority differ on the permissible levels of transactions as well as the application, expertise, and systems requirements associated with operating a derivatives program.

DATES: Comments must be received on or before July 29, 2013.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Web Site: http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- *E-Mail:* Address to *regcomments@ncua.gov.* Include ''[Your name]—Comments on Proposed Rule—Derivatives'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

FOR FURTHER INFORMATION CONTACT: Justin M. Anderson or Lisa Henderson, Staff Attorneys, Office of General Counsel, at the above address or telephone (703) 518–6540; J. Owen Cole, Director, Division of Capital and Credit Markets, or Rick Mayfield, Senior Capital Markets Specialist, Office of Examination and Insurance, at the above address or telephone (703) 518–6360; or Dr. John Worth, Chief Economist, Office of the Chief Economist, at the above address or telephone (703) 518–6660.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The NCUA Board (Board) is proposing to allow credit unions to engage in limited derivatives transactions [1] for the purpose of mitigating interest rate risk (IRR). This proposed authority does not, however, allow credit unions to offer derivatives. This proposed rule applies to all federal credit unions (FCUs) and all federally insured state- chartered credit unions (FISCUs) that are expressly permitted by applicable state law to engage in derivatives transactions. The Board believes this proposed rule allows eligible credit unions to utilize an additional tool to mitigate IRR, while also reducing risk to the National Credit Union Share Insurance Fund (NCUSIF).

The rule requires eligible credit unions to apply to NCUA or, in the case of a FISCU, NCUA and the applicable state supervisory authority (SSA), for either Level I or Level II derivatives authority. As discussed in greater detail below, Level I and Level II authority differ on the permissible levels of transactions as well as the application, expertise, and systems requirements.

B. The Act and NCUA's Regulations

The Federal Credit Union Act (Act) provides FCUs with the authority to invest in certain securities, obligations, and accounts.[2] For safety and soundness reasons, however, NCUA has adopted regulatory restrictions on certain investments and activities permitted by the Act.[3] Currently, derivatives are among the investments specifically prohibited by NCUA.[4]

[1] A derivative is an instrument whose price is dependent on or derived from one or more underlying assets. A derivatives transaction involves a contract between two parties, called counterparties, that exchange value based on the fluctuation of the underlying asset or index. A counterparty is the other party to the derivatives transaction and can include swap dealers and major swap participants, which are terms to identify entities that operate primarily in the derivatives market. These transactions may involve collateral and a collateral custodian, which is an entity that holds the collateral for the two contracting parties.

[2] 12 U.S.C. 1757(7) and (15).

[3] 12 CFR 703.16.

[4] *Id.* at 703.16(a). Section 703.16(a), however, provides three exceptions to the general prohibition on derivatives. First, an FCU may purchase or sell any derivatives permitted under § 703.14(g) or under § 701.21(i) of NCUA's lending regulations. Second, an FCU may purchase or sell an embedded option not required under generally accepted accounting principles (GAAP) to be accounted for separately from the host contract. Third, an FCU may enter into interest rate lock commitments or

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