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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 303, 318, 319, 320, 325, 331, 381, 417, 424, 431

[Docket No. FSIS-2015-0036]

RIN 0583-AD59

Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Supplemental proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat inspection regulations to eliminate the requirements for both ready-to-eat (RTE) and not-ready-to-eat (NRTE) pork and pork products to be treated to destroy trichinae (Trichinella spiralis) because the regulations are inconsistent with the Hazard Analysis and Critical Control Point (HACCP) regulations, and because these prescriptive regulations are no longer necessary. If this supplemental proposed rule is finalized, FSIS will end its Trichinella Approved Laboratory Program (TALP program) for the evaluation and approval of non-Federal laboratories that use the pooled sample digestion technique to analyze samples for the presence of trichinae. FSIS is also proposing to consolidate the

regulations on thermally processed, commercially sterile meat and poultry products (i.e., canned food products containing meat or poultry).

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this rulemaking. Comments may be submitted by one 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, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 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 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2015-0036. 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.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On February 27, 2001, FSIS proposed food safety performance standards for all RTE and all partially heat-treated meat and poultry products (66 FR 12590). The proposed performance standards included both levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments would be required to meet in the production of these products.

The Agency also proposed to rescind the requirements in the meat inspection regulations that prescribe treatments of pork and pork products to eliminate trichinae because the requirements are inconsistent with the HACCP regulations (9 CFR part 417).

The Agency further proposed to require that all thermally processed, commercially sterile meat and poultry products be processed to either eliminate or control the growth of Clostridium botulinum, depending on the pH of the product or other factors affecting the growth of that pathogen. The processing of a low-acid canned product that receives thermal or

other sporicidal lethality processing would have had to meet a 12-$\log_{10}$ reduction standard for C. botulinum. The processing of acidified low-acid products and of some cured products and other canned products in which pathogen growth is controlled by factors other than the thermal process would have had to prevent growth rather than achieve any specific decimal reduction of C. botulinum. All thermally processed, commercially sterile products would have had to be commercially sterile and their containers hermetically sealed.

Finally, the Agency proposed that each establishment that produces RTE meat and poultry products would have to test food contact surfaces for Listeria species (spp.) to verify the efficacy of its sanitation standard operating procedures unless it had incorporated one or more controls for Listeria monocytogenes (Lm) into its HACCP plan.

Because of the length of time since the publication of the proposed rule, FSIS is providing the public an opportunity to comment on this supplemental proposed rule. In this supplemental proposed rule, FSIS is only addressing the proposed changes to the regulations on control of trichinae in pork products and on thermally processed, commercially sterile meat and poultry products. FSIS is re-proposing the changes to remove the trichinae requirements, consistent with what FSIS originally proposed in 2001. In addition, rather than what it proposed in

2001, FSIS is proposing to combine the meat and poultry canning regulations into a new part in the regulations and to make minor changes that improve the clarity of the regulations and remove redundant sections. These minor changes are described below in the responses to comments.

FSIS addressed Lm in the interim final rule "Control of Listeria monocytogenes in RTE Meat and Poultry Products," published June 6, 2003 (68 FR 34208), and affirmed the interim final rule with minor changes on June, 19, 2015 (80 FR 35178). Therefore, FSIS has concluded that requiring establishments to test for Listeria spp. is unnecessary because post-lethality interventions and formulation of RTE meat and poultry products with growth inhibitors is much more effective in preventing listeriosis than testing product or food contact surfaces (see 80 FR 35178, 35184). FSIS is withdrawing that and the other provisions of the 2001 proposed rule because the Agency's current regulations and inspection program have been effective at preventing adulterated RTE product from entering commerce.

Based on available data, FSIS is confident that it is successfully carrying out its mission to protect public health by enforcing safeguards designed to ensure that RTE products do not become contaminated with pathogens of concern, including Lm and Salmonella. Since FSIS issued the 2001 proposed rule described above, the percent positive in FSIS testing for Lm in

RTE products has decreased from 1.32 percent in CY 2001 to 0.32 percent in CY 2014. The percent positive in FSIS testing for Salmonella in RTE products has decreased from 0.15 percent in CY 2001 to 0.04 percent in CY 2014. The Agency considers the RTE regulatory results to be an excellent indicator of the trends in pathogen presence in RTE products over several years. This downward trend shows that the current regulatory requirements have been effective in controlling Lm and Salmonella in RTE meat and poultry products.

Pathogens adulterate RTE products, and establishments are required to produce RTE products that do not have detectable levels of pathogens (e.g., Salmonella). Also, establishments are required to stabilize RTE products to inhibit the growth of spore-forming bacteria (e.g., C. botulinum and C. perfringens). If establishments' labels indicate that their products are RTE by not including safe handling instructions, they are required to process the products to render them RTE, in accordance with 9 CFR 317.2(l) and 381.125(b). FSIS requires establishments to validate their processes to achieve at least a 6.5 $\log_{10}$ reduction of Salmonella for cooked beef, roast beef, and cooked corned beef products (9 CFR 318.17); a 5-$\log_{10}$ reduction for uncured meat patties (which establishments achieve if they meet the time temperature requirements in 9 CFR 318.23); a 7-$\log_{10}$ reduction for cooked poultry products (9 CFR 381.150); or an

equivalent lethality. To assist establishments in meeting these requirements, FSIS has issued guidance on lethality and stabilization in RTE products, "Appendix A, Guidance on Relative Humidity and Time/Temperature for Cooking/Heating and Applicability to Production of Other Ready-to-Eat Meat and Poultry Product Compliance Guidelines for Meeting Lethality Performance Standards For Certain Meat And Poultry Products;" "Appendix B, Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization);" "Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products;" and "FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks." The guidance documents are available on FSIS's Web site at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index. Although there are no specific lethality requirements for other fully cooked products, as noted above, they must be produced to eliminate any detectable pathogens. By following the Guidance in Appendix A and Appendix B, establishments can meet this requirement.

FSIS reviews establishments' supporting documentation for their lethality and stabilization processes to verify that they are meeting regulatory requirements. FSIS is updating its guidance documents to ensure that industry has the necessary information to effectively address hazards. In addition, the Agency has finalized validation guidance so that establishments

have information necessary to validate that their HACCP systems effectively address these hazards in RTE product. The guidance is available on FSIS's Web site at http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES. Inspectors began verifying that large establishments meet all validation requirements on January 4, 2016 and will begin verifying that small and very small establishments meet all validation requirements on April 4, 2016 (80 FR 27557).

The Supplemental Proposed Rule

Consistent with the 2001 proposed rule, this supplemental proposed rule will, if finalized, remove the provisions for the prescribed treatment of pork and pork products under 9 CFR 318.10 to provide establishments with the flexibility to determine whether and how they need to treat the products to eliminate trichinae. If this supplemental proposed rule is finalized, establishments will have the flexibility provided by the HACCP regulations (9 CFR part 417) to develop appropriate science-based controls for trichinae and other parasitic hazards in pork. All establishments producing pork products will have to determine whether trichinae is a hazard reasonably likely to occur in their processes. If it is, they must address this hazard in their HACCP plans or in a prerequisite program.

Many establishments producing pork products already address trichinae in their HACCP plans or in a prerequisite program (see FSIS Notice 14-15, Prescribed Treatment to Destroy Trichinae in Pork, and Products Containing Pork, as Required by 9 CFR 318.10, available on FSIS's Web site at http://www.fsis.usda.gov/wps/wcm/connect/16732ee6-e159-4810-a423-9c31aee26c38/14-15.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=16732ee6-e159-4810-a423-9c31aee26c38). As explained in this notice, if an establishment considers trichinae in its hazard analysis and determines that it is reasonably likely to occur, FSIS inspection program personnel (IPP) will verify whether the establishment is implementing any of the procedures in 9 CFR 318.10(c) or alternative procedures in its HACCP plan. If trichinae is considered and determined not to be reasonably likely to occur, IPP will review the decision and may question the adequacy of the analysis. If trichinae is not considered, IPP will verify whether the establishment meets the criteria in 9 CFR 318.10(c).

If this supplemental proposed rule is finalized, all establishments producing pork products must assess whether trichinae is a hazard reasonably likely to occur. If the answer is yes, establishments must assess whether their products should be treated for elimination of live trichinae, or whether special

cooking instructions are necessary on the label of the products. Establishments must also assess whether safe handling labels are sufficient to ensure that the products are cooked to temperatures necessary to eliminate any possible live trichinae. Establishments may decide to treat their products for trichinae or to include special cooking instructions on labels based on how consumers typically prepare the products or the likelihood of the products being confused with RTE products. Their decisions may also be based on whether their suppliers participate in the U.S. Trichinae Certification Program, which is a voluntary pre-harvest pork safety program administered by the Animal and Plant Health Inspection Service (APHIS) (see 9 CFR part 149).

According to the Centers for Disease Control and Prevention, the risk for Trichinella infection associated with commercial pork has decreased substantially in the United States since the 1940s, when data collection on trichinellosis cases first began. During the period from 2008 to 2012, only 10 cases of trichinellosis were linked to commercial pork products.[1] FSIS is aware that the risk of infection with Trichinella is increased in organic, pasture raised swine and feral swine that

[1] Wilson, Nana O., Hall, Rebecca L., Montgomery, Susan P., et al. Trichinellosis Surveillance — United States, 2008-2012. MMWR Surveill Summ 2014;64(No. SS-1): 1.

have access to rodents and wildlife infected with Trichinella.[2] FSIS has developed a draft compliance guide for establishments to follow should this supplemental proposed rule become final. The draft compliance guide is designed to help establishments, particularly small and very small establishments, in understanding the controls that are effective for the prevention and elimination of trichinae and other parasites in RTE and NRTE pork products. FSIS has posted this draft compliance guide on its Web page (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index) and is requesting comments on the guidance.

In July 2015, the Codex Alimentarius Commission (Codex) adopted risk-based guidelines for the control of Trichinella spp. parasites in pork.[3] In addition, FSIS is aware that the National Pork Producers Council and the National Pork Board have been supportive of efforts to establish a U.S. compartment of negligible risk for Trichinella in accordance with the World Organization for Animal Health (OIE)[4] guideline. FSIS's draft

[2] Wilson, Nana O., Hall, Rebecca L., Montgomery, Susan P., et al. Trichinellosis Surveillance — United States, 2008–2012. MMWR Surveill Summ 2014;64(No. SS-1): 6.
[3] Guidelines for the Control of Trichinella Spp. in Meat of Suidae (2015). Retrieved from http://www.codexalimentarius.org/download/standards/13896/CXG_086e_2015.pdf
[4] World Organisation for Animal Health Terrestrial Animal Health Code. Retrieved from http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/chapitre_trichinella_spp.pdf

compliance guide is consistent with the Codex and OIE guidelines.

If this supplemental proposed rule is finalized, FSIS will end its Trichinella Approved Laboratory Program (TALP program). Since the 1980s, FSIS has operated the TALP program for the evaluation and approval of non-Federal laboratories that use the pooled sample digestion technique to analyze samples for the presence of trichinae (see 9 CFR 318.10 (e)). There is only one laboratory enrolled in the TALP program. FSIS is proposing to end this program to make more efficient use of its resources. If this supplemental proposed rule is finalized, establishments may test product samples for the presence of trichinae using a validated testing method that is equivalent to the pooled sample digestion technique, or they may use another effective test method to verify that their system is working.

Consistent with the 2001 proposed rule, FSIS also is proposing to remove the following referential and related provisions concerning required treatment to eliminate trichinae: the reference to the required trichinae treatment in 9 CFR 303.1(f); the requirement under 9 CFR 319.106(b) that country ham products and dry cured pork shoulder be treated for the destruction of possible trichinae; the requirement under 9 CFR 319.145(a)(2) that when pork muscle tissue is combined with beef

or veal, or both, in the preparation of certain Italian sausage products, it be treated for the destruction of possible live trichinae; the record retention requirement under 9 CFR 320.1(b)(7) concerning sample results and calculation results as required by processing procedures in 9 CFR 318.10(c)(3)(iv) (Methods 5 and 6) to destroy trichinae; the provision in 9 CFR 325.7(a) for including pork that has been refrigerated to destroy trichinae in the category of products that require special supervision between official establishments under official seal; the provision in 9 CFR 331.5(a)(1)(ii) that any meat or meat food product is adulterated if it is a RTE pork product that has not been treated to destroy trichinae as prescribed in 9 CFR 318.10; and the requirement under 9 CFR 424.21(a)(3)(ii) and (iii) that when pork muscle tissue is combined with poultry products, it must be treated for the destruction of possible live trichinae.

Thermally Processed, Commercially Sterile Products

FSIS is not proposing to finalize the proposed performance standard for thermally processed, commercially sterile products. As discussed below, commenters opposed FSIS's changes, and based on its review of the comments, FSIS has concluded that the proposed changes are unnecessary. Rather, FSIS is proposing to combine the regulations for thermally processed, commercially sterile products in 9 CFR 381.300 through 381.311 and 318.300

through 318.311 and recodify them into one new 9 CFR part 431. These regulations have been effective in ensuring production of safe unadulterated product. Between 2001 and 2014, there were only 11 recalls of thermally processed, commercially sterile products. Of the 11 recalls, one recall was for products that were contaminated with C. botulinum; one recall was for products that were contaminated with foreign material; three recalls were for products that were underprocessed; and six recalls were for products that were mislabeled and contained an ingredient of public health concern.

In 9 CFR 318.301(f)(2) and 381.301(f)(2), which address containers and closures (proposed 9 CFR 431.2(f)(2)), FSIS is proposing to remove the requirement that an establishment obtain the Administrator’s approval before using an alternative time lapse between container closure and the initiation of the thermal process. Under this supplemental proposed rule, the maximum time lapse between closing and initiation of thermal processing would be two hours unless data are available from the establishment's processing authority demonstrating that an alternate time period is safe and will not result in product spoilage.

FSIS is proposing to remove the redundant descriptions of equipment (e.g., bleeders, vents) common to the several types of retort systems (batch still, batch agitating, continuous rotary,

and hydrostatic) in 9 CFR 318.305 and 381.305 (proposed 9 CFR 431.6) and to replace them with a single paragraph (b)(1) that describes equipment common to all the systems.

In the same sections, paragraph (h)(2), FSIS is proposing to remove the requirement for Agency prior approval of the chemicals used by the establishment because the Agency no longer approves these chemicals.

In 9 CFR 318.309 and 381.309 on finished product inspection (proposed 9 CFR 431.10), FSIS is proposing to redesignate paragraphs and to remove reserved paragraphs (b) and (c) in order to make the section easier to understand.

FSIS also is proposing to replace every mention of "area supervisor" with "District Office" to reflect FSIS's current organization. Additionally, in accordance with Executive Orders 12866 and 12988, which emphasize the need for plain language, FSIS is proposing to replace the word "shall" with "must" to simplify the effect of the regulations and make them easier to understand.

Official establishments that produce thermally processed, commercially sterile meat and poultry products are reminded that they are subject to the HACCP regulations in 9 CFR part 417 and are required to conduct a hazard analysis for all such products. However, the HACCP regulations at 9 CFR 417.2(b)(3) exempt these establishments from having to address food safety hazards

associated with microbiological contamination if the establishments comply with the canning regulations in 9 CFR 318.300 through 318.311 and 381.300 through 381.311 (which FSIS is proposing to consolidate in a new 9 CFR part 431). The canning regulations are based on HACCP principles, and there are obvious parallels between them and the HACCP regulations in approach to controlling food safety hazards.

However, because the regulations in proposed 9 CFR part 431 primarily address microbial hazards, processors of thermally processed, commercially sterile meat and poultry products in hermetically sealed containers must carry out hazard analyses and develop and implement HACCP plans to address any chemical or physical hazards that are reasonably likely to occur. The proposed regulations in 9 CFR part 431, and the establishment's associated process documentation, would then serve a function similar to that of a prerequisite program. The documentation would be required to be kept under 9 CFR 417.5(a)(1) as documentation supporting a determination that the food safety hazards associated with microbiological contamination are not reasonably likely to occur in its operations (see FSIS Directive 7530.2, Verification Activities in Canning Operations that Choose to Follow the Canning Regulations, available on FSIS's Web site at http://www.fsis.usda.gov/wps/wcm/connect/49aeef48-21b9-4e46-ad02-269ff11183e5/7530_2.pdf?MOD=AJPERES).

Comments on the 2001 Proposed Rule and FSIS Response

FSIS received approximately 13 comments on the proposed removal of the trichinae control regulations and the amendment of the thermal processing regulations from trade associations representing meat and poultry processors, companies that produce meat and poultry products, a company that manufactures packaging for liquid food products, and a farmer-owned cooperative. Following are summaries and responses to the comments.

Trichinae control

Comment: Many comments from trade associations representing meat and poultry processors, companies that produce meat and poultry products, and the farmer-owned cooperative supported the proposal to eliminate the prescriptive trichinae control regulations. Other comments from companies that produce meat and poultry products recommended retaining the regulations. One comment from a company that produces meat and poultry products asked what effect elimination of the trichinae control regulations would have on Toxoplasma (T.) gondii, a protozoan parasite that can cause the disease toxoplasmosis, in pork. Another comment from a company that produces meat and poultry products stated that safe handling labeling would not adequately inform all consumers that raw pork product needs to be cooked thoroughly. For example, the commenter stated that some raw products may have a "cooked" appearance because they contain

ingredients such as wine, paprika, or curing agents. Also, the commenter stated that consumers who do not know English would have difficulty relying on a safe-handling label.

Another comment from a company that produces meat and poultry products said that the requirements for destruction of trichinae should be retained, but that the requirements should be reevaluated as on-farm practices improve. This commenter suggested that the Agency provide an option for processors to be able to use pork from suppliers with control programs that ensure trichinae-free pork.

Response: FSIS is proposing to eliminate the trichinae control regulations, as it proposed in 2001, largely because of their inconsistency with HACCP. Compliance with the HACCP regulations for RTE and NRTE products will ensure that trichinae and other parasites, including T. gondii, are eliminated. Because both trichinae and T. gondii have a high sensitivity to heat compared with other pathogens (e.g., Salmonella), the organisms would be rendered non-infective if pork were cooked at the times and temperatures recommended for removing bacterial hazards. Therefore, even if the prevalence of T. gondii were to increase in pork and pork products, the likelihood that T. gondii can survive cooking and cause foodborne illness is negligible.

In 2007, EcoSure, an independent food safety audit company, conducted a consumer cooking temperature audit that involved the collection of data from primary shoppers of over 900 households geographically dispersed across the country.[5] Participants were asked to record the final cooking temperature and name the main ingredient of any meal they prepared during the week of the study. Current cooking practices as captured in the 2007 EcoSure dataset show that approximately 76 percent of consumers are cooking pork products at the times and temperatures recommended for removing bacterial hazards.[6] However, the 2007 EcoSure dataset does not specifically include the time from when the final cooking temperature was recorded to when consumption occurred. It is likely that product in this dataset encountered a range of dwell times.

FSIS recommends in its guidance concerning whole cuts of pork a cooking temperature of 145 [deg]F. with 3 minutes dwell time for cooking whole cuts of pork. Available data support that this time/temperature combination would be equivalent to cooking at 160 [deg]F. without holding a product at that temperature for any dwell time. FSIS's guidance concerning cooking whole cuts of pork is located at http://blogs.usda.gov/2011/05/25/cooking-meat-check-the-new-recommended-temperatures/.

[5] EcoSure-EcoLab. (2007). EcoSure 2007 Cold Temperature Database. FoodRisk.org. available at: http://foodrisk.org/exclusives/EcoSure/.
[6] EcoSure-EcoLab. (2007). EcoSure 2007 Cold Temperature Database. FoodRisk.org. available at: http://foodrisk.org/exclusives/EcoSure/.

FSIS's guidance reflects the same standards that the Agency uses for cooked meat products produced in federally inspected meat establishments. These standards rely on the rest time of three minutes to achieve a safe product. Therefore, FSIS believes that safe handling statements are adequate to inform consumers about the time/temperature sufficient to ensure the product is fully cooked.

Additionally, FSIS requires that safe handling instructions be prominently and conspicuously placed on labels so that intended users are fully aware that raw products, including raw products that may have a "cooked" appearance, must be cooked for safety (9 CFR 317.2(b)). The low rates of trichinellosis cases in recent years further demonstrate that safe handling statements are adequate to protect consumers from trichinae.

As for the comment that consumers who do not know English would have difficulty relying on a safe-handling label, FSIS does not require products that are intended for domestic distribution to be labeled in languages other than English. However, the safe handling instructions are also accompanied by graphic symbols. The graphic symbols are intended to be visual reminders to all people reading the instructions and to convey messages to people who have difficulty reading English (59 FR 14539). Therefore, the graphics convey the necessary information

to consumers who do not read English. The low incidence of illness also supports this conclusion.

With respect to the comment that the requirements for destruction of trichinae should be retained until on-farm practices improve, FSIS has entered into an agreement with APHIS, the National Pork Producers Council, and two pork processors to pilot test a trichinae certification program to identify risk factors for trichinae infection and to certify production units that voluntarily adopted practices that reduce or eliminate the risk of trichinae. This program was finalized by APHIS in 2008 (73 FR 60464, October 10, 2008) and has encouraged the trend, referred to by the commenter, toward sound on-farm management practices to reduce trichinae risk. In the last 10-15 years, the swine industry has improved its biosecurity practices which not only reduce disease spread but also address risk factors for Trichinella such as rodent control, rapid removal of dead animals, minimizing feed exposure to rodents, and keeping animal feed and housing areas free of materials that could harbor rodents.[7],[8] Industry led initiatives like the PQA Plus certification program

[7] United States Department of Agriculture, Animal and Plant Health Inspection Service. (2008). National Animal Health Monitoring System Swine 2006, Part IV: Changes in the U.S. Pork Industry, 1990-2006. Retrieved from https://www.aphis.usda.gov/animal_health/nahms/swine/downloads/swine2006/Swine2006_dr_PartIV.pdf

[8] United States Department of Agriculture, Animal and Plant Health Inspection Service. (2015). National Animal Health Monitoring System Swine 2012, Part 1: Baseline Reference of Swine Health and Management in the United States, 2012. Retrieved from https://www.aphis.usda.gov/animal_health/nahms/swine/downloads/swine2012/Swine2012_dr_PartI.pdf

(http://www.pork.org/pqa-plus-certification/) and the Common Industry Audit (soon to include review of Trichinella risk factors; http://www.pork.org/common-industry-audit/) also support the practices described above. Because on-farm practices have improved, and the prevalence of Trichinella in U.S. swine is extremely low,[9] FSIS is not proposing to retain the trichinae regulations.

Regarding the suggestion that the Agency keep the current regulations but add an option for processors who obtain pork from suppliers with trichinae-control programs, processors who determine that trichinae is a hazard reasonably likely to occur in their products already have available to them this option for controlling the hazard (see FSIS Notice 14-15 available at http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/fsis-notices).

Thermally Processed, Commercially Sterile Products

Comment: Seven comments from trade associations and companies that produce meat and poultry products opposed the Agency's proposed performance standard for thermally processed, commercially sterile products. One commenter asserted that the existing regulations had worked for many years, and that there was no reason to change them. One comment from a trade association stated that the cost to industry to revalidate

[9] Seroprevalence of Trichinella and Toxoplasma in U.S. Grower/Finisher Pigs, 2006. (2011). Retrieved from https://www.aphis.usda.gov/animal_health/nahms/swine/downloads/swine2006/Swine2006_is_trich.pdf

processes for compliance with the proposed performance standard would be excessive and would run into the millions of dollars. Another stated that, while experienced processing firms would continue to produce safe product under the proposed performance standard, new, inexperienced firms would inevitably fail and endanger public health.

One commenter stated that the proposed performance standard would introduce an inconsistency with FDA regulations (21 CFR part 113), with which some establishments under FSIS jurisdiction and inspection also must comply. Another stated that the proposed standard would create regulatory disharmonies with the recommended code of practice of the Codex Alimentarius Commission[10]. The commenters argued that FSIS should not change the current regulations because they are essentially the same as FDA's regulations and Codex's recommended code of practice.

A commenter from a trade association stated that rather than promulgating a performance standard, the Agency should consider combining and recodifying the currently separate requirements for meat and poultry products.

The same commenter requested that FSIS eliminate the following requirements because the commenter argued that they do not involve food safety: examination and cleaning of empty

[10] Codex Alimentarius Commission. 1979. Recommended International Code of Hygienic Practice for Low-Acid and Acidified Low-Acid Canned Foods (CAC/RCP 23-1979).

containers (9 CFR 318.301(a); 381.301(a)) and the handling of containers after closure (9 CFR 318.301(f)(1); 381.301(f)(1)) because the practices are not relevant to container integrity; equipment maintenance (9 CFR 318.305(g); 381.305(g)) because these practices are more appropriate for a prerequisite program; and incubation of canned products (9 CFR 318.309(d)(1) and (2); 381.309(d)(1) and (2)) because it is a form of end-product testing that is ineffective as a routine means for ensuring the safety of canned products.

Additionally, the commenter requested that FSIS eliminate the remaining prior approval requirements that may have been overlooked when the Agency previously removed most of its prior approval requirements.

Finally, the commenter suggested that FSIS consolidate redundant requirements in the sections on equipment and procedures for heat processing systems (9 CFR 318.305(b); 381.305(b)) because a number of requirements are common to two or more of the retort systems.

Response: The Agency agrees that it should keep its regulations consistent with FDA's regulations and with Codex's code of practice in order to minimize confusion for processors. Additionally, the Agency's existing regulations are effective at ensuring food safety as evidenced by the fact that, as explained above, there have been minimal food product recalls involving

thermally processed, commercially sterile products since the proposed rule published in 2001. FSIS has found no reason to believe that it underestimated the cost of the proposed rule; however, because the current regulations are effective, the Agency agrees with the commenters that the additional requirements in the proposed rule are unnecessary.

Therefore, the Agency is proposing that the requirements for thermally processed, commercially sterile meat and poultry products be consolidated in a single part of the regulations (9 CFR part 431) and to make minor changes that improve the clarity of the regulations and remove redundant sections. As is discussed above, FSIS is proposing to remove the Administrator's prior approval requirement before an establishment may use an alternative time lapse between container closure and the initiation of the thermal process(9 CFR 318.301(f)(2); 381.301 (f)(2)). FSIS also is proposing to replace the redundant descriptions of equipment (e.g., bleeders, vents) common to the several types of retort systems (batch still, batch agitating, continuous rotary, and hydrostatic) with a single paragraph that describes equipment common to all the systems (9 CFR 318.305 and 381.305). Combining the regulations will eliminate any confusion for processors of both meat and poultry products and inspection personnel over minor wording differences between the two sets of

regulations by combining and recodifying the separate requirements into a single section.

FSIS is not proposing changes to the requirements for the cleaning of empty containers (9 CFR 318.301(a); 381.301(a)) or to the handling of containers after closure (9 CFR 318.301(f)(1); 381.301(f)(1)), as recommended by the commenter, because these are food safety requirements. The regulations were implemented to ensure the canned product is commercially sterile. To be and remain commercially sterile, the container must be hermetically sealed and receive a heat process that renders the container free of microorganisms capable of growth at non-refrigerated temperatures. Container integrity has a direct impact on whether the container is commercially sterile. If a container, lid, or cover is damaged upon receipt or before filling, then it is likely that it will not remain hermetically sealed, and that the product will not remain commercially sterile. FSIS also is not proposing the changes to the equipment maintenance requirements that the commenter recommended (9 CFR 318.305; 381.305) because these are food safety requirements as well, and in FSIS's experience, the majority of recalls for under processing are the result of human error and equipment failure, which includes poor maintenance. For example, in the one recall mentioned above for products contaminated with C. botulinum, FSIS found problems with equipment maintenance at the

establishment that produced products contaminated with C. botulinum.

FSIS is not making the changes to the incubation requirements that the commenter recommended (9 CFR 318.309, 381.309) because they help prevent cans with evidence of spoilage from entering commerce.

However, consistent with the commenter's recommendation, FSIS is proposing to remove the requirement that the Administrator approve an establishment's use of an alternative time lapse between container closure and the initiation of the thermal process before the establishment may use the alternative (9 CFR 318.301(f)(2); 381.301(f)(2)). This proposal will allow for more flexibility. Therefore, under the proposed change, the maximum time lapse between closing and initiation of thermal processing would be two hours unless data are available from the establishment's processing authority demonstrating that an alternate time period is safe and will not result in product spoilage.

Also, consistent with what the commenter recommended, FSIS is proposing to remove the requirement for Agency prior approval of chemicals used by the establishment because the Agency no longer approves these chemicals. However, FSIS is not proposing to make any other changes to the prior approval requirements. FSIS already allows establishments to develop an alternate

document procedure for handling process deviations if they do not want to hold product pending Agency review. FSIS has provided sufficient flexibility in the regulations, and the other prior approval requirements are still necessary to ensure food safety.

Finally, consistent with what the commenter recommended, FSIS is proposing to replace the redundant descriptions of equipment (e.g., bleeders, vents) common to the several types of retort systems (batch still, batch agitating, continuous rotary, and hydrostatic) (9 CFR 318.305; 381.305) with a single paragraph that describes equipment common to all the systems (proposed 9 CFR 431.6).

Executive Order 12866

This supplemental proposed rule has been designated as a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the proposed rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

FSIS is removing the trichinae treatment requirements under 9 CFR 318.10 as this action will give industry the flexibility under HACCP to develop science-based food safety controls to address trichinae and other pork associated parasitic hazards. The removal of the requirements for trichinae treatment of pork

products is unlikely to impose additional costs on the industry because the establishments can address trichinae in their existing HACCP plans. If an establishment has identified trichinae as a hazard reasonably likely to occur, the establishment would have to ensure that the process it uses effectively eliminates the hazard under HACCP. Under FSIS Notice 14-15, Prescribed Treatment to Destroy Trichinae in Pork, and Products Containing Pork, as Required by 9 CFR 318.10, establishments can use alternative procedures to those prescribed in the regulations, as long as establishments address the hazard in their HACCP plans. Establishments have the flexibility provided by the HACCP regulations to develop appropriate science-based controls for trichinae and other parasitic hazards in pork. Among the controls that can be employed are on-farm trichinae certification of hogs, lethality treatment for RTE product, and, for NRTE products, conspicuous labeling and validated cooking instructions (FSIS Notice 14-15).

FSIS inspection program personnel verify that establishments effectively address these hazards. Under the supplemental proposed rule, FSIS will end TALP, saving the Agency an average of $13,750 per year ($4,000 annual material cost + $9,000 labor cost). TALP is a program under which FSIS has evaluated and approved non-Federal- laboratories that use the pooled sample design technique to analyze samples for the

presence of trichinae. There is only one laboratory enrolled in the TALP program. FSIS is proposing to eliminate this program because very few establishments are using the laboratory that is in the program. The program is no longer necessary, and eliminating it will allow the Agency to make more efficient use of its resources.

The Agency also is proposing to combine the regulations for thermally processed, commercially sterile meat and poultry products into one new 9 CFR Part 431 and to make minor changes to improve clarity and remove redundant requirements. As is discussed above, FSIS is proposing to remove the Administrator's prior approval requirement before an establishment may use an alternative time lapse between container closure and the initiation of the thermal process(9 CFR 318.301(f)(2); 381.301(f)(2)). FSIS also is proposing to replace the redundant descriptions of equipment (e.g., bleeders, vents) common to the several types of retort systems (batch still, batch agitating, continuous rotary, and hydrostatic) with a single paragraph that describes equipment common to all the systems (9 CFR 318.305 and 381.305).

There are no additional costs associated with combining the canning regulations or with these other minor changes. FSIS is not proposing any new requirements for canning establishments

and is providing additional flexibility by removing prior approval provisions.

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this supplemental proposed rule would not have a significant economic impact on a substantial number of small entities in the United States, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

The rule will affect 447 very small establishments and 222 small establishments that produce pork and pork products in the United States. FSIS is providing additional flexibility to these establishments. FSIS has developed a draft compliance guide designed to help small and very small establishments to understand the controls that are effective for the prevention and elimination of trichinae and other parasites in RTE and NRTE pork products. There are 29 very small establishments and 80 small establishments that produce thermally processed, commercially sterile meat and poultry products in the United States. The supplemental proposed rule does not impose any additional costs on small and very small establishments because these establishments already are in compliance with the canning regulations, and combining the separate (meat and poultry) canning regulations into one part is an administrative action.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this proposed rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this proposed rule will be preempted; (2) no retroactive effect will be given to this proposed rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this proposed rule.

Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal

implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this proposed rule on Indian tribes and determined that this rulemaking does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA will, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain combined 6 8 12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture

Director, Office of Adjudication

1400 Independence Avenue, SW

Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register .

FSIS also will make copies of this 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 our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-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/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects

9 CFR Part 301

Meat inspection.

9 CFR Part 303

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 319

Food grades and standards, Food labeling, Frozen foods, Meat inspection, Oils and fats.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 325

Meat inspection, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 331

Intergovernmental regulations, Meat inspection.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food Labeling, Food packaging, Government employees, Grant programs-agriculture, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polycholorinated biphenyls (PCB's), Poultry and poultry products inspection, Reporting and recordkeeping requirements.

9 CFR Part 417

Meat inspection, Poultry and poultry products inspection, Reporting and recordkeeping requirements.

9 CFR Part 424

Food additives, Food packaging, Meat inspection, Poultry and poultry products.

9 CFR Part 431

Meat inspection, Poultry and poultry products inspection, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS proposes to amend title 9, chapter III, of the Code of Federal Regulations as follows:

PART 301 – DEFINITIONS

1. The authority citation for part 301 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.7, 2.18, 2.53.

§ 301.2 [Amended]

2. Section 301.2 is amended by removing the last sentence in the definition of "Process authority" and the last sentence in the definition of "Process schedule" and adding in their places the sentence "This definition does not apply to part 431 of this chapter."

PART 303 – EXEMPTIONS

3. The authority citation for part 303 is revised to read as follows:

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 303.1 [Amended]

4. Paragraph § 303.1(f) is amended by removing the second sentence.

PART 318 – ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCT

5. The authority citation for part 318 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 318.10 [Removed and reserved]

6. Section 318.10 is removed and reserved.

§ 318.17 [Removed and reserved]

7. Section 318.17 is removed and reserved.

§ 318.23 [Removed and reserved]

8. Section 318.23 is removed and reserved.

Subpart G [Removed and reserved]

9. Subpart G, consisting of §§ 318.300 through 318.311, is removed and reserved.

PART 319 – DEFINITIONS AND STANDARDS OF IDENTITY AND COMPOSITION

10. The authority citation for part 319 continues to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 319.106 [Amended]

11. In § 319.106, paragraph (b) is removed; paragraphs (c)(5) and (6) are removed and reserved; paragraphs (c) and (d)

are redesignated as paragraphs (b) and (c), respectively; and the Effective Date Note is removed.

§ 319.145 [Amended]

12. In § 319.145, paragraph (a)(2) is amended by removing the third sentence.

PART 320 – RECORDS, REGISTRATION, AND REPORTS

13. The authority citation for part 320 is revised to read as follows:

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

14. In § 320.1, paragraph (b)(6) is revised; paragraph (b)(7) is removed; paragraphs (b)(8) through (11) are redesignated as paragraphs (b)(7) through (10), respectively. The revision reads as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(6) Records of canning as required by part 431 of this chapter.

* * * * *

PART 325 – TRANSPORTATION

15. The authority citation for part 325 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 325.7 [Amended]

16. In § 325.7, paragraph (a) is amended by removing the phrase, "pork that has been refrigerated to destroy trichinae,".

PART 331 – SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

17. The authority citation for part 331 is revised to read as follows:

AUTHORITY: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

§ 331.5 [Amended]

18. In § 331.5, paragraph (a)(1)(ii) is amended by removing the phrase, "or it is a ready-to-eat pork product which has not been treated to destroy trichinae as prescribed in § 318.10 of this subchapter for products at federally inspected establishments;".

PART 381 – POULTRY PRODUCTS INSPECTION REGULATIONS

19. The authority citation for part 381 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 451-472; 7 CFR 2.18, 2.53.

20. In § 381.175, paragraph (b)(3) is revised to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(3) Records of canning as required by part 431 of this chapter.

* * * * *

Subpart X [Removed and reserved]

21. Subpart X, consisting of §§ 381.300 through 381.311, is removed and reserved.

PART 417 – HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

22. The authority citation for part 417 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 451-472, 601-695; 7 CFR 2.18, 2.53.

23. Paragraph 417.2(b)(3) is revised to read as follows:

§ 417.2 Hazard Analysis and HACCP plan.

* * * * *

(b) * * *

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 431 of this chapter.

* * * * *

PART 424 – PREPARATION AND PROCESSING OPERATIONS

24. The authority citation for part 424 is revised to read as follows:

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 451-472, 601-695; 7 CFR 2.18, 2.53.

§ 424.21 [Amended]

25. In § 424.21, paragraphs (a)(3)(ii) and (iii) are removed and paragraph (a)(3)(i) is redesignated as (a)(3).

26. Part 431 is added to read as follows:

PART 431 - THERMALLY PROCESSED, COMMERCIALLY STERILE PRODUCTS

Sec.

AUTHORITY: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 451-472, 601-695; 7 CFR 2.18, 2.53.

§ 431.1 Definitions.

Abnormal container. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

Acidified low acid product. A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

Bleeders. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

Canned product. A meat or poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term “product” as used in this part means “canned product.”

Closure technician. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this part and designated by the establishment to perform such examinations.

Code lot. All production of a particular product in a specific size container marked with a specific container code.

Come-up time. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

Critical factor. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

Headspace. That portion of a container not occupied by the product.

(1) Gross headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) Net headspace.

The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

Hermetically sealed containers. Air-tight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) Rigid container. A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of

up to 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(2) Semirigid container. A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(3) Flexible container. A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

Incubation tests. Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

Initial temperature. The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

Low acid product. A canned product in which any component has a pH value above 4.6.

Process schedule. The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

Process temperature. The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

Process time. The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

Processing authority. The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this part.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

Seals. Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

Shelf stability. The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms

capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

Thermal process. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

Venting. The removal of air from a retort before the start of process timing.

Water activity. The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 431.2 Containers and closures.

(a) Examination and handling of empty containers. (1) Empty containers, closures, and flexible pouch roll stock must be evaluated by the establishment to ensure that they are free of structural defects and damage that may affect product or container integrity. Such an examination should be based on a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock must be stored, handled, and conveyed in such a manner

that will prevent damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers must be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) Closure examinations for rigid containers (cans)—(1) Visual examinations. A closure technician must visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, must be taken. In addition to the double seams, the entire container must be examined for product leakage or obvious defects. A visual examination must be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, must be recorded. Visual examinations must be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician at the beginning of production, immediately following every jam in the closing

machine and after closing machine adjustment (including adjustment for changes in container size).

(2) Teardown examinations. Teardown examinations of double seams formed by each closing machine head must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head must be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end must be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including

adjustment for a change in container size). The following procedures must be used in teardown examinations of double seams:

(i) One of the following two methods must be employed for dimensional measurements of the double seam.

(A) Micrometer measurement. (*1*) For cylindrical containers, measure the following dimensions (Figure 1 to § 431.2) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

(*i*) Double seam length--W;

(*ii*) Double seam thickness--S;

(*iii*) Body hook length--BH; and

(*iv*) Cover hook length--CH.

(*2*) Maximum and minimum values for each dimensional measurement must be recorded by the closure technician.

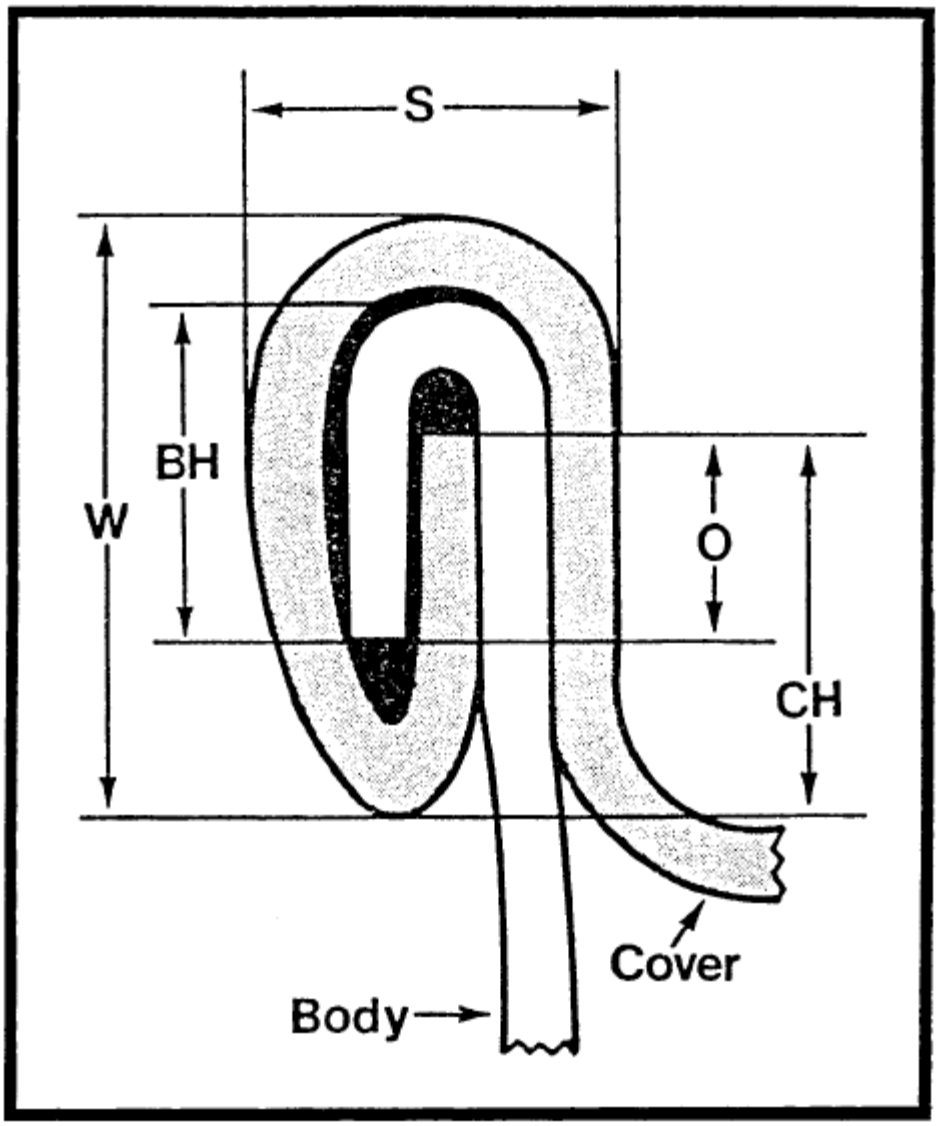

Figure 1 to § 431.2—Micrometer Measurement of Cylindrical Containers

(B) Seamscope or seam projector. Required measurements of the seam include thickness, body hook, and overlap.

(ii) Seam thickness. Seam thickness must be obtained by micrometer. For cylindrical containers, at least two locations,

excluding the side seam juncture, must be used to obtain the required measurements.

(iii) Seam tightness. Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined must be stripped to assess the degree of wrinkling.

(iv) Side seam juncture rating. Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook must be stripped to examine the cover hook droop at the juncture for containers having side seams.

(v) Examination of noncylindrical containers. Examination of noncylindrical containers (e.g., square, rectangular, "D" - shaped, and irregularly-shaped) must be conducted as described in paragraphs (b)(2)(i), (ii), (iii), and (iv) of this section except that the required dimensional measurements must be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) Closure examinations for glass containers—(1) Visual examinations. A closure technician must visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine must be taken and recorded. In addition to the closures,

the entire container must be examined for defects. Visual examinations must be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations must be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) Closure examinations and tests. Depending upon the container and closure, tests must be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine must be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, must be promptly recorded by the closure technician. The establishment must have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing

machine, and after closing machine adjustment (including adjustment for a change in container size).

(d) Closure examinations for semi-rigid and flexible containers—(1) Heat seals—(i) Visual examinations. A closure technician must visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, must be taken and recorded. In addition to examining the heat seals, the entire container must be examined for product leakage or obvious defects. Visual examinations must be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken must be promptly recorded.

(ii) Physical tests. Tests determined by the establishment as necessary to assess container integrity must be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests must be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure must be on file and available for review by Program employees. Test results along with any

necessary corrective actions, such as adjusting or repairing the sealing machine, must be recorded.

(2) Double seams on semirigid or flexible containers must be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer must also be made and recorded.

(e) Container coding. Each container must be marked with a permanent, legible, identifying code mark. The mark must, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) Handling of containers after closure. (1) Containers and closures must be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closure of containers and initiation of thermal processing must be 2 hours unless data are available from the establishment's processing authority demonstrating that an alternative time period is safe and will not result in product spoilage.

§ 431.3 Thermal processing.

(a) Process schedules. Prior to the processing of canned product for distribution in commerce, an establishment must have

a process schedule (as defined in § 431.1) for each canned meat or poultry product to be packed by the establishment.

(b) Source of process schedules. (1) Process schedules used by an establishment must be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements must be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority must amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, must be made available by the establishment to the Program employee upon request.

(c) Submittal of process information. (1) Prior to the processing of canned product for distribution in commerce, the establishment must provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules must be maintained on file by the establishment. Upon request by Program employees, the establishment must make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment must provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors must not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

§ 431.4 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule must be measured, controlled, and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) General. (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible containers, and to some extent semirigid containers, during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) Continuous rotary and batch agitating retorts. (1) Minimum headspace; and

(2) Retort reel speed.

(c) Hydrostatic retorts. Chain or conveyor speed.

(d) Steam/air retorts. (1) Steam/air ratio; and

(2) Heating medium flow rate.

§ 431.5 Operations in the thermal processing area.

(a) Posting of processes. Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, must be posted in a conspicuous place near the thermal processing equipment. Alternatively, such

information must be available to the thermal processing system operator and the inspector.

(b) Process indicators and retort traffic control. A system for product traffic control must be established to prevent product from bypassing the thermal processing operation. Each basket, crate, or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, must be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles must be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts must be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) Initial temperature. The initial temperature of the contents of the coldest container to be processed must be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins must be operated to assure that such water will not lower

the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) Timing devices. Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time, and retort venting, must be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events must have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices must correspond within 15 minutes to the time of the day recorded on written records required by § 431.7.

(e) Measurement of pH. Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) must be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 431.6 Equipment and procedures for heat processing systems.

(a) Instruments and controls common to different thermal processing systems—(1) Indicating temperature devices. Each retort must be equipped with at least one indicating temperature device that measures the actual temperature within the retort.

The indicating temperature device, not the temperature/time recording device, must be used as the reference instrument for indicating the process temperature.

(i) Mercury-in-glass thermometers. A mercury-in-glass thermometer must have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer must be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test must be maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard must be repaired and tested for accuracy before further use, or replaced.

(ii) Other devices. Temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, must meet known, accurate standards for such devices when tested for accuracy. The records of such testing must be available to FSIS program employees.

(2) Temperature/time recording devices.

Each thermal processing system must be equipped with at least one temperature/time recording device to provide a permanent

record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy must be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but must never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment must be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers must have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism must be accurate.

(i) Chart-type devices. Devices using charts must be used only with the correct chart. Each chart must have a working scale of not more than 55 °F/inch (or 12 °C/cm.) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations must not exceed 2 °F degrees (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices must print temperature readings at intervals that will assure that the parameters of the process

time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) Other devices. Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) Steam controllers. Each retort must be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) Air valves. All air lines connected to retorts designed for pressure processing in steam must be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) Water valves. All retort water lines that are intended to be closed during a process cycle must be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) Pressure processing in steam—(1) Common to batch still, batch agitating, continuous rotary retorts, and hydrostats. (i) The

basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices must be installed either within the retort shell or in external wells attached to the retort. External wells must be connected to the retort through at least a 3/4 inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for the external wells must emit steam continuously during the entire thermal processing period.

(ii) Steam inlet. The steam inlet to each retort must be large enough to provide steam for proper operation of the retort, and must enter at a point(s) to facilitate air removal during venting.

(iii) Bleeder and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment must have on file documentation that the mufflers do not impede the removal of air from the retort. Such documentation must consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information must be made available to Program employees for review.

(iv) Bleeders. Bleeders, except those for external wells of temperature devices and hydrostatic retorts, must have a 1/8 inch (or 3 mm) or larger openings and must be wide open during the entire process, including the come-up time. All bleeders must be arranged so that the retort operator can observe that they are functioning properly. For horizontal retorts, batch agitating retorts, and continuous rotary retorts, bleeders must be located within approximately 1 foot (or 30 cm) of the outmost locations of containers at each end along the top of the retort. Additional bleeders must be located not more than 8 feet (2.4 m) apart along the top. This information must be maintained on file by the establishment and made available to Program employees for review. Vertical retorts must have at least one bleeder opening located in the portion of the retort opposite the steam inlet. Hydrostatic retorts must have bleeder openings 1/4 inch (or 6 mm) or larger which are to be located in the steam chamber(s) opposite the point of steam entry. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort.

(2) Batch still retorts—(i) Crate supports. Vertical still retorts with bottom steam entry must employ bottom retort crate

supports. Baffle plates must not be used in the bottom of retorts.

(ii) Steam spreader. Perforated steam spreaders, if used, must be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts must be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information must be maintained on file by the establishment and made available to Program employees for review.

(iii) Condensate removal. In retorts having a steam inlet above the level of the lowest container, a bleeder must be installed in the bottom of the retort to remove condensate. The condensate bleeder must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must be tested at the beginning of each shift for proper functioning and the results recorded. If the

alarm system is not functioning properly, it must be repaired before the retort is used.

(iv) Stacking equipment—(A) Equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort must be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle must have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(B) Divider plates. Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment must have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation must be in the form of heat distribution data or documentation from a processing authority. This information must be made available to Program employees for review.

(v) Vents. (A) Vents must be located in that portion of the retort opposite the steam inlet and must be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents must be controlled by a gate, plug cock, or other full-flow valve which must be fully opened to permit rapid removal of air from retorts during the venting period.

(B) Vents must not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold must be controlled by a gate, plug cock, or other full-flow valve and the manifold must be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge must not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts must lead to the atmosphere. The manifold header must not be controlled by a valve and must be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(C) Some typical installations and operating procedures are described below. Other retort installations, vent piping

arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation must be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information must be maintained on file by the establishment and made available to Program employees for review.

(D) For crateless retort installations, the establishment must have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information must be maintained on file by the establishment and made available to Program employees for review.

(E) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(*1*) Venting horizontal retorts. (*i*) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

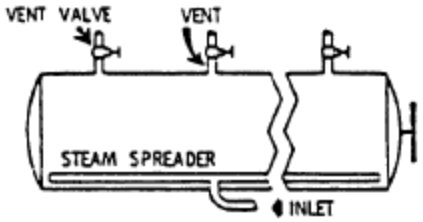

Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents must not be more than 2 1/2 feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves must be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*ii*) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

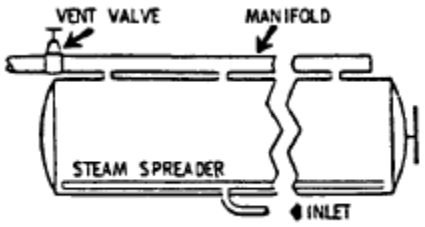

Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2 1/2 feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2 1/2 inches

(6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve must be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(*iii*) Venting through water spreaders.

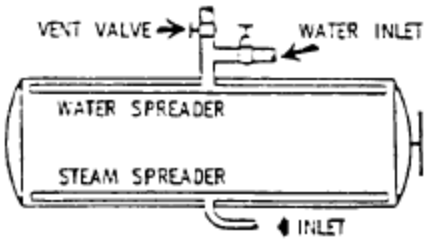

Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2 1/2 inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1 1/2 inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length, 2 inches (or 5 cm). The number of holes must be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent must be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*iv*) Venting through a single 2 1/2 inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

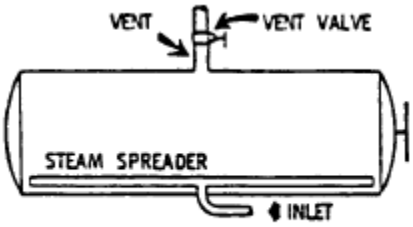

Figure 4.

Specifications (Figure 4): A 2 1/2 inch (6.4 cm) vent equipped with a 2 1/2 inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve must be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(*2*) *Venting vertical retorts*. (*i*) Venting through a 1 1/2 inch (3.8 cm) overflow.

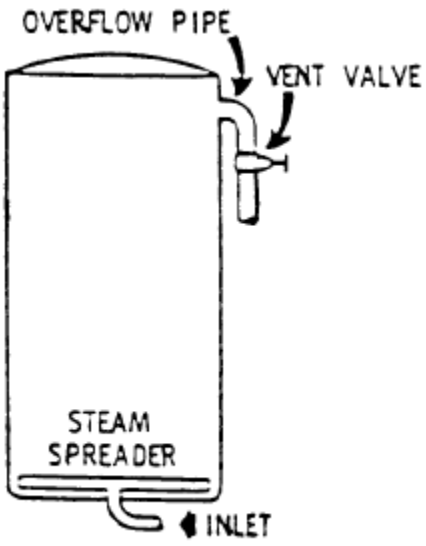

Figure 5.

Specifications (Figure 5): A 1 1/2 inch (3.8 cm) overflow pipe equipped with a 1 1/2 inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1 1/2 inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve must be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(*ii*) Venting through a single 1 inch (2.5 cm) side or top vent.

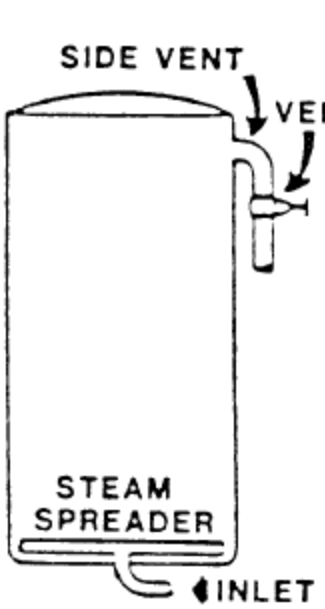

Figure 6

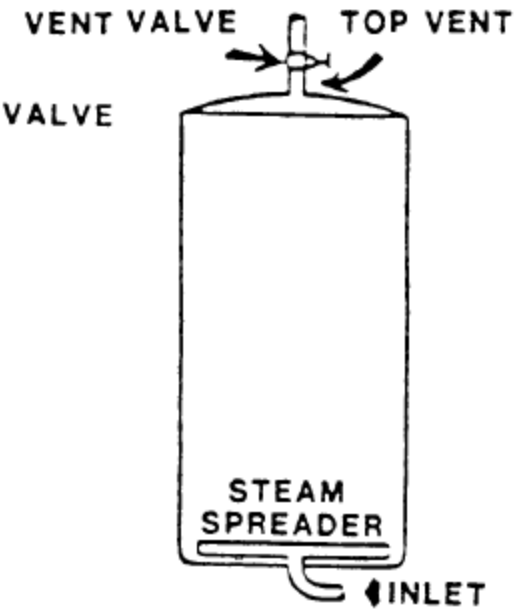

Figure 7

Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve must be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(3) Batch agitating retorts—(i) Venting and condensate removal. The air in the retort must be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure must be kept on file by the establishment and

made available to Program employees for review. At the time the steam is turned on, the drain must be opened to remove steam condensate from the retort. A bleeder must be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(ii) Retort or reel speed timing. The retort or reel speed must be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed must be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer must be determined and recorded at least once per

shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(4) Continuous rotary retorts—(i) Venting and condensate removal. The air in the retort must be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure must be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain must be opened to remove steam condensate from the retort. A bleeder must be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder must be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder must be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems must be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system must

be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(ii) Retort speed timing. The rotational speed of the retort must be specified in the process schedule. The speed must be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed must be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(5) Hydrostatic retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, indicating temperature devices must be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water

temperatures in the hydrostatic water legs, at least one indicating temperature device must be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe must be installed either within the steam dome or in a well attached to the dome. Each probe must have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes must be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam inlet. The steam inlets must be large enough to provide steam for proper operation of the retort.

(iii) Bleeders. Bleeder openings 1/4 inch (or 6 mm) or larger must be located in the steam chamber(s) opposite the point of steam entry. Bleeders must be wide open and must emit steam continuously during the entire process, including the come-up time. All bleeders must be arranged in such a way that the operator can observe that they are functioning properly.

(iv) Venting. Before the start of processing operations, the retort steam chamber(s) must be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing must be

kept on file at the establishment and made available to Program employees for review.

(v) Conveyor speed. The conveyor speed must be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed must be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed must be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(vi) Bleeders and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment must have documentation that the mufflers do not impede the removal of air from the retort. Such documentation must consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information must be maintained on file by the establishment and made available to Program employees for review.

(c) Pressure processing in water—(1) Common to batch still and agitating retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section.

(ii) Pressure recording device. Each retort must be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) Heat distribution. Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort must be kept on file at the establishment and made available to Program employees for review.

(iv) Drain valve. A non-clogging, water-tight drain valve must be used. Screens must be installed over all drain openings.

(2) Batch still retorts. (i) The indicating temperature device bulbs or probes must be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe must be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe must extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe must be located at the

bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe must be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers must have filter systems to ensure a supply of clean, dry air.

(ii) Crate supports. A bottom crate support must be used in vertical retorts. Baffle plates must not be used in the bottom of the retort.

(iii) Stacking equipment. For filled flexible containers and, where applicable, semi-rigid containers, stacking equipment must be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(iv) Water level. There must be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water must cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or

water sprays, the water level must be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods must be provided. The retort operator must check and record the water level at intervals to ensure it meets the specified processing parameters.

(v) Air supply and controls. In both horizontal and vertical still retorts, a means must be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry must be controlled by an automatic pressure control unit. A non-return valve must be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure must be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it must be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file

by the establishment and made available to Program employees for review.

(vi) Water recirculation. When a water recirculation system is used for heat distribution, the water must be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader must be uniformly distributed. The suction outlets must be protected with screens to keep debris from entering the recirculation system. The pump must be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) Cooling water entry. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(3) Batch agitating retorts. (i) The indicating temperature device bulb or probe must extend directly into the water without a separable well or sleeve. The recorder/controller probe must be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) Stacking equipment. All devices used for holding product containers (e.g., crates, trays, divider plates) must be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(iii) Water level. There must be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water must completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods must be provided. The retort operator must check and record the adequacy of the water

level with sufficient frequency to ensure it meets the specified processing parameters.

(iv) Air supply and controls. Retorts must be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry must be controlled by an automatic pressure control unit. A non-return valve must be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure must be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it must be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review.

(v) Retort or reel speed timing. The retort or reel speed timing must be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed must be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to

provide a continuous record of the speed. The accuracy of the recording tachometer must be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts must be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments is a satisfactory means of preventing unauthorized changes.

(vi) Water recirculation. If a water recirculation system is used for heat distribution, it must be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader must be uniformly distributed. The suction outlets must be protected with screens to keep debris from entering the recirculation system. The pump must be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort must be documented by heat distribution data or other documentation from a processing authority, and such data must be

maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(viii) Cooling water entry. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) Pressure processing with steam/air mixtures in batch retorts. (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes must be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Recording pressure controller. A recording pressure controller must be used to control the air inlet and the steam/air mixture outlet.

(3) Circulation of steam/air mixtures. A means must be provided for the circulation of the steam/air mixture to prevent

formation of low-temperature pockets. The efficiency of the circulation system must be documented by heat distribution data or other documentation from a processing authority, and such data must be maintained on file by the establishment and made available to Program employees for review. The circulation system must be checked to ensure its proper functioning and must be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference must be made to the equipment manufacturer for details of installation, operation, and control.

(e) Atmospheric cookers—(1) Temperature/time recording device. Each atmospheric cooker (e.g., hot water bath) must be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) Heat distribution. Each atmospheric cooker must be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker must be kept on file by the establishment and made available to Program employees for review.

(f) Other systems. All other systems not specifically delineated in this section and used for the thermal processing of canned product must be adequate to produce shelf-stable products consistently and uniformly.

(g) Equipment maintenance. (1) Upon installation, all instrumentation and controls must be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system must be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing must be checked by the establishment for leaks. Defective valves must be repaired or replaced as needed.

(4) Vent and bleeder mufflers must be checked and maintained or replaced by the establishment to prevent any reduction in bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule must be developed and implemented to assure that the holes are maintained at their original size.

(6) Records must be kept on all maintenance items that could affect the adequacy of the thermal process. Records must include the date and type of maintenance performed and the person conducting the maintenance.

(h) Container cooling and cooling water. (1) Potable water must be used for cooling except as provided for in paragraphs (h)(2) and (3) of this section.

(2) Cooling canal water must be chlorinated or treated with a chemical having a bactericidal effect equivalent to chlorination. There must be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals must be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused must be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, must be constructed and installed so that they can be cleaned and inspected. In addition, the establishment must

maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) Post-process handling of containers. Containers must be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like must be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

§ 431.7 Processing and production records.

At least the following processing and production information must be recorded by the establishment: date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 431.4 regarding the control of critical factors must be recorded. In addition, where applicable, the following information and data must also be recorded:

(a) Processing in steam—(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(2) Batch agitating retorts. In addition to recording the information required for batch still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) Continuous rotary retorts. Record the retort system number, the approximate total number of containers retorted,

product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed must be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) must be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) must be observed and recorded at the time the first container enters the retort and thereafter as specified in § 431.305(b)(3)(v).

(4) Hydrostatic retorts. Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device must be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments

must be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, must be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) Processing in water—(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(2) Batch agitating retorts. In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) Processing in steam/air mixtures. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per

retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder must be read at the same time at least once during process timing and the observed temperatures recorded.

(d) Atmospheric cookers—(1) Batch-type systems. For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) Continuous-type systems. Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

§ 431.8 Record review and maintenance.

(a) Process records. Charts from temperature/time recording devices must be identified by production date,

container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 431.7. Each entry on a record must be made at the time the specific event occurs, and the recording individual must sign or initial each record form. No later than 1 working day after the actual process, the establishment must review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, must be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart must be made available to Program employees for review.

(b) Automated process monitoring and recordkeeping. Automated process monitoring and recordkeeping systems must be designed and operated in a manner that will ensure compliance with the applicable requirements of § 431.7.

(c) Container closure records. Written records of all container closure examinations must specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records must be signed or initialed by the container closure technician and must be reviewed and signed by the establishment within 1 working day after the actual production to ensure that

the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart must be made available to Program employees for review.

(d) Distribution of product. Records must be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) Retention of records. Copies of all processing and production records required in § 431.7 must be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

§ 431.9 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it must be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbial contamination; or,

(2) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(3) Paragraph (c) of this section.

(c) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) Deviations identified in-process. If a deviation is noted at any time before the completion of the intended process schedule, the establishment must:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 431.3(a) and (b) and is filed with the inspector in accordance with § 431.3(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment must provide the inspector the following:

(A) A complete description of the deviation along with all necessary supporting documentation;

(B) A copy of the evaluation report; and

(C) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (c)(1)(iii) of this section must not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product must be set aside for further evaluation in accordance with paragraph (c)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product must be handled in accordance with paragraphs (c)(1)(iii) and (iv) of this section or in accordance with the following procedures:

(A) Emergency stops. (1) When retort jams or breakdowns occur during the processing operations, all containers must be given an emergency still process (developed per § 431.3(b)) before the retort is cooled or the retort must be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in

transfer valves between retort shells at the time of a jam or breakdown must be removed and either reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed must be handled as "U.S. Inspected and Condemned," as defined in § 301.2 of this chapter, or as "U.S. Condemned," as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process must be noted on the temperature/time recording device and entered on the other production records required in § 431.7.

(B) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel must be stopped and the following actions must be taken:

(1) For temperature drops of less than 10 °F (or 5.5 °C) either:

(i) All containers in the retort must be given an emergency still process (developed per § 431.3(b)) before the reel is restarted;

(ii) Container entry to the retort must be prevented and an emergency agitating process (developed per § 431.3(b)) must be used before container entry to the retort is restarted; or

(iii) Container entry to the retort must be prevented and

the reel restarted to empty the retort. The discharged containers must be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as "U.S. Inspected and Condemned," as defined in § 301.2 of this chapter, or as "U.S. Condemned," as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(2) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort must be given an emergency still process (developed per § 431.3(b)). The time the reel was stopped and the time the retort was used for a still retort process must be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 431.7. Alternatively, container entry to the retort must be prevented and the reel restarted to empty the retort. The discharged containers must be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed must be handled as "U.S. Inspected and Condemned," as defined in § 301.2 of this chapter, or as "U.S. Condemned," as defined in § 381.1(b) of this chapter, and disposed of in accordance with part 314 of this chapter or with § 381.95 of this chapter, as applicable.

(2) Deviations identified through record review. Whenever a deviation is noted during review of the processing and

production records required by § 431.8(a) and (b), the establishment must hold the product involved and the deviation must be handled in accordance with paragraph (c)(1)(iii) of this section.

(d) Process deviation file. The establishment must maintain full records regarding the handling of each deviation. Such records must include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records must be maintained in a separate file or in a log that contains the appropriate information. The file or log must be retained in accordance with § 431.8(e) and must be made available to Program employees upon request.

§ 431.10 Finished product inspection.

Finished product inspections must be handled according to:

(a) An HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(b) An FSIS-approved total quality control system;

(c) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated

with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) Incubation of shelf stable canned product—(i) Incubator. The establishment must provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) Incubation temperature. The incubation temperature must be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature must be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) must be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) Product requiring incubation. Shelf stable product requiring incubation includes:

(A) Low acid products as defined in § 431.1; and

(B) Acidified low acid products as defined in § 431.1.

(iv) Incubation samples.

(A) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment must select at least one container for incubation.

(B) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment must select at least one container per 1,000 for incubation.

(C) Only normal-appearing containers must be selected for incubation.

(v) Incubation time. Canned product requiring incubation must be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (b)(1)(ii) of this section.

(vi) Incubation checks and record maintenance. Designated establishment employees must visually check all containers under incubation each working day and the inspector must be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment must record at least the product name, container size, container code, number of containers incubated, in and out dates, and

incubation results. The establishment must retain such records, along with copies of the temperature/time recording charts, in accordance with § 431.8(d).

(vii) Abnormal containers. The finding of abnormal containers (as defined in § 431.1) among incubation samples is cause to officially retain at least the code lot involved.

(viii) Shipping. No product must be shipped from the establishment before the end of the required incubation period. An establishment wishing to ship product prior to the completion of the required incubation period must submit a written proposal to the District Office. Such a proposal must include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the District Office, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) Container condition— (i) Normal containers. Only normal-appearing containers must be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to program employees.

(ii) Abnormal containers. When abnormal containers are detected by any means other than incubation, the establishment must inform the inspector, and the affected code lot(s) must not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

§ 431.11 Personnel and training.

All operators of thermal processing systems specified in § 431.6 and container closure technicians must be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

§ 431.12 Recall procedure.

Establishments must prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure must be made available to Program employees for review.

Done in Washington, DC, on March 16, 2016.

Alfred V. Almanza

Acting Administrator.

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