Draft FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products

December 2017

This guidance document is designed to help small and very small plants producing ready-to-eat (RTE) egg products to meet the new regulatory requirements under the Egg Products Inspection Regulations proposed rule. In particular, this guideline covers:

- Regulatory requirements associated with the safe production of RTE egg products by implementing current regulatory time and temperature provisions;
- Options plants can use to achieve lethality and cooling performance standards;
- Safe harbor documents to support procedures that would develop a safe product; and
- Recommendations for meeting the sampling and testing requirements for detection and identification of *Salmonella* spp. in finished RTE egg products

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Preface

What is the purpose of this Compliance Guideline?

This guideline contains information to help plants producing ready-to-eat (RTE) egg products that undergo pasteurization, heat-treatment, cooling, and freezing to comply with new regulatory requirements in the proposed rule on Egg Products Inspection Regulations (Docket No. FSIS-2005-0015), should that proposed rule be finalized. Until then, this compliance guideline should not be used.

Under proposed 9 Code of Federal Regulations (CFR) 591.1(a), all official plants would have to comply with the requirements contained in 9 CFR 416, Sanitation, 9 CFR 417, Hazard Analysis and Critical Control Point Systems (HACCP), and 9 CFR 500, Rules of Practice. Under proposed 9 CFR 591.1(b), an "official establishment" or "establishment" will now include a plant that processes egg products. This guideline includes:

- Recommendations for meeting proposed regulatory requirements associated with the safe production of RTE egg products by implementing current regulatory time and temperature provisions;

- Options plants can use to achieve lethality and cooling performance standards;

- Safe harbor documents to support procedures that would develop a safe product; and

- Recommendations for meeting the sampling and testing requirements for detection and identification of *Salmonella* spp. in finished RTE egg products

Note: Plants may also seek guidance from University Extension Service specialists within the State that the plants are located to comply with new regulatory requirements should the requirements be finalized and in effect.

This Compliance Guideline follows the procedures in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). More information can be found on the Food Safety and Inspection Service (FSIS) Web page.

Should the rule become final, FSIS intends to finalize this guideline. The recommendations in the guideline will not be **requirements** that must be met. Under the rule, plants may choose to implement different procedures than those outlined in this guideline, but they would need to support why those procedures are effective.

This guideline is focused on small and very small plants in support of the Small Business Administration's initiative to provide small and very small plants with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all egg products plants may be able to apply the

recommendations in this guideline. It is important that small and very small plants have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large plants can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small plants provides them with information that may be otherwise unavailable to them. FSIS published a proposed rule to bring the egg products regulations under a HACCP regulatory structure.

The proposed rule would remove the prescriptive time and temperature parameters for egg products pasteurization, heat-treatment, freezing, and cooling. Instead, FSIS will require that plants support and validate procedures for lethality treatments, cooling, and freezing into their HACCP systems and develop written Sanitation Standard Operating Procedures (Sanitation SOPs).

How can I comment on this guideline?

FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 120 days and the document will be updated in response to the comments received. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including CD-ROMs, and hand - or courier-delivered submittals: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and docket title: *FSIS Compliance Guidelines for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products*. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Is this version of the guideline final?

No. Should the proposed rule on Egg Products Inspection Regulations become final, a final version of this guidance will be issued to reflect feedback received from all stakeholders and in response to public comments.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the AskFSIS database or submit questions through AskFSIS. Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter RTE Egg Products Compliance Guideline
Question Field:	Enter question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Sampling** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue**.

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FSIS Compliance Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products

Background

FSIS has proposed to amend the egg products inspection regulations by requiring official plants that process egg products to develop and implement Hazard Analysis and Critical Control Point (HACCP) Systems, Sanitation Standard Operating Procedures (Sanitation SOPs), and Sanitation Performance Standards (SPS) in accordance with 9 CFR Part 416 and 9 CFR Part 417. In addition, FSIS is proposing to eliminate selected regulatory provisions inconsistent with current FSIS HACCP and Sanitation SOP regulations. FSIS is also proposing that official plants produce egg products to be edible without additional preparation to achieve food safety. In other words, the finished product must be free of detectable pathogens, such as *Salmonella* spp. (insert link to proposed rule here, when available). Additionally, FSIS will continue to sample egg products for *Salmonella* spp. to verify compliance with the statute and regulatory requirements. On September 21, 2016, FSIS began analyzing all domestic and imported pasteurized egg products that it analyzes for *Salmonella spp.* for *Listeria monocytogenes* (Lm). [1]

Key Point

Ready-to-eat (RTE) product: A product that is in a form that is edible without additional preparation to achieve food safety and that may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE products are not required to bear a safe-handling instruction.

The statutory provisions require that egg products are "Ready-To-Eat" (RTE) and egg products inspected at an official plant are pasteurized and not adulterated before the product is shipped into commerce (21 U.S.C. 1036(a)). Because pasteurized egg products are considered RTE, this means they have been prepared so that they can be safely consumed as is, meaning without any additional cooking.

Existing 9 CFR 590.570 would be replaced by a new regulation specifying that egg products are considered RTE and do not require additional steps to ensure food safety, consistent with the definition of "ready-to-eat" product as stated in 9 CFR Part 430.1.

FSIS has proposed to adopt HACCP as the organizing structure for its egg products food safety program because HACCP has been proven to be an optimal framework for building science-based process control into food production systems to prevent food safety hazards.

[1] FSIS tests pasteurized egg products for Lm as a measure of environmental cleanliness.

Plants using existing HACCP systems developed before the issuance of this document that do not have the documents from its initial validation on file would need to gather the necessary data. The Compliance Guideline HACCP Systems Validation document contains further guidance for plants that no longer have the in-plant validation data.

"Safe harbors" are considered as recognized procedures that can be employed without any further validation studies; nonetheless, the plant is required to perform Element 2 of the validation process.

- Plants can meet the new requirements by implementing the former regulatory time and temperature provisions in 9 CFR 590.570 and 9 CFR 590.575. FSIS will consider these provisions to be "safe harbors." Plants will not have to gather additional scientific support for their process if they choose to use these safe harbors.

- Plants can also meet the new regulatory requirements by implementing the former regulatory time and temperature provisions for cooling and freezing that the proposed rule will remove from 9 CFR 590.530 and 9 CFR 590.536. Overall, plants can choose to continue using their current manufacturing practices by following these safe harbor examples. Here, however, the plant would need to validate that it is properly applying the FSIS time and temperature combinations provided in the guidance material and conduct monitoring and verification activities in the plant's operating environment.

- Under the new regulations, plants producing RTE egg products that choose to use the former regulations must incorporate these procedures into its HACCP system (i.e., HACCP plan).

- Use of the safe harbor procedures will prevent the outgrowth of pathogens. As under any other procedures in a HACCP plan that is addressing pathogens, plants will also need to continue to monitor those operating parameters and maintain documentation verifying that they are following these procedures.

Introduction

Salmonella spp. are bacterial pathogens that cause diarrhea and fever and may result in *Salmonella*-induced chronic conditions such as aseptic reactive arthritis and Reiter's syndrome (a combination of urethritis, conjunctivitis, and arthritis). The Centers for Disease Control and Prevention (CDC) reported that nontyphoidal *Salmonella* spp. are one of leading causes of foodborne illness, with an estimated 1 million cases of foodborne *Salmonella* infections annually in the U.S. (Scallan et al., 2011). *Salmonella* spp. contamination in RTE products can be due to under-processing by not meeting the time and temperature requirement for specific egg products. Also, contamination occurs in the post-processing environment. In this post-processing environment, contamination can be introduced from contact with product contact surfaces that are contaminated with *Salmonella* spp., improper handling by egg products plant employees, and insect or animal vectors. If plants do not address pathogen reduction in their HACCP systems or do not have a process that is validated to achieve the necessary level of reduction, adulterated products may be released into commerce.

RTE products found positive for *Salmonella* spp. are considered adulterated. FSIS requires plants to hold or control products that it tests for pathogens such as *Salmonella* spp. (see 9 CFR 590.504(d)).

Food Safety Systems and the HACCP Framework

HACCP Requirements

The HACCP requirements will ensure that egg products plants are taking appropriate measures at lethality treatments, cooling, and freezing process steps to reduce food safety hazards at critical points in their processes where the risk of contamination is greatest.

Contamination with *Salmonella* spp. can be a food safety hazard that is reasonably likely to occur (RLTO) in the HACCP system. Federally-inspected egg products plants will be required to conduct a hazard analysis as part of their HACCP system. The hazard analysis is required to include "food safety hazards that can occur before, during, and after entry" into the plant to comply with 9 CFR 417.2(a)." Therefore, as part of its hazard analysis, each egg products plant should consider addressing *Salmonella* spp. in its HACCP system, such as at the lethality treatment, cooling, and freezing process steps. Plants may determine that the Sanitation SOP or a prerequisite program is an appropriate and suitable means to effectively prevent the occurrence of certain food safety hazards so they are not reasonably likely to occur (NRLTO).

Definition

The **HACCP system** is defined as the HACCP plan in operation, including the HACCP plan itself. The HACCP plan in operation includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

- Prerequisites to HACCP are the Sanitation SOPs (9 CFR 416.11-17) and Sanitation Performance Standards (SPS) (9 CFR 416.1-6) regulations.
- These regulatory requirements clearly define each plant's responsibility to consistently follow effective sanitation procedures to minimize the risk of direct product contamination and adulteration.
- Under the proposed rule, each processor would be required to develop and maintain a written Sanitation SOP. The Sanitation SOPs would specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every egg product. As part of the Sanitation SOP, a plant employee would record results of daily sanitation checks at the frequencies stated in the Sanitation SOP.

Under 9 CFR Part 417, when developing a written HACCP plan (9 CFR 417.2(b)), a plant would conduct a hazard analysis to identify and list the biological, chemical, or physical food safety hazards that are reasonably likely to occur in its production process for a particular product and the measures necessary to prevent, eliminate, or reduce the occurrence of those hazards to an acceptable level.

Key Point

FSIS recommends that establishments use the Sanitation Performance Standards Compliance Guide to meet the sanitation performance standards. The guide references methods already proven to be effective in maintaining sanitary conditions in meat and poultry establishments that can also be applied in egg product plants.

The plant would then identify the points in each of its processes at which control is necessary to achieve this goal (9 CFR 417.2(c)(2)).

Written validated HACCP plans may include, but are not limited to, items in the list below in order to meet the regulatory requirements of 9 CFR 417:

Key Point

FSIS recommends that egg product plants use the Compliance Guideline HACCP Systems Validation document to ensure that the HACCP systems are properly validated.

- Identification of hazards reasonably likely to occur in the production process such as *Salmonella* spp.;
- Identification and description of the critical control point (CCP) for each identified hazard such as a lethality treatment, cooling, and freezing in the HACCP plan;
- Specification of the critical limit that must be met at each CCP, and, if appropriate, a target limit such as identifying time and temperature parameters for the lethality treatment, cooling and freezing parameters;
- Description of the monitoring procedure, frequency, and device to be used, such as using a calibrated thermometer to monitor the time and temperature at lethality and cooling process steps;
- Description of the corrective action to be taken if the critical limit has not been met;
- Description of the records that would be generated and maintained regarding this CCP;
- Description of the verification activities (e.g., direct observation, records review, calibration, etc.) and the frequency at which they are to be conducted along with support for these procedures and frequencies); and
- The names, maintained on file, of the HACCP-trained individuals who participate in the hazard analysis and subsequent development of the HACCP plans;

Where practicable, the HACCP records should be reviewed by a plant employee other than the one whom produced the record before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be the reviewer. The reviewer would sign the records. Lastly, HACCP records generated would be retained on site in accordance with 9 CFR 417.5(e)(2.) for at least 1 to 2 years based on the type of product (9 CFR 417.5(e)(1)).

HACCP Plan to Control Hazards

Under HACCP, egg products plants are required to produce product to be edible without additional preparation to achieve food safety by controlling, eliminating, or reducing microbial hazards. In other words, the finished product must be free of detectable pathogens, such as *Salmonella*, and have no

detectable toxins or levels of toxin-producing organisms, such as *Staphylococcus aureus*, that would be a public health concern. In addition, they need to verify that they are addressing the hazards and that their plan is working (9 CFR 417.4(a)). Consistent with the current regulations, the proposed regulations would require microbiological sampling and testing to verify the absence of *Salmonella* spp. in the finished product.

- If the plant controls hazards such as *Salmonella* spp. as part of its HACCP plan, when FSIS or the plant finds that a positive *Salmonella* spp. result may be likely due to a failure in its lethality process, and the plant has addressed lethality as a CCP, then the plant would be required to take corrective actions.

- As part of its corrective actions, the plant would be required to take steps to identify and eliminate the cause of the deviation, according to 9 CFR 417.3(a)(1). Further, the plant would be required to ensure that its CCP is under control (9 CFR 417.3(a)(2)). The plant would not be allowed to produce and ship RTE product until its CCP is under control and it has taken steps to prevent recurrence per 9 CFR 417.3(a)(3). In addition, the plant would be required to initiate measures to ensure that no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce as per 9 CFR 417.3(a)(4).

CCP deviations may possibly occur in spite of the best efforts of a plant to maintain process control. Heating and/or cooling deviations occur when the plant fails to meet its heating (i.e., pasteurization, heat-treatment) CCP critical limit or cooling process schedule. A common cause of heating deviations is under-processing by not meeting the time and temperature combination. Common causes for cooling deviations are inadequate chilling of the egg product, power failures, or breakdown of refrigeration equipment.

When the heating and cooling process steps are addressed through CCPs, as part of corrective actions, plants are required to determine the cause of all critical limit deviations (9 CFR 417.3(a)(1)) and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Recurring deviations constitute unacceptable risks within the HACCP system.

If the cooling is addressed through a prerequisite program, as part of corrective actions, plants are required to reassess to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan (9 CFR 417.3(b)(4)). In addition, the plant may not be able to continue to support its decisions in its hazard analysis that *Salmonella* spp. or toxin-producing organisms are NRLTO if it has continual or repetitive deviations from its cooling prerequisite program (9 CFR 417.5(a)(1)).

If a plant fails to support decisions made in the hazard analysis and shows existing continual or repetitive deviations from the prerequisite programs and/or CCPs, there could be an imminent food safety concern that has an impact on public health. This outcome can lead to FSIS taking an enforcement action according to the Rules of Practice (9 CFR Part 500).

Validation, Verification, Reassessment

9 CFR 417.4(a)(1) requires that establishments conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan **validation period**, the

establishment would be required to repeatedly test the adequacy of the CCP's, critical limits, monitoring, verification, and recordkeeping procedures, and corrective actions set forth in the HACCP plan. **Validation** also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities. See the FSIS Compliance Guideline HACCP Systems Validation for more information.

Scientific Support Available for Lethality Requirements for Egg Products

- There are generally five types of information that can be used to demonstrate compliance with the new regulatory requirements in the proposed rule on Egg Products Inspection Regulations. These are published processing guidelines, challenge studies, peer-reviewed scientific or technical data or information, pathogen modeling programs, and expert advice form processing authorities. Finished product sampling results alone cannot be used to validate lethality procedures because they do not provide information on the incoming pathogen load and, consequently, the level of pathogen reduction achieved is unknown. FSIS recommends that plants use the Compliance Guideline HACCP Systems Validation document to ensure that their HACCP systems are properly validated.

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- The time and temperature combinations for pasteurization provided in the tables listed in the Appendix at the end of this document are estimated to achieve the lethality performance standard for specific egg products based on data and models that are presently available to FSIS.

Challenge Studies

- One of the most definitive validation tools available is the inoculated pack or challenge study of the time and temperature to be used by the plant for pasteurizing egg products. Pathogen challenge studies should be conducted in a testing laboratory and not in the processing plant environment. Further, such studies should be undertaken by individuals who have a thorough knowledge of laboratory methods used in lethality research for *Salmonella* spp. in liquid or dried egg products. Also, data gathered in-house as part of a research project or other study designed to determine the reduction of *Salmonella* spp. that is achieved by the process can be used as support in the challenge study. FSIS recommends that plants use the Compliance Guideline HACCP Systems Validation document to ensure that the HACCP systems are properly validated.
- Challenge studies should contain equivalent levels of detail as peer-reviewed scientific literature and should use methodology equivalent to that used in peer-reviewed research. For more information on conducting challenge studies, please review the article published by the National Advisory Committee on Microbiological Criteria for Foods in the Journal of Food Protection in 2010.

Peer-Reviewed Journal Articles

- Published studies are peer-reviewed studies or research studies on the pasteurization of egg products that can serve as initial validation of the pasteurization time and temperature. Studies using products and processes similar to those of the plant will contain the most relevant information and may be used as validation. The plant should not use studies that do not represent its process and products.

    - Predictive food microbiology uses models (i.e., mathematical equations) to describe the growth, survival, or inactivation of microbes in food systems. Listed below are peer-reviewed studies using various mathematical equations to determine inactivation of heat-resistant *Salmonella* spp. strains:

        - Jordan, S.S., Gurtler, J.B., Marks, H.M., Jones, D.R. and Shaw, W.K. 2011. A mathematical model of inactivation kinetics for a four-strain composite of *Salmonella* Enteritidis and Oranienburg in commercial liquid egg yolk. Food Micro. 28:67-75.

        - Gurtler, J.B., Marks, H.M., Bailey, R.B, Juneja, V. and Jones, D.R. 2013. Kinetics Model Comparison for the inactivation of *Salmonella* Enteritidis and Oranienburg in 10% salted liquid whole egg. Foodborne Pathog Dis. 10:492-499.

        - Gurtler, J.B., Marks, H.M., Jones, D.R, Bailey, R.B, and Bauer, N.E. 2011. Modeling the thermal inactivation kinetics of heat-resistant *Salmonella* Enteritidis and Oranienburg in 10 percent salted liquid egg yolk. J. Food Prot. 74:882-892.

Computer Modeling

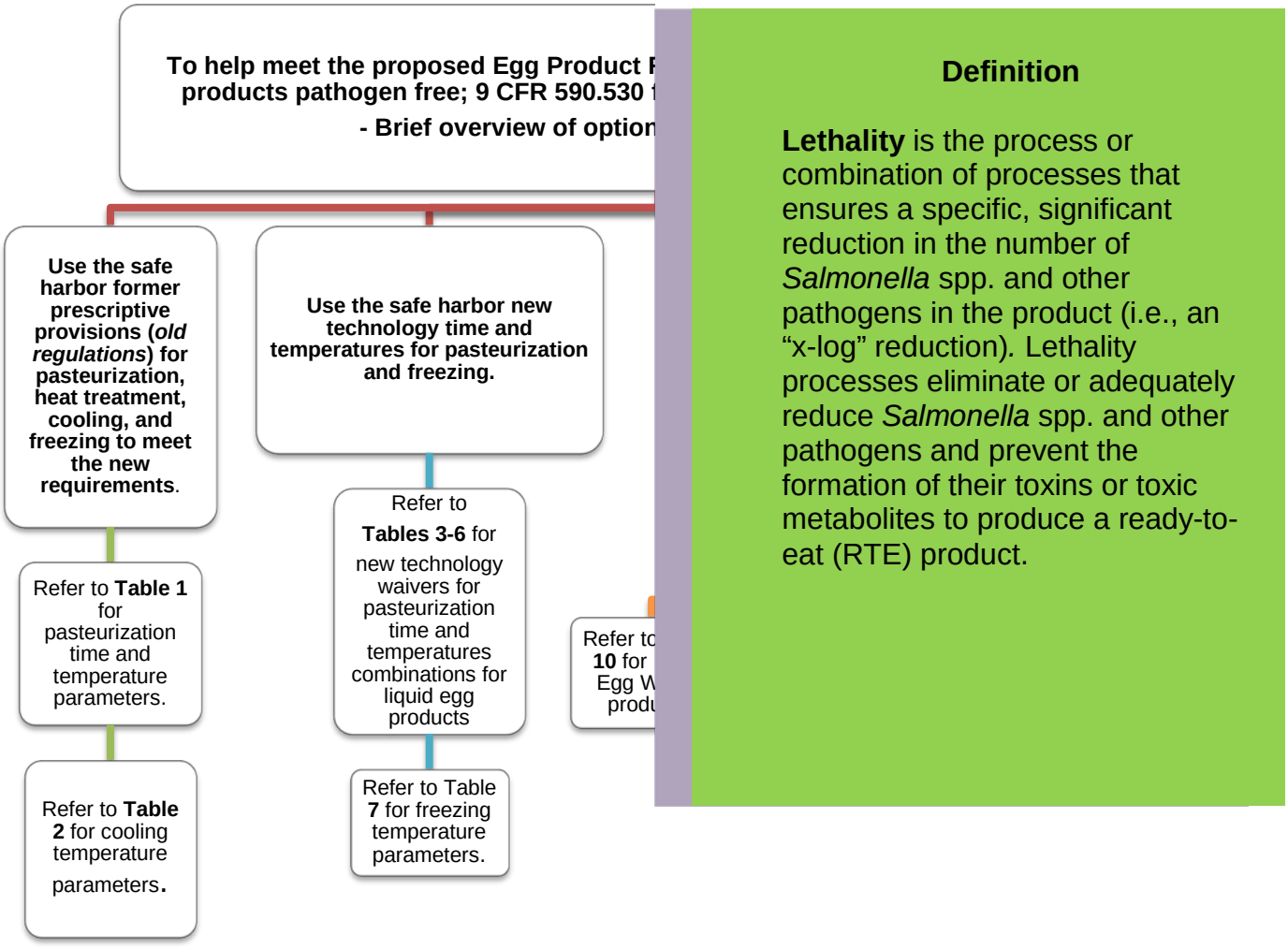
- FSIS is not presently aware of any computerized software lethality models for the inactivation of *Salmonella* spp. in liquid or dried egg products that have been distributed for public use. However, such models might be developed and thus could be used for demonstrating compliance if the model is applicable and validated for the plant's particular product. Individual plants can develop their own computer models using data from the published literature, provided that the assumptions used for developing the models are scientifically sound.

Lethality Requirements for Specific Egg Products

Egg products include whole eggs, egg whites, and egg yolk in frozen, refrigerated liquid and dried forms available in many different formulations. This guidance section provides information on tables of time and temperature combinations for pasteurization, cooling parameters, heat-treatment, and freezing processes. The information provided are recognized as safe harbors, which are considered validated processes.

Figure 1 (below) illustrates the options available to plants to use to comply with the new regulatory requirements in the proposed rule on Egg Products Inspection Regulations.

Figure 1. Overview of Options Available to Meet the New Regulatory Requirements and Where they are Discussed Throughout the Document.



Current Egg Products Regulations for Pasteurization, Heat-Treatment, Cooling, and Freezing

In this section, the current regulations for pasteurization and cooling are shown in Tables 1 and 2, which could be used as a resource to meet new regulatory requirements, should they become final. Additionally, the regulations for heat treatment of dried egg whites and the former regulations for freezing operations are also provided below and would be options to meet the proposed regulatory requirements.

Table 1. Pasteurization Requirements That Could Be Used As Safe Harbor Times and Temperatures

Liquid Egg Products	Minimum Temperature Requirements (°F)	Minimum Holding Time Requirements (Minutes)
Whole egg	140	3.5
Whole egg blends (less than 2 percent added nonegg ingredients)	142 140	3.5 6.2
Fortified whole egg and blends (24–38 percent egg solids, 2–12 percent added nonegg ingredients)	144 142	3.5 6.2
Salt whole egg (with 2 percent or more salt added)	146 144	3.5 6.2
Sugar whole egg (2–12 percent sugar added)	142 140	3.5 6.2
Plain yolk	142 140	3.5 6.2
Sugar yolk (2 percent or more sugar added)	146 144	3.5 6.2

Salt yolk (2–12 percent salt added)	146 144	3.5 6.2

Table 2. Minimum Cooling and Temperature Requirements for Liquid Egg Products That Could Be Used As Safe Harbor Times and Temperatures*

Product	Liquid (other than Salt product) to be held 8 hrs. or less	Liquid (other than Salt product) to be held in excess of 8 hrs.	Liquid Salt Product	Temperature within 2 hrs. after Pasteurization	Temperature within 3 hrs. after Stabilization
Whites (not to be Stabilized)	55°F or lower	45°F or lower	----------	45°F or lower	----------
Whites (to be Stabilized)	70°F or lower	55°F or lower	----------	55°F or lower	**
All Other Product (except product with 10% or more Salt added)	45°F or lower	40°F or lower	----------	If to be held 8 hrs. or less, 45°F or lower ---------- If to be held in excess of 8 hrs, 40°F or lower.	If to be held 8 hrs. or less, 45°F or lower. ---------- -- If to be held in excess of 8 hrs., 40°F or lower
Liquid Egg Product with 10% or more Salt added	----------	----------	If to be held 30 hrs. or less, 65°F or lower ---------- - If to be held in excess of 30 hrs., 45°F or lower	65°F or lower ***	

*** -** Unpasteurized product temperature within 2 hours from time of breaking
**** -** Stabilized liquid whites should be dried as soon as possible after removal of glucose. The storage of stabilized liquid whites should be limited to that necessary to provide a continuous operation
***** -** The cooling process should be continued to assure that any salt product to be held in excess of 24 hrs. is cooled and maintained at 45°F or lower.

Liquid eggs would be considered satisfactorily cooled only when the entire mass reaches the required temperature. The temperature of previously cooled product may rise because of further processing operations such as blending, homogenizing, or reconstituting dried products. The temperature must be reduced again to meet the safe harbors.

Heat Treatment of Egg Whites (590.575)

Heat treatment of dried whites is an approved method for pasteurization and the product should be heated throughout for such times and at such temperatures as will result in *Salmonella* spp.-negative product.

The product to be heat treated should be held in the heat treatment room in closed containers and should be spaced to assure heat penetration and air circulation such that the product reaches the desired time/temperature combination. Each container should be identified as to type of product (spray or pan dried) and with the lot number or production code number.

The minimum times and temperatures for heat treatment of spray or pan dried albumen should be as follows:

1) Spray dried albumen should be heated throughout to a temperature not less than 130°F and held continuously at such temperature not less than 7 days.
2) Pan dried albumen should be heated throughout to a temperature of not less than 125°F and held continuously at such temperature not less than 5 days.

Dried whites which have been heat treated in the dried form should be sampled and analyzed for the presence of *Salmonella* spp*.*

Dried whites processed and tested in accordance with all of the applicable requirements specified in 590.575 may be labeled ‘‘Pasteurized.’’

Freezing Operations (590.536)

Freezing rooms should be kept clean and free from objectionable odors.

1) Nonpasteurized egg products that are to be frozen should be solidly frozen or reduced to a temperature of 10°F or lower within 60 hours from time of breaking.
2) Pasteurized egg products that are to be frozen should be solidly frozen or reduced to a temperature of 10°F or lower within 60 hours from time of pasteurization.

The temperature of products not solidly frozen should be taken at the center of the container.

Containers should be stacked so as to permit circulation of air around the containers and the outside of liquid egg containers should be clean and free from evidence of liquid egg. Frozen egg products should be examined by organoleptic examination after freezing to determine their fitness for human food.

Safe Harbor Time and Temperature Combinations from Historical New Technology Waivers

This guidance section provides information on safe harbor time and temperature combinations derived from successful new technology waivers that achieve the lethality performance standards for specific egg products and freezing parameters, which FSIS also considers to be scientifically validated processes. Time and temperatures combinations for pasteurization of various liquid egg products are in Tables 3, 4, 5, and 6. The freezing parameters are in Table 7. These tables could be used as resources to meet the proposed regulations, should they become final.

Table 3. Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for *Salmonella* spp. Derived from New Technology Waivers That Can Be Used for Various Egg White Products

Liquid Egg White Formulations	Pasteurization Temperature and Time	Egg Solids (%)
Egg Whites 99.31%; Golden Morn Pre-Mix 0.55%; Sodium Hexametaphosphate 0.05%; Defoamer 0.04%; Egg Yolk Flavoring 0.03% ;Vitamin Pre-Mix 0.02%	135°F / 3.5 min	11-13%
Egg Whites 99.36%; Golden Morn Pre-Mix 0.55%; Egg Yolk Flavoring 0.04%; Defoamer 0.04%; Vitamin Pre-Mix 0.02%	135°F / 3.5 min	11-13%
Egg Whites 99.74%; Propylene Glycol 0.15%; Guar Gum 0.08%; Triethyl Citrate 0.03%	134°F / 3.5 min or 126°F / 3.6 min, with hydrogen peroxide	11-13%
Egg Whites 99.74%; Propylene Glycol 0.13%; Triethyl Citrate 0.08%; Xanthan Gum 0.06%	134°F / 3.5 min or 126°F / 3.6 min, with hydrogen peroxide	11-13%
Egg Whites 99.96%; Anti-foam 0.04%	135°F / 3.5 min	11.5-12.5%
Egg Whites 77.41%; Whole Egg 21.90%; Salt 0.30%; Citric Acid 0.15%; Propylene Glycol 0.10%; Xanthan Gum 0.10%; Beta Carotene 0.04%	142°F / 3.5 min	14-16%
Egg Whites 64.41%; Water 16.50%; Whole Egg 16.00%; Non-Fat Dry Milk 2.00%; Maltodextrin 0.50%; Modified Food Starch 0.25%; Xanthan Gum 0.15%; Citric Acid 0.15%; Annatto 0.04%	149°F / 3.5 min	14 -16%
Egg Whites 99.31%; Golden Morn Pre-Mix 0.55%; Sodium Hexametaphosphate 0.05%; Defoamer 0.04%; Egg Yolk Flavoring 0.03% ;Vitamin Pre-Mix 0.02%	135°F / 3.5 min	11-13%
Egg Whites 99.36%; Golden Morn Pre-Mix 0.55%; Egg Yolk Flavoring 0.04%; Defoamer 0.04%; Vitamin Pre-Mix 0.02%	135°F / 3.5 min	11-13%
Egg Whites 99.74%; Propylene Glycol 0.15%; Guar Gum 0.08%; Triethyl Citrate 0.03%	134°F / 3.5 min or 126°F / 3.6 min, with hydrogen peroxide	11-13%
Egg Whites 99.74%; Propylene Glycol 0.13%; Triethyl Citrate 0.08%; Xanthan Gum 0.06%	134°F / 3.5 min or 126°F / 3.6 min, with hydrogen peroxide	11-13%
Egg Whites 99.96%; Anti-foam 0.04%	135°F / 3.5 min	11.5-12.5%

Table 4. Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for *Salmonella* spp. Derived from New Technology Waivers That Can Be Used for Various Whole Egg Products

Liquid Whole Egg Product Formulations	Pasteurization Temperature and Time	Egg Solids (%)
Whole Egg 76.40%; Water 19.00%; Egg Whites 3.78%; Salt 0.35%; Propylene Glycol 0.20%; Xanthan Gum 0.12%; Citric Acid 0.15%	**142°F / 3.5 m**	**18-20%**
Whole Egg 49.03%; Egg Whites 41.01%; Water 7.69%; Whole Milk 1.00%; Maltodextrin 0.50%; Salt 0.30%; Guar Gum 0.18; Citric Acid 0.15%; Xanthan Gum 0.12%; Annatto 0.03%	**142°F / 3.5 min**	**18-20%**
Whole Egg 76.40%; Water 18.91 - 19.00%; Egg Whites 3.78%; Salt 0.35%; Citric Acid 0.15 - 0.24%; Propylene Glycol 0.20%; Xanthan Gum 0.12%	**142°F / 3.5 min**	**19-21%**
Whole Egg 68.23%; Egg Whites 17.36%; Water 12.14%; Whole Milk 1.35%; Maltodextrin 0.50%; Guar Gum 0.17%; Citric Acid 0.15%; Xanthan Gum 0.11%	**142°F / 3.5 min**	**19-22%**
Whole Egg 78.83%; Water 18.00%; Nonfat Dry Milk 2.30%; Salt 0.40%; Propylene Glycol 0.20%; Citric Acid 0.15%; Xanthan Gum 0.12%	**149°F / 3.5 min**	**21-22%**
Whole Egg 78.83%; Water 17.91 - 18.00%; Nonfat Dry Milk 2.30%; Salt 0.40%; Citric Acid 0.15 - 0.24%; Propylene Glycol 0.20%; Xanthan Gum 0.12%	**14°8F / 3.5 min**	**21-22%**
Whole Egg 94.72 - 96.51%; Water 2.63 - 4.63%; Nonfat Dry Milk 0.50%; Citric Acid 0.15 -0.36	**149°F / 3.5 min**	**23-25%**
Whole Egg 66.54%; Sugar 32.66%; Maltodextrin 0.29%; Glycerin 0.29%; Sodium Bicarbonate 0.22%; Sodium Alginate 0.02%	**Start with pasteurized whole egg, after ingredients added, re-pasteurize at 155°F for 4 min**	**24-26%**

Table 5. Safe Harbor Pasteurization Time and Temperature Combinations for Achieving Minimal Lethality Performance for *Salmonella* spp. Derived from New Technology Waivers That Can Be Used for Various Egg Yolk Products

Liquid Egg Yolk Product Formulations	Pasteurization Temperature and Time	Egg Solids (%)
Egg Yolk 95.45%; Salt 2.5%; Maltodextrin 2.0%; Phospholipase 0.05%	**151°F/ 3.5 min**	**45-47%**
Egg Yolk 99.95%; Phospholipase 0.05%	**152°F / 3.5 min**	**45-47%**
Egg Yolk 90.83%; Salt 2.5%; Dried Glucose 2.0%; Phospholipase 0.05%	**149F°/ 3.5 min**	**45-47%**
Egg Yolk 95.5%; Salt 2.5%; Maltodextrin 2.0%	**152°F / 3.5 min**	**45-47%**
Egg Yolk 95.45%; Salt 2.5%; Corn Syrup Solids 2.0%; Phospholipase 0.05%	**152°F / 3.5 min**	**45-47%**
Egg Yolk 95.5%; Salt 2.5%; Corn Syrup Solids 2.0%	**152°F / 3.5 min**	**45-47%**
Egg Yolk 99.67%; Peroxide 0.22%; Glucose Oxidase 0.11%	**142°F/3.5 min for liquid, 157°F / 2 hrs in hot room**	**45-47%**

Table 6. Safe Harbor Time and Temperature Combination for Achieving Minimal Lethality Performance for *Salmonella* spp. Derived from New Technology Waivers That Can Be Used for Enzyme Modified Egg Products

Egg Product	Pasteurization Time and Temperature
Enzyme Modified Egg Products	**Product is held at a minimum temperature of 130°F and not over a maximum of 140°F during batch pasteurization for a minimum of 5 hours**

Table 7. Safe Harbor Time and Temperature Combinations for Freezing Derived From New Technology Waivers That Can Be Used for All Liquid Egg Products

Method	Time and Temperature Requirement
***Freezing**	**Extends the freezing requirement of 60 hours or reduced to a temperature of 10°F from the time of pasteurization to 144 hours for liquid egg products** ***Product shall not be stored in the pasteurized silo in excess of 36 hours**
Freezing	**Extends the freezing requirement of 60 hours from the time of pasteurization to 96 hours for liquid egg products**
Freezing	**Extends the freezing requirement of 96 hours from the time of pasteurization to 144 hours for liquid egg products**
Freezing	**Allows for *non-pasteurized* egg products which are to be frozen to be solidly frozen or reduced to a temperature of 10°F or lower within 144 hours from time of breaking**

Control of Pathogens in Liquid Egg Products

Using data and models that are presently available to FSIS, this guidance section provides information on tables of time and temperature combinations for pasteurization that are estimated to control pathogens in specific egg products such that they are ready-to-eat and do not require additional steps to ensure food safety. The time and temperature tables are located at the end of the document in the Appendix for Pasteurization Time and Temperature Tables. The proposed times and temperatures for *Salmonella* spp. depend on the type of egg product being produced: egg white, whole egg, or egg yolk, regardless of product formulation.

The former times and temperatures listed in 9 CFR 590.570 would be replaced by a new regulation specifying that egg products are ready-to-eat and do not require additional steps to ensure food safety, which is consistent with the definition of "ready-to-eat" product as stated in 9 CFR Part 430.1.

In particular, the proposed 9 CFR 590.570 Control of Pathogens in Egg Products states:

- Egg products must be produced to be edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

- Egg products are not required to bear a safe-handling instruction or other labeling that directs that the product must be cooked or otherwise treated for safety.

Liquid Egg Products

The liquid egg products consist of whites, yolks, whole eggs, and blends of whole eggs and yolks. Tables 9-11 in the Appendix at the end of this document should allow processors to provide times and temperatures for selected processes. Some egg products, such as those containing salt and sugar, may require higher pasteurization times and temperatures. The Appendix includes tables that provide different combinations of temperatures and times for 12 different liquid egg products, including: plain egg white at four different pH values (7.8, 8.2, 8.8, and 9.3); plain whole egg and plain egg yolk; 10% added sugar or 10% added salt to liquid plain whole egg or to liquid plain egg yolk; and five formulated liquid egg products. Plants can select which option is necessary to use.

Liquid Egg Whites

Pasteurization can adversely affect the functional properties of egg products depending on the time and temperature used. Egg white proteins are particularly susceptible to heat damage, therefore requiring lower heating temperatures (International Egg Pasteurization Manual). For egg whites, the effectiveness of eliminating *Salmonella* spp. at specific times and temperatures are improved at higher pH values, such as plain egg white at four different pH values (7.8, 8.2, 8.8, and 9.3), thereby reducing the heat-resistance of *Salmonella* spp. Metal ions can be added to restore foaming properties of egg whites after pasteurization. During pasteurization, chemical reagents are commonly added to stabilize the conalbumin, which forms a heat stable complex with metal ions. Moreover, hydrogen peroxide, which is a recognized bactericidal agent, can also be added to liquid egg whites to reduce microbial contamination. It allows for the pasteurization of egg whites at relatively low

temperatures (Eskin and Shahidi, 2012). The Appendix includes Tables 9-11, which provide different combinations of times and temperatures. Plants can select which time and temperature combination is suitable for their egg processing operation. For example, from the Appendix in Table 10, for Plain Egg White, a pH of 7.8 is needed (at a pasteurization temperature of 140ºF and dwell time (i.e., holding time) of 21 seconds) to obtain the proposed minimal lethality to ensure pathogens are non-detectable.

Liquid Whole Eggs

Whole eggs often consist of blended non-egg ingredients. Examples include salt, sugar, or corn syrup, which are added to whole eggs to prevent egg yolk gelation during freezing or impart functional properties to the liquid whole egg product. Whole eggs that do not contain blended ingredients may be pasteurized at times and temperatures lower than egg yolks. To use the time and temperature combinations for liquid whole egg products, the plant should select Table 11 in the Appendix. For example, for 10% Salt Whole Egg, at a pasteurization temperature of 150ºF, a holding time of 78 seconds is needed to obtain the proposed lethality to ensure adequate pasteurization and that pathogens are non-detectable.

Liquid Egg Yolks

Salmonella spp. may acquire greater heat-resistance more readily in egg yolk than in egg whites, but yolk functional properties are less sensitive to higher temperatures. Freezing liquid egg yolk can result in gelation of the yolk that is reduced by adding sugar, salt, glycerol, or other similar materials at levels from 10% to 15% (Carter, 1968). Salted egg yolk has a high viscosity after storage; this may play a role in the increased heat resistance using salted yolk (International Egg Pasteurization Manual). *Salmonella* spp. have been shown to be most heat resistant at near neutral pH; therefore, *Salmonella* spp. may be more viable in egg yolks (pH 6.0) than in egg whites (pH 9.1). Hence, the thermal treatment/condition for egg yolk is more severe than egg whites (Eskin and Shahidi, 2012). To use the time and temperature combinations for egg yolk products, plants should select Table 12 in the Appendix. For example, select 10% Sugar Egg Yolk, at a pasteurization temperature of 155ºF. To obtain the proposed lethality to ensure pathogens are non-detectable, a 17-second dwell time is needed to ensure sufficient pasteurization.

Alternatively, plants may choose not to use the Time-Temperature Combinations for Achieving Minimal Lethality Performance for Liquid Egg Products Tables provided at the end of this compliance guideline, and implement a customized process that is designed to achieve the same probabilities of viable *Salmonella* spp. in 100 mL of egg product to ensure adequate pasteurization.

Dried Egg Products

The proposed lethality standards also apply to dried egg products. Dried or dehydrated egg products are known as egg solids and typically are spray dried to remove most of the moisture. Dried product that is not subjected to a pasteurization treatment in a liquid state must be subjected to a thermal treatment in the dried state that will impart a lethality not less than those proposed for the appropriate type of product (Table 9). FSIS is aware that such treatments are performed for certain types of dried egg white products. This section discusses the processing of dried egg white products.

Lethality models for *Salmonella* were constructed based on a Weibull inactivation curve using the measured levels reported in the Jung and Beuchat (1999) paper for *Salmonella* and data sent to FSIS from the Agricultural Research Service. For *Salmonella*, it was estimated that, for a 5% moisture product, more than 21 days at 54°C/129.2°F would be needed to achieve lethality of 5.7 $\log_{10}$; for an 8% moisture product, more than 12 days would be needed. Other models predicted that even more days would be required to achieve a lethality of 5.7 $\log_{10}$. Table 8 provides estimates of the minimum number of days at 54°C/129.2°F that would be required to obtain at least a lethality of 5.7 $\log_{10}$.

The percent moisture referred to in Table 8 refers to the moisture content at the initial state, at the commencement of pasteurization. For example, a plant places one lot of dried egg whites into the hot room, with the initial percent moisture ranging from 6% to 8%. The dried egg whites would have to be held for the number of days associated with the lowest initial percent moisture level (6%) to meet the minimum lethality of 5.7 $\log_{10}$; the lot would have to be held for a minimum of 18 days.

Table 8. Estimated minimum number of days at 54°C/129.2°F needed to obtain at least a lethality of 5.7 $\log_{10}$ for *Salmonella* spp. in dried egg white product, as a function of the percent moisture of product before pasteurization.

Percent (%) Moisture	4	5	6	7	8
Minimal days	26	22	18	15	13

Likewise, as with liquid egg products, information from challenge studies, published studies, and computer modeling can be used to demonstrate that a process complies with the lethality performance requirements. Plants can also develop alternative lethality protocols for dried egg products based on yield-equivalent-weight (grams) sample which is the specific dried product yield to the liquid product. For example, if 100 mL of liquid egg white product produced approximately 13 grams of dried product, the alternative lethality value would be determined with respect to the 13 grams of dried product rather than 100 mL of liquid product. The procedures given in this section also apply for establishing alternative lethality parameters for dried egg products.

Microbiological Sampling and Testing Program

The proposed 9 CFR 590.580 Pathogen Reduction Standards Testing regulation requires that:

- Official plants must test to determine that the production of egg products is in compliance with the Egg Products Inspection Act and the egg products inspection regulations.

- To ensure adequate pasteurization:
  - Pasteurized liquid, frozen, and dried egg products, and heat treated dried egg whites must be sampled and analyzed for the presence of *Salmonella* spp.
  - As a “safe harbor,” the frequency of sampling and testing can be supported by skip lot testing, which is presented at the end of this document in the Appendix for Safe Harbor

Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products. However, dried egg product requires 100% sampling.

- Such testing must be performed in a manner sufficient such that it is possible for the official plant to verify that the system is capable of eliminating *Salmonella* spp. at the time that the annual reassessment occurs, and as regularly as necessary between annual reassessments, to show that the system, when tested, is working.
- Samples must be analyzed for the presence of *Salmonella* spp. with such frequency, and using such laboratory methods as is sufficient to ensure that product is not adulterated.
- Samples must be drawn from the final packaged form.
- To meet the regulatory requirements, the plant must develop and implement a written microbiological sampling and testing program.
- Egg products plants are required to maintain control of egg products that have been sampled and tested for public health hazards, e.g*., Salmonella* spp., until the test results become available to comply with the proposed 9 CFR 590.504 regulation.

Written Microbiological Sampling Program

The following elements should be included in the written sampling program:

- A description of the sample collection procedures, including how random sampling is achieved, how the sample is collected, and how samples are handled to ensure sample integrity, and the name or title of the plant employees designated to collect the samples for testing.

- Information on the analytical method used to analyze the samples and identify the laboratory performing the analysis. The method used should be validated by a recognized independent testing body. Further information can be found in the Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory

- The microbiological organisms (i.e., *Salmonella* spp.) that it will test for to monitor the effectiveness of its process control.

- The locations within the process where samples are collected.

- The frequency of sample collection.

Microbiological Testing Method

The egg products plant should ensure that microbiological testing meets its food safety needs. A plant needs to determine whether sample analysis will be performed by an outside laboratory or in its own microbiological testing laboratory onsite (if available). The test method used should be validated for the target organisms and for the sample matrix being analyzed to ensure accuracy of the results. It should also be a method validated by a recognized independent body, such as the Association of Official Analytical Chemists (AOAC).

Because of the costs and the logistics involved with maintaining an onsite microbiological testing laboratory, plants may choose to have samples analyzed by an outside laboratory. FSIS has made available the compliance guideline, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document should be particularly useful to very small plants when they are selecting a commercial or private laboratory to analyze plant microbiological samples. Plants should clearly communicate their needs to the testing laboratory and direct them to any necessary testing protocols or other guidance, including this document, on the FSIS Web site.

Key Point

FSIS has also made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations or the detection of relevant foodborne pathogens (i.e., *Salmonella* spp.).

Plants that select a laboratory that does not apply appropriate testing methods or effective Quality Control/Quality Assurance (QC/QA) practices may not receive reliable or useful testing results. FSIS has also made available a list of Foodborne Pathogen Test Kits Validated by Independent Organizations for the detection of relevant foodborne pathogens (i.e., *Salmonella* spp.*, Campylobacter, E. coli* O157:H7, and *Listeria* spp., including *L. monocytogenes*). These lists are intended to be informational and are not an endorsement or approval of any particular method, regardless of its inclusion in the list.

To prevent cross contamination, FSIS recommends that a microbiological testing laboratory be segregated from manufacturing areas and that access to the laboratory space be limited. If the plant will be performing testing for pathogens onsite, then they should have the following additional safeguards in place to ensure food safety and security:

- Follow requirements for Biosafety Level II laboratory operation as outlined in Biosafety in Microbiological and Biomedical Laboratories (BMBL)

- Restrict access to the laboratory to trained staff and ensure that the laboratory is operating under the supervision of a qualified microbiologist or equivalent.

Recordkeeping

Upon implementation of the sampling program, the plant must maintain records sufficient to document the implementation and monitoring of sample collection to comply with the proposed 9 CFR 590.580. It is recommended that records include the testing procedures, including support for the adequacy of the testing frequency, and the test results and information such as the:

- Time, date, and location of the sample collection.
- Sample collector's name.
- Name or description of the product or sample source.
- Lot information and producer.

All entries should be dated and initialed by the sample collector immediately upon completion of the entry. If an outside laboratory is used for testing, then these records should also include information

such as date the sample was shipped to the laboratory for analysis. The outside laboratory should document the:

- Date received;
- Condition of the sample upon receipt, including sample temperature, if applicable;
- Date the analysis was started and completed; and the
- Analytical result.

Test results should also be recorded and linked to the sample collection records by a sample number, form number, or some other unique identifier.

Records:

1) Should be maintained in a way that ensures the integrity of the data;
2) May be maintained in an electronic format, provided there are measures in place to ensure the security of the information; and
3) Should be readily accessible for review by the plant and FSIS inspection program personnel upon request.

Actions in Response to Test Results

- If FSIS collects a sample of a RTE product and the product tests positive for *Salmonella* spp. or Lm, FSIS considers the lot adulterated. The plant is required to take corrective actions according to 9 CFR 417.3(a) or (b), depending on whether the plant controls *Salmonella* spp. or Lm through its HACCP plan or prevents it through a prerequisite program.

- If product is positive for *Salmonella* spp. or Lm and the plant does not want to condemn the product, it can be reprocessed with the assurance that the egg product is free of detectable pathogens.

New Technologies

- If the plant chooses to develop and implement applications that incorporate such substances ingredients that are not recognized as safe and suitable under the conditions of its intended use, such as those listed in FSIS Directive 7120.1, "Safe and Suitable Ingredients in Meat, Poultry, and Egg Products" and those that are listed in 9 CFR 424.21(c), then it is subject to new technology notification process.

- Plants can submit a new technology notification and protocol to FSIS.

Key Point

FSIS recommends that plants use the FSIS Compliance Guideline Procedures for New Technology Notifications and Protocol document, which provides guidance concerning the procedures for preparing and submitting a new technology notification and protocol to FSIS.

- In the request, plants should provide data to justify the new technology request.

References

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Appendix for Safe Harbor Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products

Safe Harbor Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products

Sampling for each product category will begin at the 100 percent frequency level unless or until a history of compliance has been established (60 consecutive lots are *Salmonella* spp. negative). For each category, one type of product will be identified for sampling each day on a rotation basis. (Each product within a category does not need to be sampled every day).

No history of compliance for a category – every lot must be sampled until 60 consecutive lots are found to be *Salmonella* spp. negative.

Level 1 – 1 lot sampled for every 2 lots produced.

Level 2 – 1 lot sampled for every 4 lots produced.

Level 3 – 1 lot sampled for every 8 lots produced.

Reducing the Sampling Frequency – At Plant's Option

1. To reduce the sampling frequency from 100 percent to Level 1, 60 consecutive lots within a product category must be *Salmonella* spp. negative.
2. To reduce the sampling frequency from Level 1 to Level 2, 60 sampled lots within the product category must be *Salmonella* spp. negative.
3. To reduce the sampling frequency from Level 2 to Level 3, 60 sampled lots within the product category must be *Salmonella* spp. negative.

NOTE: Plants currently sampling under one of the three reduced sampling levels may maintain that level until sampling results indicate that an increase in sampling frequency is required or that the sampling frequency may be reduced.

Action Required for *Salmonella* spp. Positive Lots

1. If a *Salmonella* spp. positive[2] lot is found at any of the 3 reduced sampling levels, the plant must immediately begin sampling the entire product category at 100 percent.
2. Once 60 consecutive lots of that product are *Salmonella* spp. negative, sampling frequency may resume at the level attained before the positive was found. However, if the product initially identified as *Salmonella* spp. positive is not sampled during those 60 consecutive lots, the next lot produced of that product must be sampled.
3. If 2 lots within the same category are found to be *Salmonella* spp. positive within a 12-month period, the plant must return to the 100 percent sampling level for that category. Once 60 consecutive lots are *Salmonella* spp. free, the plant must then satisfy the requirements for both Level 1 and Level 2 before moving to Level 3.

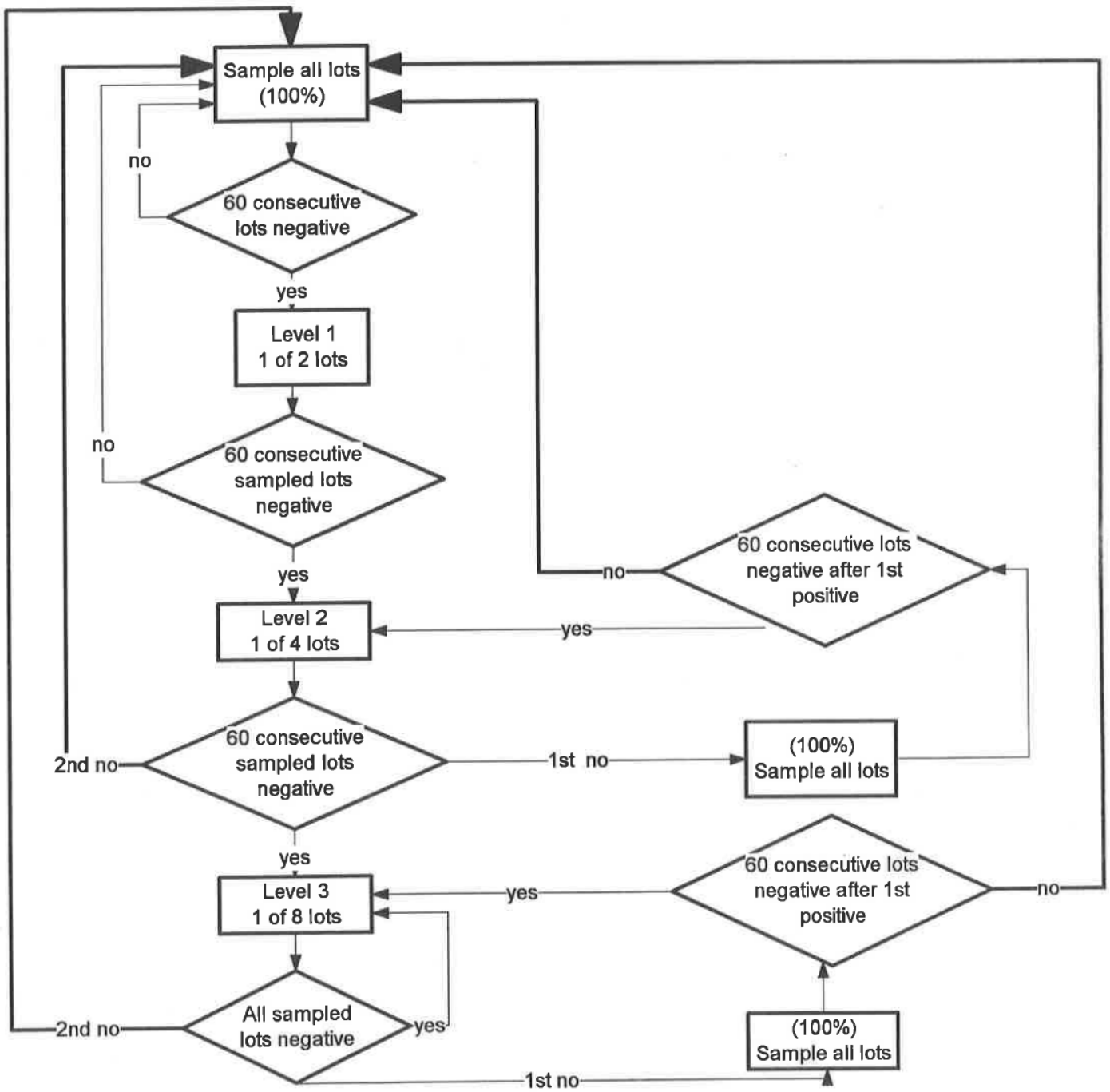
[2] See the section titled Microbiological Testing Method for a discussion about the expectations of method choices.

Required Records

The egg products inspection regulations require that the plant maintain records for each lot of product production. Records must be maintained for 2 years and must be available to a program employee upon request. Records must contain the following information:

1. Type of product, category, and lot number of each lot product.
2. Number, net weight, and type of containers in each lot, e.g., 125 30-lb can; 250 30 pound cases (6 5-pound cartons).
3. For each lot sampled, the lot number, date sampled, number of samples taken, portion of the lot from which the sample(s) was taken, i.e., container number, pallet number, etc., and the sampling level for that category of product.
4. Individual sample results.
5. Name and location of the recognized laboratory performing analyses.

Figure 2. Egg Products Sampling Flow Diagram



***Notes:** Plants without a sampling history or plants producing products in a new product category must begin sampling at the 100% level.

Plants currently under one of the three reduced sampling levels may maintain that level until sampling results indicate that an increase in sampling frequency is required, or that the sampling frequency may be reduced.

Appendix for Pasteurization Time and Temperature Tables

Table 9. Time-Temperature Combination Table for Achieving Minimal Lethality Performance for Various Liquid Egg Whites Products Needed to Obtain 5.7-log Lethality for *Salmonella* spp.

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Plain Egg White, pH=7.8	Plain Egg White, pH=8.2	Plain Egg White, pH=8.8	Plain Egg White, pH=9.3
127.5	**53.1**	---	---	---	36.45 min
128.0	**53.3**	---	---	---	31.26 min
128.5	**53.6**	---	---	---	26.81 min
129.0	**53.9**	---	---	---	23.00 min
129.5	**54.2**	---	---	---	19.72 min
130.0	**54.4**	---	---	38.32 min	16.92 min
130.5	**54.7**	---	---	33.27 min	14.91 min
131.0	**55.0**	---	36.70 min	28.72 min	12.45 min
131.5	**55.3**	---	31.07 min	24.62 min	10.68 min
132.0	**55.6**	32.16 min	26.12 min	20.95 min	9.16 min
132.5	**55.8**	27.02 min	21.80 min	17.69 min	7.85 min
133.0	**56.1**	22.56 min	18.08 min	14.82 min	6.74 min
133.5	**56.4**	18.71 min	14.88 min	12.33 min	5.78 min
134.0	**56.7**	15.43 min	12.18 min	10.19 min	4.96 min
134.5	**56.9**	12.64 min	9.90 min	8.36 min	4.25 min
135.0	**57.2**	10.30 min	8.00 min	6.81 min	3.65 min
135.5	**57.5**	7.11 min	6.42 min	5.52 min	3.13 min
136.0	**57.8**	5.65 min	5.13 min	4.44 min	2.68 min
136.5	**58.1**	4.47 min	4.08 min	3.56 min	2.30 min
137.0	**58.3**	3.51 min	3.22 min	2.83 min	1.98 min
137.5	**58.6**	2.75 min	2.54 min	2.24 min	1.69 min
138.0	**58.9**	2.15 min	1.99 min	1.77 min	87 sec
138.5	**59.2**	1.67 min	93 sec	84 sec	75 sec
139.0	**59.4**	78 sec	72 sec	65 sec	65 sec
139.5	**59.7**	60 sec	56 sec	51 sec	56 sec
140.0	**60.0**	47 sec	44 sec	39 sec	48 sec
140.5	**60.3**	36 sec	33 sec	31 sec	41 sec
141.0	**60.6**	27 sec	26 sec	24 sec	35 sec
141.5	**60.8**	21 sec	20 sec	18 sec	30 sec
142.0	**61.1**	---	---	---	26 sec
142.5	**61.4**	---	---	---	23 sec
143.0	**61.7**	---	---	---	19 sec
143.5	**61.9**	---	---	---	17 sec
144.0	**62.2**	---	---	---	14 sec
144.5	**62.5**	---	---	---	---
145.0	**62.8**	---	---	---	---
145.5	**63.1**	---	---	---	---

---: No applicable time and temperature combination to meet desired lethality performance standard for liquid egg white products

Table 10. Time-Temperature Combination Table for Achieving Minimal Lethality Performance for Various Liquid Whole Egg Products Needed to Obtain 6.0-log Lethality for *Salmonella* spp.

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Plain Whole Egg	Scrambled Egg Mix USDA (30.27% Solids)*	Scrambled Egg Mix USDA (22.43% Solids)**	Comments
133.0	**56.1**	---	---	29.42 min	
133.5	**56.4**	---	---	25.04 min	
134.0	**56.7**	---	13.91 min	21.32 min	
134.5	**56.9**	---	12.45 min	18.15 min	
135.0	**57.2**	28.82 min	11.15 min	15.47 min	
135.5	**57.5**	25.22 min	10.00 min	13.18 min	
136.0	**57.8**	22.07 min	8.97 min	11.23 min	
136.5	**58.1**	19.32 min	8.05 min	9.58 min	
137.0	**58.3**	16.91 min	7.23 min	8.17 min	
137.5	**58.6**	14.80 min	6.50 min	6.98 min	
138.0	**58.9**	12.95 min	5.84 min	5.96 min	
138.5	**59.2**	11.34 min	5.26 min	5.09 min	
139.0	**59.4**	9.92 min	4.73 min	4.35 min	
139.5	**59.7**	8.69 min	4.26 min	3.72 min	
140.0	**60.0**	7.60 min	3.84 min	3.18 min	
140.5	**60.3**	6.65 min	3.46 min	2.73 min	
141.0	**60.6**	5.82 min	3.12 min	2.34 min	
141.5	**60.8**	5.10 min	2.82 min	2.00 min	
142.0	**61.1**	4.46 min	2.55 min	1.72 min	
142.5	**61.4**	3.90 min	2.30 min	89 sec	
143.0	**61.7**	3.42 min	2.08 min	77 sec	
143.5	**61.9**	2.99 min	1.88 min	66 sec	
144.0	**62.2**	2.62 min	1.70 min	57 sec	
144.5	**62.5**	2.29 min	93 sec	49 sec	
145.0	**62.8**	2.01 min	84 sec	42 sec	
145.5	**63.1**	1.76 min	76 sec	36 sec	
146.0	**63.3**	93 sec	69 sec	32 sec	
146.5	**63.6**	81 sec	62 sec	27 sec	
147.0	**63.9**	71 sec	57 sec	24 sec	
147.5	**64.2**	62 sec	51 sec	21 sec	
148.0	**64.4**	54 sec	47 sec	18 sec	
148.5	**64.7**	48 sec	42 sec	16 sec	
149.0	**65.0**	42 sec	38 sec	---	
149.5	**65.3**	36 sec	35 sec	---	
150.0	**65.6**	32 sec	32 sec	---	
150.5	**65.8**	28 sec	29 sec	---	
151.0	**66.1**	25 sec	26 sec	---	
151.5	**66.4**	21 sec	24 sec	---	
152.0	**66.7**	19 sec	22 sec	---	
152.5	**66.9**	17 sec	20 sec	---	
153.0	**67.2**	---	18 sec	---	

***: Scrambled Egg Mix USDA (30.27% Solids) Ingredients:** Whole egg – 24.2% solids; nonfat dry milk – 95% solid; vegetable oil, salt, and water

****: Scrambled Egg Mix USDA (22.43% Solids) / Scrambled egg mix, pH 6.5 to 6.8 Ingredients:** Whole egg – 24.2% solids; nonfat dry milk – 95% solid; xanthan gum, citric acid, and water

---: No applicable time and temperature combination to meet desired lethality performance for whole egg products

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	10% Salt Whole Egg	10% Sugar Whole Egg
136.0	**57.8**	---	26.43 min
136.5	**58.1**	---	21.13 min
137.0	**58.3**	---	16.99 min
137.5	**58.6**	---	13.74 min
138.0	**58.9**	---	11.18 min
138.5	**59.2**	---	9.15 min
139.0	**59.4**	---	7.53 min
139.5	**59.7**	---	6.23 min
140.0	**60.0**	---	5.18 min
140.5	**60.3**	---	4.33 min
141.0	**60.6**	25.67 min	3.64 min
141.5	**60.8**	19.06 min	3.07 min
142.0	**61.1**	14.64 min	2.60 min
142.5	**61.4**	11.56 min	2.22 min
143.0	**61.7**	9.34 min	1.90 min
143.5	**61.9**	7.69 min	1.63 min
144.0	**62.2**	6.43 min	85 sec
144.5	**62.5**	5.44 min	74 sec
145.0	**62.8**	4.65 min	65 sec
145.5	**63.1**	4.01 min	56 sec
146.0	**63.3**	3.49 min	50 sec
146.5	**63.6**	3.05 min	44 sec
147.0	**63.9**	2.67 min	39 sec
147.5	**64.2**	2.36 min	35 sec
148.0	**64.4**	2.08 min	30 sec
148.5	**64.7**	1.84 min	27 sec
149.0	**65.0**	1.63 min	24 sec
149.5	**65.3**	87 sec	22 sec
150.0	**65.6**	78 sec	20 sec
150.5	**65.8**	69 sec	18 sec
151.0	**66.1**	62 sec	17 sec
151.5	**66.4**	55 sec	---
152.0	**66.7**	49 sec	---
152.5	**66.9**	44 sec	---
153.0	**67.2**	39 sec	---
153.5	**67.5**	35 sec	---
154.0	**67.8**	31 sec	---
154.5	**68.1**	27 sec	---
155.0	**68.3**	24 sec	---
155.5	**68.6**	22 sec	---
156.0	**68.9**	20 sec	---
156.5	**69.2**	18 sec	---
157.0	**69.4**	16 sec	---
157.5	**69.7**	15 sec	---

						158.0	**70.0**	13 sec	---

Table 11. Time-Temperature Combination Tables for Achieving Minimal Lethality Performance for Various Liquid Egg Yolk Products Needed to Obtain 6.2-log Lethality for *Salmonella* spp**.**

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Plain Egg Yolk	10% Salt Egg Yolk	10% Sugar Egg Yolk
138.0	**58.9**	---	---	22.77 min
138.5	**59.2**	---	---	18.57 min
139.0	**59.4**	17.81 min	---	15.24 min
139.5	**59.7**	16.31 min	---	12.57 min
140.0	**60.0**	14.93 min	20.62 min	10.43 min
140.5	**60.3**	13.66 min	17.87 min	8.70 min
141.0	**60.6**	12.51 min	15.53 min	7.29 min
141.5	**60.8**	11.45 min	13.53 min	6.14 min
142.0	**61.1**	10.48 min	11.81 min	5.20 min
142.5	**61.4**	9.60 min	10.34 min	4.41 min
143.0	**61.7**	8.78 min	9.07 min	3.77 min
143.5	**61.9**	8.04 min	7.97 min	3.23 min
144.0	**62.2**	7.36 min	7.02 min	2.78 min
144.5	**62.5**	6.74 min	6.19 min	2.40 min
145.0	**62.8**	6.17 min	5.47 min	2.08 min
145.5	**63.1**	5.65 min	4.84 min	1.81 min
146.0	**63.3**	5.17 min	4.29 min	95 sec
146.5	**63.6**	4.73 min	3.81 min	83 sec
147.0	**63.9**	4.33 min	3.39 min	74 sec
147.5	**64.2**	3.96 min	3.01 min	65 sec
148.0	**64.4**	3.63 min	2.69 min	57 sec
148.5	**64.7**	3.32 min	2.40 min	51 sec
149.0	**65.0**	3.04 min	2.14 min	46 sec
149.5	**65.3**	2.78 min	1.91 min	41 sec
150.0	**65.6**	2.55 min	1.71 min	37 sec
150.5	**65.8**	2.33 min	93 sec	33 sec
151.0	**66.1**	2.14 min	83 sec	30 sec
151.5	**66.4**	1.95 min	75 sec	28 sec
152.0	**66.7**	1.79 min	67 sec	26 sec
152.5	**66.9**	1.64 min	60 sec	24 sec
153.0	**67.2**	90 sec	54 sec	22 sec
153.5	**67.5**	83 sec	49 sec	21 sec
154.0	**67.8**	76 sec	44 sec	19 sec
154.5	**68.1**	69 sec	40 sec	18 sec
155.0	**68.3**	63 sec	36 sec	17 sec
155.5	**68.6**	58 sec	33 sec	16 sec
156.0	**68.9**	53 sec	29 sec	16 sec
156.5	**69.2**	49 sec	27 sec	---
157.0	**69.4**	45 sec	24 sec	---
157.5	**69.7**	41 sec	22 sec	---
158.0	**70.0**	38 sec	20 sec	---
158.5	**70.3**	35 sec	18 sec	---
159.0	**70.6**	32 sec	17 sec	---
159.5	**70.8**	29 sec	15 sec	---
160.0	**71.1**	27 sec	14 sec	---

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Fortified Egg Yolk "Tex" (48.84% Solids)*	Fortified Egg Yolk "Tex" (32.49% Solids)**	Comments
132.5	**55.8**	---	25.56 min	
133.0	**56.1**	---	22.74 min	
133.5	**56.4**	---	20.07 min	
134.0	**56.7**	---	17.71 min	
134.5	**56.9**	---	15.63 min	
135.0	**57.2**	---	13.79 min	
135.5	**57.5**	---	12.17 min	
136.0	**57.8**	---	10.74 min	
136.5	**58.1**	---	9.48 min	
137.0	**58.3**	---	8.37 min	
137.5	**58.6**	---	7.39 min	
138.0	**58.9**	---	6.53 min	
138.5	**59.2**	---	5.76 min	
139.0	**59.4**	---	5.09 min	
139.5	**59.7**	---	4.49 min	
140.0	**60.0**	23.66 min	3.97 min	
140.5	**60.3**	20.48 min	3.51 min	
141.0	**60.6**	17.73 min	3.10 min	
141.5	**60.8**	15.35 min	2.73 min	
142.0	**61.1**	13.28 min	2.42 min	
142.5	**61.4**	11.50 min	2.13 min	
143.0	**61.7**	9.95 min	1.89 min	
143.5	**61.9**	8.61 min	1.67 min	
144.0	**62.2**	7.46 min	89 sec	
144.5	**62.5**	6.45 min	78 sec	
145.0	**62.8**	5.59 min	69 sec	
145.5	**63.1**	4.84 min	62 sec	
146.0	**63.3**	4.19 min	54 sec	
146.5	**63.6**	3.62 min	48 sec	
147.0	**63.9**	3.14 min	42 sec	
147.5	**64.2**	2.71 min	38 sec	
148.0	**64.4**	2.35 min	33 sec	
148.5	**64.7**	2.03 min	30 sec	
149.0	**65.0**	1.76 min	26 sec	
149.5	**65.3**	92 sec	23 sec	
150.0	**65.6**	80 sec	21 sec	
150.5	**65.8**	69 sec	18 sec	
151.0	**66.1**	60 sec	16 sec	
151.5	**66.4**	52 sec	---	
152.0	**66.7**	45 sec	---	
152.5	**66.9**	39 sec	---	
153.0	**67.2**	33 sec	---	
153.5	**67.5**	29 sec	---	
154.0	**67.8**	26 sec	---	
154.5	**68.1**	22 sec	---	

*** Fortified Egg Yolk "Tex" (48.84% Solids) Ingredients:** Egg yolk – 43% solid; 80% solid corn syrup, salt, and water

** **Fortified Egg Yolk "Tex" (32.49% Solids) Ingredients:** Whole egg – 24.2% solids; egg yolk – 43% solid; 36 DE corn syrup solids, salt, and water

---: No existing time and temperature combination to meet desired lethality performance standard for egg yolk products

160.5	**71.4**	24 sec	---	---

155.0	**68.3**	19 sec	---	
155.5	**68.6**	17 sec	---	
156.0	**68.9**	14 sec	---	

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