FSIS Food Safety Guideline for Egg Products

September 9, 2020

This guideline is designed to help small and very small plants producing egg products meet the new regulatory requirements under the Egg Products Inspection Regulations Final Rule. This guideline covers:

- Regulatory requirements associated with the safe production of egg products;
- Hazard Analysis and Critical Control Point (HACCP) requirements;
- Options to achieve lethality and/or safe cooling and freezing; and
- Recommendations for meeting the sampling and testing requirements for detection and identification of *Salmonella* spp. in egg products.

FSIS Food Safety Guideline for Egg Products

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Preface

This is a revised version of the *FSIS Guideline for Small and Very Small Plants that Produce Ready-to-Eat (RTE) Egg Products.* It has been updated in response to comments received on the previous version and renamed. In addition, the guideline now includes updates for hazards related to *Listeria monocytogenes (Lm)* and residues, updates concerning amendments to the regulations, former regulatory parameters for defrosting, and changes to improve its readability.

This guideline represents FSIS's current thinking on these topics and should be considered usable when applicable provisions in the egg products rule becomes effective.

The information in this guideline is provided to assist egg products plants in meeting the regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations. Under the regulations, plants may choose to implement different procedures than those outlined in this guideline, but they would need to validate and support how 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 businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act (SBREFA). However, all egg products plants may 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 information, focusing the guideline on the needs of small and very small plants provides them with assistance that may be otherwise unavailable to them.

Under the final rule, (*Egg Products Inspection Regulations*) egg products plants will be required to meet HACCP and sanitation requirements consistent with meat and poultry product regulations. This rule removes the prescriptive time and temperature parameters for egg products pasteurization, heat treatment, freezing, and cooling procedures. Instead, FSIS requires that plants support and validate procedures for lethality treatments, cooling, and freezing in its HACCP system and develop written Sanitation Standard Operating Procedures (Sanitation SOPs).

In addition, egg products are required to be edible without additional preparation to achieve food safety and are, therefore, considered ready-to-eat (RTE).

Purpose of this Guideline

This guideline contains information to assist plants producing egg products that undergo pasteurization, heat treatment, cooling, and freezing in complying with the new regulatory requirements in the final rule.

Under 9 Code of Federal Regulations (CFR) 591.1(a), all egg products plants have to comply with the requirements contained in 9 CFR 416, *Sanitation* (one year after the final rule issues), 9 CFR 417,

Hazards Analysis and Critical Control Point Systems (HACCP) (two years after the final rule issues), and 9 CFR 500, *Rules of Practice* (60 days after the final rule issues). This guideline includes information on:

- Regulatory requirements associated with the safe production of egg products;
- HACCP requirements;
- Options to achieve lethality and/or safe cooling and freezing; and
- Recommendations for meeting the sampling requirements for detection of *Salmonella* spp. in egg products.

Plants can always seek guidance from State university extension service specialists and HACCP Coordinators on developing programs and plans not provided in this guideline to comply with new regulatory requirements. Plants that follow the recommendations in this guideline are likely to meet the regulatory requirements.

Changes from the Previous Version

This guideline, dated September 9, 2020, is final. FSIS will update this guideline as necessary should new information become available.

FSIS made the following change to this guideline to reflect the comments received on the previous version during the comment period for the proposed rule and to include additional scientific information:

- Revised the section Pasteurization of Liquid Egg Whites (9 CFR 590.570) to state why the former regulatory time and temperature requirements for pasteurization of liquid egg whites was not included in Table 1 and to explain under what circumstances these combinations could be used;
- Added *Lm* as a potential hazard in egg products, such as 10% salted egg products, and FSIS time and temperature pasteurization recommendations to destroy *Lm*;
- Added the section Defrosting Operations (9 CFR 590.539) for frozen egg products that need to be defrosted or tempered;
- Included egg substitutes and freeze-dried egg products;
- Added acceptable culture testing methods for *Salmonella*;
- Reorganized the Food Safety Systems and the HACCP Framework, Microbiological Testing Method, and New Technologies sections to improve clarity and make it more streamlined.

Questions Regarding Topics in this Guideline

If the desired information cannot be found within the 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 guidance 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 **Egg Products 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**.

FSIS Food Safety Guideline for Egg Products

Background

Bacteria and viruses are common causes of foodborne illness and may be present in the environment, in live animals and on raw food. Eggs have been identified as important reservoirs for pathogens. Pathogens can be transferred to eggs during formation inside the hen; laying; and egg breaking, handling, and other processing steps.

Previous FSIS regulations included prescriptive requirements for egg products plants to address contamination and did not allow flexibility for egg products plants to innovate. Under this final rule, FSIS has adopted HACCP as the organizing structure for its egg products food safety program, consistent with current requirements in the meat and poultry products inspection regulations.

Egg Products Final Rule: Amendments to the Regulations

In the final rule, FSIS amended the egg products inspection regulations to require all federally-inspected egg products plants to develop and implement HACCP systems, Sanitation SOPs, and Sanitation Performance Standards (SPS) to design and support the food safety system (9 CFR 416 and 9 CFR 417).

Implementation of HACCP, Sanitation SOPs, and SPS provides greater flexibility and incentives for innovation. This final rule also aligns egg products regulations with the meat and poultry products regulations. The amendments include the following (this guideline addresses the items bolded below):

- **Eliminate the current regulations that are inconsistent with HACCP, Sanitation SOPs, and SPS requirements;**
- **Specify that egg products are required to be edible without additional preparation to achieve food safety;**
- **Assert FSIS jurisdiction over egg substitutes and freeze-dried egg products;**
- Allow for the use of irradiated shell eggs in the production of egg products, provided the egg product subsequently undergoes pasteurization or another lethality treatment;
- Provide for generic approval as part of the prior label approval system for egg products under 9 CFR 412.2;
- Make changes to labeling requirements for shell eggs that are consistent with the Food and Drug Administration (FDA) regulations;

- Require special handling instructions on egg products that require special handling to maintain their wholesome condition;

- Eliminate the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment;

- Incorporate egg products plants under 9 CFR 500, *Rules of Practice* that the Agency follows when initiating administrative enforcement actions;

- Change the Agency's interpretation of the requirement for continuous inspection.

The information contained within this guideline is applicable to egg products, including egg substitutes and freeze-dried egg products. Egg substitutes are low-cholesterol egg products. They are characterized as egg whites with non-egg yolk replacers such as vegetable oil, nonfat dry milk, soy protein, gums, food coloring, artificial flavors, and vitamins and minerals (for nutritional fortification). Freeze-dried egg products consist of an egg product that is flash frozen and placed in a vacuum chamber to remove ice particles.

Egg substitutes	Egg whites with added color, mineral, or vitamin, and sold as a low-cholesterol alternative to whole egg products.
Freeze-dried egg products	Egg product that is flash frozen and placed in a vacuum chamber.
Egg products	Broken shell eggs that are processed into liquid, frozen, or dried egg white, egg yolk, or whole egg products. Full definition may be found in 9 CFR 590.5.

Known Pathogens of Concern in Egg Products

While egg products can be contaminated by several pathogens, the two most common pathogens are *Salmonella* and *Lm*.

SALMONELLA

Salmonella spp. are bacterial pathogens that cause foodborne illnesses. The most common symptoms of salmonellosis are diarrhea, abdominal cramps, and fever within 12 to 72 hours after eating the contaminated food. The illness usually lasts 4 to 7 days. Salmonellosis may result in *Salmonella*-induced chronic conditions such as aseptic reactive arthritis and Reiter's syndrome (a combination of urethritis, conjunctivitis, and arthritis). Older adults, infants, and persons with weakened immune systems are more likely to develop a severe illness. The Centers for Disease Control and Prevention (CDC) reported that nontyphoidal *Salmonella* spp. are one of the leading causes of foodborne illness, with an estimated 1 million illnesses, 19,300 hospitalizations, and 380 deaths annually in the United States (Scallan, et.al., 2011).

Salmonella spp. contamination in the final egg products can be due to underprocessing by not meeting the time and temperature parameters to achieve full lethality. Contamination can also occur

in the post-processing environment through contact with contaminated food contact surfaces, improper handling, addition of ingredients, 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 pathogen reduction, adulterated products may be released into commerce. Egg products found positive for *Salmonella* spp. or other pathogens are adulterated. FSIS requires plants to maintain control of products until test results (either plant testing or FSIS testing) confirm the product does not contain pathogens, such as *Salmonella* spp. (9 CFR 590.504(e)).

LISTERIA MONOCYTOGENES (Lm)

Lm is a bacterium that is found in moist environments, soil, and decaying vegetation and can persist along the food continuum. Listeriosis is a serious infection usually caused by eating food contaminated with *Lm*. The CDC estimates that infection with *Lm* causes about 1,600 illnesses, 1,500 hospitalizations, and 260 deaths in the United States each year. Listeriosis is rare, but its fatality rate is very high (about 20 percent, compared with 0.5 percent for *Salmonella* or *Escherichia coli (E. coli)*). It primarily affects older adults, pregnant women, newborns, and people with weakened immune systems (Scallan, et.al., 2011).

Transfer of *Lm* from the environment or employees is a hazard of concern in RTE foods, including egg products. *Lm* can survive and grow at cool temperatures (as low as just above freezing). Because of *Lm* growth and survival characteristics, *Lm* is usually persistent in the environment and is commonly referred to as a harborage organism (i.e., it can form biofilms, which is a community of organisms firmly attached to a surface, that allow *Lm* to grow to high numbers in the environment and protect it from sanitizers).

Lm can cross-contaminate food contact surfaces and foods. Improper sanitation, improper equipment maintenance, product handling, and employee practices post-lethality can lead to the transfer of *Lm* to egg products, causing them to become adulterated. Egg products contaminated with *Lm* are considered adulterated. FSIS requires plants to maintain control of products until test results confirm the product does not contain pathogens, such as *Lm* (9 CFR 590.504(e)).

While *Lm* is a hazard of concern in egg products, FSIS recommends that plants continue to use *Salmonella* as an indicator of effective pasteurization in egg products because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 733). Refer to the section Liquid Egg Yolks for reprocessing recommendations of egg products that test positive for *Lm*.

Food Safety Systems and the HACCP Framework

The statutory provisions require that egg products are pasteurized and not adulterated before shipping into commerce (21 U.S.C. 1036(a)). Because egg products undergo a lethality step to destroy pathogens of concern in the finished product, they can be safely consumed “as is,”

Key Point

Plants are required to process egg products to be edible without additional preparation to achieve food safety.

meaning without any additional cooking or food safety interventions. Consistent with HACCP, under the final rule, the former 9 CFR 590.570 regulation was replaced by a new regulation specifying that 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. Hazards such as *Salmonella* and *Lm* can be prevented, eliminated, or reduced through developing a food safety system. FSIS uses the HACCP framework as its food safety system. HACCP has multiple components that together form the HACCP system.

HACCP Requirements

The HACCP system is defined as the food safety system in operation, including the HACCP plan. The HACCP plan includes the hazard analysis, supporting documentation, and all HACCP records. The first step in developing a HACCP plan is to conduct a hazard analysis (9 CFR 417.2(a)). The hazard analysis must include all biological, physical, and chemical food safety hazards that can occur before entry into the plant and throughout the processing and storage. The plant would then identify the points in each of its processes at which control is necessary to prevent, eliminate, or reduce each hazard (9 CFR 417.2(c)(2)).

Definition

The **HACCP system** is defined as the food safety system in operation, including the HACCP plan, to prevent, eliminate, or reduce food safety hazards. The HACCP plan includes the hazard analysis, supporting documentation, including prerequisite programs and scientific documentation used to support decisions, and all HACCP records.

Plants implement measures to address those hazards identified in the hazard analysis into their HACCP system, such as at the lethality treatment, cooling, and freezing process steps. For each hazard identified in the hazard analysis, the plant determines if the hazard is reasonably likely to occur (RTLO) or not reasonably likely to occur (NRLTO). For any RLTO hazard, plants are required to develop a critical control point (CCP) in their HACCP plan. Plants may also determine that a prerequisite program effectively prevents the occurrence of certain food safety hazards, so they are NRLTO, for which a CCP is not required. Prerequisite programs to HACCP may include Sanitation SOPs (9 CFR 416.11-17), as well as other prerequisite programs, such as purchase specifications. Prerequisite programs to prevent hazards should be designed and monitored to ensure they are working as intended.

Written validated HACCP plans (9 CFR 417.2(b)) may include, but are not limited to, items in the list below in order to meet the 9 CFR 417 regulatory requirements:

- Identification of hazards RLTO in the production process, such as *Salmonella* spp. and *Lm*;
- Identification and description of the CCP for each identified hazard 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, cooling, and

freezing procedures;

- Description of the monitoring procedure, frequency, and monitoring device to be used, such as a calibrated thermometer to monitor the 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 at each CCP; and
- Description of the verification activities (e.g., direct observation, records review, calibration) and the frequency at which they are to be conducted along with support for these procedures and frequencies.

In addition to developing a hazard analysis and HACCP plan, processors are required to develop and maintain written Sanitation SOPs to minimize the risk of direct product contamination and adulteration (9 CFR 416.11-17). The regulations require that the plant's Sanitation SOPs specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every egg product. As part of the Sanitation SOPs, a plant employee is required to record results of sanitation checks at the frequencies stated in the Sanitation SOPs.

All the records generated from monitoring CCPs, Sanitation SOPs, and other prerequisite programs become part of the HACCP system records. When conducting a pre-shipment review, the HACCP records must be reviewed and signed by a plant employee. When practicable, the review should be conducted by an employee other than the one who produced the record before the product is distributed in commerce, and preferably by someone trained in HACCP or the responsible plant official (9 CFR 417.5(c)). Lastly, HACCP records must be retained in accordance with 9 CFR 417.5(e). for at least 1 year for refrigerated products and 2 years for frozen, preserved, or shelf-stable products.

HACCP Plan to Control Hazards

Pasteurized egg products must be free of detectable pathogens (*Salmonella* and *Lm*) and have no violative levels of residues (pesticides, heavy metals, persistent organic pollutants) or detectable toxins or levels of toxin-producing organisms that would be a public health concern. Egg products plants produce safe product by controlling, eliminating, and reducing microbiological, physical, and chemical hazards, where identified, throughout their HACCP system.

During completion of the hazard analysis, plants are required to consider and account for hazards that could occur at the farm (*Salmonella,* residues), during transportation to the plant (checking seals on trucks, performing organoleptic examinations on incoming products), and during processing at the plant (lethality, cooling, and freezing procedures, storage conditions). Plants need to verify on an ongoing basis that they are addressing the hazards identified in the hazard analysis and that the HACCP plan is functioning to ensure food safety (9 CFR 417.4(a)). Consistent with the former regulations, the amended regulations require plant-performed microbiological sampling and testing to

verify the absence of *Salmonella* spp. in the finished product. Plants are required to maintain control of the egg products until the testing results are received (9 CFR 590.504(e)). Egg products may be moved from a plant before the plant receives laboratory results only if the plant retains control of the product.

In the hazard analysis, the plant determines if a hazard is RLTO (addressed through a CCP) or NRLTO (typically addressed through Sanitation SOPs or other prerequisite programs).

Process deviations may occur despite the best efforts of a plant to maintain process control. Heating and cooling deviations occur when the plant fails to meet its heating (i.e., pasteurization, heat treatment) or cooling process schedule. Failure to meet the time and temperature combination is a common cause of heating deviations and can result in underprocessing. Common causes for cooling deviations include inadequate chilling due to large volumes, improper agitation of the product, power failures, or refrigeration equipment breakdowns. When processing deviations occur, a plant is required to take corrective action to bring the process back in control (9 CFR 417.3).

- When the identified hazards are addressed through CCPs, plants are required to determine the cause of all critical limit deviations (9 CFR 417.3(a)(1)), regain control of the CCP (9 CFR 417.3(a)(2)), and ensure measures are established to prevent recurrence (9 CFR 417.3(a)(3)). Recurring deviations constitute an unacceptable risk within the HACCP system. In addition, the plant would be required to initiate measures to ensure that no product potentially injurious to health or otherwise adulterated because of the deviation enters commerce (9 CFR 417.3(a)(4)).

- When the identified hazards are addressed through a prerequisite program, plants are required to reassess their HACCP plan to determine whether the newly identified deviation (i.e., 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 the decisions in its hazard analysis that the identified hazard is NRLTO if it has continual or repetitive deviations from its prerequisite program (9 CFR 417.5(a)(1)).

If a plant fails to support decisions made in the hazard analysis or demonstrates ongoing or repetitive CCP or prerequisite program deviations, there could be an imminent food safety concern that may have an impact on public health. Producing product with potential food safety concerns can result in a regulatory control action or an enforcement action by FSIS, according to the Rules of Practice (9 CFR 500).

Validation, Verification, Reassessment

Validation is the process of demonstrating that the HACCP system as designed can adequately control potential hazards to produce a safe, unadulterated product. Validation is a key step to determine if a HACCP system is effective (9 CFR 417.4(a)(1)).

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.

Validation ensures that the HACCP system is designed and functioning appropriately. Validation has two elements as described in the Compliance Guideline HACCP Systems Validation.

Element 1 involves supporting the decisions made in the hazard analysis (hazards as RLTO or NRLTO) and in the HACCP plan (critical operating parameters, such as time and temperature). Examples of support are provided in the section Scientific Support Availability for Lethality Requirements in Egg Products. Plants can meet the new requirements by implementing the former regulatory time and temperature parameters in 9 CFR 590.530, 9 CFR 590.536, 9 CFR 590.539, 9 CFR 590.570, and 9 CFR 590.575 or any of the other time and temperature parameters included in this guideline. FSIS considers these parameters to be safe harbors. **Safe harbors** are recognized procedures that can be employed without any further validation studies. Plants will not have to gather additional scientific support for their process if they choose to use these safe harbors. Plants that choose to use the former regulations must incorporate these procedures into their HACCP system (i.e., HACCP plan, prerequisite programs, Sanitation SOPs).

Element 2 involves collecting 90 calendar days of in-plant data to demonstrate that the system is capable of meeting the critical operating parameters. The in-plant validation may include in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures (CCPs and prerequisite programs), as written into a HACCP system, can be executed within a particular plant to achieve the process's intended result. 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. Plants using safe harbors to satisfy Element 1 are still required to meet Element 2 of the validation process.

Once the HACCP system is validated, the plant will need to perform on-going **verification** and continue to monitor those operating parameters, review records generated by the HACCP system, and maintain documentation verifying that they are following these procedures (9 CFR 417.4(a)(2)). At least annually, and anytime a process is changed, the plant must **reassess** their HACCP system to ensure the decisions made in the hazard analysis and HACCP plan are still valid (9 CFR 417.4(a)(3)).

Scientific Support Available for Lethality Requirements for Egg Products

There are generally six types of information that can be used to demonstrate compliance with the new scientific support regulatory requirements in the final rule on Egg Products Inspection Regulations: (1) published processing guidelines, (2) challenge studies, (3) peer-reviewed scientific or technical data or information, (4) pathogen modeling programs, (5) expert advice from processing authorities, and (6) former egg products regulations. 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. FSIS recommends that plants refer to the guidance provided in the FSIS Compliance Guideline HACCP Systems Validation to ensure that their HACCP systems are properly validated.

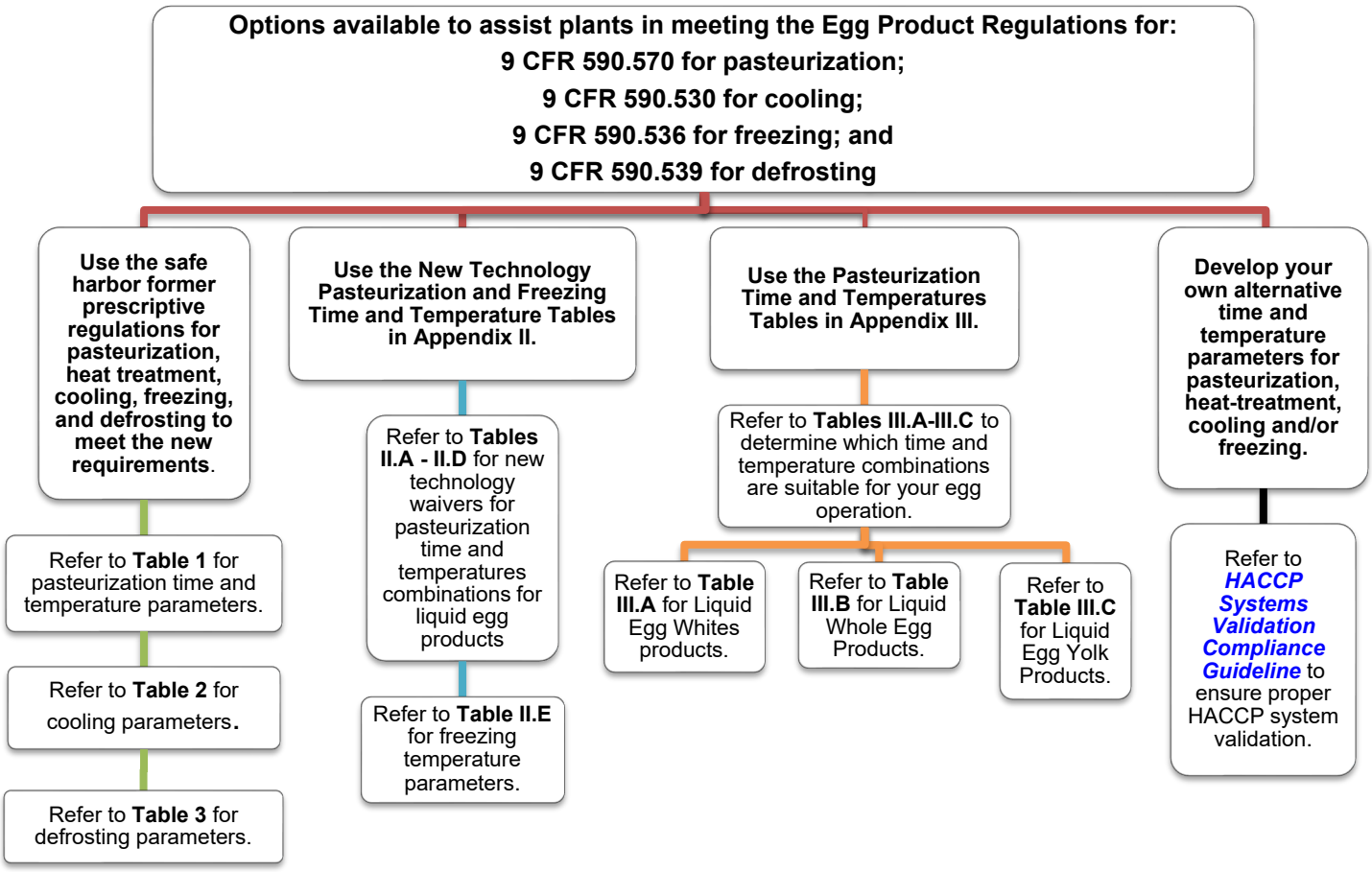
(1) Published Processing Guidance

This guideline, as well as other guidance available on FSIS's Guidance Website, are examples of Published Processing Guidance. This Egg Products Guideline contains safe harbors from former egg products regulations, options from approved New Technology waivers, and the mathematical time and temperature combinations for pasteurization. Figure 1 illustrates the options that plants may use to comply with the new regulatory requirements in the final rule.

Appendix II, *New Technology Pasteurization and Freezing Time and Temperature Tables*, provides tables of validated pasteurization and freezing time and temperature parameters from historical FSIS New Technology waivers and No Objection Letters (NOLs). These tables can be used as resources to meet the proposed regulations.

Appendix III, Pasteurization Time and Temperature Tables, provides tables of pasteurization time and temperature combinations that are calculated to achieve the lethality performance standard for specific egg products based on data and models that are presently available to FSIS. FSIS considers these to be scientifically validated processes and safe harbors to meet regulatory requirements.

Figure 1. Overview of Options Available to Meet the New Regulatory Requirements



(2) Challenge Studies

One of the most definitive validation tools available is the inoculated pack or challenge study of the time and temperature used by the plant for egg products pasteurization. Challenge studies involve inoculating the product with a known amount of a pathogen and calculating the level of reduction or elimination that is achieved. Since challenge studies introduce hazards to the product, they should be conducted in a testing laboratory and not in the processing plant environment. 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.

The challenge study design, including a description of the process and all critical operating parameters affecting the reduction or elimination, and the achieved level of pathogen reduction or elimination should be documented and maintained as part of the HACCP system. Challenge studies should be based on a sound statistical design that ensures confidence in the data and employs positive and negative controls. The statistical design should include the number of samples collected at each time interval and the number of study replicates needed to ensure the validity of the study. Quantitative methods such as power analysis may be used to assess the statistical quality of a study. 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.

(3) Peer-Reviewed Journal Articles

Published studies, such as peer-reviewed research studies on the pasteurization of egg products, can serve as initial validation of pasteurization time and temperature parameters. Published studies should include the time and temperature requirements to achieve a specific log reduction and type of product and formulation (e.g., whole egg; whole egg with citric acid). Additional parameters could include viscosity and pH of the egg product used. To be used as part of initial validation, the study selected should describe products and processes similar to those used by the plant. The plant should not use published studies whose study parameters do not represent the plant's process and products. For example, a study on the pasteurization time and temperature for liquid egg whites is not adequate supporting documentation for the pasteurization of whole eggs.

(4) Pathogen Modeling Programs

FSIS is not presently aware of any publicly available computerized software available on lethality models for the inactivation of *Salmonella* spp. in liquid or dried egg products. However, such models might be developed without FSIS awareness and could be used for demonstrating compliance if the model is applicable and validated for the plant's product. Individual plants can develop their own computer models using data from published literature, provided that the assumptions used for developing the models are scientifically sound.

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 Microbiology. 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 Pathogens and Disease. 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. Journal of Food Protection. 74:882-892.

- Gurtler, J. B., V. K. Juneja, D. R. Jones, and A. Purohit. 2019. Thermal inactivation kinetics of three heat-resistant *Salmonella* strains in whole liquid egg. Journal of Food Protection. 82(9):1465-1471.

(5) Expert Advice from Processing Authority

Expert advice from processing authorities may be used as scientific or technical support. Such expert advice should include reference to established scientific principles as well as reference to peer-reviewed scientific data. Expert advice from processing authorities should not rely on expert opinion alone. The scientific principles and data should relate to the plant's product and process as well as the hazard identified in the hazard analysis. One example of how expert advice may be used is a processing authority's justification for why a different limit of a critical operational parameter from the one studied in the scientific support should not impact the effectiveness of an intervention. As part of the justification, in addition to their own expert opinion, the processing authority should cite one or more peer-reviewed scientific data sets or documents that provide a science-based rationale for why the different limit of the critical operational parameter should be at least equally as effective from the one in the scientific support.

(6) Former Egg Products Regulations

The former regulations for pasteurization, heat treatment of dried egg whites, cooling, freezing, and defrosting operations could be used by a plant to meet new regulatory requirements. The former regulations are recognized as safe harbors and are considered validated processes.

Pasteurization Operations (9 CFR 590.570)

Table 1 provides the former pasteurization requirements for liquid egg products. It should be noted that the time and temperature parameter for the pasteurization of liquid egg whites under the former regulations are not included here as it does not achieve the same level of lethality as for other liquid egg products and can only be used under certain conditions. In general, FSIS considers a 5-$\log_{10}$ reduction of *Salmonella* to be safe in products that are edible without additional preparation to achieve food safety, including egg products. This will eliminate up to 100,000 Colony Forming Units

per gram (CFU/g) pathogenic organisms before the number of bacteria overwhelms the lethality treatment. The conditions under which liquid egg whites may be processed using the former regulatory time and temperature pasteurization combination are described in the "Pasteurization of Liquid Egg Whites" section.

Table 1. Former Pasteurization Requirements for Liquid Egg Products That Could Be Used as Safe Harbors

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

Pasteurization of Liquid Egg Whites (9 CFR 590.570)

Based on the scientific literature, the former regulatory pasteurization time and temperature for liquid egg whites (134°F for 3.5 minutes) did not achieve a 5-$\log_{10}$ reduction (International Egg Pasteurization Manual, USDA FSIS 1998 Risk Assessment) of *Salmonella*. This time and temperature combination may be used as a safe harbor if the eggs did not originate from a farm that is positive for *Salmonella* Enteritidis.

The time and temperature requirements of the former pasteurization regulations were based on a pH of about 9 for egg whites, as described in the USDA FSIS 1998 Risk Assessment. At the time the regulations were written, it would take eggs 3 to 5 days to arrive at the processing plant. During this time, the pH of the albumen would rise from about 7.8 to 9.4. However, current practice allows for the eggs to arrive at the processing plant much sooner, when the pH is closer to 7.8. The pH of albumen, or the egg white, has a significant effect on the reduction of *Salmonella* Enteritidis when liquid egg white is pasteurized. *Salmonella* Enteritidis is more sensitive to heat at higher pH levels, thus making egg pasteurization more effective.

Egg whites have natural antimicrobial properties that limit *Salmonella* growth. These properties include lysozyme, ovotransferrin, vitamin chelating proteins, and proteinase inhibitors (Baron *et. al.*, 2016). With these inherent properties, it is possible that egg whites may not require a process that achieves a 5-$\log_{10}$ reduction of *Salmonella* under certain conditions (refrigerated within 36 hours of lay; not originating from a farm that has *Salmonella* Enteritidis-positive eggs). These antimicrobial properties would limit the growth of *Salmonella* cells present in the egg white, thus allowing for

greater effectiveness of the former pasteurization time and temperature combination before the lethality treatment is overwhelmed.

Available studies examined *Salmonella* in eggs from chickens infected with *Salmonella.* Humphrey *et. al.*, (1989, 1991) enumerated *Salmonella* from the egg, but also looked at *Salmonella* growth when inoculated into different parts of the egg (albumen versus yolk). Garibaldi *et. al.*, (1969) enumerated *Salmonella* from whole egg and from the albumen while Gast and Beard (1992) enumerated the *Salmonella* from the whole egg. Their studies demonstrated that most eggs had less than 1-$\log_{10}$ of *Salmonella* per egg while a few eggs had 2.1-$\log_{10}$ of *Salmonella*. Humphrey *et. al.,* (1991) determined that *Salmonella* inoculated into the outer edge of the albumen was less likely to grow than when inoculated next to the yolk membrane, fresh eggs were less likely to support *Salmonella* growth regardless of its position in the albumen, and that *Salmonella* positive eggs contained less than 1.3-$\log_{10}$ of *Salmonella* when stored at room temperature for less than three weeks. Gast and Beard (1992) studied the effect of storage temperature on frequency of isolation and concentration of *Salmonella* in eggs from experimentally infected hens and determined that eggs stored at 45°F for 7 days had 0.75-$\log_{10}$ of *Salmonella*. Since that time, the industry has continued to lower *Salmonella* levels in egg products. FSIS performed a *Salmonella* baseline survey from 2012 to 2013. Results of that baseline indicate that raw liquid whole egg samples had -0.60-$\log_{10}$ to -0.31-$\log_{10}$ (95% confidence interval) *Salmonella*, meaning that there was 1 *Salmonella* organism per 2 to 4 mL. Raw liquid egg whites had -0.92-$\log_{10}$ to -0.24-$\log_{10}$ *Salmonella*, meaning that there was 1 *Salmonella* organism per 2 to 8 mL. In addition, FSIS sampling indicated that pasteurized egg whites had a *Salmonella* prevalence of 0.61% from 1995 to 1999. That prevalence decreased to 0.19% from 2013 to 2018.

However, the FDA Final Rule: Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation (74 FR 33030, July 9, 2009) requires all eggs diverted from a farm that has *Salmonella* Enteritidis be treated using a technology or process that achieves a 5-$\log_{10}$ destruction of *Salmonella* Enteritidis. Since the former regulatory pasteurization time and temperature for liquid egg whites does not achieve a 5-$\log_{10}$ reduction, it was not included in Table 1. Considering this, egg products plants could use the former regulatory pasteurization time and temperature of 134°F for 3.5 minutes as a safe harbor, provided that the eggs are not diverted from a farm that has *Salmonella* Enteritidis. If plants are using the former pasteurization time and temperature combination and receive multiple positive *Salmonella* results, then they will be required to reassess their hazard analysis and make appropriate corrective actions. Plants pasteurizing liquid egg whites that require a 5-$\log_{10}$ reduction of *Salmonella* may refer to the section Liquid Egg Whites for acceptable time and temperature combinations.

Heat Treatment of Dried Egg Whites (9 CFR 590.575)

Heat treatment of dried whites is an approved method of pasteurization. The product should be heated throughout for the necessary time and temperature that will result in a reduction of *Salmonella* spp. to undetectable levels.

The product for heat treatment should be in closed containers to prevent post-lethality exposure. The containers should be placed in a heat treatment room with adequate spacing between the containers

to assure heat penetration and air circulation so that all product reaches the desired time and temperature combination. Each container should include information on the product type (spray or pan dried) and the production lot number or production code.

Former regulatory times and temperatures for heat treatment of spray or pan dried albumen are as follows:

- Spray dried albumen should be heated throughout to a temperature not less than 130°F and held continuously at such temperature for a minimum of 7 days; or

- Pan dried albumen should be heated throughout to a temperature of not less than 125°F and held continuously at such temperature for a minimum of 5 days.

Cooling Operations (9 CFR 590.530)

Table 2 provides the former cooling requirements for liquid egg products. Liquid egg products 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. Prior to pasteurization, the liquid egg products listed in Table 2 would need to be brought to the respective temperature within two hours of breaking.

Table 2. Former Cooling and Temperature Requirements for Liquid Egg Products That Could Be Used as Safe Harbors

Product	Non-Salted Liquid Product to be held 8 hours or less	Non-Salted Liquid Product to be held more than 8 hours	Salted Liquid Product	Temperatures within 2 hours after Pasteurization	Temperatures within 3 hours after Stabilization
White (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	[1]
All other product with less than 10% added salt	45°F or lower	40°F or lower	_____	45°F or lower if to be held 8 hours or less 40°F or lower if to be held more than 8 hours	45°F or lower if to be held 8 hours or less 40°F or lower if to be held more than 8 hours
All other product with 10% or more added salt	_____	_____	65°F or lower if to be held for 30 hours or less 45°F or lower if to be held more than 30 hours	65°F or lower[2]	

1 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.
2 The cooling process should be continued to assure that any salt product to be held more than 24 hours is cooled and maintained at 45°F or lower.

Freezing Operations (9 CFR 590.536)

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

- Non-pasteurized egg products intended for freezing should be solidly frozen or reduced to a temperature of 10°F or lower within 60 hours from time of breaking. Non-pasteurized frozen egg product would need to be defrosted or tempered (see Defrosting Operations) prior to pasteurization.

- Pasteurized egg products intended for freezing 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 to allow sufficient air circulation around the containers. The outside of liquid egg containers should be clean and free from evidence of liquid egg, shell, or debris. Frozen egg products should be examined organoleptically after freezing to determine their fitness for human food.

Defrosting Operations (9 CFR 590.539)

Frozen egg products which are to be defrosted must be defrosted in a sanitary manner. Frozen egg products should be examined organoleptically prior to defrosting to determine their fitness for human food. Table 3 provides acceptable tempering and defrosting operations for frozen egg products.

Table 3. Former Defrosting Requirements for Liquid Egg Products That Could Be Used as Safe Harbors

Product Type	Temper / Defrost Option	Temperature	Time	Special Considerations
Dried Albumen	Ambient	-	-	For production of dried albumen
Egg Products	Ambient	40°F or lower	48 hours or less	Liquid product maintained at 50°F or lower
Egg Products	Ambient	Greater than 40°F	24 hours or less	
Egg Products	Running Water	70°F or lower	-	Plastic or metal container

Once the product has been defrosted, it should be maintained at 40°F or less, unless it is to be pasteurized or stabilized by glucose removal. Defrosted liquid product shall not be held more than 16 hours prior to processing or drying.

Control of Pathogens in Egg Products

The times and temperatures for destroying *Salmonella* spp. are dependent upon the type of egg product being produced: egg white, whole egg, or egg yolk, as well as product formulations such as added salt or sugar. In addition to the former regulatory pasteurization time and temperatures already provided in Pasteurization Operations (9 CFR 590.570), Appendix II and Appendix III provide pasteurization time and temperature tables. Along with eliminating and reducing pathogens during the lethality step, plants also need to control for pathogens after the lethality step by limiting the cross-contamination potential. The subsequent sections provide detailed information for the control of pathogens in each specific product type as well as at the post-lethality step.

Liquid Egg Products

Liquid egg products include whites, yolks, whole eggs, blends of whole eggs and yolks, and egg substitutes. Some egg products, such as those containing salt and sugar, may require higher pasteurization times and temperatures. Appendix III includes Tables III.A through III.C that provide different combinations of times and temperatures for 14 different types of 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 should select the option that will allow them to meet the requirements for their specific processes.

Liquid Egg Whites

Pasteurization can adversely affect the functional properties of liquid egg whites depending on the time and temperature used. Egg white proteins are particularly susceptible to heat damage and, therefore, require lower heating temperatures (International Egg Pasteurization Manual) to preserve functionality. A 5-$\log_{10}$ reduction of *Salmonella* spp. in liquid egg whites with lower pasteurization times and temperatures can be achieved by raising the pH. The higher pH values work to reduce the heat resistance of *Salmonella* spp. 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). Appendix III, Table III.A provides different combinations of times and temperatures at four different pH values (7.8, 8.2, 8.8, and 9.3) that achieve a 5-$\log_{10}$ reduction of *Salmonella* and, thus, may be used for egg whites originating from farms that have positive *Salmonella* Enteritidis eggs. Plants can select which time and temperature combination is suitable for their egg products processing operation. For example, a pH of 7.8 at a pasteurization temperature of 140ºF and holding time of 21 seconds is needed to ensure adequate pasteurization and that pathogens are non-detectable in *Salmonella* Enteritidis-diverted eggs.

For liquid egg products with a lower pH, additional ingredients may be added to improve lethality while preserving the functionality. Chemical reagents and metal ions are commonly added to stabilize the proteins that contribute to the egg white's functionality in cooking and baking. Hydrogen peroxide, 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).

Liquid Whole Eggs

Liquid whole eggs often consist of blended non-egg ingredients, including salt, sugar, or corn syrup. These are added to whole eggs to prevent egg yolk gelation during freezing or impart functional properties to the liquid whole egg product. Liquid 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 without added ingredients, the plant should refer to Table III.B in Appendix III. For example, 10% salt whole egg at a pasteurization temperature of 150ºF requires a holding time of 78 seconds to ensure adequate pasteurization and that pathogens are non-detectable.

Liquid Egg Yolks

Liquid egg yolk has a higher viscosity (due to higher fat and protein content) than egg whites, thus decreasing the lethality of *Salmonella* to heat (Li, *et.al.*, 2005). In addition, *Salmonella* spp. are the most heat resistant at near neutral pH, similar to the conditions of the egg yolk (Eskin and Shahidi, 2012). As a result of the higher viscosity and near neutral pH, *Salmonella* spp. may acquire greater heat-resistance more readily in egg yolk than in egg whites. Hence, the pasteurization for egg yolk is higher and longer than egg whites. Sugar, salt, glycerol, or other similar ingredients are often added at levels of 10 to 15% to reduce the gelation that can occur when freezing liquid egg yolk (Carter, 1968). *Salmonella* spp. are more resistant when salt is added due to lowering of the water activity. Consequently, salted egg yolk requires increased time and temperature for effective pasteurization than non-salted egg yolk (Palumbo, *et.al.*, 1995).

Scientific studies have also identified that *Lm* has a much higher heat resistance in salted egg yolk products (Palumbo *et al.*, 1995; Michalski *et al.*, 2000; Huang, 2019). FSIS has determined that a pasteurization temperature of 155°F with a minimum holding time of 12 to 13 minutes is needed in order to achieve a 5-$\log_{10}$ reduction of *Lm* in the 10% salted egg yolk, based on the D-values from three published thermal death time studies (Palumbo *et. al.*, 1995; Michalski *et. al.*, 2000; Huang, 2019).

In the past, *Salmonella* has been used as the indicator of lethality because of the association of *Salmonella* Enteritidis foodborne illnesses with eggs and because *Salmonella* Enteritidis can infect the egg during the developmental process inside the chicken (FSIS Risk Assessment, 1998; FSIS Risk Assessment, 2005). FSIS recommends that plants continue to use *Salmonella* as an indicator of effective pasteurization in egg products because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 733). If the plant's scientific support demonstrates that its lethality treatment achieves sufficient reduction in *Salmonella*, it does not need to provide additional support that adequate reduction in other pathogens is achieved. However, if a sample tests positive for *Lm*, the plant should verify that inadequate lethality was not the root cause as part of its corrective actions (9 CFR 417.3(b)). If reprocessing the adulterated product, the plant would need to repasteurize at 155°F for 12 to 13 minutes or provide alternate scientific support for the pasteurization time and temperature required to achieve a 5-$\log_{10}$ reduction of *Lm*.

To use the time and temperature combinations for egg yolk products, plants should refer to Table III.C in Appendix III. For example, 10% sugar egg yolk at a pasteurization temperature of 155ºF requires a holding time of 17 seconds to ensure adequate pasteurization and that *Salmonella* spp. are non-detectable. Alternatively, plants may choose not to use the tables in Appendix III and implement a customized process that is designed to ensure egg products are edible without additional preparation to achieve food safety. Plants would need to provide adequate scientific support for any processes not provided in this guideline. See the section Scientific Support Available for Lethality Requirements for Egg Products for examples of scientific support.

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 (i.e., dried egg white products) in a liquid state must be subjected to a heat treatment in the dried state that will impart a lethality necessary to ensure pathogens are non-detectable. This section discusses the processing of dried egg white products. Since dried egg yellows are pasteurized first prior to drying, control of pathogens in dried egg yellows is discussed in the sections Liquid Whole Eggs, Liquid Egg Yolks, and Post-Lethality Handling and Sanitation.

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 the USDA Agricultural Research Service. For *Salmonella*, it was estimated that a product containing 5% moisture requires more than 21 days at 54°C/129.2°F to achieve lethality of 5.7 $\log_{10}$; a product containing 8% moisture requires more than 12 days. Other models predicted that even more time would be required to achieve a lethality of 5.7 $\log_{10}$. Table 4 provides estimates of the minimum number of days at 54°C/129.2°F that would be required to obtain a minimum lethality of 5.7 $\log_{10}$.

The percent moisture described in Table 4 refers to the moisture content at the initial state, at the beginning 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 4. Estimated Minimum Number of Days at 54°C / 129.2°F to obtain at least a lethality of 5.7$\log_{10}$ ***for Salmonella spp. in*** *Dried Egg White Product, Based on the Percent Moisture of product before pasteurization.*

Percent (%) Moisture	4	5	6	7	8
Minimum Number of Days at 54°C/129.2°F	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.

Post-Lethality Handling and Sanitation

Eliminating and reducing pathogens during the lethality step is just part of controlling pathogens. After lethality, plants need to control their processing environment to prevent contamination of product with pathogens from product handling. Although *Salmonella* contamination in eggs is typically due to

under processing it may also occur due to cross-contamination in the post-lethality environment. *Lm* contamination can also be a concern if products are exposed post-lethality. Although liquid egg product processes tend to have limited contact with food contact surfaces post-lethality, any opportunity for contact could result in the potential for post-lethality contamination. In one previous case of an *Lm* positive in a liquid egg product, the investigation identified that there was a leak in the closed pasteurization system that likely led to cross-contamination.

In addition, liquid egg products may be exposed post-lethality during the drying process, such as with spray-dried or pan-dried egg product. Sanitary conditions in drying rooms need to be maintained to prevent contamination of the product during drying and collection.

Furthermore, plants producing egg substitutes may add color additives to pasteurized egg whites. If this is the case, then the egg substitute product will need to be repasteurized. The addition of an ingredient post-pasteurization presents a hazard in which contamination could occur.

Microbiological Sampling and Testing Program

Egg product plants are required to conduct pathogen sampling to ensure their HACCP system is functioning adequately and that the products are free from the presence of *Salmonella* spp. and *Lm.* The amended 9 CFR 590.580 pathogen reduction standards testing regulation requires that:

- Plants must test to determine that the production of egg products is in compliance with the Egg Products Inspection Act (EPIA) and the egg products inspection regulations. Egg products plants are required to hold and 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 in accordance with 9 CFR 590.504.

- To verify 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.;
  - Testing must be performed in a manner sufficient to verify that the HACCP system is capable of eliminating *Salmonella* spp. and that the system is working;
  - As a safe harbor, the frequency of sampling and testing liquid and frozen egg products can be supported by skip lot testing, which is described in Appendix I: Safe Harbor Sampling Rates for *Salmonella* spp. Verification Testing for Liquid and Frozen Egg Products;
  - Samples must be analyzed for the presence of *Salmonella* spp. at a frequency and using a laboratory method (see section Microbiological Testing Method) that will ensure that the product is not adulterated (9 CFR 590.580(b)(2)); and
  - Samples must be collected from the final packaged form (9 CFR 590.580(b)(3)).

- Plants are not required to analyze for the presence of *Lm.*

Written Microbiological Sampling Program

To meet the regulatory requirements, the plant must develop and implement a written microbiological sampling and testing program. At a minimum, the written sampling program must include:

- 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;

- A description of the analytical method used to test the samples and the name and location of the microbiology testing laboratory performing the analysis. The method used should be validated by a recognized independent testing body. Further information can be found in the FSIS Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory;

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

- The locations within the plant's production process where samples are collected;

- The frequency of sample collection; and

- Scientific and technical documentation to support the design of the sampling program. Further information on scientific and technical documentation can be found in the FSIS Compliance Guideline HACCP Systems Validation.

Microbiological Testing Method

Egg products plants 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 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) Official Method of Analysis or International Organization for Standardization (ISO). FSIS has 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,* Shiga toxin-producing *E. coli*, and *Listeria* spp., including *Lm*). 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.

A rapid screening method may be used if that method is validated for egg products and is approved by a recognized independent body or the FSIS Rapid Screening Method as described in the Microbiological Laboratory Guidebook. Presumptive positives from the rapid screening methods may

be confirmed using an accepted culture method. If the rapid screening method is not used, plants may use an accepted cultural method. Accepted culture methods include:

- FSIS Microbiology Laboratory Guidebook, Chapter 4 – Identification of *Salmonella* from Meat, Poultry, Pasteurized Egg Products, and Siluriformes Products and Carcass and Environmental Sponges; or

- FDA Bacteriological Analytical Method, Chapter 5 – *Salmonella*.

For plants electing to use an outside laboratory, FSIS has made available the guidance, Establishment Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory. This guidance document should be particularly useful to plants when they are selecting a commercial or private laboratory to analyze 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 Guidance Website. 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.

For plants electing to maintain their own microbiological testing laboratory, FSIS recommends that the laboratory be segregated from manufacturing areas and that access to the laboratory space be limited to prevent cross-contamination. If the plant will be testing for pathogens onsite, then they should follow requirements for Biosafety Level II laboratory operation as outlined in to ensure food safety and security.

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 9 CFR 590.580. It is recommended that records include the testing procedures, including support for the adequacy of the testing frequency, the test results, and other 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; and

- 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 the 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
- 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. The testing records:

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

Actions in Response to Test Results

Plants are required to test egg products for the presence of *Salmonella.* In addition, FSIS will collect samples to analyze for *Salmonella, Lm,* and violative residues[3]. Plants are required to hold or maintain control of lots samples for *Salmonella* or *Lm* (meaning, hold the product at the plant or move the product to another location but keep the product under plant control). FSIS recommends but does not require that the plant hold or maintain control of lots sampled for violative residues. If a sample of an egg product tests positive for *Salmonella* spp., *Lm*, or a violative residue, FSIS considers the lot adulterated. The section Lotting Practices provides FSIS's guidance on defining lots. The plant is required to take corrective actions according to 9 CFR 417.3(a) or (b), depending on whether the plant controls the applicable hazard 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 destroy the product, it can be reprocessed with the assurance that the egg product will be rendered free of detectable pathogens.

[1] Acceptable electronic formats include scanned images of the original paper records, saved email attachments of laboratory results, etc. It is not acceptable to transcribe original official records to an alternate format, such as Excel, and then discarding the official record.
[2] Accessibility of records for IPP review does not mean that plants are required to grant IPP access to the plant computer.
[3] On September 21, 2016, FSIS began analyzing all domestic and imported pasteurized egg products that it analyzes for *Salmonella* spp. and for *Lm* (as a measure of environmental cleanliness). On September 27, 2018, FSIS began analyzing egg products for residues, such as pesticides.

- If the product contains a violative residue, the product must be destroyed as reprocessing of the product will not remove the violative residue.

Lotting Practices

If either a plant sample or an FSIS sample is found positive for *Salmonella* or *Lm*, or found to contain violative levels of residues, the lot representing that sample (henceforth, sampled lot) is considered adulterated. When a sampled lot is found adulterated, multiple lots may be implicated. Proper lotting may be instrumental in reducing the impact of reprocessing product (for *Salmonella* or *Lm* positive product) or product recalls (for product that was not held). Lots should be designed so that if the sampled lot was found adulterated, the product in other lots can be deemed independent and not implicated.

The sampled lot definition will differ based on microbiological versus chemical analyses.

For microbiological analyses, a typical lot can be defined as one day's production (physically separated pasteurization run) of each type of product. A physically separated pasteurization run means that product has been separated from other production lots by cleaning and sanitizing, such that there is no potential contamination between separate lots of product. This may include cleaning the entire system (pasteurizer, clean-in-place (CIP) lines to packaging room, final packing/filling equipment). The following factors may be considered when FSIS determines what additional lots may be implicated if the sampled lot is found adulterated:

- Egg products plants are not required to perform a CIP procedure between each lot production. However, if egg products are stored or packaged using common pipelines and equipment that have not been cleaned and sanitized prior to establishing another individual lot, FSIS cannot recognize the product subsequently produced as a separated product lot;

- Plants may store multiple lots in a common area. The plant must maintain sanitary conditions to prevent contamination of the product(s) during storage and consider possible cross-contamination if products from different lots are stored in the same cooler, freezer, or dry egg products cool storage;

- Plants may define a lot differently based on the product group. For example, dried egg whites undergo a heat treatment, rather than a pasteurization run. In this case, the sampled lot would be all products present in the same heat treatment room at the same time;

- Because *Salmonella* can contaminate final egg products as a result of underprocessing, if one lot of egg product tests positive by FSIS and another lot of product received the same lethality treatment, scientific support is necessary to justify why the later lot should not be implicated; and

- In addition, some plants may store more than one lot of pasteurized product in one pasteurized egg product silo without conducting a cleanup between lots. When this occurs, FSIS would consider the sampled lot to consist of all co-mingled pasteurized runs.

A plant may reduce its lot size when collecting a microbiological sample, or when FSIS is collecting a microbiological sample, to facilitate holding the product, as long as the change does not interfere with collecting a representative sample. A reduction of lot size may be accomplished by breaking fewer eggs or pasteurizing smaller amounts of liquid eggs. FSIS is not aware of a mechanism to reduce the lot size of dried egg whites, as fewer boxes in the room would alter heat distribution and no longer reflect normal operations.

For chemical analyses, FSIS generally considers the sampled lot to be all products originating from the same poultry farm. In general, poultry management practices result in the entire flock being treated at the same time rather than individually. Most plants may combine egg products from shell eggs coming from multiple poultry farms into a single production run. If this is the case, then all poultry farms represented in a violative-positive production run would be implicated unless the plant can supportably justify the exclusion of certain farms.

Plants may reduce the number of farms representing the sampled lot when FSIS is collecting a residue sample. By reducing the number of farms comprising a lot, fewer farms would be implicated if the sample was found violative. In addition, plants may reduce implicated lots by using the sampled lot in only one product type and not combining the sampled lot with egg products from other farms until the results are received. It is up to the plant to determine the size of the lot.

New Technologies

The amended regulations provide more flexibility for plants to innovate with new technologies that can improve efficiency and food safety. However, there may still be occasion for plants to request a waiver or No Objection Letter (NOL) for certain innovations. Plants may submit a new technology notification and protocol through AskFSIS. In the request, plants should provide data to justify the new technology request.

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 addition, egg products plants may only use sanitizers and color additives that are 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)). If a plant chooses to develop and implement applications that incorporate such substances or ingredients that are not recognized as safe and suitable, then it must apply for an NOL through the new technology notification process.

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

Liquid and Frozen Egg Products

Sampling of lots 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 production day on a rotation basis. (Each product within a category does not need to be sampled every day).

- **100 percent sampling (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

To reduce the sampling frequency:

1. From 100 percent to Level 1: 60 consecutive lots within a product category must be *Salmonella* spp. negative.
2. From Level 1 to Level 2: 60 sampled lots within the product category must be *Salmonella* spp. negative.
3. 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 further reduced.

Action Required for *Salmonella* spp. Positive Lots

1. If a *Salmonella* spp. positive[4] lot is found at any of the 3 reduced sampling levels, the plant must immediately begin sampling the entire product category at 100 percent.

[4] See the section, titled "Microbiological Testing Methods" for information on the expectations of test method choices.

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.

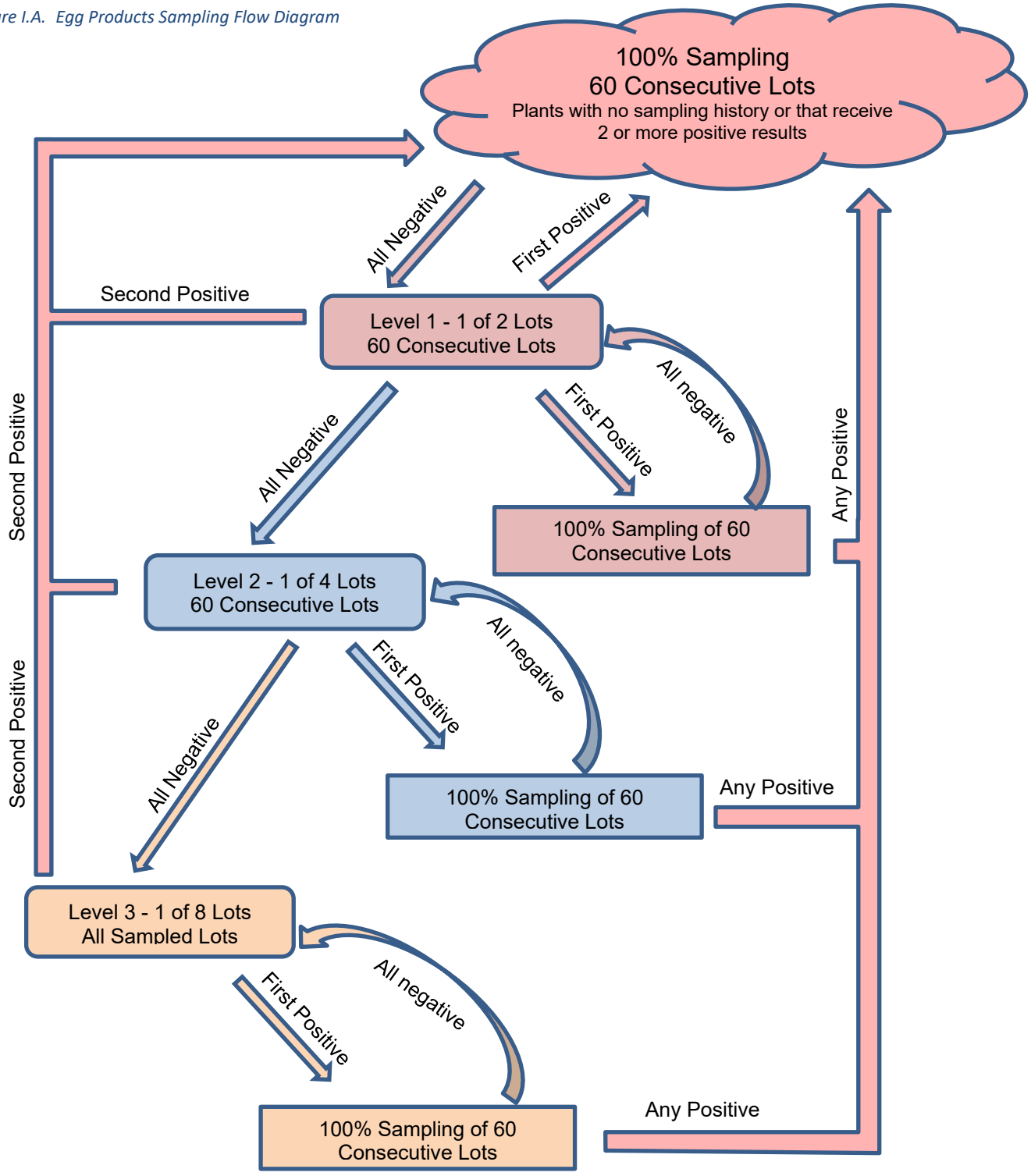
3. If 2 lots within the same category are found to be *Salmonella* spp. positive within a 12-month period, the plant must return to the 100 percent sampling level for that category. Once 60 consecutive lots are *Salmonella* spp. free, the plant must then satisfy the requirements for both Level 1 and Level 2 before moving to Level 3.

Required Records

The egg products inspection regulations require a plant to maintain records for each lot of product produced. Records must be maintained for at least 1 year for refrigerated products and 2 years for frozen, preserved, or shelf-stable productsand must be available to FSIS program employees upon request. Records must contain the following information:

- Type of product, category, and lot number of each product lot;
- Number, net weight, and type of containers in each lot, (e.g., 125 30-pound can; 250 30-pound cases (6 5-pound cartons));
- For each lot sampled, the lot number, date sampled, number of samples collected, 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;
- Individual sample results; and the
- Name and location of the recognized laboratory performing the analyses.

Figure I.A. Egg Products Sampling Flow Diagram



NOTE: Plants without a sampling history or plants producing a new product category begin sampling at the 100% sampling frequency.

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

Appendix II: New Technology Pasteurization and Freezing Time and Temperature Tables

Under the former regulations, plants had submitted protocols to implement alternate procedures and waive the prescriptive regulatory requirement. The protocols from those waivers and NOLs have been incorporated in the tables below as additional options for plants to use as safe harbors. The following tables include various product formulations for egg whites, whole egg, egg yolk, and enzyme modified egg products and their respective approved pasteurization time and temperature parameters, as well as alternate freezing parameters.

Table II.A. Acceptable 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 (11-13% Solids)	Pasteurization Temperature / Time
Egg Whites 99.96%; Anti-foam 0.04%	135°F / 3.5 min
Egg Whites 99.7-99.9%; Non-Egg Ingredients 0.1-0.3% (e.g., Solvent; Thickener, Stabilizer)	134°F / 3.5 min or 126°F / 3.6 min, with hydrogen peroxide
Egg Whites 99.3-99.4%; Non-Egg Ingredients 0.6-0.7% (e.g., Emulsifier; Defoamer; Flavor; Vitamin)	135°F / 3.5 min

Table II.B. Acceptable 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 or Yolk with Added Egg Whites or Other Ingredients*

Liquid Whole Egg / Yolk with Added Egg Whites or Other Ingredients (14-22% Egg Solids)	Pasteurization Temperature / Time
Whole Egg 16%; Egg Whites 64.4%; Water 16.5%; Non-Fat Dairy 2%; Other Non-Egg Ingredients <1.1% (e.g., Thickener/Stabilizer, Preservative; pH Buffer; Colorant)	149°F / 3.5 min
Whole Egg 46-53%; Egg Whites 47-53%	140°F / 3.5 min
Whole Egg 21-77%; Egg Whites 3.7-77.4%; Water 0-12.14%; Other Non-Egg Ingredients <1-5.13 (e.g., Thickener/Stabilizer; Solvent; pH Buffer/Preservative; Dairy; Salt; Colorant; Lipid, Vitamin/Colorant)	142°F to 144°F / 3.5 min
Whole Egg 78-95%; Egg Whites 0-2.58%; Water 0-18%; Non-Egg Ingredients 3-4% (e.g., Non-Fat Dairy; pH Buffer/Preservative; Salt; Solvent; Thickener/Stabilizer; Vitamin)	149°F / 2.5 minutes
Whole Egg 78-80%; Water 19-21%; Non-Egg Ingredients 0.56-0.85% (e.g., Salt; Thickener/Stabilizer; Solvent; pH Buffer/Preservative; Colorant, Flavor)	142°F / 3.5 min
Egg Yolk 19-20%; Egg Whites 79-81%	140°F / 3.5 min

Table II.C. Acceptable 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 Formulations (23-28% Solids)	Pasteurization Temperature / Time
Pasteurized Whole Egg 66.54%; Sugar 32.66%; Other Non-Egg Ingredients 0.8% (e.g., Thickener/Stabilizer; Solvent/Preservative/Sweetener; pH Buffer; Binder)	Re-Pasteurize at 155°F for 4 minutes
Whole Egg 67-69%; Egg Whites 11-27%; Water 0-19%; Other Non-Egg Ingredients 0.5-6% (e.g., Lipid; Thickener/Stabilizer; Emulsifier; Dairy; Salt; pH Buffer; Preservative; Stabilizer; Flavor)	144°F / 3.5 minutes
Whole Egg 94-99%; Non-Egg Ingredients 1-6% (e.g., Water; Non-Fat Dairy; pH Buffer/Preservative; Thickener/Stabilizer; Emulsifier; pH Buffer/Stabilizer; Vitamin)	144°F to 149°F / 3.5 minutes

Table II.D. Acceptable 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 (43-47% Egg Solids)	Pasteurization Temperature / Time
Egg Yolk 99.95%; Enzyme 0.05%	152°F / 3.5 minutes
Egg Yolk 99.67%; Peroxide 0.22%; Glucose Oxidase 0.11%	142°F/3.5 minutes for liquid, 157°F / 2 hours in hot room
Egg Yolk 95-99.99%; Non-Egg Ingredients 0-5% (e.g., Salt, Binder; Enzyme)	134.6°F / minimum of 5 hours; not to exceed 24 hours
Egg Yolk 93-99.5%; Salt 2.5-4.1%; Non-Egg Ingredients 2% (e.g., Thickener/Stabilizer, Enzyme)	151°F to 152°F / 3.5 minutes
Egg Yolk 90.83%; Salt 2.5%; Other Non-Egg Ingredients 2% (e.g., Sweetener/Thickener; Enzyme)	149F°/ 3.5 minutes
Egg Yolk 89.95%; Salt 10%; Enzyme 0.05%	150°F / 3.5 minutes
Pasteurized Whole Egg 73-74%; Non-Egg Ingredients 26-27% (Thickener/Emulsifier; Binder; Salt; Water) *This product is only 38% solids due to the difference between egg product and the replacement solids	Re-Pasteurize at 148°F / 3.5 minutes
Egg Yolk 80%; Salt or Sugar 20%	146°F / 3.5 minutes or 144°F / 6.2 minutes

Table II.E. Acceptable Safe Harbor Pasteurization 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 / 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 II.F. Acceptable Safe Harbor Time and Temperature Combinations for Freezing Derived from New Technology Waivers That Can Be Used for All Liquid Egg Products

Method	Time / 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 more than 36 hours
Freezing	Extends the freezing requirement of 60 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

Appendix III: Pasteurization Time and Temperature Tables

To provide additional safe harbors for the pasteurization of egg products, FSIS calculated time and temperature combinations to achieve a specific log reduction in egg whites at four different pH, five different whole egg formulations, and five different egg yolk formulations.

Table III.A. Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella *spp. That Can Be Used for Various Liquid Egg Whites to Obtain a 5.7-log$_{10}$ Lethality*

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 minutes
128.0	**53.3**	---	---	---	31.26 minutes
128.5	**53.6**	---	---	---	26.81 minutes
129.0	**53.9**	---	---	---	23.00 minutes
129.5	**54.2**	---	---	---	19.72 minutes
130.0	**54.4**	---	---	38.32 minutes	16.92 minutes
130.5	**54.7**	---	---	33.27 minutes	14.91 minutes
131.0	**55.0**	---	36.70 minutes	28.72 minutes	12.45 minutes
131.5	**55.3**	---	31.07 minutes	24.62 minutes	10.68 minutes
132.0	**55.6**	32.16 minutes	26.12 minutes	20.95 minutes	9.16 minutes
132.5	**55.8**	27.02 minutes	21.80 minutes	17.69 minutes	7.85 minutes
133.0	**56.1**	22.56 minutes	18.08 minutes	14.82 minutes	6.74 minutes
133.5	**56.4**	18.71 minutes	14.88 minutes	12.33 minutes	5.78 minutes
134.0	**56.7**	15.43 minutes	12.18 minutes	10.19 minutes	4.96 minutes
134.5	**56.9**	12.64 minutes	9.90 minutes	8.36 minutes	4.25 minutes
135.0	**57.2**	10.30 minutes	8.00 minutes	6.81 minutes	3.65 minutes
135.5	**57.5**	7.11 minutes	6.42 minutes	5.52 minutes	3.13 minutes
136.0	**57.8**	5.65 minutes	5.13 minutes	4.44 minutes	2.68 minutes
136.5	**58.1**	4.47 minutes	4.08 minutes	3.56 minutes	2.30 minutes
137.0	**58.3**	3.51 minutes	3.22 minutes	2.83 minutes	1.98 minutes
137.5	**58.6**	2.75 minutes	2.54 minutes	2.24 minutes	1.69 minutes
138.0	**58.9**	2.15 minutes	1.99 minutes	1.77 minutes	87 seconds
138.5	**59.2**	1.67 minutes	93 seconds	84 seconds	75 seconds
139.0	**59.4**	78 seconds	72 seconds	65 seconds	65 seconds
139.5	**59.7**	60 seconds	56 seconds	51 seconds	56 seconds
140.0	**60.0**	47 seconds	44 seconds	39 seconds	48 seconds
140.5	**60.3**	36 seconds	33 seconds	31 seconds	41 seconds
141.0	**60.6**	27 seconds	26 seconds	24 seconds	35 seconds
141.5	**60.8**	21 seconds	20 seconds	18 seconds	30 seconds
142.0	**61.1**	---	---	---	26 seconds
142.5	**61.4**	---	---	---	23 seconds
143.0	**61.7**	---	---	---	19 seconds
143.5	**61.9**	---	---	---	17 seconds
144.0	**62.2**	---	---	---	14 seconds
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 III.B. Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella *spp. That Can Be Used for Various Liquid Whole Egg to Obtain 6.0-log$_{10}$ Lethality*

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Plain Whole Egg	Scrambled Egg Mix USDA (30.27% Solids)[1]	Scrambled Egg Mix USDA (22.43% Solids)[2]	Comments		Degrees Fahrenheit (°F)	Degrees Celsius (°C)	10% Salt Whole Egg	10% Sugar Whole Egg
133.0	56.1	---	---	29.42 minutes			136.0	57.8	---	26.43 minutes
133.5	56.4	---	---	25.04 minutes			136.5	58.1	---	21.13 minutes
134.0	56.7	---	13.91 minutes	21.32 minutes	**1 Scrambled Egg Mix USDA (30.27% Solids) Ingredients:** Whole egg – 24.2% solids; nonfat dry milk – 95% solid; vegetable oil, salt, and water		137.0	58.3	---	16.99 minutes
134.5	56.9	---	12.45 minutes	18.15 minutes			137.5	58.6	---	13.74 minutes
135.0	57.2	28.82 minutes	11.15 minutes	15.47 minutes			138.0	58.9	---	11.18 minutes
135.5	57.5	25.22 minutes	10.00 minutes	13.18 minutes			138.5	59.2	---	9.15 minutes
136.0	57.8	22.07 minutes	8.97 minutes	11.23 minutes			139.0	59.4	---	7.53 minutes
136.5	58.1	19.32 minutes	8.05 minutes	9.58 minutes			139.5	59.7	---	6.23 minutes
137.0	58.3	16.91 minutes	7.23 minutes	8.17 minutes			140.0	60.0	---	5.18 minutes
137.5	58.6	14.80 minutes	6.50 minutes	6.98 minutes			140.5	60.3	---	4.33 minutes
138.0	58.9	12.95 minutes	5.84 minutes	5.96 minutes			141.0	60.6	25.67 minutes	3.64 minutes
138.5	59.2	11.34 minutes	5.26 minutes	5.09 minutes			141.5	60.8	19.06 minutes	3.07 minutes
139.0	59.4	9.92 minutes	4.73 minutes	4.35 minutes			142.0	61.1	14.64 minutes	2.60 minutes
139.5	59.7	8.69 minutes	4.26 minutes	3.72 minutes	**2 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		142.5	61.4	11.56 minutes	2.22 minutes
140.0	60.0	7.60 minutes	3.84 minutes	3.18 minutes			143.0	61.7	9.34 minutes	1.90 minutes
140.5	60.3	6.65 minutes	3.46 minutes	2.73 minutes			143.5	61.9	7.69 minutes	1.63 minutes
141.0	60.6	5.82 minutes	3.12 minutes	2.34 minutes			144.0	62.2	6.43 minutes	85 seconds
141.5	60.8	5.10 minutes	2.82 minutes	2.00 minutes			144.5	62.5	5.44 minutes	74 seconds
142.0	61.1	4.46 minutes	2.55 minutes	1.72 minutes			145.0	62.8	4.65 minutes	65 seconds
142.5	61.4	3.90 minutes	2.30 minutes	89 seconds			145.5	63.1	4.01 minutes	56 seconds
143.0	61.7	3.42 minutes	2.08 minutes	77 seconds			146.0	63.3	3.49 minutes	50 seconds
143.5	61.9	2.99 minutes	1.88 minutes	66 seconds			146.5	63.6	3.05 minutes	44 seconds
144.0	62.2	2.62 minutes	1.70 minutes	57 seconds			147.0	63.9	2.67 minutes	39 seconds
144.5	62.5	2.29 minutes	93 seconds	49 seconds			147.5	64.2	2.36 minutes	35 seconds
145.0	62.8	2.01 minutes	84 seconds	42 seconds			148.0	64.4	2.08 minutes	30 seconds
145.5	63.1	1.76 minutes	76 seconds	36 seconds			148.5	64.7	1.84 minutes	27 seconds
146.0	63.3	93 seconds	69 seconds	32 seconds			149.0	65.0	1.63 minutes	24 seconds
146.5	63.6	81 seconds	62 seconds	27 seconds			149.5	65.3	87 seconds	22 seconds
147.0	63.9	71 seconds	57 seconds	24 seconds	**--- No applicable time and temperature combination to meet desired lethality performance for whole egg products**		150.0	65.6	78 seconds	20 seconds
147.5	64.2	62 seconds	51 seconds	21 seconds			150.5	65.8	69 seconds	18 seconds
148.0	64.4	54 seconds	47 seconds	18 seconds			151.0	66.1	62 seconds	17 seconds
148.5	64.7	48 seconds	42 seconds	16 seconds			151.5	66.4	55 seconds	---
149.0	65.0	42 seconds	38 seconds	---			152.0	66.7	49 seconds	---
149.5	65.3	36 seconds	35 seconds	---			152.5	66.9	44 seconds	---
150.0	65.6	32 seconds	32 seconds	---			153.0	67.2	39 seconds	---
150.5	65.8	28 seconds	29 seconds	---			153.5	67.5	35 seconds	---
151.0	66.1	25 seconds	26 seconds	---			154.0	67.8	31 seconds	---
151.5	66.4	21 seconds	24 seconds	---			154.5	68.1	27 seconds	---
152.0	66.7	19 seconds	22 seconds	---			155.0	68.3	24 seconds	---
152.5	66.9	17 seconds	20 seconds	---			155.5	68.6	22 seconds	---
153.0	67.2	---	18 seconds	---			156.0	68.9	20 seconds	---
							156.5	69.2	18 seconds	---
							157.0	69.4	16 seconds	---
							157.5	69.7	15 seconds	---
							158.0	70.0	13 seconds	---

Table III.C. Time and Temperature Combinations for Achieving Minimal Lethality Performance for Salmonella *spp. That Can Be Used for Various Liquid Egg Yolk to Obtain a 6.2-log10 Lethality*

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Plain Egg Yolk	10% Salt Egg Yolk	10% Sugar Egg Yolk
138.0	**58.9**	---	---	22.77 minutes
138.5	**59.2**	---	---	18.57 minutes
139.0	**59.4**	17.81 minutes	---	15.24 minutes
139.5	**59.7**	16.31 minutes	---	12.57 minutes
140.0	**60.0**	14.93 minutes	20.62 minutes	10.43 minutes
140.5	**60.3**	13.66 minutes	17.87 minutes	8.70 minutes
141.0	**60.6**	12.51 minutes	15.53 minutes	7.29 minutes
141.5	**60.8**	11.45 minutes	13.53 minutes	6.14 minutes
142.0	**61.1**	10.48 minutes	11.81 minutes	5.20 minutes
142.5	**61.4**	9.60 minutes	10.34 minutes	4.41 minutes
143.0	**61.7**	8.78 minutes	9.07 minutes	3.77 minutes
143.5	**61.9**	8.04 minutes	7.97 minutes	3.23 minutes
144.0	**62.2**	7.36 minutes	7.02 minutes	2.78 minutes
144.5	**62.5**	6.74 minutes	6.19 minutes	2.40 minutes
145.0	**62.8**	6.17 minutes	5.47 minutes	2.08 minutes
145.5	**63.1**	5.65 minutes	4.84 minutes	1.81 minutes
146.0	**63.3**	5.17 minutes	4.29 minutes	95 seconds
146.5	**63.6**	4.73 minutes	3.81 minutes	83 seconds
147.0	**63.9**	4.33 minutes	3.39 minutes	74 seconds
147.5	**64.2**	3.96 minutes	3.01 minutes	65 seconds
148.0	**64.4**	3.63 minutes	2.69 minutes	57 seconds
148.5	**64.7**	3.32 minutes	2.40 minutes	51 seconds
149.0	**65.0**	3.04 minutes	2.14 minutes	46 seconds
149.5	**65.3**	2.78 minutes	1.91 minutes	41 seconds
150.0	**65.6**	2.55 minutes	1.71 minutes	37 seconds
150.5	**65.8**	2.33 minutes	93 seconds	33 seconds
151.0	**66.1**	2.14 minutes	83 seconds	30 seconds
151.5	**66.4**	1.95 minutes	75 seconds	28 seconds
152.0	**66.7**	1.79 minutes	67 seconds	26 seconds
152.5	**66.9**	1.64 minutes	60 seconds	24 seconds
153.0	**67.2**	90 seconds	54 seconds	22 seconds
153.5	**67.5**	83 seconds	49 seconds	21 seconds
154.0	**67.8**	76 seconds	44 seconds	19 seconds
154.5	**68.1**	69 seconds	40 seconds	18 seconds
155.0	**68.3**	63 seconds	36 seconds	17 seconds
155.5	**68.6**	58 seconds	33 seconds	16 seconds
156.0	**68.9**	53 seconds	29 seconds	16 seconds
156.5	**69.2**	49 seconds	27 seconds	---
157.0	**69.4**	45 seconds	24 seconds	---
157.5	**69.7**	41 seconds	22 seconds	---
158.0	**70.0**	38 seconds	20 seconds	---
158.5	**70.3**	35 seconds	18 seconds	---
159.0	**70.6**	32 seconds	17 seconds	---
159.5	**70.8**	29 seconds	15 seconds	---
160.0	**71.1**	27 seconds	14 seconds	---
160.5	**71.4**	24 seconds	---	---

Degrees Fahrenheit (°F)	Degrees Celsius (°C)	Fortified Egg Yolk "Tex" (48.84% Solids)[1]	Fortified Egg Yolk "Tex" (32.49% Solids)[2]	Comments
132.5	**55.8**	---	25.56 minutes	
133.0	**56.1**	---	22.74 minutes	
133.5	**56.4**	---	20.07 minutes	**1 Fortified Egg Yolk "Tex" (48.84% Solids) Ingredients:** Egg yolk – 43% solid; 80% solid corn syrup, salt, and water
134.0	**56.7**	---	17.71 minutes	
134.5	**56.9**	---	15.63 minutes	
135.0	**57.2**	---	13.79 minutes	
135.5	**57.5**	---	12.17 minutes	
136.0	**57.8**	---	10.74 minutes	
136.5	**58.1**	---	9.48 minutes	
137.0	**58.3**	---	8.37 minutes	2 **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
137.5	**58.6**	---	7.39 minutes	
138.0	**58.9**	---	6.53 minutes	
138.5	**59.2**	---	5.76 minutes	
139.0	**59.4**	---	5.09 minutes	
139.5	**59.7**	---	4.49 minutes	
140.0	**60.0**	23.66 minutes	3.97 minutes	
140.5	**60.3**	20.48 minutes	3.51 minutes	
141.0	**60.6**	17.73 minutes	3.10 minutes	
141.5	**60.8**	15.35 minutes	2.73 minutes	**--- No existing time and temperature combination to meet desired lethality performance standard for egg yolk products**
142.0	**61.1**	13.28 minutes	2.42 minutes	
142.5	**61.4**	11.50 minutes	2.13 minutes	
143.0	**61.7**	9.95 minutes	1.89 minutes	
143.5	**61.9**	8.61 minutes	1.67 minutes	
144.0	**62.2**	7.46 minutes	89 seconds	
144.5	**62.5**	6.45 minutes	78 seconds	
145.0	**62.8**	5.59 minutes	69 seconds	
145.5	**63.1**	4.84 minutes	62 seconds	
146.0	**63.3**	4.19 minutes	54 seconds	
146.5	**63.6**	3.62 minutes	48 seconds	
147.0	**63.9**	3.14 minutes	42 seconds	
147.5	**64.2**	2.71 minutes	38 seconds	
148.0	**64.4**	2.35 minutes	33 seconds	
148.5	**64.7**	2.03 minutes	30 seconds	
149.0	**65.0**	1.76 minutes	26 seconds	
149.5	**65.3**	92 seconds	23 seconds	
150.0	**65.6**	80 seconds	21 seconds	
150.5	**65.8**	69 seconds	18 seconds	
151.0	**66.1**	60 seconds	16 seconds	
151.5	**66.4**	52 seconds	---	
152.0	**66.7**	45 seconds	---	
152.5	**66.9**	39 seconds	---	
153.0	**67.2**	33 seconds	---	
153.5	**67.5**	29 seconds	---	
154.0	**67.8**	26 seconds	---	
154.5	**68.1**	22 seconds	---	
155.0	**68.3**	19 seconds	---	
155.5	**68.6**	17 seconds	---	
156.0	**68.9**	14 seconds	---	

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