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Centers for Epidemiology
and Animal Health

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An Assessment of the Risk Associated with the Movement of Pasteurized Liquid Egg and Its Products Into, Within, and Outside of a Control Area during a Highly Pathogenic Avian Influenza Outbreak

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Collaboration between the Egg Sector Working Group, the University of Minnesota's Center for Animal Health and Food Safety, and USDA:APHIS:VS:CEAH.

Safeguarding Animal Health

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1 Abbreviations and Definitions

AHPA	Animal Health Protection Act
APHIS	Animal and Plant Health Inspection Service
AI	Avian Influenza
CADIA	Center for Animal Disease Information and Analysis
CEAH	Centers for Epidemiology and Animal Health
CFR	Code of Federal Regulations
GMP	Good Manufacturing Practices
FDA	Food and Drug Administration
FSIS	Food Safety Inspection Service
HA	Haemagglutinin
HACCP	Hazard Analysis and Critical Control Points
HPAI	Highly pathogenic avian influenza
HPNAI	Highly pathogenic notifiable avian influenza
LE	Liquid egg
LPAI	Low pathogenic avian influenza
NA	Neuraminidase
NAHEMS	National Animal Health Emergency Management System
OIE	World Organization for Animal Health, Office International des Epizooties
PLE	Pasteurized Liquid Egg
RT-PCR	Reverse Transcription Polymerase Chain Reaction
U.S.	United States of America
USDA	United States Department of Agriculture
VS	Veterinary Services

Buffer Surveillance Zone

The zone immediately surrounding the infected zone is the buffer surveillance zone. The buffer surveillance zone and the infected zone comprise the control area.

Continuous Inspection

Continuous inspection requires that the FSIS inspector be on the egg products processing premises whenever pasteurization equipment is operating.

Control Area

A control area, consisting of an infected zone and a buffer surveillance zone, will be established to ensure the rapid and effective containment of the disease.

Initially, the entire State, Commonwealth, Tribal Nation, or territory may be declared a control area and subject to movement restrictions until appropriate surveillance and epidemiological evidence has been evaluated and the extent of the outbreak is known. All susceptible bird and other livestock movement will be stopped for a period long enough to determine the scope of the disease outbreak. The potential modes of transmission of HPAI will be considered when determining the minimum size and shape of a control area. Movement control through the use of permits should be maintained until the disease is eradicated.

Egg

The shell egg of the domesticated chicken. Shell eggs of turkeys, ducks, geese, and guineas are outside the scope of this assessment.

Infected Zone

In an outbreak of HPAI, the infected zone initially will encompass the perimeter of all presumptive or confirmed positive premises and include as many of the contact premises as the situation requires logistically or scientifically. The boundary of the infected zone initially should be at least 2 miles (3 kilometers) beyond the perimeters of the presumptive or confirmed infected premises. The boundaries may be modified (either expanded or reduced) by Incident Command as new information becomes available. The actual distance in any one direction is determined by factors such as known characteristics of the virus, environmental conditions (terrain, weather, wind), the pattern of animal density and movements, the distribution and movements of susceptible wild and feral livestock, processing activities (livestock and products), and the effect on nonrisk commodities. Boundaries of the infected zone can be modified when tracing and surveillance results become available and other listed factors become better defined.

Movement Permit

A VS Form 1-27, a State-issued permit, or a letter – customized to the applicant's situation – generated by the Permit Team and issued at the discretion of Incident Command to allow the movement of pasteurized liquid egg or its product from a premises or a geographic area described in a quarantine order.

Negligible Risk

For this risk analysis, the term "negligible risk" means there is a very low likelihood that moving pasteurized liquid egg products will cause infection in another premises. The specific magnitude cannot be determined, as there is no evidence that these products have ever served as a transmission pathway. In quantitative terms, this is defined as a likelihood of less than 1/1,000,000 that moving these products will result in infection in another premises. This particular likelihood is used to be consistent with other common meanings for the term, as discussed in Appendix 13. The determination of "negligible risk" suggests that allocating additional resources to mitigate this risk may not be a cost-effective use of resources (depending on circumstances).

Pasteurize

The process of subjecting each particle of egg product to heat in order to destroy harmful viable microorganisms, including highly pathogenic avian influenza virus.

Pasteurized Liquid Egg Product

Any pasteurized liquid egg product, with or without added ingredients. The addition of ingredients to liquid egg after pasteurization is outside of the scope for this assessment.

2 Executive Summary

This document assesses the risk that the movement of pasteurized liquid egg and its products during a highly pathogenic avian influenza (HPAI) outbreak in the poultry egg industry in the United States will result in HPAI infection in another poultry premises. This assessment includes movement into, within, and outside of pasteurization facilities that are under continuous FSIS inspection.

This risk assessment is a joint effort between the Egg Products Industry working group, the University of Minnesota's Center for Animal Health and Food Safety, and USDA-APHIS-VS-CEAH to support permits for moving pasteurized liquid egg and associated products safely and in a timely fashion during an outbreak.

This risk assessment is intended to identify potential pathways associated with the movement of pasteurized liquid egg and its products, and assess their corresponding likelihoods of carrying the virus off of an infected premises and then causing infection in another poultry premises despite all current and future preventive measures in place during an outbreak. This risk assessment will ultimately provide the framework necessary for decision makers to:

- Quickly assess the effectiveness of preventive measures as they pertain specifically to the pasteurization, handling, and movement of pasteurized liquid egg and its products.
- Consider implementing a permit system, which would allow uninfected egg pasteurization facilities that are under continuous FSIS inspection to move pasteurized liquid egg and its products into, within, and outside of the control area during a HPAI outbreak.

To address this objective, we have identified three major risk nodes: (1) pasteurization process, (2) handling of pasteurized liquid egg and its products, and (3) movement of pasteurized liquid egg and its products. In particular, this document assesses:

- The likelihood that HPAI virus would be present in liquid egg and its products after pasteurization.
- The likelihood that the holding tank(s), packaging, facilities, and operations would fail to prevent contamination of already pasteurized liquid egg and its products with HPAI virus.
- The likelihood that the movement of commercial vehicles carrying pasteurized liquid egg and its products would mechanically transmit HPAI virus outside of the control area and cause infection in another poultry production premises.

This document is as an evolving product-specific risk assessment that will be reviewed and updated as necessary before and during an outbreak to incorporate the latest scientific information and preventive measures. If the Incident Command System is activated in response to a HPAI outbreak, APHIS (and incident command staff) will review this risk assessment with respect to the situation in order to assess industry requests for movement of these products.

Overall Finding and Conclusion

The risk that movement of pasteurized liquid egg and its products into, within, and outside of a control area during a highly pathogenic avian influenza outbreak would cause an HPAI outbreak in another poultry production premises in the United States is *negligible*.

Unless major failures or significant deviations occur in the process of pasteurization described below, this document concludes that the likelihood that HPAI virus would be present in liquid egg and/or its products after pasteurization is negligible. Similarly, our analysis concludes that the risk associated with HPAI virus being re-introduced to already pasteurized, virus-free liquid egg through the holding tank(s), packaging materials and premises environments is negligible. Lastly, if movement controls and all other recommended preventive and biosecurity measures described below are strictly followed, the likelihood that the movement of commercial vehicles carrying pasteurized liquid egg and/or its products would mechanically transmit HPAI virus and cause an HPAI outbreak in another poultry production premises is negligible.

3 Introduction

In the event of a highly pathogenic avian influenza (HPAI) outbreak in the U.S. poultry industry, local, State, and Federal authorities will implement a foreign animal disease emergency response. This response consists of a control and eradication strategy that will utilize quarantine and movement control measures to prevent further spread of HPAI virus (59). In addition to compliance with such measures, State and/or Federal authorities will also issue official permits to allow movement of birds and their products from premises identified in a quarantine order during an outbreak. A request for a movement permit must be supported by a risk assessment (or some scientifically based logical argument) to demonstrate that the risk associated with the movement of the product in question is acceptable[a].

Completing these types of risk assessments in a timely manner during an outbreak can be challenging. Risk assessments can take more time to conduct than the shelf life of some of the perishable ingredients or products that need to be moved. For these products, the risk may be evaluated before an outbreak occurs. Pasteurized liquid egg is one such product.

This document assesses the risk associated with the movement of pasteurized liquid egg and its products into, within, and outside of a control area during a HPAI outbreak. It takes into consideration all applicable regulations, existing preventive measures already in place[b], as well as all additional preventive measures that will be put in place during an outbreak.

The risk analytic approach of this risk assessment is to: (1) identify all possible pathways associated with the movement of pasteurized liquid egg and its products, and (2) assess their corresponding likelihoods of carrying the virus despite all current and future preventive measures that will be in place during an outbreak.

This risk assessment does not guarantee that movement will be permitted during a HPAI outbreak. Rather, it provides the framework necessary for decision makers to assess the effectiveness of the preventive measures as they pertain specifically to the pasteurization, handling, and movement of pasteurized liquid egg and its products. This risk assessment allows decision makers to consider implementing additional control measures that may permit egg pasteurization facilities that are not known to be infected with HPAI virus and under continuous FSIS inspection to move pasteurized liquid egg and its products into, within, and outside of the control area during a HPAI outbreak.

4 Scope

[a] During an outbreak, APHIS conducts numerous product-specific risk assessments taking into consideration all permit requirements and preventive measures currently in place.

[b] Normal day-to-day operations and preventive measures are in place via Good Manufacturing Practices (GMP), State regulations and Federal regulations as required by FSIS, FDA, and APHIS.

This assessment is applicable to FSIS-inspected pasteurized liquid egg processing facilities that may or may not have laying hens on-site and may or may not accept eggs from other egg producers.

This assessment is not intended to be a regulatory review of the effectiveness of FSIS and FDA programs. We did not directly evaluate their utility, but did review information related to other HPAI outbreaks and any potential connections to pasteurized liquid egg.

5 Significant Assumptions Used in the Risk Assessment

This assessment is proactive in nature and cannot address the specific circumstances surrounding an outbreak in detail. Therefore, we are making some assumptions to establish context and applicability. These assumptions are:

- That an HPAI outbreak has been detected, APHIS is implementing the HPAI Response Plan, and some degree of planning has taken place at other levels. The APHIS HPAI Response Plan is intended to complement regional, State, and industry plans and APHIS recommends their continued development.
- Pasteurized liquid egg production facilities may have HPAI infection in their laying flocks but it has not yet been detected. If it was known with absolute certainty that HPAI infection was not present there would be no risk. Conversely, if HPAI infection has been detected, it is assumed that Incident Command would shut down the production premises, movement of product would not be allowed, and any associated laying facilities would be depopulated. This situation also does not pose a risk, as the premises would cease production.
- Pasteurized liquid egg production facilities do not deliver their products to other poultry production facilities. Pasteurized liquid egg is assumed to be delivered to food processors or commercial food establishments.
- The assessment is applicable to most (*but not all*) of the situations that may arise during an outbreak. As discussed in the movement section, permits to move liquid pasteurized egg may be issued for movement to slaughter/processing or for movement under conditions described on a movement permit. These conditions depend on the circumstances and they cannot be known in advance. Therefore, the risk will depend on the circumstances and this assessment can only provide information and cannot make recommendations.
- FSIS regulations and inspection activities are effective in preventing pathogens from coming into contact with pasteurized liquid egg. A review of FSIS recalls from 2003 to 2008 did not show any recalls related to liquid pasteurized egg (69). An earlier study of meat and poultry recalls did not show any instances where egg products were the subject of a recall (54). We assume that these measures will mitigate the risks, as described below.

6 Highly Pathogenic Avian Influenza Overview

6.1 Definition of Highly Pathogenic Notifiable Avian Influenza

HPAI is defined[c] in the Code of Federal Regulations, Title 9, Part 53, Section 53.1 as:

- Any influenza virus that kills at least 75 percent of eight 4- to 6- week old susceptible chickens within ten days following intravenous inoculation with 0.2 ml of a 1:10 dilution of a bacteria-free, infectious allantoic fluid.
- Any H5 or H7 virus that does not meet the criteria in paragraph (1) of this definition, but has an amino acid sequence at the hemagglutinin cleavage site that is compatible with highly pathogenic avian influenza viruses.[d]
- Any influenza virus that is not a H5 or H7 subtype and that kills one to five chickens and grows in cell culture in the absence of trypsin (56).

6.2 Agent and Host Range

Avian influenza (AI) virus is a heat labile, single-stranded RNA virus of the *Orthomyxoviridae* family (14;18;37;49;51). There are three antigenically distinct types of influenza viruses within the *Orthomyxoviridae* family: types A, B, and C. Types B and C are typically found only in humans. Influenza A viruses include all AI viruses and can infect a wide variety of animals including birds, pigs, horses, marine mammals, and humans.

The two surface glycoproteins of the influenza virus, haemagglutinin (HA) and neuraminidase (NA), are the most important antigenic sites for the production of protective immunity in the host; however, these proteins also have the greatest variation (14;18;37;49;51). With regard to influenza A viruses, there are sixteen different subtypes of HA (H1 to H16) and nine different subtypes of NA (N1 to N9) (78).

Although a few viruses of relatively few subtype combinations have been isolated from mammalian species, all subtypes, in the majority of combinations have been isolated from avian species (1;2;14;49;51). While all bird species are thought to be susceptible to AI, some are more susceptible than others. Most infections with AI viruses are subclinical or induce mild disease syndromes, consisting primarily of respiratory disease (2;25;51). These viruses are designated as low pathogenic avian influenza (LPAI). A few isolates of H5 and H7 subtypes are very virulent and induce severe disease with morbidity and mortality rates reaching 100 percent (2;14;49). These viruses are termed HPAI.

All H5 or H7 isolates of both low and high pathogenicity and all HPAI isolates regardless of subtype are reportable to state and national veterinary authorities and to the OIE (9). Although other LPAI viruses may cause significant morbidity and production losses, they are not considered to be reportable diseases.

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[c] While there are other avian influenza types that are notifiable to OIE, we are using this definition to maintain consistency with the APHIS HPAI Response Plan.

[d] The probability of not causing mortality is 4% (There have been 24 HPAI outbreaks since 1959 and only one was categorized as HPAI based solely on molecular criteria).

There are many examples of H5 and H7 virus isolates that are not pathogenic, so antigenic configuration alone does not determine pathogenicity (14). Migratory waterfowl have yielded more influenza viruses than any other group, while turkeys and chickens have experienced the most substantial disease problems (14;18).

6.3 Geographic Distribution of H5N1 HPAI

Since 2003, 60 countries have reported H5N1 HPAI in domestic poultry and wildlife[e] (83).

6.4 Resistance to Chemical and Physical Agents

AI viruses are relatively sensitive to inactivation by lipid solvents such as detergents (14). The viruses are easily inactivated by physical agents such as heat, extremes of pH, nonisotonic conditions, and dryness;[f] however, their infectivity can be maintained for several weeks at 4º C. Formalin and beta-propiolactone can be used to eliminate the infectivity of the viruses while preserving hemagglutinating and neuraminidase activity. AI virus can survive for several days in the albumen and yolk of eggs stored at cool temperatures (10º to 18º C) (6).

Effective disinfectants against influenza A viruses include heat, sodium hypochlorite solution, formalin, or One-Stroke Environ (14). However, removal of organic material is required for effective decontamination as pathogenic influenza viruses can survive for long periods in cold and moist environments, such as in liquid manure. The virus has been demonstrated to survive in cold and moist environments (such as liquid manure) for up to 105 days after depopulation. Virus infectivity is retained in fecal matter for 30-35 days at 4º C and seven days at 20º C (59).

6.5 Transmission

Circumstantial evidence seems to support the hypothesis that exposure to migratory waterfowl, sea birds, or shore birds is a risk factor for introducing virus into domestic poultry populations (1;3;7;26). Since virus can be isolated in large quantities from feces and respiratory secretions of infected birds, an important mode of transmission is the mechanical transfer of infective feces (3;14). Once introduced into a flock, virus can be spread from flock to flock by direct movement of infected birds and indirect movement of contaminated equipment, egg flats, feed trucks, and service crews, or other means. Windborne transmission may occur when farms are closely situated and appropriate air movement exists (3).

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[e] List current as of July 2, 2007: Afghanistan, Albania, Austria, Azerbaijan, Bangladesh, Bosnia and Herzegovina, Bulgaria, Burkina Faso, Cambodia, Cameroon, China, Cote d'Ivorie, Croatia, Czech Republic, Denmark, Djibouti, Egypt, France, Georgia, Germany, Ghana, Greece, Hong Kong (SARPRC), Hungary, India, Indonesia, Iraq, Iran, Israel, Italy, Japan, Jordan, Kazakhstan, Korea (Republic of), Kuwait, Laos, Malaysia, Mongolia, Myanmar, Niger, Nigeria, Pakistan, Palestinian Autonomous Territories, Poland, Romania, Russia, Saudi Arabia, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sudan, Sweden, Switzerland, Thailand, Togo, Turkey, Ukraine, United Kingdom, and Vietnam.

[f] For example, it has been shown that measures intended to reduce *Salmonella* contamination/infection/transmission are just as effective (or more effective) for controlling AI viruses.

6.6 Incubation Period

The incubation period can range from three to seven days depending on the isolate, dose of inoculum, species, and age of the bird (10).

6.7 Clinical Signs

In birds, the clinical signs associated with HPAI include marked depression with ruffled feathers, lack of appetite, excessive thirst, decreased egg production, soft-shelled or misshapen eggs, respiratory signs (coughing and sneezing), and watery diarrhea. Mature chickens frequently have swollen, cyanotic combs, wattles, and edema surrounding the eyes. The mortality rate can reach 100%, often within 48 hours (10).

The presence or absence of symptoms and their severity caused by HPAI viruses depend on the type of bird species affected, in wild and domestic ducks they can be asymptomatic, whereas they are lethal in terrestrial birds (43).

6.8 Gross Lesions

In mature birds, gross lesions may consist of subcutaneous edema of the head and neck, fluid in the nares, oral cavity, and trachea, congested conjunctivae and kidneys, and petechial hemorrhages which cover the abdominal fat, serosal surfaces, peritoneum, and surface under the keel (10). In layers, the ovary may be hemorrhagic or degenerated and necrotic. The peritoneal cavity is frequently filled with yolk from ruptured ova, causing severe airsacculitis and peritonitis in birds that survive longer than seven days.

6.9 Diagnosis[g]

HPAI is a differential to be considered in any flock where marked depression, inappetence, and/or a drastic decline in egg production are followed by sudden deaths; however, a conclusive diagnosis is dependent on the isolation and identification of the virus (10). In the laboratory, nine to eleven day-old embryonated chicken eggs are inoculated with supernatant from swab or tissue specimens submitted in appropriate transport media (50). If a HPAI virus is the causative agent, the embryo will die within 48-72 hours; however, a small proportion will not die, depending on the virulence of the virus. If the virus isolated is identified as influenza Type A, its serologic identity (HA and NA type) is determined by hemagglutinin and neuraminidase inhibition testing with monospecific antisera. In the case of H5 or H7 subtypes, amnioalantoic fluid may be analyzed using the RRT-PCR[h] test. Pathogenicity is subsequently determined through inoculation studies or by verifying the presence of multiple basic amino acids at the hemagglutinin precursor protein (HA0) cleavage site in order to identify viruses that have the capacity to become highly pathogenic (see Section 2.1). H5 or H7 virus subtypes can often be identified in the clinical specimen by RRT-PCR and the amino acid sequence can be determined (in order to predict virulence) without isolating the virus in less than 24 hours (42).

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[g] For more information on diagnostic criteria, review the case definition in the National Avian Influenza Surveillance Plan, Part 1, Section H, page 24, at http://www.aphis.usda.gov/vs/nahss/poultry/index.htm.

[h] RRT-PCR: Real-Time Reverse Transcription-Polymerase Chain Reaction (11).

6.10 Laboratory Specimens

AI viruses can be isolated from tracheal, oronasal, or cloacal swabs (10). Sample collection should follow protocols shown in the USDA National HPAI Response Plan.(60). If large numbers of birds are to be sampled, swabs from up to five birds can be pooled in the same tube of brain and heart infusion broth (50). These specimens are then taken to USDA-approved laboratories (e.g., NAHLN or NAHLN-approved laboratories) where a RT-PCR test is run.

6.11 Differential Diagnosis

HPAI can resemble several other avian diseases including velogenic viscerotropic Newcastle disease, infectious bronchitis, infectious laryngotracheitis, mycoplasmosis, infectious coryza, fowl cholera, aspergillosis, and *Escherichia coli* infection (25). It also must be differentiated from heat exhaustion and severe water deprivation.

6.12 Control and Eradication

The overall goal for response to a highly contagious disease such as HPAI is to detect, control, and eradicate the agent as quickly as possible to return individual farms to normal production and the U.S. to disease free status. Control and eradication will rely on three basic principles: (59)

1. Preventing contact between birds and other susceptible livestock and HPAI virus.
2. Stopping the growth and spread of HPAI virus by infected birds and other livestock.
3. Increasing the disease resistance of birds and other susceptible livestock.

Likelihood that HPAI virus would be present in liquid egg after pasteurization

This portion of the risk assessment evaluates the likelihood that HPAI virus would be present in liquid egg after pasteurization. This risk assessment does not cover plants not under continuous FSIS inspection nor does it assess the risk associated with the addition of ingredients post pasteurization.

Failure of pasteurization to inactivate HPAI virus in liquid egg

- **Risk Factors:** Inadequate treatment temperature and/or time and inadequate recordkeeping
- **Current Preventive Measures:** Standard industry pasteurization protocols and FSIS requirements outlined in 9CFR590
- **Additional Preventive Measures** (to be implemented by industry during an outbreak)**:** None needed
- **Overall Risk:** Negligible

6.13 Background Information

Pasteurization using heat application is the most common procedure used to inactivate infectious agents in liquid egg products. When pasteurization requirements are followed, conditions are sufficient to inactivate AI viruses in multiple liquid egg products.

This portion of the risk assessment will describe:

- The effect of pasteurization on HPAI virus,
- The minimum pasteurization temperature and holding time requirements for various liquid egg products, and
- The minimum standards required for egg product premises design, pasteurization equipment specifications, and FSIS inspection requirements.

6.14 Resistance of HPAI Virus to Heat Treatment

Based on our review of the scientific literature, the pasteurization requirements specified in 9CFR590.570 are adequate to inactivate any HPAI virus in liquid egg products that may have been received from egg production facilities where HPAI infection has occurred but has not yet been detected. This opinion is consistent with comments by the U.S. concerning HPAI inactivation given to the OIE (55)·(4) and with a published report of the European Food Safety Authority (40). One earlier study indicated that these standards may be questionable in one situation (27), but this may be due to differences in methods, as discussed below.

Studies on the Effects of Pasteurization on HPAI Infectivity

As noted by the European Food Safety Authority in 2005 (41), there have been very few studies that specifically address the effects of pasteurization on HPAI infectivity reduction. The two studies we have found are generally consistent in their findings.

The effect of pasteurization temperatures (57º C and 62º C) on the infectivity of HPAI virus (A/chicken/Pennsylvania/83) diluted (1:100) in yolk, albumen, and normal allantoic fluid was evaluated by King (13;28). Viral concentrations used were similar to the AIV titer ($\geq 10^{4.9}$ EID_{50}/ml) in eggs from hens experimentally infected with the same virus subtype in previous studies. Data from this study demonstrated that a treatment of 57º C for at least ten minutes and 62º C for at least five minutes resulted in the inactivation of the HPAI virus in albumen and allantoic fluid, respectively. King (13, 28) did not determine the effect of low pasteurization temperatures (57º C) on yolk during the 5, 10, and 15 minute treatment times. King concluded that a minimum holding time of 3.5 minutes or more would provide marginal results for influenza virus titers comparable to those in the study (i.e., titers in eggs from infected hens).

A more recent study conducted by Swayne and Beck (48) on the effect of pasteurization was carried out on H5N2 HPAI strains (13). Data from this study demonstrated that while virus was not completely inactivated at 55º C, temperatures 55.6º C and above did inactivate the virus. HPAI virus added to homogenized whole egg, liquid egg white, and 10% salted egg yolk was completely inactivated when using the minimum required pasteurization temperature and holding times as specified in 9CFR590.570.

6.14.1 Variation between King and Swayne and Beck Studies

While the referenced literature indicates that AI viruses are inactivated by pasteurization, not all data on the effects of pasteurization temperature and time agree. King demonstrated that a treatment of 57º C between five and ten minutes resulted in the inactivation of HPAI virus in albumen (28), whereas, Swayne and Beck demonstrated that the pasteurization time required to inactivate HPAI virus in albumen (55.6º C, 3 min or 56.7º C, 2.7 min) was less than the time required by industry standard pasteurization protocols (55.6º C, 6.2 min or 56.7º C, 3.5 min) (48). These discrepancies can be explained by differences in study design.

In a side-by-side comparison, Swayne and Beck explain the differences in results between the two studies by suggesting that their heat inactivation studies may have been more precise than previous studies due to the use of thin-walled, small volume plastic tubes and precision thermocycler plates rather than thick-walled, large volume glass vials and water bath methods. Previous inactivation studies (using *Salmonella* spp.) have demonstrated that thin-walled capillary tubes provide more accurate results than large glass tubes because capillary tubes have instant come-up[i] and cool down times (32;39).

[i] An industry term for the time taken for product to reach pasteurization treatment temperature.

The 12 ml flat bottomed glass-vial used by King in the water bath method may have allowed air to provide an "insulating" effect which prevented uniform heating of the sample (46). In the study by King, the volume of sample material was considered to be small (2 ml) and the time to attain treatment temperature was considered to be short. For this reason, King considered the sampling time and treatment times to be equivalent and the actual time taken for the sample to reach treatment temperature was not measured. In contrast, Swayne and Beck report that treatment time using the thermocycler method began after the specified volume of sample (80µl) reached the desired treatment temperature and the actual treatment time of the sample material was reported. It is important to note that the objective of both studies was to design the most appropriate system to *evaluate the heat sensitivity of HPAI virus* at pasteurization temperatures in the laboratory and *not to model the kinetics of pasteurization* as they might occur in pasteurization equipment used in an egg processing premises.

Virus Survival as Reported by King(28)										
			Virus isolation at treatment time in minutes							
Virus	Temperature	Diluent	0	5	10	15	30	40	50	60
A/Ch/Pa/83	57°C	Yolk	+(4.8)	ND	ND	ND	--	ND	ND	--
		Albumen	+(5.2)	+	--	--	--	ND	ND	--
A/Ch/Pa/83	62°C	Allantoic Fluid	+(5.0)	--	ND	--	--	ND	ND	--

6.14.2 Approximate HPAI Infectivity Reduction at Five Minutes/57°C

In the King study (28), virus infectivity of 5.2 EID_{50}/ml (albumen) and 4.8 EID_{50}/ml (yolk) was determined for the initial pool of sample material at time 0 before heat treatment. After the initiation of heat treatment, viable virus was present in albumen at 5 minutes (resulting in embryo death), but the viral titer was not determined for this set of test samples. Embryo death did not occur at or subsequent to the 10-minute treatment period. While the minimal detectable titer of the assay used was not reported, the level of virus present at the 10-minute treatment time was likely within the limits of the assay. Since infectivity was present after heat treatment at 5 minutes, the author concluded that increased time or temperature requirements were needed for pasteurization of yolk based on the current 3.5-minute requirement at 57° C, 60° C, or 61° C.

6.14.3 Swayne and Beck (47)

In the Swayne and Beck study, similar methods were used to determine initial viral titers in sample materials as described by King. Initial virus concentration in product ranged from $10^{4.5}$ to $10^{6.4}$ EID_{50}/ml. In contrast with King, the minimal detectable titer of the assay used in the study was reported. Knowing the cutoff point or sensitivity of the test better enables an estimate to be made on the amount of virus present after heat treatment. Since a viral titer of 1.97 $\log_{10}$ EID_{50}/ml was determined to be the lowest titer that resulted in at least one embryo death in serial dilution inoculation studies, it can be reasoned that a viral titer of at least 1.97 $\log_{10}$ EID_{50}/ml was present at 57° C after 3 minutes of heat treatment, but not after the 4 minute sample treatment interval.

From these data, D_t values were determined by fitting a curve to the data and predicting the time for reduction of titers. These data were used to compare experimental treatment times with industry pasteurization time temperature standards and to derive the length of time needed to inactivate HPAI in eggs. The authors concluded that time required to reduce virus titers below the EID_{50} needed to infect chickens (10^0 EID_{50} HPAI virus/ml) is less than the time required in industry standard pasteurization protocols.

D_t values (time to reduce virus titer by 90% or 10^1 EID_{50}), for four egg products artificially infected with AI viruses (Swayne and Beck, (47))					
		Egg products			
Virus	Temperature	Homogenized whole egg (sec)	Liquid egg white (sec)	10% salted yolk (sec)	Dried egg white[j, k] (days)
HPAI/PA/H5N2	55°C	643.8	256.7	20.3	2.2
	57°C	268.5	22.9	<20	1.4
	59°C	22.3	<19	<20	1.3
	61°C	<19	<19	<20	1.0
	63°C	<19	<19	<20	0.2

Estimation of pasteurization times for egg products based on D_t values of the study including the time to inactivate HPAI to a level of 10^0 EID_{50}/ml, which is below the dose that can infect chickens with H5N2 HPAI. (Adapted from Swayne and Beck (47))				
Egg Product	Temperature	Industry time standard	Calculated D_t Values	Time to inactivate HPAI in eggs
Whole egg	60°C	210 sec	27.2 sec	133 sec
Whole egg blends	60°C	372 sec	27.2 sec	133 sec
Whole egg blends	61.1°C	210 sec	13.6 sec	67 sec
Liquid egg white	55.6°C	372 sec	37.1 sec	182 sec
Liquid egg white	56.7°C	210 sec	33.1 sec	162 sec
10% Salted yolk	62.2°C	372 sec	<20 sec	<98 sec
10% Salted yolk	63.3°C	210 sec	<20 sec	<98 sec
Dried egg white	54.4°C	7 to 10 days	3.1 days	15.2 days
Dried egg white	67°C	15 days	0.12 days	0.59 days

6.14.4 Pasteurization Temperature and Time Requirements

Pasteurization of eggs in the U.S. is carried out in compliance with 9CFR590.570 (Appendix 3). 9CFR590.570 describes the minimum required pasteurization temperature and holding times for various liquid egg products.

The 2006 Terrestrial OIE Animal Health Code lists guidelines for pasteurization temperatures and holding times necessary for inactivation of HPAI virus in various liquid egg products (Appendix 7). These guidelines include an established safety margin of 100 times over the temperature and holding times shown to be necessary to inactivate HPAI virus based on recent pasteurization studies on liquid egg products.

[j] Note that dried egg white is not a liquid and is outside the scope of this assessment.
[k] The Agricultural Research Service is currently studying inactivation requirements for HPAI virus in this product (45).

In all but one case (albumen/liquid egg white), the pasteurization requirements specified in 9CFR590.570 exceed the OIE guidelines. In all cases, the liquid egg pasteurization requirements as specified in 9CFR590.570 and the OIE guidelines exceed the pasteurization temperature and time estimates suggested by Swayne and Beck (47) for complete elimination of AI virus, as shown below.

USDA Requirements (9CFR590.570)			OIE Guidelines			Research Estimates		
Product	Temperature ºF (ºC)	Time Minutes (Seconds)	Product	Temperature ºF (ºC)	Time Minutes (Seconds)	Product	Temperature ºF (ºC)	Time Minutes (Seconds)
Whole egg	140 (60)	3.5 (210)	Whole egg	140 (60)	3.1 (188)	Whole egg	140 (60)	(133)
Whole egg blends (less than two percent added non-egg ingredients)	142 (61)	3.5 (210)	Whole egg blends (all blends including fortified whole egg blends)	140 (60) 142 (61)	3.1 (188) 1.6 (94)	Whole egg blends	140 (60) 142 (61)	(133) (67)
Salt yolk (2-12 percent salt added)	144 (62) 146 (63)	6.2 (372) 3.5 (210)	10% Salt yolk	144 (62)	2.3 (138)	10% salt yolk	144 (62) 146 (63)	(<98) (<118)
Albumen (without use of chemicals)	132 (56) 132 (58)	6.2 (372) 3.5 (210)	Liquid Egg White	132 (56) 134 (58)	4.3 (256) 3.8 (228)	Liquid Egg White	132 (56) 134 (58)	(182) (162)

6.14.5 Premises Design, Equipment Specifications, and Inspection Requirements

9CFR590.570 specifies the minimum standards required for premises design, equipment specifications, and inspection for liquid egg pasteurization. Pasteurization equipment for liquid egg must include a holding tube (to ensure adequate time at the set temperature), an automatic diversion valve (to recycle any liquid egg that does not reach the required temperature), thermal controls, and recording devices. The recording devices continuously monitor and automatically record the temperature of the heated liquid egg product.

6.15 Evaluation of Risk

The risk evaluated in this section is that of failure of pasteurization to inactivate HPAI virus in pasteurized liquid egg or its products.

The evaluation of the risk associated with the pasteurization process is conducted in two parts:

- Resistance of HPAI Virus to Heat Treatment - This is an assessment of the likelihood that HPAI virus will survive the minimum required pasteurization temperature and holding times as specified in 9CFR590.570.
- Premises Design, Equipment Specifications, and Inspection Requirements – This is an assessment of the likelihood that equipment failure will result in inadequate of pasteurization.

In each part, all possible pathways where the pasteurization process could fail to inactivate HPAI virus are identified and their associated risks are assessed.

6.15.1 Pasteurization Temperature and Time Requirements

Heat application to egg products artificially infected with AI viruses resulted in virus inactivation when heating temperatures and times were similar to those used in commercial pasteurization of liquid egg products (48). In homogenized whole egg, liquid

egg white, and 10% salt yolk, the time necessary to inactivate H5N2 HPAI (A/chicken/Pennsylvania/1370/83) virus from $10^{4.9}$ ELD_{50}/ml[l] to 10^{0} ELD_{50}/ml[m] is less than is required by 9CFR590.570. Although these are only a few of the many liquid egg products produced in the U.S., the pasteurization principles and their ability to inactivate AI viruses are directly applicable to other liquid egg products when using the requirements specified in 9CFR590.570 (Dr. David Swayne, personal communication, August 14, 2007, Appendix 8).

While this risk assessment assumes that all liquid egg products virus inactivation only occurs at pasteurization temperatures, some additional thermal death of AI virus likely occurs during the time the product is being heated to achieve the pasteurization temperature; one laboratory study reported that a liquid egg sample would spend 20 to 30 seconds at a temperature of at least 50° C before reaching pasteurization temperature (24).

6.15.2 Premises Design, Equipment Specifications, and Inspection Requirements

Accuracy and reliability of the pasteurization system is ensured through proper design and installation of equipment which is compliant with 3-A and E 3-A Sanitary Standards per USDA FSIS regulations (63). Additionally, equipment is maintained via routine instrument calibrations for temperature and flow rates and scheduled preventive maintenance of the system.

All plants pasteurizing eggs under the 9CFR590.24 are required to have continuous inspection by a FSIS inspector (Appendix 3)(63). The inspector must be on premises whenever pasteurization equipment is operating unless specifically exempted.

The above portion of the risk assessment describes the typical conditions under which the egg products processing industry operates, and does not account for the possibility of process failure. Equipment failure can result in inadequate pasteurization. However, this should not be a concern since pasteurization equipment is required to have an automatic diversion system should time and/or temperature standards not be met. Automatic diversion prevents non-pasteurized product from moving forward in the process. Continuous inspection by USDA FSIS is also in place to help monitor this risk. Ongoing verification of adherence to pasteurization standards is documented at the plant by the USDA FSIS inspector and company personnel. A continuous recording, called the process chart, documents the time and temperature of fluids passing through the pasteurizer. The process chart for each lot[n] of product is reviewed by the FSIS inspector to certify that pasteurization time and temperatures have met regulations (Appendix 9).

6.16 Conclusion

When pasteurization requirements are followed, conditions are sufficient to inactivate AI viruses in commercially produced and internationally traded pasteurized liquid egg.

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[l] The maximum titre in eggs laid by HPAI/PA/83 infected hens.

[m] Titre insufficient to infect chickens with a similar H5N2 HPAI virus, A/chicken/Queretero/14588/95.

[n] A "production lot" is usually a large amount of packaged product designated as being part of the same production lot (82).

While inactivation of AI viruses in liquid egg is dependent on the type of egg product, virus strain, temperature of the process, length of treatment, and concentration of the virus, the likelihood that HPAI virus might be present in whole egg, whole egg blends, liquid egg white, and 10% salted yolk after applying USDA FSIS pasteurization standards and processes is negligible.

Expert opinion supports the same conclusion for the efficacy of the pasteurization on HPAI virus in other liquid egg products, such as fortified whole egg and blends, salt whole egg, sugar whole egg, plain yolk, and sugar yolk (Dr. David Swayne, personal communication, August 14, 2007, Appendix 8).

In summary, the USDA FSIS standard pasteurization times and temperatures are effective in inactivating AI viruses in multiple pasteurized liquid egg products (Dr. David Swayne, personal communication, August 14, 2007, Appendix 8).

7 Analysis of the risk associated with handling operations

This portion of the risk assessment evaluates the potential risk of post-pasteurization reintroduction of HPAI virus during "handling" of pasteurized liquid egg and its products that are intended for transport off premises within a control area during a HPAI outbreak.

Failure of handling operations to prevent contamination of already pasteurized liquid egg and egg products with HPAI virus

- **Risk Factors:** Holding tank not cleaned properly, integrity breach in the handling system and/or equipment, contaminated packaging, contaminated personnel contacting pasteurized product, pests contaminating facilities, packaging process contaminating product.
- **Current Preventive measures:** Good Manufacturing Practices (GMPs) and FDA requirements as outlined in 21CFR110.80; FSIS measures as outlined in 9CFR590 Chapter 3, which covers requirements for the inspection of egg products, and facilities sanitation.
- **Additional Preventive measures** (to be implemented by industry during an outbreak)**:** None needed
- **Overall Risk:** Negligible

7.1 Background Information

The term "handling" in this risk assessment is defined as the process of taking pasteurized liquid egg from the pasteurized storage tank by either pumping it directly into tankers for transport and further processing off site or into internal pipes for further on-premises processing such as cooking, drying, and packaging. After on-site processing, pasteurized liquid egg products are moved to the appropriate distribution warehouses to be transported off the premises to various places both within and outside the control area (Figure 1). This portion of the risk assessment evaluates the potential risk of introducing HPAI virus during this "handling" process as depicted in Figure 1.

Federal regulations concerning eggs and their handling are written to ensure food safety by preventing the contamination of food with particular pathogens such as *Salmonella spp.* and *Escherichia coli*. Given the relatively greater vulnerability of AI viruses, these measures should be just as, or more, effective in mitigating the risk that pasteurized liquid egg will cause an outbreak in a poultry premises. With the increased threat of HPAI exposure during an outbreak, this section evaluates these regulations to ascertain if they are also effective in preventing any potential contamination associated with HPAI virus, not only from the perspective of food safety but also from that of virus containment in the event of a HPAI outbreak. Thus, the evaluation of risk in this section constitutes examining all Federal regulations and required GMPs concerning pasteurized liquid egg during handling, as well as any additional preventive measures, such as voluntary HACCP programs. Based on our review, we conclude that existing FSIS and FDA regulations, if implemented properly, are sufficient to prevent HPAI virus contamination of liquid pasteurized egg without resorting to any additional preventive measures such as plant-specific voluntary HACCP programs, which might exist in some but not all egg-processing plants.

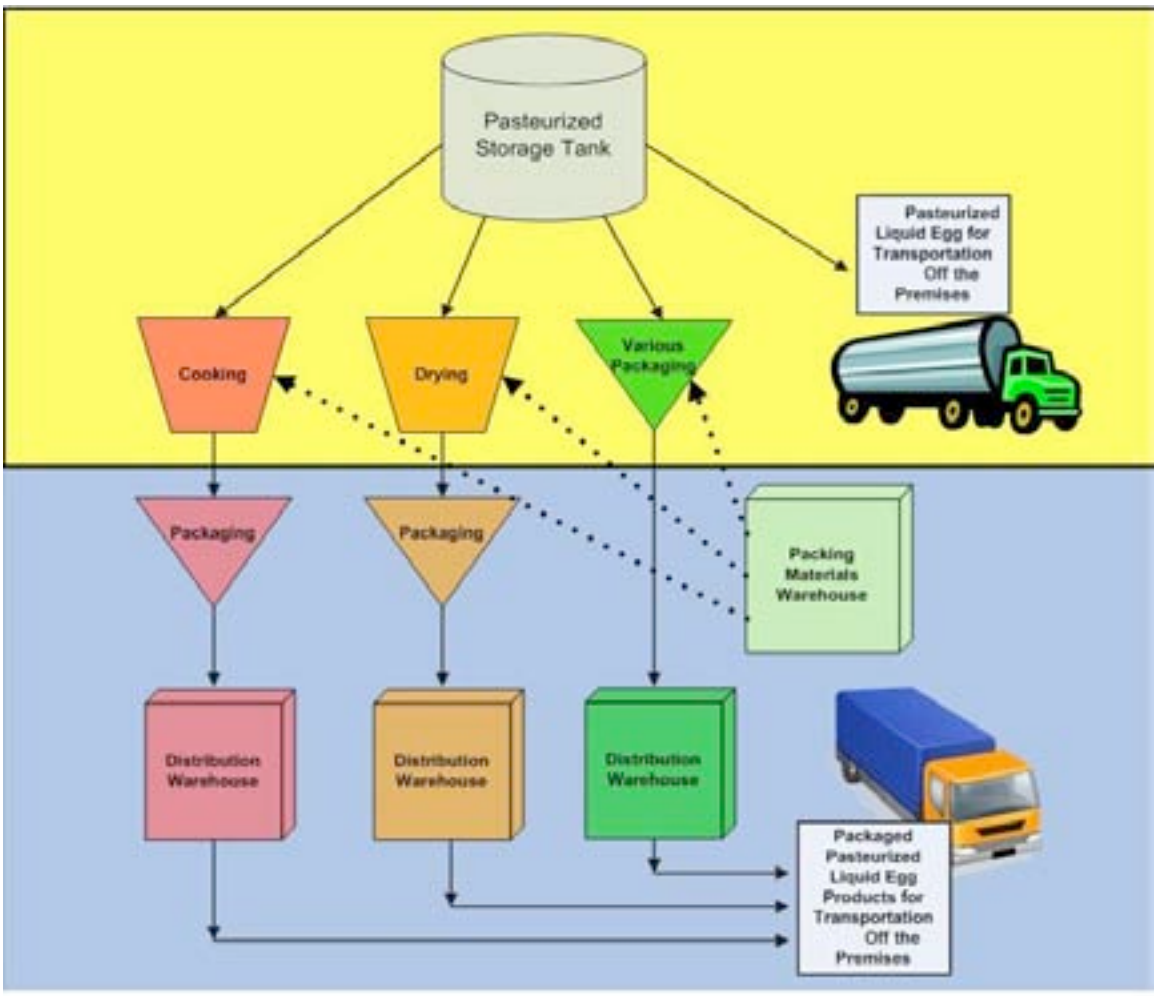

Figure 1. ***Handling Operations***

This figure shows the journey of liquid egg product after pasteurization until it is put on conveyance trucks to be transported off the premises. Pasteurized liquid egg can go either from the pasteurizer (or from pasteurized storage tank) directly onto large tankers and be transported off the premises, or it can be processed on premises into a variety of products through cooking, drying, or packaging. From there, pasteurized liquid egg and its products typically go to their appropriate distribution warehouses to be transported off the premises later.

7.2 Evaluation of Risk

The evaluation of the risk associated with the handling operations used for pasteurized liquid egg and its products is conducted in two parts:

- Internal contamination – This is an assessment of the likelihood that HPAI virus contamination could occur in pasteurized liquid egg and/or its products after pasteurization (Figure 1 – yellow area).
- External or environmental contamination – This is an assessment of the likelihood that HPAI virus could be present on the exterior of packages containing pasteurized liquid egg and/or its products (Figure 1 – blue area).

In each part, all possible pathways where HPAI virus could contaminate products are identified, and their associated risks are assessed.

7.2.1 Internal Contamination

The risk associated with "internal contamination" constitutes the potential introduction of HPAI virus into the already pasteurized liquid egg or its products. There are two possible pathways for internal contamination of the pasteurized liquid egg or its products to occur:

1. Cross-contamination of the pasteurized liquid egg and/or
2. Contamination of the interior of the packaging materials.

Cross contamination of the pasteurized liquid egg can occur due to a breach in the pipes through which the pasteurized liquid egg is pumped during processing, thereby exposing it to the environment, or due to system failure resulting in the mixing of pasteurized and non-pasteurized products.

Contamination of the interior of the packaging materials used to house the pasteurized liquid egg products can occur if the virus is in the warehouse where the packaging materials are stored. If HPAI virus is in the environment surrounding the warehouse, it might find its way into the warehouse and ultimately to the interior of the packaging materials used to contain pasteurized liquid egg or its products. This possible pathway would most likely be through exposure from external sources associated with movement through the receipt of packaging materials, ingredients, supplies, and the distribution of finished products.

7.2.2 External or Environmental Contamination

External or environmental contamination constitutes the contamination of the outside of the packaging materials used to contain the pasteurized liquid egg and its products. Thus, the only risk pathway under consideration in this part of the assessment is that HPAI virus is present on the outside of the packaging materials. If exterior package contamination occurs, then the virus could "hitchhike" on the outside of the package to conveyance trucks and be transported off of the premises (Figure 1 – blue area). Note that consideration of this pathway is necessary from the perspective of virus containment in the event of an undetected HPAI outbreak on the premises.

This pathway can occur if HPAI virus finds its way to the warehouse and ultimately to the outside of the packaging materials used to house pasteurized liquid egg or its products. As stated above, the virus may enter the warehouse through external sources associated with the receipt of packaging materials, ingredients, supplies, and the distribution of finished products.

7.2.3 Preventive Measures

Preventive measures considered in this risk assessment are limited to the mandatory Federal regulations and requirements that are relevant to eggs and their handling.

Every Federally inspected egg-processing premises is mandated by law to follow all relevant Federal requirements and regulations. Currently, all federally inspected egg-

processing facilities are required to have GMPs but not HACCP programs - though some egg-processing plants do have voluntary HACCP already in place in anticipation that they will be mandatory in the future. Because HACCP programs are currently voluntary for the egg industry and are neither uniformly designed nor implemented across all egg-processing facilities, this risk assessment views them only as additional preventive measures aimed at enhancing and not replacing the mandatory Federal regulations, and evaluates the risk accordingly. That is, risk is evaluated without relying on any additional preventive measures through HACCP beyond what is mandated by the relevant Federal regulations. A few of the regulations relevant to handling are included below. The complete list of these regulations is given in Appendices 1 through 5. Though not relevant for evaluating the risk here, Appendix 11 gives an overview of FSIS inspection under HACCP programs and is included for reference.

Industry GMPs

Good Management Practices are a set of plant-specific accepted best practices for the processing, warehousing, and distribution of pasteurized liquid egg and its products. As of December 2007, all federally inspected egg-processing plants are mandated by law to have GMPs and to comply with all Federal regulations that pertain to handling and processing of eggs.

Prevention of post-pasteurization contamination of liquid egg products is dependent on GMPs as well as on the premises' design, cleaning and sanitation protocols, and operating procedures. Pasteurized liquid egg products must meet inspection criteria in order to be labeled at the time they leave the FSIS inspected plant, bearing the official inspection legend and official plant number in legible forms on their shipping containers or immediate containers, or both, when required by regulations.

FSIS and FDA Relevant Regulations

The USDA FSIS continually inspects plants producing pasteurized liquid egg and its products. FSIS requires adherence to GMPs as well as Federal regulations. Inspectors ensure that products are properly pasteurized and that facilities are maintained and operated in a manner that prevents contamination (65). Daily verification of adherence to standards is documented by the inspector on Form PY203 (Appendix 9), or Form 159, Daily Report of Plant Operation (Appendix 10).

In addition to continuous inspection, FSIS regulations also cover premises design. For instance, unless products are packaged by an automatic, closed packaging system, regulations specify that a separate draw-off room with a filtered positive pressure air ventilation system be provided for packaging (66).

Similarly, there are FSIS regulations covering equipment specifications. Tanks, vats and their covers must be of approved construction and operated under sanitary conditions. Tanks can be located partially outside of the premises as long as all openings terminate inside the processing room (66).

Products produced in FSIS inspected facilities must be labeled with the official inspection legend and official plant number before leaving the premises (75). The mark of inspection (Appendix 4)(64) deems the product to be disease free, including free of HPAI virus.

While the FSIS regulates the production of pasteurized liquid egg and its products, the FDA requires that plants use GMPs to prevent contamination of human food, including plants that are exempted under the 9CFR590 regulations (71). FDA regulations require proper sanitation and handling of food products to prevent contamination from all sources including: contamination from other products or ingredients; metals and other materials; storage containers; and poorly trained, unsanitary or unhealthy employees (71). Other relevant regulations can be found in Appendices 1 to 6.

In addition to best practices and adherence to regulations, the egg product industry will take additional steps as necessary during an outbreak. In such a situation, communication would increase between industry, State and Federal authorities, Incident Command personnel, and other appropriate parties regarding the situation in the field and the implementation of additional preventive measures as needed. Furthermore, industry would increase awareness of disease and preventive measures among employees, contractors, vendors, distributors and all relevant persons and parties.

7.3 Evaluation

Three pathways have been identified from the handling of pasteurized liquid egg and its products through which HPAI virus could be transported off of the premises:

1. Cross-contamination of the pasteurized liquid egg.
2. Contamination of the inside of the packaging materials.
3. HPAI virus present on the outside of the packaging materials.

This section contends that the potential risk associated with all three pathways can be effectively reduced to negligible through the proper implementation of the existing preventive measures already in place by Federal regulations.

1. Internally, a breach in the containment of the pasteurized liquid egg leading to actual contamination of pasteurized liquid egg at any egg pasteurization premises is highly unlikely. Should a breach or containment failure occur, it would be indicated by changes on various gauges (such as those reporting temperatures, pressures, and flow volumes) that pasteurization is no longer occurring within the requirements shown in the applicable FSIS and FDA regulations. As production of non-compliant product could result in regulatory action by FSIS, we believe it is reasonable to assume that production will stop until the problem is indentified and resolved.
2. In order for HPAI virus to be present on the interior of the packages used for pasteurized liquid egg and its products, two consecutive events must occur: (1) HPAI virus must get into an area where such packages are located, and (2) HPAI virus must survive the cleaning and disinfection of the *interior* of such packages before they are filled with pasteurized liquid egg. The probability of each of these two events is very small. Since these two events are chronologically dependent, their probabilities must be multiplied resulting in a much smaller probability of their consecutive occurrence. Therefore, it is highly unlikely that the virus would be present in the interior of the packages used to fill pasteurized liquid egg and its products *and* that it would survive cleaning and disinfection before filling.

3. Externally, contamination of the external packaging materials resulting in the transport of the virus off of the premises is also highly unlikely. Here too, two consecutive events must take place for the virus to be transported outside the premises externally on the outside of the packages: (1) HPAI virus must get into an area where such packages are located, and (2) HPAI virus must survive the cleaning and disinfection of the *exterior* of such packages. These events could happen if only there is a lax in biosecurity or a significant failure in the application of the preventive measures, e.g., spraying, disinfection, etc. as specified in the Federal regulations and verified by FSIS, which needs re-evaluation during an outbreak. As argued above - and despite the fact that during an outbreak situation, the risk of undetected, infected materials moving onto the premises might be higher - the probability each of these two events is small as long as all preventive measures as specified in the Federal regulations are appropriately applied. As before, since these two events are chronologically dependent, their probabilities must be multiplied resulting in a smaller probability of their consecutive occurrence. It is, therefore, highly unlikely that the virus would be transported outside the premises on the *exterior* of the packages.

7.4 Conclusion

If all of the relevant Federal and industry requirements and preventive measures described above are adhered to, the potentially elevated risk associated with the three pathways identified through the handling of pasteurized liquid egg and its products during an outbreak can be mitigated to negligible. Thus, the likelihood that HPAI virus might be introduced during handling of pasteurized liquid egg and its products in egg processing plants under continuous FSIS inspection is negligible.

8 Likelihood that the movement of a vehicle carrying pasteurized liquid egg would mechanically transmit HPAI virus and thus cause an HPAI outbreak in another poultry premises

Likelihood that movements of vehicles carrying pasteurized liquid egg would result in infection at another poultry premises

- **Risk Factors:** Contamination of transport vehicle and/or tanker, inadequate cleaning and/or disinfection, cross contamination during movement, and failure of biosecurity practices for personnel
- **Current Preventive Measures:** Tankers inspected and sealed on-site by FSIS personnel as outlined in 9CFR 590.410. Also the requirement that the grounds of a food plant be kept in conditions to prevent the contamination of food as outlined in 9CFR 590 and 21CFR110.20
- **Additional Preventive Measures** (to be implemented by industry during an outbreak)**:** Cleaning and disinfection of the truck/tanker exterior and/interior, and personnel biosecurity requirements
- **Overall Risk:** Negligible

8.1 Background Information

To date, there has been no evidence published of a liquid egg processing premises contributing to the spread of any AI virus. A review of the scientific literature and response planning documents indicate that movements of contaminated equipment (including vehicles) *between poultry premises* is the primary means of spreading HPAI (61), but there have been no reports of vehicles transporting PLE or their contents causing infection at another poultry premises (40). (8;12;17;44)As HPAI virus has also been found on the outer surfaces of egg shells, the movement of shell eggs has been cited as a potential pathway (61). While pathways involving the movement of shell eggs are of concern in an HPAI outbreak, they are outside the scope of this assessment and will not be evaluated. However, these pathways will be addressed in follow-on risk assessments.

8.2 Potential Hazards

The potential hazards associated with the transportation of pasteurized liquid egg or its products are:

- Contamination of the vehicle or driver on a premises,
- Cross-contamination of the vehicle or driver due to exposure to traffic at truck stops, scales, or maintenance facilities, and/or
- Contamination of the vehicle or driver caused by multiple stops, which may include visiting an infected premises.
- Contaminated vehicles moving PLE between production premises.
- Contaminated vehicles moving PLE causing infection through bioaerosols that enter other poultry production facilities.

Many of the vehicles that haul pasteurized liquid egg and its products only come into contact with the docks at processing facilities, where Federal rules regulate the condition of the grounds to limit the potential for contamination. However, some vehicles may

enter a premises from other egg production facilities and may serve as possible sources for cross-contamination. Approximately 80% of the vehicles transporting pasteurized liquid egg and its products are headed to locations which rarely have poultry present, such as processing plants, warehouses, or retail locations (77).

Vehicles and drivers moving pasteurized liquid egg and its products generally do not have direct contact with live bird production and thus have no opportunity to become contaminated with HPAI virus. To date, there have been no reports in the scientific literature that vehicles moving pasteurized liquid egg or its products have been contaminated with or contributed to the spread of HPAI virus during an outbreak.

For an HPAI viral-contaminated vehicle carrying PLE to spread virus to an uninfected premises, the following pathway would have to be viable:

1. The vehicle was improperly cleaned and disinfected and this failure was not recognized by responsible state or federal official at the C&D location.
2. The movement permit issued by Incident Command routes the vehicle by a poultry production premises, or the vehicle violates the conditions specified in the movement permit and uses another route.
3. The vehicle, while in transit, sheds enough HPAI virus to cause an outbreak.
4. The virus survives in the environment and bypasses any biosecurity measures in place at the vulnerable premises and causes infection.

As illustrated, this pathway is viable only if three simultaneous failures occur during the movement permitting process:

- The vehicle is so poorly cleaned that it carries enough infective material to infect another premises;
- This failure is not noticed by the responsible official; and
- Incident Command staff is either unaware or does not consider the locations of other poultry production premises or the vehicle deviates from the route shown on the permit.

Given the lack of evidence for this pathway and systematic failures that would have to occur for it to be viable, we consider the likelihood of occurring to be negligible.

8.3 Current Mitigations

Existing preventive measures include Federal regulations and industry best practices. The full text of relevant regulations can be found Appendices 1 to 6. These serve to ensure that vehicles are in a sanitary condition

The FSIS continually inspects plants producing pasteurized liquid egg and its products. FSIS requires adherence to GMPs as well as Federal regulations. The movement of pasteurized liquid egg and its products is also regulated. General regulatory requirements for FSIS-inspected premises and movements involving them are specified in

9CFR325.1(68) (Appendix 1)(31), 9CFR590.410(b), and 9CFR590.500(b) and (c)(31;63).

FSIS requires that premises be clean and free of odors and waste materials that could attract vermin. Additionally, buildings are to be well built and maintained as to prevent the entrance of vermin (31;63).

FSIS requirements for the movement of pasteurized liquid egg and its products apply to movement by truck, rail, and other means of conveyance. Means of conveyance must be clean and free of any potential contaminants. Vehicles are not to contain food that is not properly packaged or enclosed to ensure protection from airborne contaminants (31;63).

Other regulations (9CFR590.410(b))(68) requires that all egg products bear an official label before leaving an FSIS-inspected premises and that containers moving bulk shipments between FSIS-inspected premises be sealed.

All vehicles hauling liquid egg products that enter a FSIS continuously inspected plant are inspected by FSIS regulatory officials for seal integrity, leaks, the presence of labels and correct documentation. For all conveyances leaving the premises, the following applies:

- For outgoing tankers carrying pasteurized liquid egg, the surfaces in which the egg comes into contact with are inspected by FSIS personnel as specified in 9CFR325.1(68) and 9CFR590.410(67), and the tanker is sealed and labeled to ensure integrity.
- For other vehicles carrying packaged pasteurized liquid egg and its products, industry personnel generally inspect interiors.

8.4 Mitigation Measures during an Outbreak

In the event of a HPAI outbreak, various movement and control measures will be implemented by local, State and/or Federal authorities as part of the disease control effort (57). The movement controls shown in the APHIS HPAI Response Plan will generally restrict the movement of eggs and egg products to:

- Other premises or to slaughter/processing (if moving within the Control Area); or,
- To further processing (if moving out of the Infected Zone).

The movement control policy is shown below: (61)

> **Controlled Movement of Birds, Other Livestock, and Their Products Permits for Movement**
>
> Following an established regulation or policy memo, Federal and State authorities can issue an official permit for movement of domesticated birds and other susceptible livestock and their products to allow their movement from a premises or a geographic area described in a quarantine order. A request for a movement permit must be supported by a risk assessment.
>
> **Permits for Movement within a Control Area**

Permits to move domesticated birds and other livestock and materials from premises to premises within a control area can be issued if:
• No birds or other livestock on that premises have shown clinical signs of HPAI for 42 days and disease free status has been verified within 24 hours prior to movement;
• No susceptible species were added to the premises of origin for 42 days;
• The premises of origin is not an infected premises, contact premises, or suspect premises, and there is no detectable evidence of HPAI (see Appendix C);
• Transport conveyances for the birds and other livestock and product meet acceptable biosecurity standards.

Movement to Slaughter within a Control Area
Permits to move to slaughter (for human food use) or processing (e.g., eggs and egg products) can be issued if (a) the birds and other livestock or products meet the requirements of USDA's Food Safety and Inspection Service for food use; and (b) the birds and other livestock or products are eligible for a permit for movement from premises to premises or for movement directly to slaughter.

Movement Out of an Infected Zone
No susceptible birds or livestock species or products posing a risk of AI transmission may leave the infected zone unless they are (a) going directly to slaughter at an approved slaughter premises established in the buffer surveillance zone; (b) going directly to a processing premises in the buffer surveillance zone; and/or (c) meet criteria described on a permit. No materials posing risk of AI transmission may leave the infected zone except by permit.

Note that permit policy will generally allow only product to move only to a processing premises, another premises (if moving within the Control Area), or only under the particular conditions shown in the permit. If movement is restricted only to the transport of PLE to further processing facilities, there will not be a biologically plausible pathway for re-introduction to another poultry premises. While this assessment cannot mandate specific mitigations in advance of an outbreak, consideration should be given to allowing vehicles carrying PLE to move only to a processing premises and forbid stops at other poultry premises along the way.

In addition to movement permits, effective cleaning and disinfection procedures are included in these measures (58). The egg product industry recognizes the potential risk from vehicles/conveyances and the importance of preventing this risk. They have proposed a model movement control plan for regulating the movement of vehicles transporting egg products during an outbreak (Appendix 6)(74). This model movement control plan has been endorsed by the United Egg Producers/United Egg Association and addresses issues specific to the egg product industry as suggested in the APHIS HPAI Response Plan (61).

The egg product industry model movement control plan includes cleaning and disinfecting all vehicles transporting egg products that move into[o], within or outside of a control area. Cleaning and disinfection is required before a movement permit will be issued. The movement control plan does not require vehicles to be cleaned and disinfected on the premises, but it does require that cleaning and disinfection be done before a movement permit is issued. In addition, tires and wheel wells of vehicles moving pasteurized liquid egg or its products must be cleaned and disinfected before leaving premises within a control area. Vehicles moving pasteurized liquid egg or its products into a control area do not need to be cleaned and disinfected before entering, and movement permits are not required. Cleaning and disinfection requires the use of an EPA approved AI disinfectant (72),[p] following a standard protocol that requires vehicle interior and exterior cleaning and disinfection.

Specific protocols for cleaning and disinfection exist and new ones may need to be developed depending on the circumstances. For example, vehicle cleaning and disinfection guidelines are given in the November 2005 Draft National Animal Health Emergency Management System (NAHEMS) Cleaning and Disinfection Operational Guidelines from the USDA (58), FSIS (62;63), and published literature (16;20;30).

8.5 Evaluation

The movement controls shown in the APHIS HPAI Response Plan (if correctly implemented) will eliminate any plausible biological pathway that could cause viral contamination by PLE to a premises outside of the Control Area, as permits will be issued for movement to either a processing premises (and ultimately to consumers, and therefore will not come into contact with another poultry production premises) or for currently unknown circumstances where movement is needed. In the latter case, additional information specific to the situation will be needed to adequately assess the risk.

There may be a risk for cross-contamination from traffic at truck stops, scales, or maintenance facilities: however, we have been unable to find any evidence that cross-contamination from this source has ever occurred. The risk of commercial vehicles becoming contaminated with HPAI virus while at a public location is equivalent to that of any other vehicle present; this includes the risk associated with driving past an infected premises. In addition, there are no known cases of movement of a consumer product from a pasteurized liquid egg premises causing or spreading HPAI or END virus (Dr. David Halvorson, personal communication).

The egg product industry model movement control plan contains provisions for movement controls and cleaning and disinfection during an outbreak. These plans are

[o] Vehicles carrying egg products into a Control Area will be subject to cleaning and disinfection when they arrive at their delivery points.

[p] According to the EPA webpage referenced in the text, "Although there are no antimicrobial products registered specifically against the H5N1 subtype of **avian influenza A** viruses, EPA believes based on available scientific information that the currently registered **avian influenza A** products, when applied in strict accordance with the label directions, will be effective against the H5N1 strain."

similar to ones developed to control the Exotic Newcastle Disease outbreak in California (69) and were found to be effective in that situation.

8.6 Conclusion

The movement controls given in the APHIS HPAI Response Plan will block the primary transmission pathway (the movement of contaminated vehicles from one poultry premises to another). This will be accomplished by generally allowing movements only from production premises to processing/retail facilities where no poultry will be present.

In addition, in the event of an outbreak, vehicles would be cleaned and disinfected before movement and the likelihood of a vehicle becoming contaminated in transit appears is negligible. In addition, most vehicles and drivers transporting pasteurized liquid egg or its products from a processing premises will not encounter other commercial poultry. While transportation of liquid pasteurized egg may pose other, hypothetical, risks, we are following established WTO precedent (22) and not considering them in this assessment.

The likelihood that the movement of a vehicle carrying liquid pasteurized egg or its products would mechanically transmit HPAI virus is negligible.

9 Overall Conclusion

The overall risk associated with the movement of pasteurized liquid egg and its products into, within, and outside of a control area during a highly pathogenic avian influenza outbreak in the poultry industry in the United States is *negligible*. Unless major failures or significant deviations occur in the process of pasteurization, the likelihood that HPAI virus would be present in liquid egg and/or its products after pasteurization is negligible. Similarly, our analysis concludes that the risk associated with HPAI virus being re-introduced to already pasteurized, virus-free liquid egg through the holding tank(s), packaging materials, and premises environments is negligible. Lastly, if movement controls and all other recommended preventive and biosecurity measures described below are strictly followed, the likelihood that the movement of commercial vehicles carrying pasteurized liquid egg and/or its products would mechanically transmit HPAI virus outside of the control area during an outbreak is negligible. The overall risk of moving pasteurized liquid egg and/or its products into, within, and outside of a control area during a HPAI outbreak is negligible.

However, it should be remembered that:

- **It was assumed that the processing premises is in compliance with applicable laws and regulations;**
- **The assessment is based on current (May 2008) information and will need to be reviewed and revised as circumstances warrant; and,**
- **The assessment aids, but does not replace, the judgment of on-scene officials.**

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10 Appendix 1. Selected Portions of 9CFR325.

[Code of Federal Regulations]
[Title 9, Volume 2]
[Revised as of January 1, 2006]
From the U.S. Government Printing Office via GPO Access
[CITE: 9CFR325]

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 325_TRANSPORTATION

Sec.
325.1 Transactions in commerce prohibited without official inspection legend or certificate when required; exceptions; and vehicle sanitation requirements.
325.2 Parcel post and ferries deemed carriers.
325.3 Product transported within the United States as part of export movement.
325.4 [Reserved]
325.5 Unmarked inspected product transported under official seal between official establishments for further processing; certificate.
325.6 Shipment of paunches between official establishments under official seal; certificate.
325.7 Shipment of products requiring special supervision between official establishments under official seal; certificate.
325.8 Transportation and other transactions concerning certain undenatured lungs or lung lobes from official establishments or in commerce; provisions and restrictions.
325.9 [Reserved]
325.10 Handling of products which may have become adulterated or misbranded; authorization and other requirements.
325.11 Inedible articles: denaturing and other means of identification; exceptions.
325.12 [Reserved]
325.13 Denaturing procedures.
325.14 Certificates, retention by carrier.
325.15 Evidence of proper certification required on waybills; transfer bills, etc., for shipment by connecting carrier; forms of statement.
325.16 Official seals; forms, use, and breaking.
325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.
325.18 Diverting of shipments, breaking of seals, and reloading by carrier in emergency; reporting to Regional Director.
325.19 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.
325.21 Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

Source: 35 FR 15605, Oct. 3, 1970, unless otherwise noted.

Sec. 325.1 Transactions in commerce prohibited without official inspection legend or certificate when required; exceptions; and vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any product which is capable of use as human food unless the product and its container, if any, bear the official inspection legend as required under parts 316 and 317 of this subchapter or such product is exempted from the requirement of inspection under part 303 of this subchapter.
(b) (1) No carrier shall transport or receive for transportation in commerce (including transportation in the course of importation) and no person shall offer for transportation any carcass, part thereof, meat or meat food product until a certificate, if required for such transportation by this part, is made and furnished to the carrier in one of the forms prescribed in this part.
(2) Product imported into the United States may be transported and offered or received for transportation if such product is conveyed in railroad cars, trucks or other means of conveyance, prior to inspection, to an authorized place of inspection, as provided in Sec. 327.6 of this part.
(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, meat or meat food products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation in commerce or in any State designated under Sec. 331.2 of this subchapter, any such meat or meat food product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Program's discretion and shall be adequate to determine if product in such conveyance is, or when moved could become, adulterated. Circumstances of transport that can be reasonably anticipated shall be considered in

making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Product placed in any means of conveyance that is found by the inspector to be in such condition that the product may have become adulterated shall be removed from the means of conveyance and handled in accordance with Sec. 318.2(d) of this subchapter.
[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 23700, June 11, 1976; 47 FR 17274, Apr. 22, 1982; 56 FR 65180, Dec. 16, 1991]

…
Sec. 325.5 Unmarked inspected product transported under official seal between official establishments for further processing; certificate.

(a) Any product which has been inspected and passed may be transported from one official establishment to another for further processing without each article being marked with the official inspection legend, if it is so transported in a railroad car, motor truck, or other means of conveyance which is sealed by a Program employee with an official seal of the Department prescribed in Sec. 312.5(a) of this subchapter. Unless 25 percent or more of the contents of each car or other means of conveyance consists of product not marked with the inspection legend, transportation will not be permitted under this paragraph.

…
Sec. 325.14 Certificates, retention by carrier.

All original certificates delivered to a carrier in accordance with this part shall be filed separate and apart from all its other papers and records or identified in such a manner as to be readily checked by Department employees. Every certificate required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction has occurred.

…
Sec. 325.16 Official seals; forms, use, and breaking.

(a) The official seals required by this part shall be those prescribed in Sec. 312.5(a) of this subchapter.
(b) Except as provided in Sec. 325.18(b), official seal affixed under this part shall be affixed or broken only by Program employees, and no person other than a Program employee shall affix, detach, break, change, or tamper with any such seal in any way whatever. Commission of any such acts contrary to this regulation is a criminal offense.

Sec. 325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.

Unloading any product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any product or any other commodity in the means of conveyance while en route from one official establishment to another official establishment is not permitted, except that product transported under Sec. 325.5 from one official establishment to another for further processing may be unloaded and stored in transit at any approved warehouse which is operated under the identification service provided under the regulations in part 350 of subchapter B of this chapter and which has railroad facilities or a receiving dock for unloading the product directly into such warehouse: Provided, That the product is stored in rooms which are of such size and type as will not result in adulteration or misbranding of the product: And provided further, That the product is transported to and from such warehouse, and under official seal as provided in Sec. 325.5 and stored in such rooms at such warehouse.

11 Appendix 2. Selected Portions of 9CFR417

[Code of Federal Regulations]
[Title 9, Volume 2]
[Revised as of January 1, 2007]
From the U.S. Government Printing Office via GPO Access
[CITE: 9CFR417]

TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 417_HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53.

Source: 61 FR 38868, July 25, 1996, unless otherwise noted.
…
Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

...

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter--all species.

(ii) Raw product--ground.

(iii) Raw product--not ground.

(iv) Thermally processed--commercially sterile.

(v) Not heat treated--shelf stable.

(vi) Heat treated--shelf stable.

(vii) Fully cooked--not shelf stable.

(viii) Heat treated but not fully cooked--not shelf stable.

(ix) Product with secondary inhibitors--not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and
(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.
(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.
(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.
(2) The HACCP plan shall be dated and signed:
(i) Upon initial acceptance;
(ii) Upon any modification; and
(iii) At least annually, upon reassessment, as required under Sec. 417.4(a) (3) of this part.
(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[61 FR 38868, July 25, 1996, as amended at 62 FR 61009, Nov. 14, 1997]

…
Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.
(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:
(i) The calibration of process-monitoring instruments;
(ii) Direct observations of monitoring activities and corrective actions; and
(iii) The review of records generated and maintained in accordance with Sec. 417.5(a) (3) of this part.
(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect

the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.
(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.
(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

…
Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:
(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and
(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.
(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:
(a) Reviewing the HACCP plan;
(b) Reviewing the CCP records;
(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
(d) Reviewing the critical limits;
(e) Reviewing other records pertaining to the HACCP plan or system;
(f) Direct observation or measurement at a CCP;
(g) Sample collection and analysis to determine the product meets all safety standards; and
(h) On-site observations and record review.

12 Appendix 3. Selected Portions of 9CFR590.

[Code of Federal Regulations]
[Title 9, Volume 2]
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TITLE 9--ANIMALS AND ANIMAL PRODUCTS
CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 590_INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)--Table of Contents

Sec. 590.5 Terms defined.

For the purpose of these regulations, unless the context otherwise requires, the following terms shall be construed, respectively, as follows:
Acceptable means suitable for the purpose intended and acceptable to the Administrator.

Act means the applicable provisions of the Egg Products Inspection Act (Pub. L. 91-597, 84 Stat. 1620 et seq.).
…
Egg product means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following products, among others, are exempted as not being egg products: Freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing eggs or egg products, provided, such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Balut and other similar ethnic delicacies are also exempted from inspection under this part.

…
Label means a display of any printed, graphic, or other method of identification upon the shipping container, if any, or upon the immediate container, including but not limited to, an individual consumer package of eggs and egg products, or accompanying such product.

…

Official certificate means any certificate prescribed by regulations of the Administrator for issuance by an inspector or other person performing official functions under this part.

Official device means any device prescribed or authorized by the Secretary for use in applying any official mark.

Official identification means the official inspection mark or any other symbol prescribed by regulations of this part to identify the status of any article.

Official inspection mark means any symbol prescribed by the regulations of the Administrator showing that egg products were inspected in accordance with this part.

Official standard means the standards of quality, grades, and weight classes for eggs.

Office of inspection means the office of any inspector.

Pasteurize means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms by such processes as may be prescribed by these regulations.

…

Plant means any place of business where egg products are processed:

(a) Exempted plant means any plant where the Administrator has determined the facilities and operating procedures meet such standards as may be prescribed by this part, and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of U.S. Consumer Grade B for shell eggs, and where an exemption has been granted.

(b) Official plant means any plant in which the plant facilities, methods of operation and sanitary procedures have been found suitable and adequate by the Administrator for the continuous inspection of egg products in accordance with this part and in which inspection service is carried on.

…

Processing means manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products at official plants.

Producer-packer means any producer who sorts eggs only from his own production and packs them into their various qualities.

…

[36 FR 9814, May 28, 1971, as amended at 37 FR 6657, Apr. 4, 1972; 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46070, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982; 54 FR 37289, Sept. 8, 1989; 60 FR 49168,

Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995; 63 FR 45674, Aug. 27, 1998; 63 FR 69971, Dec. 17, 1998]

…

Sec. 590.24 Egg products plants requiring continuous inspection.

No plant in which egg products processing operations are conducted shall process egg products without continuous inspection under these regulations, except as expressly exempted in Sec. 590.100.

…

Sec. 590.26 Egg products entering or prepared in official plants.

Eggs and egg products processed in an official plant shall be inspected, processed, marked, and labeled as required by these regulations. Egg products entering an official plant shall have been inspected, processed, marked, and labeled as required by these regulations.

Sec. 590.200 Records and related requirements.

(a) Persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, including hatcheries, shall maintain records showing, for a period of 2 years, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of an authorized representative of the Secretary, permit him, at reasonable times, to have access to and to copy all such records.

(b) Production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, leakers, loss, inedible, etc., bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc., as determined by the Administrator, shall be maintained by all egg processing operations, except that, official egg products plants which use all shell eggs received and do not reship any shell eggs need only to maintain records indicating the amount of eggs received, date received, and the name and address of the shipper.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 63 FR 69971, Dec. 17, 1998]

Sec. 590.402 Egg products inspection certificates.

(a) Upon request of the applicant or the Service, any inspector is authorized to issue an egg products inspection certificate with respect to any lot of egg products inspected by him. In addition, an inspector is authorized to issue an inspection certificate covering product inspected in whole or in part by another inspector when the inspector has

knowledge that the product is eligible for certification based on personal examination of the product or official inspection records.

(b) Each egg products inspection certificate shall show the name and address of the processor, the class and quantity of the egg products covered by such certificate, such shipping marks as are necessary to identify such products, all pertinent information concerning the wholesomeness thereof, and such other information as the Administrator may prescribe or approve.

Sec. 590.410 Shell eggs and egg products required to be labeled.

(a) All shell eggs packed into containers destined for the ultimate consumer shall be labeled to indicate that refrigeration is required, e.g., ``Keep Refrigerated,'' or words of similar meaning.

(b) Containers and portable tanks of edible egg products, prior to leaving the official plant, shall be labeled in accordance with Sec. Sec. 590.411 through 590.415 and shall bear the official identification shown in Figure 2 of Sec. 590.412 or Figure 3 or 4 of Sec. 590.415. Bulk transport shipments of liquid pasteurized egg products to nonofficial outlets need not be sealed. Bulk shipments of liquid egg products transported from one official plant to another shall be sealed and accompanied by an official certificate.

[40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 45675, Aug. 27, 1998]

Sec. 590.411 Requirement of formulas and approval of labels for use in official egg products plants.

(a) No label, container, or packaging material which bears official identification may bear any statement that is false or misleading. Any label, container, or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label, container, or packaging material bearing official identification may be used unless it is approved by the Administrator in accordance with paragraph (b) of this section. The use of finished labels must be approved as prescribed by the Administrator. If the label is printed on or otherwise applied directly to the container or packaging material, the principal display panel thereof shall be considered as the label.

(b) No label, container, or packaging material bearing official identification may be printed or prepared for use until the printers' or other final proof has been approved by the Administrator in accordance with the regulations in this part, the Egg Products Inspection Act, the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated under these acts. Copies of each label submitted for approval shall be accompanied by:

(1) A statement showing by their common or usual names the kinds and percentages of the ingredients comprising the egg product. A range may be given in cases where the percentages may vary from time to time. Formulas are to be expressed in terms of a liquid product except for products which are dry blended. Also, for products to be dried, the label may show the ingredients in the order of descending proportions by weight in the dried form. However, the formula submitted must include the percentage of ingredients in both liquid and dried form.

(2) When required, scientific data demonstrating that the substance or mixture is safe and effective for its intended use and does not promote deception or cause the product to be otherwise adulterated or misbranded.

(c) Containers of product bearing official identification shall display the following information:

(1) The common or usual name, if any, and if the product is comprised of two or more ingredients, such ingredients shall be listed in the order of descending proportions by weight in the form in which the product is to be marketed (sold), except that ingredients in dried products (other than dry blended) may be listed in either liquid or dried form. When water (excluding that used to reconstitute dehydrated ingredients back to their normal composition) is added to a liquid or frozen egg product or to an ingredient of such products (in excess of the normal water content of that ingredient), the total amount of water added, including the water content of any cellulose or vegetable gums used, shall be expressed as a percentage of the total product weight in the ingredient statement on the label.

(2) The name, address, and ZIP code of the packer or distributor. When the distributor is shown, it shall be qualified by such terms as “packed for”, “distributed by”, or “distributors”;

(3) The lot number or approved alternative code number indicating date of production;

(4) The net contents;

(5) Official identification and plant number;

(6) Egg products which are produced in an official plant from edible shell eggs of other than current production or from other egg products produced from shell eggs of other than current production, shall be clearly and distinctly labeled in close proximity to the common or usual name of the product, e.g., ``Manufactured from eggs of other than current production";

(7) Egg products produced from edible shell eggs or the egg product produced from such shell eggs of the turkey, duck, goose, or guinea shall be clearly and distinctly labeled as to the common or usual name of the product indicating the type of eggs or egg products used in the product, e.g., ``Frozen whole turkey eggs," ``Frozen whole chicken and turkey

eggs." Egg products labeled without qualifying words as to the type of shell egg used in the product shall be produced only from the edible shell egg of the domesticated chicken or the egg product produced from such shell eggs.

(d) Liquid or frozen egg products identified as whole eggs and prepared other than in natural proportions, as broken from the shell, shall have a total egg solids content of 24.20 percent or greater.

(e) Nutrition information may be included on labels used to identify egg products, providing such labeling complies with the provisions of 21 CFR Part 101, promulgated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Since these regulations have different requirements for consumer packaged products than for bulk packaged egg products not for sale or distribution to household consumers, label submission shall be accompanied with information indicating whether the label covers consumer packaged or bulk packaged product. Nutrition labeling is required when nutrients, such as proteins, vitamins, and minerals are added to the product, or when a nutritional claim or information is presented on the labeling, except for the following which are exempt from nutrition labeling requirements:

(1) Egg products shipped in bulk form for use solely in the manufacture of other food and not for distribution to household consumers in such bulk form or containers.

(2) Products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label, or in advertising, which is supplied for institutional food use only: Provided, that the manufacturer or distributor provides the required nutrition information directly to those institutions.

(3) Any nutrient(s) included in product solely for technological purpose may be declared solely in the ingredients statement, without complying with nutrition labeling, if the nutrient(s) is otherwise not referred to in labeling or in advertising. All labels showing nutrition information or claims are subject to review by the Food and Drug Administration prior to approval by the Department.

(f) If the Administrator has reason to believe that the statement on formulation shows the product to be adulterated or misbranded or that any labeling, or the size or form of any container in use or proposed for use in respect to egg products at any official plant is false or misleading in any way, he may direct that such use be withheld unless the labeling or container is modified in such a manner as he may prescribe so that it will not be false or misleading, and/or the formulation of the product is altered in such a manner that he may prescribe so that it is not adulterated, or would not cause misbranding. Any person so denied the approval of any label shall be notified promptly of the reasons for the denial on a form approved by the Administrator. If the person using or proposing to use the label does not accept the determination of the Administrator, he may request a hearing by filing with the Administrator within 10 days after receiving the notice of denial, a written application for a hearing setting forth specifically, the errors alleged to have been made by the Administrator in denying approval of the label. The use of the label shall be

withheld pending hearing and final determination by the Administrator if the Administrator so directs. Hearings held pursuant to this subsection shall be presided at by the Administrator. The applicant shall be given the opportunity to present evidence both oral and written in support of his allegation that the Administrator erred in denying approval of the label. The notice of denial together with all other available data and information used as a basis for such denial shall be considered part of the record. The Administrator may take official notice of such matters as are judicially noticed by the Courts of the United States and of any other matter of technical, scientific, or commercial fact of established character. The Administrator shall make his final determination with respect to the matter upon the basis of evidence before him. Such determination shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

[37 FR 6658, Apr. 1, 1972, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 53 FR 23751, June 24, 1988; 60 FR 49169, Sept. 21, 1995]

Sec. 590.412 Form of official identification symbol and inspection mark.

(a) The shield set forth in Figure 1 containing the letters ``USDA'' shall be the official identification symbol for purposes of this part and, when used, imitated, or simulated in any manner in connection with a product, shall be deemed to constitute a representation that the product has been officially inspected.
(b) The inspection mark which is to be used on containers of edible egg products shall be contained within the outline of a shield and with the wording and design set forth in Figure 2 of this section, except the plant number may be preceded by the letter ``P'' in lieu of the word ``plant''. Alternatively, it may be omitted from the official shield if applied on the container's principal display panel or other prominent location and preceded by the letter ``P'' or the word ``Plant''.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

Sec. 590.414 Products bearing the official inspection mark.

Egg products which are permitted to bear the inspection mark shall be processed in an official plant from edible shell eggs or other edible egg products and may contain other edible ingredients. The official mark shall be printed or lithographed and applied as a part of the principal display panel of the container but shall not be applied to a detachable cover.

Sec. 590.500 Plant requirements.

(a) The plant shall be free from objectionable odors, dust, and smoke laden air.

(b) The premises shall be free from refuse, rubbish, waste, and other materials and conditions which constitute a source of odors or a harbor for insects, rodents, and other vermin.

(c) The buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of vermin.

(d) Rooms shall be kept free from refuse, rubbish, waste materials, odors, insects, rodents, and from any conditions which may constitute a source of odors or engender insects and rodents. Materials and equipment not currently needed shall be handled or stored in a manner so as not to constitute a sanitary hazard.

(e) Doors and windows that open to the outside shall be protected against the entrance of flies and other insects. Doors and windows serving rooms where edible product is exposed shall be so designed and installed to prevent the entrance of dust and dirt. Doors leading into rooms where edible product is processed shall be of solid construction and such doors, other than freezer and cooler doors, shall be fitted with self-closing devices.

(f) Doors and other openings which are accessible to rodents shall be of rodent-proof construction.

(g) There shall be an efficient drainage and plumbing system for the plant and premises. Drains and gutters shall be properly installed with approved traps and vents. The sewage system shall have adequate slope and capacity to readily remove waste from the various processing operations. Floor drains shall be equipped with traps, and constructed so as to minimize clogging. In new or remodeled construction the drainage systems from toilets and laboratories shall not be connected with other drainage systems within the plant.

(h) The water supply (both hot and cold) shall be ample, clean, and potable, with adequate pressure and facilities for its distribution throughout the plant or portion thereof utilized for egg processing and handling operations and protected against contamination and pollution. A water report, issued under the authority of a State or municipal health agency, certifying to the potability of the water supply shall be obtained by the applicant and furnished to the Administrator whenever such report is required by the Administrator.

(i) The floors, walls, ceiling, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish to permit their ready and thorough cleaning. The floors and curbing shall be watertight.

(j) Each room and each compartment in which any shell eggs or egg products are handled or processed shall be so designed, constructed, and maintained to insure

processing and operating conditions of a clean and orderly character, free from objectionable odors and vapors, and maintained in a clean and sanitary condition.

(k) Every precaution shall be taken to exclude dogs, cats, and vermin (including, but not being limited to, rodents and insects) from the plant, or portion thereof utilized in which shell eggs or egg products are handled or stored.

…

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

Sec. 590.502 Equipment and utensils; PCB-containing equipment.

(a) Equipment and utensils used in processing shell eggs and egg products shall be of such design, material, and construction as will:

(1) Enable the examination, segregation, and processing of such products in an efficient, clean, and satisfactory manner;

(2) Permit easy access to all parts to insure thorough cleaning and sanitizing. So far as is practicable, all such equipment shall be made of metal or other impervious material which will not affect the product by chemical action or physical contact.

(b) Except as authorized by the Administrator, in new or remodeled equipment and equipment installations, the equipment and installation shall comply with the applicable 3-A or E-3-A Sanitary Standards and accepted practices currently in effect for such equipment.

(c) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official plant shall not contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and nonfood processing equipment and machinery, and any replacement parts for such equipment and machinery. Totally enclosed capacitors containing less than 3 pounds of PCBs are exempted from this prohibition.

Sec. 590.504 General operating procedures.

(a) Operations involving processing, storing, and handling of shell eggs, ingredients, and egg products shall be strictly in accord with clean and sanitary methods and shall be conducted as rapidly as practicable. Pasteurization, heat treatment, stabilization, and other processes shall be in accord with this part and as approved by the Administrator. Processing methods and temperatures in all operations shall be such as will prevent a deterioration of the egg products.

(b) Shell eggs and egg products processed in official plants shall be subjected to constant and continuous inspection throughout each and every processing operation. Any shell egg or egg product which was not processed in accordance with these regulations or is not fit for human food shall be removed and segregated.

(c) All loss and inedible eggs or egg products shall be placed in a container clearly labeled ``inedible'' and containing a sufficient amount of approved denaturant or decharacterant, such as FD&C brown, blue, black, or green colors, meat and fish by-products, grain and milling by-products, or any other substance, as approved by the Administrator, that will accomplish the purposes of this section. Shell eggs shall be crushed and the substance shall be dispersed through the product in amounts sufficient to give the product a distinctive appearance or odor. Notwithstanding the foregoing, and upon permission of the Inspector, the applicant may hold inedible product in containers clearly labeled inedible which do not contain a denaturant if such inedible product is denatured or decharacterized prior to shipment from the official plant: Provided, That such product is properly packaged, labeled, segregated, and inventory controls are maintained. In addition, product shipped from the official plant for industrial use or animal food need not be denatured or decharacterized, provided, that such product is properly packaged, labeled, segregated, and inventory controls are maintained, and that such product is shipped under Government seal and certificate and received at the destination location by an inspector or grader as defined in this part.

(d) The inspector may, prior to receipt of laboratory results for salmonella, or for other reasons such as labeling as to solids content, permit egg products to be shipped from the official plant when he has no reason to suspect noncompliance with any of the provisions of this part. However, such shipments shall be made under circumstances which will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as the Administrator may determine to assure compliance with this part.

(e) Pasteurizing, stabilizing, or drying operations shall start as soon as practicable after breaking to prevent deterioration of product, preferably within 72 hours from time of breaking for egg products other than whites which are to be desugared.

(f) Each person who is to handle any exposed or unpacked egg products or any utensils or container which may come into contact with egg product, shall wash his hands and maintain them in a clean condition.

(g) No product or material which creates an objectionable condition shall be processed, stored, or handled in any room, compartment, or place where any shell eggs or egg products are processed, stored or handled.

(h) Only germicides, insecticides, rodenticides, detergents, or wetting agents or other similar compounds which will not deleteriously affect the eggs or egg products when used in an approved manner and which have been approved by the Administrator, may be used in an official plant. The identification, storage, and use of such compounds shall be in a manner approved by the Administrator.

(i) Utensils and equipment which are contaminated during the course of processing any shell eggs or egg products shall be removed from use immediately and shall not be used again until cleaned and sanitized.

(j) Any substance or ingredient added in the processing of any egg products shall be clean and fit for human food.

(k) Packages or containers for egg products shall be of sanitary design and clean when being filled with any egg products; and all reasonable precautions shall be taken to avoid soiling or contaminating the surface of any package or container liner which is, or will be, in direct contact with such egg products. Only new containers or used containers that are clean, in sound condition and lined with suitable inner liners shall be used for packaging edible egg products. Fiber containers used without liners require the approval of the Administrator.

(l) Egg products shall be inspected to determine the wholesomeness of the finished product.

(m) Egg products shall be processed in such a manner as to insure the immediate removal of blood and meat spots, shell particles, and foreign materials.

(n) Utensils and equipment, except drying units, powder conveyors, sifters, blenders, and mechanical powder coolers shall be clean and sanitized at the start of processing operations. Equipment and utensils shall be kept clean and sanitary during all processing operations.

(o) Egg products prior to being released into consuming channels shall be pasteurized in accordance with Sec. 590.570 except that dried whites prepared from nonpasteurized liquid shall be heat treated in accordance with Sec. 590.575.

(1) To assure adequate pasteurization, egg products shall be sampled and tested for the presence of salmonella. Sampling for the presence of salmonella shall be in accordance with Sec. 590.580 and product found to be salmonella positive shall be reprocessed, pasteurized, and analyzed for the presence of salmonella, or denatured.

(2) Nonpasteurized or salmonella positive egg product may be shipped from an official plant only when it is to be pasteurized, repasteurized, or heat treated in another official plant. Shipments of products from one official plant to another for pasteurization, repasteurization, or heat treatment shall be in sealed cars or trucks with an accompanying certificate stating that the product is not pasteurized or is salmonella positive. If nonpasteurized or salmonella positive products are to be stored in other than the official plant facilities, the inspector at the consignee's and consignor's plants shall be given full knowledge of the disposition of the product, including warehouse inventory receipts, until such time as product is pasteurized, repasteurized, or heat treated. The containers of such nonpasteurized or salmonella positive product shall be marked with the identification mark shown in Figure 3 of Sec. 590.415.

(3) Notwithstanding the provision of paragraph (o)(2) of this section, nonpasteurized salted egg products containing 10 percent or more salt added may be shipped from an

official plant directly to a manufacturer of acidic dressings only under the following provisions:

(i) Before such shipment is made, the manufacturer of the acidic dressing shall apply in writing and receive permission from the Administrator to receive and use unpasteurized egg products. The applicant shall sign a written statement containing the specification for the treatment of the nonpasteurized egg product in a manner that will insure that viable salmonella microorganisms are destroyed, and such processing treatment shall be approved by the Administrator prior to use.

(ii) Product shall be shipped under seal from the official plant, accompanied by an official USDA certificate stating that the product is nonpasteurized and for use in acidic dressings only.

(iii) The applicant shall acknowledge receipt of each shipment by indicating on the reverse side of the USDA certificate. ``The quantity of nonpasteurized egg product stated on this certificate was received at ----------,'' the blank being filled in with the name and address of the receiving company and the date and signature of the person completing the form. The certificate shall be returned to the USDA inspector at the origin plant.

(iv) The acidic dressing manufacturer shall maintain processing records indicating the use of each shipment of unpasteurized salted product and the code lots of acidic dressing into which it was processed. Records of the pH and the acidity expressed as percent acetic acid of each code lot shall be maintained. The records shall also demonstrate that the acidic dressing was held 72 hours prior to shipment. These records shall be maintained for 2 years and shall be available for inspection by a representative of the Department.

(v) Each container of salted egg product shipped from the official plant shall be labeled as required in Sec. 590.411, and shall bear the words ``Caution--this egg product has not been pasteurized or otherwise treated to destroy viable salmonella microorganisms,'' and shall bear the official identification shown in figure 4 of Sec. 590.415.

(p) Air which is to come in contact with product or with product contact surfaces shall come from approved filtered outside air sources.

(q) All liquid and solid waste material in the official plant shall be disposed of in a manner approved by the Administrator to prevent product contamination and in accordance with acceptable environmental protection practices.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6658, Apr. 1, 1972; 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995]

Sec. 590.515 Egg cleaning operations.

(a) The following requirements shall be met when washing shell eggs to be presented for breaking:

(1) Shell egg cleaning equipment shall be kept in good repair and shall be cleaned after each day's use or more frequently if necessary.

(2) The temperature of the wash water shall be maintained at 90 [deg] F or higher, and shall be at least 20 [deg] F warmer than the temperature of the eggs to be washed. These temperatures shall be maintained throughout the cleaning cycle.

(3) An approved cleaning compound shall be used in the wash water. (The use of metered equipment for dispensing the compound into solution is recommended.)

(4) Wash water shall be changed approximately every 4 hours or more often if needed to maintain sanitary conditions and at the end of each shift. Remedial measures shall be taken to prevent excess foaming during the egg washing operation.

(5) Replacement water shall be added continuously to the wash water of washers to maintain a continuous overflow. Rinse water and chlorine sanitizing rinse may be used as part of the replacement water. Iodine sanitizing rinse may not be used as part of the replacement water.

(6) Waste water from the egg washing operation shall be piped directly to drains.

(7) The washing operation shall be continuous and shall be completed as rapidly as possible. Eggs shall not be allowed to stand or soak in water. Immersion-type washers shall not be used.

(8) Prewetting shell eggs prior to washing may be accomplished by spraying a continuous flow of water over the eggs in a manner which permits the water to drain away, or by other methods which may be approved by the Administrator.

(b) Shell eggs shall not be washed in the breaking room or any room where edible products are processed.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

Sec. 590.516 Sanitizing and drying of shell eggs prior to breaking.

(a) Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternative procedures may be approved by the Administrator in lieu of sanitizing shell eggs washed in the plant.

(b) Shell eggs shall be sufficiently dry at time of breaking to prevent contamination or adulteration of the liquid egg product from free moisture on the shell.

[60 FR 49170, Sept. 21, 1995]

Sec. 590.520 Breaking room facilities.

(a) The breaking room shall have at least 30 foot-candles of light on all working surfaces except that light intensity shall be at least 50 foot-candles at breaking and inspection stations. Lights shall be protected with adequate safety devices.

(b) The surface of the ceiling and walls shall be smooth and made of a water-resistant material.

(c) The floor shall be of water-proof composition, reasonably free from cracks or rough surfaces, sloped for adequate drainage, and the intersections with walls and curbing shall be impervious to water.

(d) Ventilation shall provide for:

(1) A positive flow of outside filtered air through the room;

(2) Air of suitable working temperature during operations.

(e) There shall be provided adequate hand washing facilities which are easily accessible to all breaking personnel, an adequate supply of warm water, clean towels or other facilities for drying hands, odorless soap, and containers for used towels. Hand washing facilities shall be operated by other than hand operated controls.
(f) Containers for packaging egg products are not acceptable as liquid egg buckets.

(g) A suitable container conspicuously identified shall be provided for the disposal of rejected liquid.

(h) Strainers, filters, or centrifugal clarifiers of approved construction shall be provided for the effective removal of shell particles and foreign material, unless specific approval is obtained from the National Supervisor for other mechanical devices.

(i) A separate drawoff room with a filtered positive air ventilation system shall be provided for packaging liquid egg product, except product packaged by automatic, closed packaging systems.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

Sec. 590.522 Breaking room operations.

(a) The breaking room shall be kept in a dust-free clean condition and free from flies, insects, and rodents. The floor shall be kept clean and reasonably dry during breaking operations and free of egg meat and shells.

(b) All breaking room personnel shall wash their hands thoroughly with odorless soap and water each time they enter the breaking room and prior to receiving clean equipment after breaking an inedible egg.

(c) Paper towels or tissues shall be used at breaking tables, and shall not be reused. Cloth towels are not permitted.

(d) Breakers shall use a complete set of clean equipment when starting work and after lunch periods. All table equipment shall be rotated with clean equipment every 2\1/2\ hours.

(e) Cups shall not be filled to overflowing.

(f) Each shell egg shall be broken in a satisfactory and sanitary manner and inspected for wholesomeness by smelling the shell or the egg meat and by visual examination at the time of breaking. All egg meat shall be reexamined by a person qualified to perform such functions before being emptied into the tank or churn, except as otherwise approved by the National Supervisor.

(g) Shell particles, meat and blood spots, and other foreign material accidentally falling into the cups or trays shall be removed with a spoon or other approved instrument.

(h) Whenever an inedible egg is broken, the affected breaking equipment shall be cleaned and sanitized.

(i) Inedible and loss eggs as defined in Sec. 590.510 apply to this section.

(j) The contents of any cup or other liquid egg receptacle containing one or more inedible or loss eggs shall be rejected.

(k) Contents of drip trays shall be emptied into a cup and smelled carefully before pouring into liquid egg bucket. Drip trays shall be emptied at least once for each 15 dozen eggs or every 15 minutes.

(l) Edible leakers as defined in Sec. 590.510(c)(2) and checks which are liable to be smashed in the breaking operation shall be broken at a separate station by specially trained personnel.

(m) Ingredients and additives used in, or for, processing egg products, shall be handled in a clean and sanitary manner.

(n) Liquid egg containers shall not pass through the candling room.

(o) Test kits shall be provided and used to determine the strength of the sanitizing solution. (See Sec. Sec. 590.515(a) (9) and 590.552.)

(p) Leaker trays shall be washed and sanitized whenever they become soiled and at the end of each shift.

(q) Shell egg containers whenever dirty shall be cleaned and drained; and shall be cleaned, sanitized, and drained at the end of each shift.

(r) Belt-type shell egg conveyors shall be cleaned and sanitized approximately every 4 hours in addition to continuous cleaning during operation. When not in use, belts shall be raised to permit air drying.

(s) Cups, knives, racks, separators, trays, spoons, liquid egg pails, and other breaking equipment, except for mechanical egg breaking equipment, shall be cleaned and sanitized at least every 2\1/2\ hours. This equipment shall be cleaned at the end of each shift and shall be clean and sanitized immediately prior to use.

(t) Utensils and dismantled equipment shall be drained and air dried on approved self-draining metal racks and shall not be nested.

(u) Dump tanks, drawoff tanks, and churns shall be cleaned approximately every 4 hours. All such equipment and all other liquid handling equipment, unless cleaned by acceptable cleaned in-place methods, shall be dismantled and cleaned after each shift. Pasteurization equipment shall be cleaned at the end of each day's use or more often if necessary. All such equipment shall be clean and shall be sanitized prior to placing in use.

(v) Strainers, clarifiers, filtering and other devices used for removal of shell particles and other foreign material shall be cleaned and sanitized each time it is necessary to change such equipment, but at least once each 4 hours of operation.

(w) Breaking room processing equipment shall not be stored on the floor.

(x) Metal containers and lids for other than dried products shall be thoroughly washed, rinsed, sanitized, and drained immediately prior to filling. The foregoing sequence shall not be required if equally effective measures approved by the National Supervisor in writing are followed to assure clean and sanitary containers at the time of filling.

(y) Liquid egg holding vats and containers (including tank trucks) used for transporting liquid eggs shall be cleaned after each use. Such equipment shall be clean and sanitized immediately prior to placing in use.

(z) Tables, shell conveyors, and containers for inedible egg product shall be cleaned at the end of each shift.

(aa) Mechanical egg breaking machines shall be operated at a rate to maintain complete control and accurately inspect and segregate each egg to insure the removal of all loss and inedible eggs. The machine shall be operated in a sanitary manner.

(1) When an inedible egg is encountered on mechanical egg breaking equipment, the inedible egg and contaminated liquid shall be removed. The machine shall be cleaned and sanitized, or contaminated parts replaced with clean ones in the manner prescribed by the Administrator for the type of inedible egg encountered and the kind of egg breaking machine.

(2) Systems for pumping egg liquid directly from egg breaking machines shall be of approved sanitary design and construction, and designed to minimize the entrance of shells into the system and be disconnected when inedible eggs are encountered. The pipelines of the pumping system shall be cleaned or flushed as often as needed to maintain them in a sanitary condition, and they shall be cleaned and sanitized at the end of each shift. Other pumping system equipment shall be cleaned and sanitized approximately every 4 hours or as often as needed to maintain it in a sanitary condition. All liquid egg pumped directly from egg breaking machines shall be reexamined, except as otherwise prescribed and approved by the Administrator.

(3) Mechanical egg breaking equipment shall be clean and sanitized prior to use, and during operations the machines shall be cleaned and sanitized approximately every 4 hours or more often if needed to maintain them in a sanitary condition. This equipment shall be cleaned at the end of each shift.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972; 40 FR 20059, May 8, 1975; 40 FR 20941, May 14, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

Sec. 590.532 Liquid egg holding.

(a) Tanks and vats used for holding liquid eggs shall be of approved construction, fitted with covers, and located in rooms maintained in a sanitary condition. Notwithstanding the foregoing, tanks designed for installation partially outside of a room or building are acceptable, providing all openings into the tanks terminate in the processing room.

(b) Liquid egg holding tanks or vats shall be equipped with suitable thermometers and agitators.

(c) Inlets to holding tanks or vats shall be such as to prevent excessive foaming.

(d) Gaskets, if used, shall be of a sanitary type.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

Sec. 590.570 Pasteurization of liquid eggs.

(a) Pasteurization facilities: The facilities for pasteurization of egg products shall be adequate and of approved construction so that all products will be processed as provided for in this section. Pasteurization equipment for liquid egg product shall include a holding tube, an automatic flow diversion valve, thermal controls, and recording devices to determine compliance for pasteurization as set forth in paragraph (b) of this section. The temperature of the heated liquid egg product shall be continuously and automatically recorded during the process.

(b) Pasteurizing operations: Every particle of all products must be rapidly heated to the required temperature and held at that temperature for the required minimum holding time as set forth in this section. The temperatures and holding times listed in Table I of this section are minimum. The product may be heated to higher temperatures and held for longer periods of time. Pasteurization procedures shall assure complete pasteurization, and holding, packaging, facilities and operations shall be such as to prevent contamination of the product.

Table I--Pasteurization Requirements \1\

Liquid egg product	Minimum temperature requirements (deg. F.)	Minimum holding time requirements (Minutes)
Albumen (without use of chemicals)	134	3.5
	132	6.2
Whole egg	140	3.5
Whole egg blends (less than 2 percent	142	3.5
added non-egg ingredients)	140	6.2
Fortified whole egg and blends (24-38	144	3.5
percent egg solids, 2-12 percent added	142	6.2
non-egg ingredients)		
Salt whole egg (with 2 percent or more	146	3.5
salt added)	144	6.2
Sugar whole egg (2-12 percent sugar	142	3.5
added)	140	6.2
Plain yolk	142	3.5
	140	6.2
Sugar yolk (2 percent or more sugar	146	3.5
added)	144	6.2
Salt yolk (2-12 percent salt added)	146	3.5
	144	6.2

\1\ Pasteurization of egg products not listed in this table shall be in accordance with paragraph (c) of this section.

(c) Other methods of pasteurization may be approved by the Administrator when such treatments give equivalent effects to those specified in paragraph (b) of this section for those products or other products and results in a salmonella negative product.

13 Appendix 4. Selected Portion of 9CFR590, Showing Official Identification Marks and Seals

(b) The inspection mark which is to be used on containers of edible egg products shall be contained within the outline of a shield and with the wording and design set forth in Figure 2 of this section, except the plant number may be preceded by the letter "P" in lieu of the word "plant". Alternatively, it may be omitted from the official shield if applied on the container's principal display panel or other prominent location and preceded by the letter "P" or the word "Plant".

FIGURE 1.

FIGURE 2.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20008, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§590.414 Products bearing the official inspection mark.

Egg products which are permitted to bear the inspection mark shall be processed in an official plant from edible shell eggs or other edible egg products and may contain other edible ingredients. The official mark shall be printed or lithographed and applied as a part of the principal display panel of the container but shall not be applied to a detachable cover.

§590.415 Use of other official identification.

Other official identification as shown in this section shall be printed or lithographed and applied as a part of the principal display panel, but shall not be applied to a detachable cover. The plant number may be omitted from the identification if applied elsewhere on the container's principal display panel or other prominent location and preceded by the letter "P" or the word "plant". Such products shall meet all requirements for egg products which are permitted to bear the official inspection mark shown in §590.412, except for pasteurization, heat treatment, or other such methods of treatment approved by the Administrator. Such products shall not be released into consuming channels until they have been subjected to pasteurization, heat treatment, or other approved methods of treatment.

(a) All nonpasteurized egg products, except as provided in paragraph (b) of this section, shipped from an official plant in packaged form shall be marked with the identification set forth in Figure 3 of this section. After pasteurization or treatment, the product may bear the official inspection mark as shown in §590.412.

FIGURE 3.

14 Appendix 5. Selected Portions of 21CFR110

[Code of Federal Regulations]
[Title 21, Volume 2]
[Revised as of April 1, 2006]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR110]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED) PART 110_CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Subpart A_General Provisions

Sec.
110.3 Definitions.
110.5 Current good manufacturing practice.
110.10 Personnel.
110.19 Exclusions.

Subpart B_Buildings and Facilities

110.20 Plant and grounds.
110.35 Sanitary operations.
110.37 Sanitary facilities and controls.

Subpart C_Equipment

110.40 Equipment and utensils.

Subpart D [Reserved]

Subpart E_Production and Process Controls

110.80 Processes and controls.
110.93 Warehousing and distribution.

Subpart F [Reserved]

Subpart G_Defect Action Levels

110.110 Natural or unavoidable defects in food for human use that present no health hazard.

Authority: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

Source: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A_General Provisions

Sec. 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

(b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ``Food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

(h) Lot means the food produced during a period of time indicated by a specific code.

(i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ``undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ``microbial'' instead of using an adjectival phrase containing the word microorganism.

(j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

(k) Plant means the building or premises or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
(n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
(o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
(p) Shall is used to state mandatory requirements.
(q) Should is used to state recommended or advisory procedures or identify recommended equipment.
(r) Water activity is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Sec. 110.5 Current good manufacturing practice.

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

Sec. 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:
(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the

extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:
(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
(2) Maintaining adequate personal cleanliness.
(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing premises before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.
(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.
(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

…
Subpart B_Buildings and Facilities

Sec. 110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
(7) Provide, where necessary, adequate screening or other protection against pests.

Sec. 110.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
…
(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

…
Subpart E_Production and Process Controls

Sec. 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.
(a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be

reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:
(i) Maintaining refrigerated foods at 45 [deg] F (7.2 [deg] C) or below as appropriate for the particular food involved.
(ii) Maintaining frozen foods in a frozen state.
(iii) Maintaining hot foods at 140 [deg] F (60 [deg] C) or above.
(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.
(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.
(5) Work-in-process shall be handled in a manner that protects against contamination.
(6) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.
(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.
(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.
(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.
(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.
(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic

cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring of the food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible

products, unless there is no reasonable possibility for the contamination of the human food.

[51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

Sec. 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.
…

15 Appendix 6. United Egg Producers/United Egg Association Movement Control Model Plan

May 14, 2007

United Egg Producers/United Egg Association
Highly Pathogenic Avian Influenza Movement Control
Model Plan

Movement Protocol for Liquid Egg Product, Further Processed Egg Products, Inedible Egg, Table Eggs and Broken Egg Shells, Egg-Type Hatching Eggs, and Day-Old Chicks Within, Out of, and Into a Control Area

1. **Flocks that are found to be infected with highly pathogenic avian influenza (HPAI).**

    a. No movement of susceptible species or their products (e.g., shell eggs, hatching eggs, day old chicks, broken egg shells, unpasteurized liquid egg product, pasteurized egg products will be allowed off the premises, except for disposal and must be moved under permit.

2. **Flocks that are deemed to be "Contacts."**
    a. **Definition of contacts:** A contact premises is a premises with birds or other susceptible animals *or products* that have been exposed directly or indirectly to birds and other animals, products, materials, people, or aerosol from an infected premises (the specific exposure factors to be considered must be appropriate to the epidemiology of HPAI).
    b. Layer industry HPAI at risk flocks include the following.
        i. Premises with susceptible birds exposed to poultry **manure** from an infected flock (virus in manure)
        ii. Premises with susceptible birds exposed to **dead poultry** from an infected flock (virus in carcasses, etc)
        iii. Premises with susceptible birds exposed to **live poultry** from an infected flock (virus in bird & secretions & excretions)
        iv. Premises with susceptible birds exposed to **eggs or egg handling materials** from an infected flock (HPAI virus in and on egg)
        v. Premises with susceptible birds with **unprotected exposure to equipment** that have been in contact with infected birds, manure, carcasses, or eggs. Unprotected means inadequate sanitation procedures for those items/people who come into contact with an infected flock.
        vi. Premises with susceptible birds with **unprotected exposure to people** that have been in contact with infected birds, manure, carcasses, or eggs.
        vii. Premises involved in depopulation of infected flocks.

c. Minimal contact flocks that are unlikely to involve infected birds include the following.

i. Premises that are in close proximity to an infected flock but which do not fall into the at risk definition and show no unexplained increase in daily mortality.
ii. Locations who receive materials that come in contact with animals or manure but have taken precautions to protect against disease
iii. Farm workers/visitors who contact animals but who take precautions between farms (e.g. boots, coveralls, hand washing, showers, etc)
iv. Farms receiving supplies that have been in contact with birds or manure but have been cleaned and disinfected prior to leaving the premises of origin.
v. Farms receiving equipment that that have been in contact with birds or manure but have been cleaned and disinfected prior to leaving the premises of origin.

d. Non-contact flocks include the following. Non-Animal contact functions (movement that does not involve contact with animals or manure)

1. Feed delivery, supplies,
2. Office workers/visitors who may travel to multiple sites

e. Disposition of Contact Flocks.

i. Contact premises will be quarantined and will be subject to strict biosecurity measures, daily monitoring of mortality in each house, and intensive surveillance for HPAI viruses in each house by RRT-PCR testing (see 3 immediately below) for at least 42 days or until the Incident Commander is convinced that no HPAI is present on the premises.
ii. Contact premises with 75,000 hens or more will not be depopulated until a diagnosis of HPAI has been confirmed by RRT-PCR or by virus isolation.
iii. Contact premises that prove to be infected will be depopulated immediately.

3. **Determination of non-infected layer industry flocks in the Control Area.**

a. The absence of infection will be documented by requiring chickens from flocks that are not exhibiting signs of the disease and that show no unexpected increase in mortality from each house on the farm to be tested each day and found to be negative by the real time reverse transcriptase – polymerase chain reaction (RRT-PCR) or other suitable procedure as determined by the Incident Command.

i. A minimum or five chickens from the daily mortality and/or from euthanized sick birds from each house (flock) will be placed in a leak proof container (e.g. heavy duty plastic garbage bag) each morning. Each container will be labeled with the farm of origin, house of origin, and the number of birds found dead in the house that day. The containers will be taken to a designated pick-up point, typically the public road closest to the premises.

1. Rationale: In a large commercial poultry house (100,000 layers) "normal" mortality will be about 10 per day. A doubling of normal mortality to 20 due to HPAI (dead bird prevalence of 50% and flock prevalence of 0.04%) would be detected by sampling 5 dead birds. Historically, APHIS sampled 5 dead birds **per week** to monitor chicken houses in the END outbreak in CA and this plan requires daily monitoring. The proposed AI plan requires daily monitoring and will be 7 times more effective than the monitoring during the END outbreak. It is not unusual for mortality to fluctuate that much from day to day, so sampling dead/sick birds every day is likely more sensitive than monitoring weekly mortality (where a trend over 2 or 3 days might be observed before acting). It is reasonable to assume that 50% of the sick and dead birds (in a house that is infected with HPAI) would actually be shedding AI virus then a sample size of 5 birds would allow you to have 95% confidence of finding the virus in the sick or dead birds.

ii. A state or federal regulatory official or an individual authorized by the Incident Command will take a tracheal swab from each chicken. Five tracheal swabs will be pooled in a tube containing brain-heart infusion (BHI) broth. Sample pooling will be done on a per house basis. One BHI tube containing tracheal samples (5 tracheal swabs/BHI tube) will be submitted as directed by the Incident Command to an authorized State Veterinary Diagnostic Laboratory (VDL). These samples must be submitted on the day of sample collection by the state or federal regulatory official or an individual authorized by the Incident Command. The State VDL and the IC will establish the time of day by which samples must be submitted to an authorized VDL (example, by 12:30 pm). VDL personnel will perform RRT-PCR testing on these samples immediately upon receipt and electronically send test results to the Incident Command (IC) by the end of each day. The IC will report the test result information to the premises as soon as it is available.

4. Movement of liquid egg product, further processed egg products, inedible egg, table eggs and broken egg shells, egg-type hatching eggs, and day-old chicks from non-infected flocks.

a. Movement of liquid egg product, table eggs, egg-type hatching eggs, further processed egg products, and broken egg shells *within and out of* a Control Area will be allowed by permit for those flocks testing negative (see Section 3 above) as follows:

i. USDA FSIS inspected pasteurized egg products, or precooked egg products produced by plants within a control area may move within or out of the Control Area by Permit (accompanied by documentation of origin of the products). The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior

must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

ii. Unpasteurized liquid egg product may move in officially FSIS sealed vehicles per 9 CFR Chapter III Part 590.410 from breaking operations within the Control Area directly to pasteurization plants located within or out of the Control Area by permit. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

iii. Inedible egg from graders and/or breaking plants in a Control Area may move by permit for pasteurization or to approved waste disposal sites within or outside the Control Area. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

iv. Washed and graded shell eggs destined for food service, retail marketing, further processing, or for breaking may be moved out of the Control Area by permit if they have been washed and sanitized using 100 – 200 ppm chlorine solution. The transport vehicle shall be sealed by farm or company personnel under the authorization of the Incident Command. Egg handling materials used in the transport of eggs to breaking or further processing plants must be destroyed at the plant or cleaned, sanitized (following accepted procedures) and returned to the premises of origin without contacting materials going to other premises. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

v. Nest run shell eggs (not washed and sanitized) must be moved directly for washing and grading, further processing, or to an off-line breaking operation. The transport vehicle shall be sealed by farm or company personnel under the authorization of the Incident Command. Egg handling materials must be destroyed at the destination plant or cleaned, sanitized (following accepted procedures) and returned to the premise of origin without contacting materials going to other premises. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

vi. Broken eggshells on the farm or from breaking plants, pasteurization plants, and/or further processing plants may be moved by permit.

The transport vehicle shall be sealed by farm or company personnel under the authorization of the Incident Command. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

vii. Hatching eggs from source flocks tested negative for AI virus by daily mortality sampling may be moved to hatcheries within the Control Area with a permit. Egg handling materials must be destroyed at the hatchery or cleaned, sanitized (following accepted procedures) and returned to the premise of origin without contacting materials going to other premises. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

viii. Hatching eggs from source flocks tested negative for AI virus by daily mortality sampling may be moved out of the Control Area by permit. The chicks must be placed under a "post-hatch" quarantine for 30 days. Egg handling materials must be destroyed at the premises of destination or cleaned, sanitized (following accepted procedures) and returned to the premise of origin without contacting materials going to other premises. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area. The State Veterinarian of the state of destination must be faxed a copy of the restricted movement permit within 24 hours of issuance.

ix. Day-old chicks from source flocks tested negative for AI virus by daily mortality sampling may be shipped by permit within or out of the Control Area and must be placed under a 30 day quarantine. The State Veterinarian of the State of destination must be faxed a copy of the restricted movement permit within 24 hours of issuance. Hatcheries may receive eggs that originate outside the Control Area (accompanied by documents showing the origin of the eggs and the AI negative status of the source flock) without a permit. The cargo interior and exterior of the transport vehicle must be cleaned and disinfected. The driver will not be allowed outside the cab or else the cab interior must also be cleaned and disinfected. The tires and wheel wells must also be cleaned and disinfected before leaving the premises within the Control Area.

x. The Incident Command or designate will evaluate and approve the risk assessment and risk mitigation procedures necessary to move products by permit. A permit must be issued and seals placed on the vehicle by a state or federal regulatory official or a person authorized

by the Incident Command. The Incident Command will authorize procedures to break the seals outside of the control area with proper documentation.

b. Movement of liquid egg product, shell eggs, broken egg shells, and hatching eggs *into* a Control Area will be allowed without permit under the following conditions:

i. Pasteurized liquid egg product and unpasteurized liquid egg (and blends) from breaking plants and/or pasteurization plants outside a Control Area (and accompanied by documentation of origin) may move into pasteurization and/or further processing plants located in a Control Area without permit. The driver will not be allowed outside the cab or else the cab interior must be cleaned and disinfected. The exterior of the transport vehicle and the tires and wheel wells must be cleaned and disinfected before leaving the premises in a Control Area.

ii. Shell eggs may move into breaking, grading, pasteurization, and/or further processing plants from outside Control Areas (accompanied by proof of origin) without a permit. Egg handling materials must be destroyed at the plant or cleaned, sanitized (following accepted procedures) and returned to the premise of origin without contacting materials going to other premises. The driver will not be allowed outside the cab or else the cab interior must be cleaned and disinfected. The exterior of the transport vehicle and the tires and wheel wells must be cleaned and disinfected before leaving the premises within a Control Area.

iii. Broken egg shells may move into a Control Area (accompanied by proof of origin) without a permit. The driver will not be allowed outside the cab or else the cab interior must be cleaned and disinfected. The exterior of the transport vehicle and the tires and wheel wells must be cleaned and disinfected before leaving the premises within a Control Area.

iv. Hatching eggs may move into a hatchery from outside Control Areas (accompanied by proof of origin and AI tested negative flocks without a permit. Egg handling materials must be destroyed at the plant or cleaned, sanitized (following accepted procedures) and returned to the premise of origin without contacting materials going to other premises. The driver will not be allowed outside the cab or else the cab interior must be cleaned and disinfected. The cargo interior and exterior of the transport vehicle and the tires and wheel wells must be cleaned and disinfected before leaving the premises within a Control Area.

5. Determination of Release of Movement Restrictions

a. All premises within the Control Area would be eligible for release from movement restrictions as determined by the Incident Command when:

i. All infected flocks in a Control Area have been depopulated. All depopulated flock premises have been cleaned and disinfected. A

minimum of 42 days have passed, or environmental sampling has proven HPAI virus negative status for the depopulated premises.

ii. All contact premises in a control area must have been depopulated or must have been monitored for 42 days.

This plan has been written by egg industry and university personnel based on their knowledge of the egg industry. Standard Operating Procedures from the Exotic Newcastle Disease (END) outbreak were reviewed as a starting point for developing this plan.

16 Appendix 7. OIE Terrestrial Animal Health Code – Guidelines for the Inactivation of the Avian Influenza Virus.

GUIDELINES FOR THE INACTIVATION OF THE AVIAN INFLUENZA VIRUS(81)

Article 3.6.5.1.

Eggs and egg products

The following times for industry standard temperatures are suitable for the inactivation of highly pathogenic notifiable avian influenza (HPNAI) virus present in eggs and egg products:

	Temperature (°C)	Time
Whole egg	60	188 seconds
Whole egg blends	60	188 seconds
Whole egg blends	61.1	94 seconds
Liquid egg white	55.6	256 seconds
Liquid egg white	56.7	228 seconds
10% salted yolk	62.2	138 seconds
Dried egg white	67	0.83 days
Dried egg white	54.4	21.38 days

17 Appendix 8. Letter from Dr. David Swayne.

USDA

United States Department of Agriculture

Research, Education and Economics
Agricultural Research Service

Hershell Ball
Michael Foods, Inc.
120 Towers Street South
Gaylord Minnesota 55334

Dear Dr. Ball:

The majority of the scientific research done on inactivation of avian influenza and Newcastle disease viruses in poultry products has been done in my laboratory at the Southeast Poultry Research Laboratory, USDA/ARS, Athens, Georgia. This information has been used by World Organization of Animal Health (OIE) and World Health Organization to establish international standards for safe trade in animal products.

Our initial studies published in 2004 (2), demonstrated that pasteurization using the USDA/FSIS Salmonella Pasteurization Standards for temperatures and times were effective at inactivation of both low (LP) and high pathogenicity (HP) avian influenza (AI) viruses, and lentogenic and velogenic (exotic) Newcastle disease viruses (NDV) in homogenized whole eggs, liquid egg white and 10% salted yolk. Although these were only a few of the many eggs products produced in the USA, the pasteurization principles and their ability to inactivate AI viruses and NDV are directly applicable to other liquid egg products when using the USDA/FSIS standards. The following are provided as supporting information:

1) The AI and NDV are RNA viruses with an outer envelop derived from the phospholipid membrane of the replicating host cell and is susceptible to heat inactivation similar to that of other phospholipid-enveloped organisms such as salmonella bacterium or bacteriophages;
2) Viruses are non-replicating once they leave the host or when present in any products derived from the host thus indicating the quantity of these viruses will not increase in the contaminated product over time as can occur with bacteria;
3) The different liquid egg products are based on these 3 basic ingredients – whole egg, yolk and egg white – but products vary by adding salt or sugar. The addition of these compounds which are osmotic, increase the efficiency of inactivating the viruses which explains why one of the properties of salt and sugar is food preservation; and
4) Recently, we have also demonstrated that the USDA/FSIS cooking standards for salmonella are effective at inactivating both AI viruses and NDV in chicken meat (1,3,4).

ars

Southeast Poultry Research Laboratory, Office of the Director
934 College Station Road, Athens, Georgia 30605.
Voice: 706-546-3433 _ Fax: 706-546-3433 _ E-mail: dswayne@seprl.usda.gov
An Equal Opportunity Employer

In summary, the USDA/FSIS standard pasteurization times and temperatures are effective at inactivating AI viruses and NDV in multiple liquid egg products.

Sincerely,

David E. Swayne

Reference List

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2. Swayne, D.E. and J.R. Beck. 2004. Heat inactivation of avian influenza and Newcastle disease viruses in egg products. Avian Pathology 33(5):512-518.
3. Thomas, C. and D. E. Swayne. 2006. Thermal Inactivation of Newcastle Disease Virus (Ulster Strain) in Chicken Meat: Determination of Dt and Z Values. Proceedings of International Association of Food Protection August 14-18, 2006, p.124.
4. Thomas, C. and D.E. Swayne. 2007. Thermal inactivation of H5N1 high pathogenicity avian influenza virus in naturally infected chicken meat. Journal of Food Protection 70(3):674-680.

18 Appendix 9. Form PY203 Daily Report of Plant Operation.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
EGG PRODUCTS INSPECTION

DAILY REPORT OF PLANT OPERATION

NAME OF PLANT	ADDRESS OF PLANT		PLANT NUMBER
SIGNATURE OF INSPECTOR	INSPECTOR'S BADGE NUMBER	DATE	CODE DATE
PROCESSING OPERATIONS BREAKING FROM_____A.M. TO_____P.M. PASTEURIZATION FROM_____A.M. TO_____P.M.	INSPECTOR'S HOURS OF DUTY FROM_____A.M. TO_____P.M.		

INSTRUCTIONS: Give exact figures where applicable. Mark ✓ for "Yes" or "Satisfactory" and X or "No" or "Unsatisfactory".

TIME OF INSPECTION		TIME OF INSPECTION				
SANITATION/PROGRAM MONITORING		21. Organoleptic inspection and pour test.				
1. Cleanliness and sanitizing of equipment used for pasteurized liquid *(pipelines, gaskets, valves, pumps, etc.)*		22. Health and cleanliness of employees *(uniforms, hair nets, clean hands, etc.)*				
2. Cleanliness and sanitizing of equipment prior to start up.		23. Breaking or breaking machines operating in sanitary manner.				
3. Cleanliness of shell egg washers and conveyors.		24. Organoleptic examination of individual eggs.				
4. General sanitation of other areas		25. Breaking procedure when inedible is encountered *(segregate inedible, change equipment, wash hands, etc.)*				
5. Premises, receiving, and shipping areas.						
6. Refuse removal and disposal.		26. Segregation of leakers, dirties and loss for breaking.				
7. Restrooms and lunchrooms.		27. Denaturing and labelling of inedible eggs and liquid.				
8. CIP cleaning of pipelines and equipment.		28. Hydrogen peroxide test.				
9. a. Are breaking and packaging room, compressor, air filters, etc., satisfactory?		29. Sanitation - packaging room and equipment.				
		30. Product containers clean and sanitarily filled.				
9. b. Are air lines to product contact surfaces blown out and clean prior to use?		31. Container identification and labeling.				
		32. Accuracy of weighing product.				
10. Edible ingredient storage		33. Positive flow of air in processing and packaging rooms.				
11. Insecticides, rodenticides, etc., isolated from chemical compounds.		34. Processing rooms free from flies and odors.				
		35. Equipment clean and sanitized prior to use.				
12. Insecticides, rodenticides, and chemical compounds isolated from edible products.		36. Sanitation - breaking and processing rooms and equipment.				
		37. Shell strainers, egg filters efficient and cleaned.				
13. Package material storage.		38. Sanitation - transfer room, wash water and equipment.				
14. Freezers, clean, containers properly spaced, and air circulation adequate.		39. Show ppm of sanitizing spray for shell eggs				
		40. Show temperature of shell egg wash water.				
15. Is the exhaust system operable in the rest-room, transfer and refuse rooms?		41.				
		42.				
16. Tanker truck area.		43.				
17. Shell egg rooms and coolers.		44.				
18. Fly and rodent control inside and outside plant.		45.				
19. Verify Plant's Salmonella Surveillance Record		46.				
20. Verify Product Formulation/Refractometer		47.				

TEMPERATURES	TIME:				TIME:				TIME:				TIME:			
	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.	WHOLE EGGS	YOLKS	WHITES	EGG PROD.
UNPASTEURIZED LIQUID a. 2 hrs. after breaking - to be held under 8 hrs.																
b. 2 hrs. after breaking - to be held over 8 hrs.																
c. Held for shipment or processing																
PASTEURIZATION a. Recorder - controller																
b. Indicating thermometer																
c. Flow-diversion valve setting																
d. Flow-rate per minute																
e. Holding time *(minutes)*																
PASTEURIZED LIQUID a. 2 hrs. after pasteurizing - to be held under 8 hrs.																
b. 2 hrs. after pasteurizing - to be held over 8 hrs.																
c. Held for shipment																
FREEZER OR LIQUID HOLDING ROOM																

REMARKS: *(Explain any deviations from above. Use reverse, if necessary.)*

PY FORM 203 (3/16/2005) PREVIOUS EDITIONS ARE OBSOLETE

FY FORM 203 (3/16/2005) REVERSE

EGGS PROCESSED	TOTAL OF SHELL EGGS (liquid equivalent) AND LIQUID DENATURED
30 - Doz Cases	lbs.

TYPE PRODUCT PRODUCED	PRODUCTION RECORD			FINAL INSPECTION (Liquid or Frozen)				TEST WEIGHING (Finished Product)			
	NO. CONTAINER	CONT MARKED WEIGHT	POUNDS	DATE DRILLED OR INSPECTED	NO. CONTAINER	TEMP.	CONDITION	NO. CONTAINER	GROSS	TARE	NET
Inedible											
TOTAL											

REMARKS

INDICATING THERMOMETER

ACCURACY (Quarterly)	LAG (Quarterly)
± F.	SECONDS

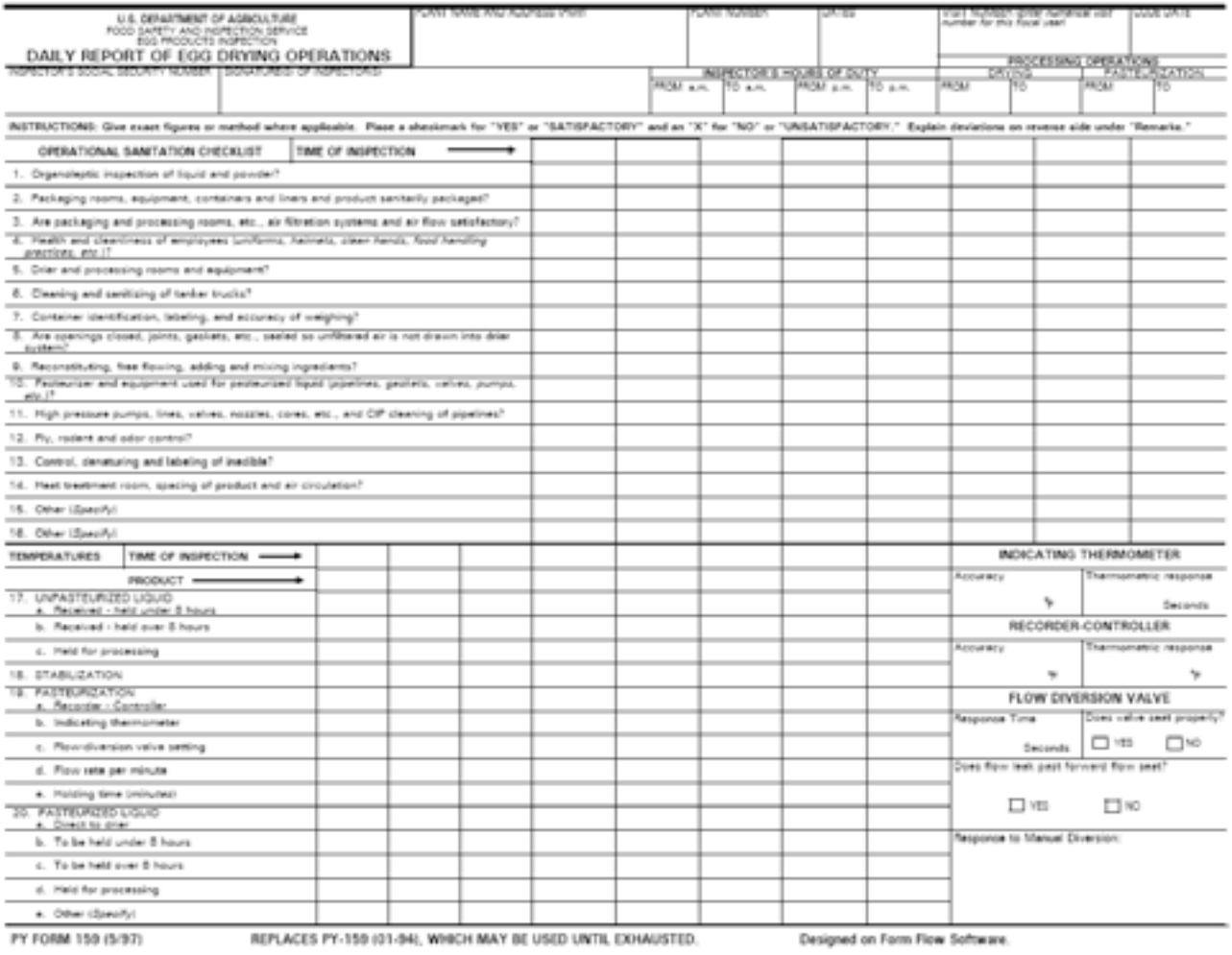
RECORDER - CONTROLLER

ACCURACY (Quarterly)	THERMOMETRIC LAG (Quarterly)	CUT-IN TEMPERATURE (Monthly)	CUT-OUT TEMPERATURE (Monthly)
± F.		± F.	± F.

FLOW-DIVERSION

RESPONSE TIME (Quarterly)	DOES VALVE SEAT PROPERLY? (Daily)
	☐ YES ☐ NO
DOES FLOW LEAK PAST FORWARD FLOW SEAT WHEN OPERATING IN DIVERSION? (Biweekly) ☐ YES ☐ NO	RESPONSE TO MANUAL DIVERSION: (Biweekly)

19 Appendix 10. PY159 Daily Report of Egg Drying Operations.



U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
EGG PRODUCTS INSPECTION

DAILY REPORT OF EGG DRYING OPERATIONS

PLANT NAME AND ADDRESS (Print) | PLANT NUMBER | DATE | PLANT NUMBER (plant identification number assigned by FSIS for this fiscal year) | WEEK ENDING

INSPECTOR'S SOCIAL SECURITY NUMBER | SIGNATURE OF INSPECTOR

INSPECTOR'S HOURS OF DUTY: FROM a.m. | TO a.m. | FROM p.m. | TO p.m.

PROCESSING OPERATIONS: DRYING: FROM | TO; PASTEURIZATION: FROM | TO

INSTRUCTIONS: Give exact figures or method where applicable. Place a checkmark for "YES" or "SATISFACTORY" and an "X" for "NO" or "UNSATISFACTORY." Explain deviations on reverse side under "Remarks."

OPERATIONAL SANITATION CHECKLIST — TIME OF INSPECTION →									
1. Organoleptic inspection of liquid and powder?									
2. Packaging rooms, equipment, containers and liners and product sanitarily packaged?									
3. Are packaging and processing rooms, etc., air filtration systems and air flow satisfactory?									
4. Health and cleanliness of employees (uniforms, hairnets, clean hands, food handling practices, etc.)?									
5. Drier and processing rooms and equipment?									
6. Cleaning and sanitizing of tanker trucks?									
7. Container identification, labeling, and accuracy of weighing?									
8. Are openings closed, joints, gaskets, etc., sealed so unfiltered air is not drawn into drier system?									
9. Reconstituting, free flowing, adding and mixing ingredients?									
10. Pasteurizer and equipment used for pasteurized liquid (pipelines, gaskets, valves, pumps, etc.)?									
11. High pressure pumps, lines, valves, nozzles, cones, etc., and CIP cleaning of pipelines?									
12. Fly, rodent and odor control?									
13. Control, denaturing and labeling of inedible?									
14. Heat treatment room, spacing of product and air circulation?									
15. Other (Specify)									
16. Other (Specify)									

TEMPERATURES — TIME OF INSPECTION →								
PRODUCT →								
17. UNPASTEURIZED LIQUID: a. Received - held under 8 hours								
b. Received - held over 8 hours								
c. Held for processing								
18. STABILIZATION								
19. PASTEURIZATION: a. Recorder - Controller								
b. Indicating thermometer								
c. Flow-diversion valve setting								
d. Flow rate per minute								
e. Holding time (minutes)								
20. PASTEURIZED LIQUID: a. Direct to drier								
b. To be held under 8 hours								
c. To be held over 8 hours								
d. Held for processing								
e. Other (Specify)								

INDICATING THERMOMETER: Accuracy °F | Thermometric response Seconds

RECORDER-CONTROLLER: Accuracy °F | Thermometric response °F

FLOW DIVERSION VALVE: Response Time Seconds | Does valve seat properly? ☐ YES ☐ NO

Does flow leak past forward flow seat? ☐ YES ☐ NO

Response to Manual Diversion:

PY FORM 159 (5/97) REPLACES PY-159 (01-94), WHICH MAY BE USED UNTIL EXHAUSTED. Designed on Form Flow Software.

SANITATION CHECKLIST TIME OF INSPECTION ⟶		DRIER SANITATION	CLEANING METHOD	INSPECTION
21. Air lines to product contact surfaces blown out and clean prior to use		29. Drier, fans and ducts		
22. Edible ingredient storage		30. Augers, pneumatic system and valves		
23. Insecticides and chemicals isolated from edible products		31. Sifters and flexible connectors		
24. Package material and product storage		32. Bags and bag house		
25. General sanitation of other areas		33. Bag section(s) changed		
26. Rest rooms and lunchrooms		34. Drier air filtration system, fan and air ducts		
27. Premises, receiving and shipping areas		35. Sanitizing or preheating augers, pneumatic, sifter, etc.		
28. Refuse removal and disposal		36. Drier system openings and exhaust closed after cleaning and shutdown		
		37. Drier preheated _____ time _____ °F Intake _____ °F Exhaust _____		

TYPE PRODUCT PRODUCED	PRODUCTION RECORD			TEST WEIGHING (*Finished Product*)			
	NUMBER CONTAINERS	SIZE CONTAINERS	POUNDS	NUMBER CONTAINERS	GROSS	TARE	NET
INEDIBLE NONDENATURED							
INEDIBLE DENATURED							
TOTAL ⟶							

REMARKS:

PRIVACY ACT STATEMENT:

The following statements are made in accordance with the Privacy Act of 1974 (5 USC 552a). Disclosure by you of your Social Security number is voluntary and is authorized under provisions of Executive Order 9397, dated November 22, 1943.

Purpose and Uses - The Social Security number will be used primarily to identify your records. The principal purpose of this form is to collect information needed to determine employee's on-the-job performance as well as employee/supervisory/plant performance on an area, regional and national level. It will also be used to develop percentages and statistics relating to grade standard tolerances. The use of the Social Security number is made necessary because of the large number of present and former Federal and State employees who have identical names and whose identities can only be distinguished by the Social Security number.

Effects of Nondisclosure - Failure to provide your Social Security number will result in an arbitrary identifier being assigned.

This program or activity will be conducted on a nondiscriminatory basis without regard to race, color, religion, national origin, age, sex, marital status, or disability.

PY FORM 159 (5 ' /97) (REVERSE)

20 Appendix 11. Inspection Under HACCP

HACCP-oriented food safety inspection changes the approach of FSIS to overseeing the safety of meat and poultry products. Under this new approach, FSIS will rely less on after-the-fact detection of product and process defects and more on verifying the effectiveness of processes and process controls designed to ensure food safety. FSIS will restructure its inspection procedures to determine that production systems prevent the production of unsafe meat and poultry products. FSIS will carry out various activities to ensure that industry HACCP systems meet the requirements of this rule, and are functioning as designed.

The establishment must comply with all regulatory requirements. The establishment must develop written plans/procedures for HACCP, SSOP, and E. coli testing. Any time inspection personnel determine that regulatory requirements have not been met, the noncompliance will be documented and appropriate enforcement action will be taken. Upon initiation, inspection personnel verify that the plan or procedure is apparently responding to all regulatory requirements. If a required feature is not included in the plan or procedure, the nonconformance is documented and enforcement action is taken. Additional verification activities and noncompliance documentation are used to determine whether there has been a system failure. Enforcement is the action taken by inspection personnel when a failure has occurred.

Appendix 12: Key Issues for Moving Pasteurized Liquid Eggs during an HPAI Outbreak

This document is intended to give emergency response staff a summary of issues and survey questions to consider when assessing the risk of moving pasteurized liquid eggs during a HPAI outbreak. It summarizes, but does not replace, the information detailed in the complete risk assessment. Given specific circumstances that occur within any outbreak, it is likely that additional information not addressed in the survey will be needed to complete the risk assessment.

1. Food Safety and Inspection Service (FSIS)
   1.1. FSIS contact for the premises: _____
   1.2. What is the FSIS overall opinion on biosecurity at the premises?
   1.3. Is FSIS aware of any additional measures the premises has implemented in response to the outbreak?
   1.4. Has FSIS found any regulatory violations in the last six months that may have led to cross-contamination of products?
   1.5. Does FSIS know of any other issues that may affect the likelihood that HPAI may contaminate products at this premises?

2. Pasteurization
   2.1. What pasteurization method is used?
   2.2. Has the pasteurization equipment malfunctioned in the last six months?
   2.3. If there have been malfunctions, what happened and what corrective actions were taken?
   2.4. Provide temperature recordings for the last three production shifts. (Note to reviewer: FSIS requirements for pasteurization are in Appendix 3 of this assessment.)
   2.5. Does the premises have any other comments or concerns related to pasteurization during this outbreak?
   2.6. Provide a copy of the premises's policies and procedures for pasteurization operations.
   2.7. Has the premises implemented any additional measures related to pasteurization in response to the outbreak?
   2.8. If additional measures have been implemented, what are they?
   2.9. Provide documentation of these additional measures.

3. Sources of eggs
   3.1. Does the premises receive eggs from offsite suppliers?
   3.2. What measures is the premises taking to exclude eggs from premises where HPAI is known to be present?
   3.3. How are communications with egg suppliers established, maintained, and used?
   3.4. Can the premises trace incoming shipments of eggs back to the suppliers?
   3.5. Has the premises received eggs from premises that were known to have HPAI present? If so, how were eggs disposed?

4. Processing and Handling
    4.1. Does the premises maintain an inventory of unprocessed eggs on-site?
    4.2. What processes are used to handle, clean, and inspect the eggs before they are pasteurized?
    4.3. Provide a copy of the premises's policies and procedures for handling, sanitizing, and storing products at the premises.
    4.4. Has the premises implemented any additional measures related to handling egg products in response to the outbreak?
    4.5. If additional measures have been implemented, what are they?
    4.6. Provide documentation of these additional measures.
    4.7. Have there been any malfunctions in the handling system (excluding pasteurization) within the last six months?
    4.8. If there have been malfunctions, what happened and what corrective actions were taken?
    4.9. About how long does the premises hold eggs and processed products before they are shipped to the customer?

5. Access Controls
    5.1. What access control measures are in place at the premises?
    5.2. What access control measures are used when there is no HPAI outbreak?
    5.3. What access control measures are used during an HPAI outbreak?
    5.4. Are these access control measures different? If so, how are they different?

6. Movement of Pasteurized Liquid Eggs
    6.1. Provide a copy of the premises's policies and procedures for moving pasteurized liquid eggs.
    6.2. Are vehicles transporting pasteurized liquid eggs segregated from other vehicles on the premises's grounds?
    6.3. Has the premises implemented any additional measures related to moving pasteurized liquid eggs in response to the outbreak?
    6.4. Does the premises use the model movement plan developed by the egg products industry? (Note to reviewer: the model movement plan is in Appendix 6 of this assessment.)
    6.5. If additional measures have been implemented (besides those shown in the model movement plan), what are they?
    6.6. Provide documentation of these additional measures.
    6.7. Where does the premises clean and disinfect vehicles transporting liquid eggs?
    6.8. What procedures are followed and what disinfectant is used?
    6.9. Are vehicles transporting liquid eggs that enter the premises's grounds cleaned and disinfected before loading or unloading cargo?

21 Appendix 13: The Use of "Negligible Risk" in this Assessment

Negligible Risk Defined for this Analysis:

For this risk analysis, the term "negligible risk" means there is a very low likelihood that moving pasteurized liquid egg products will cause infection in another poultry production premises. The specific magnitude cannot be determined, as there is no evidence that these products have ever served as a transmission pathway. In quantitative terms, "negligible risk" is defined as a likelihood of less than 1/1,000,000 that moving these products will result in infection in another premises. This particular likelihood is consistent with other common meanings for the term, as discussed below. The determination of "negligible risk" suggests that allocating additional resources to mitigate this risk may not be a cost-effective use of resources (depending on circumstances).

For this risk assessment, the term "negligible risk" means that the likelihood that moving pasteurized liquid egg products will cause infection in another poultry premises is very low. The specific magnitude cannot be determined, as we did not find evidence in the scientific literature that:

- These products have ever served as a transmission pathway; or that,
- Risks associated with this pathway have been quantitatively assessed.

Negligible Risk as Less Than 1/1,000,000

Origins

Use of the term "negligible risk" originated in efforts to regulate chemical exposures. While there is no formal definition, the term evolved in the human exposure risk assessment literature as a lifetime cancer risk of less than 1/1,000,000. This particular level was selected as it was thought to be a level of "essentially zero" risk (38). (15;34;35;36)While this level has not been formally defined in legislation, The House Committee on Commerce evaluated the use of this term by the Environmental Protection Agency, and agreed that the agency's interpretation of the term "negligible risk" to be approximately a one-in-a-million lifetime risk as appropriate.(73)

Use in Agricultural Risk Analysis

The use of risk analysis for imports of agricultural products became mandatory with the adoption of the SPS Agreement[q] in 1995.[r] Specific recommendations and standards were to be established by the appropriate technical body. For animals and animal products, this is the Office International des Epizooties (OIE, or World Organization for Animal Health) (53). The OIE has published standards and guidance (33) (80)for conducting risk analysis, but has not formally defined "negligible" in a quantitative sense (79). However, in a World Trade Organization trade dispute case (76), negligible risk was considered to be a risk whose probability is very low (21) or, as an expert consultant to the WTO Dispute Panel stated, "the standard scientific definition of "negligible" was a likelihood of between zero and one in one million."(84)

Policy Implications of a Quantitative Definition for Negligible

[q] Formally known as the "Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and Agreement on Technical Barriers to Trade (TBT)."

[r] Risk analysis is also required for moving animals and animal products during an HPAI outbreak (29).

While the 1/1,000,000 definition for negligible has substantial precedence (as shown above), there are difficulties with this approach. The 1/1,000,000 likelihood has been described as “folklore” (23), vague and inconsistent (36), and has been “used and (abused) in various policy contexts”(19). However, use of this figure is meant to be a very rough approximation and should not be given the same degree of certainty that may be applied when quantitative risk assessments can be used.

Negligible Risk as a Qualitative Measure for Agricultural Risk Analysis

The OIE has issued guidance that recommends using “negligible” to mean “not worth considering; insignificant” (33). The use of qualitative risk analysis methods by APHIS and the implied non-requirement for attaching a specific number to a level of risk has been challenged in the U.S. Court system and has been upheld as appropriate, if the analysis presents adequate scientific information (5). When used in this manner, the courts have held that the determination of risk may be based on “the cumulative effects of the multiple, overlapping, safeguards.” Furthermore, the courts have held that an “imposition of such a bright-line prohibition on qualitative standards was incorrect,” and that the Animal Health Protection Act does not require a quantified permissible level of risk (52). These opinions by the court system are also consistent with U.S. views expressed in WTO trade disputes.

22 Appendix 14: Comments from the USDA Food Safety and Inspection Service (FSIS)

We appreciate the through and meticulous review conducted by FSIS on this assessment. The comments are pertinent and reflect a high degree of knowledge and interest on the part of FSIS. Our responses to these comments are given in Appendix 15. We have made appropriate changes to the text when necessary.

Response	FSIS Comment
	Thank you for the opportunity to review the document entitled PLE 5 June 08. In general, we agree that the risk associated with moving pasteurized egg products and potentially infecting a previously non-infected premise is negligible; however, the document would be strengthened by addressing the comments below. **General Comments**
See response 1.	1) The risk assessment refers to FSIS sixty-five times and relies on FSIS and FSIS standards/regulations (and establishment compliance) to prevent the survival and spread of avian influenza in pasteurized egg products. The USDA FSIS standard pasteurization times and temperatures should be effective for eliminating *Salmonella* from pasteurized egg products. Nonetheless, *Salmonella* are found in pasteurized egg products. FSIS tests pasteurized egg products, beginning in 1995 for *Salmonella*. The FSIS Microbiological Testing Program for Pasteurized Egg Products, 1995 – 2007 can be found on the web[s]. Table 1[t] shows 90 *Salmonella* positive samples (0.43 %) out of 20,696 pasteurized egg products tested. The overall yearly prevalence has not fallen below 0.12% until 2007 when it was 0.07 % (overall 0.43 % positives from 1995-2007). For 2008 (data not available publicly) there have been no positives out of 785 samples. The risk assessment needs to acknowledge in writing that even though HPAI may be more heat labile than *Salmonella*, the results of the FSIS *Salmonella* testing suggest that HPAI could be present following even compliant pasteurization. .

[s] FSIS Microbiological Testing Program for Salmonella in Pasteurized Egg Products, Calendar Years 1995–2013

[t] http://www.fsis.usda.gov/PDF/Sal_Past_Egg_Products_Table1.pdf

Response	FSIS Comment
See response 2.	2) The risk assessment then states: "Cross contamination of the pasteurized liquid egg can occur due to a breach in the pipes through which the pasteurized liquid egg is pumped during processing, thereby exposing it to the environment, or due to system failure resulting in the mixing of pasteurized and non-pasteurized products." The risk assessment then justifies that the risk from this pathway would be negligible because "Internally, a breach in the containment of the pasteurized liquid egg leading to actual contamination of pasteurized liquid egg at any egg pasteurization premises is highly unlikely. Should a breach occur, however, FSIS and FDA regulations would mitigate any potential risk of contamination with the HPAI virus to negligible." The report is lacking any further evidence to explain how FSIS and FDA regulations would be able to mitigate, detect, and determine the extent of any potential contamination. Further elaboration in writing is needed. For example, evidence stating that a drop in pressure would be detected thus suggesting a pipe break. How would a mixing of pasteurized and non-pasteurized products be detected for the different product types?
See response 3.	3) The risk assessment would be strengthened if there was a general discussion surrounding the following issues: 1) HPAI levels in raw product, and 2) Dilution factor. The Swayne and Beck 2004 pasteurization study used a 4.9 log10 EID50/mL level to determine the effectiveness of pasteurization. However, in an outbreak situation, the levels are likely to be less for the following reasons. The 4.9 log10 EID50/mL level came from internal egg contents following 3 to 4 days post-inoculation with HPAI. This suggests that these levels represent the maximum observed for the following reasons: 1) Chickens infected with this HPAI strain required ~4days for mortality (minimum) and no eggs were produced past 4 days (Beard et al., 1984), and 2) Swayne and Beck state: "AI virus was present in… eggs laid on days 3 and 4 post inoculation (p.i.), with concentration as high as $10^{4.9}$ EID50 HPAI virus/ml egg product," suggesting multiple HPAI-contaminated eggs were laid but only the maximum was reported. Both these issues suggest that if an HPAI-infected bird did produce an internal HPAI-contaminated egg, depending on the stage of infection, the egg could contain less virus than the maximum used in the pasteurization study. Therefore, eggs pooled from an HPAI infected flock would likely not have as much virus as tested in the Swayne and Beck study. Therefore, pasteurization should be more effective that this study suggests. Regarding the dilution factor, eggs from an HPAI-infected flock are likely to be pooled with eggs from non-infected flocks. Therefore, levels again would be lower than used in Swayne and Beck.

Response	FSIS Comment
See response 4.	4) There are a number of references in the literature to "trucks" and "vehicles" acting as potential sources for avian influenza virus, classical swine fever virus, and foot and mouth disease virus. In multiple editions of Foreign Animal Diseases, the authors state that the avian influenza virus can be spread by "feed trucks". This includes the current revised 2008 seventh edition, http://www.usaha.org/pubs/fad.pdf, which states, "Once introduced into poultry, the [avian influenza] viruses … are spread from flock-to-flock or village-to-village by human endeavor such as …contaminated equipment, shoes, clothing, egg flats, feed trucks, and service crews." Section 6.5 Transmission, of the risk assessment, also states that avian influenza virus can be spread by "…indirect movement of contaminated equipment, egg flats, feed trucks, and service crews, or other means". In addition "…vehicles that haul pasteurized liquid egg and its products only come into contact with the docks at processing facilities, where Federal rules regulate the condition of the grounds to limit the potential for contamination." Just as feed trucks are acknowledged as a possible transmission source of AI, trucks carrying eggs to pasteurizing egg plants could serve as a source of spreading AI from premise to premise and/or spreading AI to grounds where live poultry truck could become cross-contaminated. In addition, what would prevent "the condition of the grounds" at FSIS inspected facilities from acting as a potential source of avian influenza virus for trucks and other vehicles once the grounds were contaminated by an incoming vehicle or other source? FSIS regulations and inspectors can not assure the grounds will be free of avian influenza nor any other virus.
See response 5.	5) "Vehicles and drivers moving pasteurized liquid egg and its products generally do not have direct contact with live bird production and thus have no opportunity to become contaminated with HPAI virus." The statement "generally do not have direct contact with live bird production" should not be used as supportive evidence for a "negligible risk". No maps showing locations of egg producers or pasteurized egg product facilities were provided to show their locations in relation to broiler production and turkey production. Three maps have been provided by the National agricultural Statistics Service in a power point presentation (attached file). The maps (although from an earlier census) show there is considerable overlap between egg, broiler and turkey production. In the face of an outbreak, there may be an increase of shell eggs diverted to pasteurized egg products facilities with trucks going to more egg producers than usual. Egg packing operations may be co-located on egg laying premises and receive eggs from a number of other producers increasing the chance for contamination of vehicles. See attached power point presentation of maps. Please address in writing this potential increase and the difficulties in terms of increased cross-contamination it may present.

Response	FSIS Comment
See response 6.	6) "There is no evidence that vehicles moving pasteurized liquid egg or its products have been contaminated with or contributed to the spread of HPAI virus during an outbreak." Absence of proof is not proof of absence. Vehicles should be regarded as a potential source of contamination. Authors need to provide evidence why trucks and or other vehicles should not be regarded as potential source of contamination.
See response 7.	7) If not already included in the emergency response plan, this risk assessment should provide a listing of all egg products establishments with a global information system coordinate for each establishment and corresponding maps depicting egg products establishments. It should also provide a map of all FSIS Districts and APHIS Regions/Areas with corresponding contact information. It should also provide a listing and maps of current FSIS poultry processing plants and contact information along with global information system coordinates. It should overlap the maps of poultry processing plants and egg products maps onto a map with highways and current poultry production farms to determine overlapping routes of trucks carrying eggs and trucks going to and from poultry processing establishments and poultry production farms.
See response 8.	8) The authors present a reasonable argument as to why the likelihood for HPAI H5N2 to survive current in industry liquid egg pasteurization protocols is very low; however, they do not discuss the impact of other HPAI strains. The section entitled "Likelihood that HPAI Virus Would Be Present In Liquid Egg After Pasteurization", would be strengthened if the authors could suggest that the strains used in the 2 pasteurizations experimental studies represented strains that were at least representative of the majority of HPAI strains that could infect US commercial poultry flocks or that the strains tested represented the upper end of HPAI heat resistant strains. If data are not available to make such an argument, then the fact that H5N2 is being used as a representative HPAI strain (e.g., for H5N1, H7N2) should be added to the section entitled, "Significant Assumptions Used in the Risk Assessment".

Response	FSIS Comment
See response 9.	**Specific Comments** (suggested change is in brackets) 3rd Bullet from bottom, page 10: Pasteurized liquid egg is assumed to be delivered to food processors or commerical [commercial] food establishments. Last Bullet, page 10: A review of FSIS recalls from 2008 to 2003 did [not] show any recalls related to liquid pasteurized egg (69). Last Bullet, page 10: An earlier study of meat and poultry recalls did not show any instances where egg products were the subject of a recall (54) [.] Section 6.4 Resistance to Chemical and Physical Agents: AI viruses are relatively sensitive to inactivation by lipid solvents such as detergents (14). The viruses are easily inactivated by physical agents such as heat, extremes of pH, nonisotonic conditions, and dryness; f [superscript] however, their infectivity can be maintained for several weeks at 4º C [reference]. Formalin and beta-propiolactone can be used to eliminate the infectivity of the viruses while preserving hemagglutinating and neuraminidase activity [reference]. AI virus can survive for several days in the albumen and yolk of eggs stored at cool temperatures (10º to 18º C) (6). Effective disinfectants against influenza A viruses include heat, sodium hypochlorite solution, formalin, or One-Stroke Environ (14). However, removal of organic material is required for effective decontamination as pathogenic influenza viruses can survive for long periods in cold and moist environments, such as in liquid manure. The virus has been demonstrated to survive in cold and moist environments (such as liquid manure) for up to 105 days after depopulation(59). Virus infectivity is retained in fecal matter for 30-35 days at 4º C and seven days at 20º C [reference]. Section 6.7 Clinical Signs: The mortality rate can reach 100%, often within 48 hours [reference]. Reference 26, 39, 46, and 64 appear to be duplicates.

Response	FSIS Comment
See response 9.	Section 6.9 Diagnosis: In the case of H5 or H7 subtypes, amnioalantoic fluid may be analyzed using the RRT-PCR [please define the first "R"] test. Section 6.10 Laboratory Specimens If large numbers of birds are to be sampled, swabs from up to five birds can be pooled in the same tube of brain and heart infusion broth [reference]. Page 17 Table title missing and not referenced in text. Page 18 Table title missing and not referenced in text. Estimation of pasteurization times for egg products based on Dt values of the study including the time to inactivate HPAI to a level of 100 EID50/ml, which is below the dose that can infect chickens with H5N2 HPAI [reference]. Page 22 Federal regulations concerning eggs and their handling are written to ensure food safety by preventing the contamination of food with particular pathogens such as *Salmonella* spp. and Escherichia coli [italicize]. Page 32 These plans are similar to ones developed to control the Exotic Newcastle Disease (END) [define in Abbreviations and Definitions] outbreak in California(69) and were found to be effective in that situation. In addition, most vehicles and drivers transporting pasteurized liquid egg or its products from a processing premises will not encounter other commerical [commercial] poultry. While transportation of liquid pasteurized egg may pose other, hypothetical, risks, we are following established WTO precedent and not considering them in this assessment [reference]. References Reference 26, 39, 46, and 64 appear to be duplicates.

Appendix 15: Responses to FSIS Comments

Response 1.	Unlike bacteria such as *Salmonella*, viruses do not multiply outside the host. Many researchers have documented that initial *Salmonella* numbers in eggs (estimated to be in the range of 100 to 103 cells [Humphrey et al]) can increase one million fold under conditions of temperatures greater than 20°C especially if incubation times exceed 20 days (Kim et al, Humphrey et al, Fleischman et al). These conditions may occur in some situations with off line egg breaking plants, but are quite unlikely with in line plants. In contrast, the initial numbers of avian influenza virus in eggs (estimated at > 104 per ml) decline with increasing time and temperature (de Witt et al). Pasteurization is designed to reduce pathogen load – generally by 5 to 7 logs. This means that pasteurization works extremely well when the pathogen load is less than that level, but is subject to failure if/when the pathogen load is higher. This suggests that presence of *Salmonella* in pasteurized product is most likely due to an initial high bacterial load, not a failure of the pasteurization procedure itself. If the initial pathogen load is 108 and the final load is 101 (a 7 log reduction) then pasteurization has been successful even if the product remains contaminated. Consequently, the results of FSIS *Salmonella* testing are not directly applicable to the influenza risk assessment. Work by Swayne and Beck show that pasteurization temperatures essentially eliminate any chance of active virus in pasteurized product. Because research has shown that *Salmonella* is largely destroyed during pasteurization, it may be that FSIS findings are plant specific and not industry specific. Also, in 2007, the *Salmonella* positive rate dropped to 0.07 percent; in 2008 it has remained at zero (to date). Based on this, it appears that compliance has improved over time. Given these results, we conclude that product that has been correctly pasteurized will be negative for HPAI and the *Salmonella* findings are not inferential for HPAI.
Response 2.	Re-worded relevant paragraph to read: Internally, a breach in the containment of the pasteurized liquid egg leading to actual contamination of pasteurized liquid egg at any egg pasteurization premises is highly unlikely. Should a breach or containment failure occur, it would be indicated by changes on various gauges (such as those reporting temperatures, pressures, and flow volumes) that pasteurization is no longer occurring within the requirements shown in the applicable FSIS and FDA regulations. As production of non-compliant product could result in regulatory action by FSIS, we believe it is reasonable to assume that production will stop until the problem is indentified and resolved.

Response 3.	We agree that pasteurization is more effective than this risk assessment suggests. Risk assessors are utilizing a very conservative set of assumptions.
Response 4.	Egg tankers use an entirely different loading dock/area than that used by egg production activities (housing, feeding, dead bird removal, etc.). Although we have participated in the discussion regarding feed trucks, it is the activity surrounding the need to deliver feed and their moving between production facilities rather than the trucks per se that is the risk for spreading HPAI.

Response 5.	Tanker trucks do not have direct contact with poultry production; nor do they usually have indirect contact with poultry production. They may have indirect contact with something that has also had indirect contact with egg production; e.g., they may be driven down a road that has been exposed to feed or manure trucks. The associated risk would be equivalent to that associated with any truck (soft drink delivery, bread delivery, etc.) that had such indirect contact. We considered adding maps of egg producers or pasteurized egg product facilities, but decided against it because: • Numbers and locations of FSIS-inspected pasteurized egg product facilities will vary over time and are ancillary to the main body of this risk assessment; therefore showing their current locations may not provide usable information during a future outbreak; and, • Specific producer locations (addresses) are protected by law and are not usually disclosable (70). Therefore, it is not possible to conduct an analysis at the level of detail suggested in the comments. However, we concur that outbreak planning efforts by Incident Command and Emergency Management would be well-served to collect and maintain such data and capability for mapping. Added the following discussion: For HPAI infection on a contaminated vehicle carrying PLE to spread to an uninfected premises, the following pathway would have to be viable: 1. The vehicle was improperly cleaned and disinfected and this failure was not recognized by responsible state or federal official at the C&D location. 2. The movement permit issued by Incident Command routes the vehicle by a poultry production premises, or the vehicle violates the conditions specified in the movement permit and uses another route. 3. The vehicle, while in transit, sheds enough HPAI virus to cause an outbreak. 4. The virus survives in the environment and bypasses any biosecurity measures in place at the vulnerable premises and causes infection. As illustrated, this pathway is viable only if three simultaneous failures occur during the movement permitting process: • The vehicle is so poorly cleaned that it carries enough infectivity to infect another premises; • This failure is not noticed by the responsible official; and • Incident Command staff is either unaware or does not consider the locations of other poultry production premises or the vehicle deviates from the route shown on the permit. Given the lack of evidence for this pathway and systematic failures that would have to occur for it to be viable, we consider the likelihood of occurring to be negligible.

Response 6.	Re-worded relevant paragraph to read (changes in **bold**): To date, there has been no evidence published of a liquid egg processing premises contributing to the spread of any AI virus. A review of the scientific literature and response planning documents indicate that movements of contaminated equipment **(including vehicles**) *between* poultry premises is the primary means of spreading HPAI, **but there have been no reports of vehicles transporting PLE or their contents causing infection at another poultry premises.** (8;12;17;40;44)… This paragraph is intended to limit the discussion only to one specific subpopulation (vehicles transporting LPE) that is contained in the general population of vehicles. As noted in the text, other types of vehicles (contaminated feed vehicles and vehicles carrying dead chickens) have been reported as causing outbreaks. In addition, while vehicles may pose virus transmission risks that have not been indentified, risks of this type are hypothetical and not readily ascertainable. Risks of this type have been the subject of disputes at the World Trade Organization and (for international trade purposes) are not viewed as legitimate subjects for regulation or analysis (22).
Response 7.	This recommendation is being considered by the Working Group for addition when this assessment is updated. As noted in Response 5, we cannot publish or map individual poultry/egg premises locations.
Response 8.	There are no known heat resistant strains of AI virus. Further the H5N2 virus that was utilized is the only USA HPAI virus available for these studies.
Response 9.	We have incorporated the FSIS suggestions in the text.