

September 29, 2015

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

A. Introduction

The undersigned submits this petition to request the Commissioner of Food and Drugs to amend the Final Rule on Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage and Transportation, published July 9, 2009 [74 FR 33030] (the "Final Rule"). In the alternative, we request that FDA temporarily adjust the requirement, as it relates to broiler hatcheries for which any eggs diverted for human consumption are sent to breakers for pasteurization, to delay the refrigeration requirement to 120 hours instead of 36. ^{1/}

B. Interests of Petitioners

The National Chicken Council (NCC) is the national, non-profit trade association representing the U.S. chicken industry. The chicken producer and processors represented by the Council account for approximately 95 percent of the chickens produced in the United States.

Based in Washington, D.C., the Grocery Manufacturers Association is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies and trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders.

The Association for Dressings and Sauces (ADS) is the international trade association representing manufacturers of salad dressings, mayonnaise and condiment sauces and the suppliers to the industry.

C. Action Requested

(1) Amend 21 C.F.R. § 118.4(e) to read as follows:

§118.4 *Salmonella* Enteritidis (SE) prevention measures

...

(e) *Refrigeration*. You must hold and transport eggs at or below 45 °F ambient temperature beginning 36 hours after time of lay; except that this requirement does not apply to eggs that are intended to be processed in accordance with Section 1036 of Title 21 of the United States Code....

^{1/} The Final Rule was promulgated pursuant to the U.S. Food and Drug Administration ("FDA") authorities under Sections 402(a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") [21 U.S.C. §§ 342(a)(4) and 371(a), respectively] and Sections 311, 361 and 368 of the Public Health Service Act ("PHS Act") [42 U.S.C. §§ 243, 264 and 271, respectively].

or

(2) In light of the current Highly Pathogenic Avian Influenza (HPAI) outbreak, exercise enforcement discretion regarding, or revise the Agency's interpretation of, this provision of the Final Rule as it applies to hatching eggs diverted to breakers for a period of two years to allow broiler hatcheries to begin refrigeration 120 hours after the time of lay instead of 36 hours. We request that FDA extend the exemption if significant additional cases of HPAI occur within the two year exemption period. We further request that, prior to the expiration of the exemption, FDA provide industry an opportunity to present further information on the safety of diverting broiler eggs to egg breakers without the 36-hour refrigeration requirement.

D. Statement of Grounds

On behalf of the undersigned's members, we request that FDA amend the Final Rule or, alternatively, that it revise temporarily the application of the Final Rule to hatching eggs for a period of at least two years. This is a limited issue that can be considered separately without impacting enforcement of the remainder of the rule.

NCC previously petitioned the agency for relief from the unanticipated burdens imposed by this rule on February 19, 2010, to which the agency responded on August 17, 2010, that it had "not been able to reach a decision on [NCC's] petition within 180 days of the filing of the petition."^{2/} NCC met with Michael Landa, Director of the Center for Food Safety and Applied Nutrition, in June 2012 to discuss continued concerns with the rule and the impending implementation date in July 2012. With no reasonable ability to comply with the new requirements, the surplus hatching egg industry has ceased to exist, imposing significant economic hardship on broiler companies—and their communities—with no benefit to food safety.

As the agency noted in the Proposed Rule, egg products are already treated for safety—the Egg Products Inspection Act requires that egg products be treated to achieve a 5-log reduction in *Salmonella* Enteritidis (SE). The rulemaking does not suggest these products are unsafe or explain what further health benefit is achieved from refrigeration prior to treatment. Nevertheless, though it provides debatable additional food safety benefit, the Final Rule imposed on farms and hatcheries an unnecessary refrigeration requirement.^{3/}

The 36-hour refrigeration requirement is incompatible with the conditions necessary for hatching chicks, as it renders the eggs useless for potential hatching by significantly degrading egg viability through chilling. Further, broiler hatcheries are unable to determine those eggs that are surplus or out-of-specification prior to setting eggs for incubation and thus cannot reasonably refrigerate eggs at 45° F prior to setting. As a direct result of the Final Rule, broiler companies have stopped selling surplus and out-of-specification hatching eggs to egg processors ("breakers") and instead are forced to dispose of these eggs, often at an additional cost. This new procedure is wasteful, and yet the Final Rule forced the broiler industry to adopt it because they cannot comply with the 36-hour refrigeration requirement.

^{2/} Letter from Dr. Nega Beru, Director, Office of Food Safety, to George Watts, President, National Chicken Council, August 17, 2010.

^{3/} FDA reinforced this requirement in a guidance document, *Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*, explaining that the Final Rule applies to owners of broiler breeder flocks who occasionally send surplus eggs to the table market or to a breaker.

The recent HPAI outbreak and resulting egg price increases have further exposed the wasteful nature of forcing the broiler industry to destroy perfectly acceptable shell eggs. More than 33 million chickens have been culled since the outbreak was first detected in December 2014, the overwhelming majority of them in the egg-laying industry. ^{4/} Since then, there have been escalating concerns throughout the food industry about the increasing shortage of breaker eggs, causing prices to increase substantially. FDA has the power to help alleviate the impact of the current HPAI outbreak without increasing any food safety risks. By lifting the 36-hour refrigeration requirement for the hatcheries industry, FDA can increase the supply of breaker eggs, which will put downward pressure on prices and provide industries reliant upon breaker eggs with the relief they so desperately need.

1. Refrigeration is Not Necessary for Hatchery Eggs Slated for Pasteurization

The Final Rule needlessly requires eggs slated for pasteurization to be refrigerated 36 hours after being laid, despite the fact that the requirement provides no additional food safety value. The Egg Product Inspections Act mandates that surplus and out-of-specification hatching eggs sold for use as egg products be treated to achieve a 5-log reduction in SE. ^{5/} Neither the Proposed Rule nor the Final Rule suggested that this 5-log reduction treatment is inadequate to render the egg products safe. To the contrary, FDA expressly stated in the Final Rule that

[A] 5-log reduction in SE ...or the processing of egg products to achieve an equivalent level of protection is appropriate to ensure the safety of shell eggs. ^{6/}

In fact, the remedy set out in the Final Rule for failure to comply with the refrigeration requirement is, in part, for the eggs to be diverted to breakers for treatment to achieve a 5-log reduction. Thus, the Final Rule is contradictory in requiring refrigeration of eggs slated for pasteurization, despite the fact that these eggs are destined to undergo treatment that will render them safe for human consumption.

We recognize that a recent FDA study suggests that a 5-log reduction would be insufficient to render safe any eggs stored at 65 °F for 5.5 days, but the conclusions of this study do not suggest that extending the refrigeration requirement from 36 to 120 hours would create a food safety risk. ^{7/} The study concluded that more than 10 percent of internally contaminated eggs would remain contaminated after in-shell pasteurization if the eggs were held at 65° F for 5.5 days.

The study's conclusions are premised upon 65° F storage for a period of 5.5 days, but we are requesting that FDA extend the refrigeration requirement from 36 to 120 hours. The study thus does not address the effectiveness of a 5-log reduction for eggs kept in 65° F for the period NCC requested. Furthermore, due to the exponential growth curve of SE over time, the 12 hour difference between the storage time of 132 hours analyzed and the storage time of 120 hours requested would account for an increase in the presence of SE in the modeled conditions not present under the proposed storage conditions.

^{4/} Lydia Mulvany, *Are We Headed for an Egg Shortage?*, Bloomberg Business (May 14, 2015), available at <http://www.bloomberg.com/news/articles/2015-05-14/bird-flu-leaves-record-high-u-s-egg-prices-alongside-dead-hens>.

^{5/} 21 U.S.C. § 1036.

^{6/} 74 FR at 33037.

^{7/} R. Pouillot, et al., *Assessment of the risk of salmonellosis from internally contaminated shell eggs following initial storage at 18 °C (65 °F), compared with 7 °C (45 °F)*, 43 Food Microbiology 16 (2014).

Moreover, studies performed at the University of Georgia indicate that storing eggs at 65° F for 120 hours would not achieve more than a 5-log growth of SE, and thus a 5-log kill step would render the eggs safe. The study tested *Salmonella* Enteritidis growth in inoculated eggs held for 0, 1, 2, 3, and 4 weeks at 4°, 10°, and 22° C (equivalent to 39.2°, 50°, and 71.6° F). ^{8/} Eggs were inoculated with SE at a dose of 10²cfu/egg. The *Salmonella* population in the inoculated eggs held at 22° C for 2 weeks only grew from the initial 2.12 log₁₀ cfu/ml to 3.36 log₁₀ cfu/ml. These eggs thus experienced a modest outgrowth of SE that could still be effectively destroyed by the 5-log kill step delivered in FSIS-regulated egg products establishments. Moreover, these eggs were not only held significantly longer than 120 hours, but at temperatures significantly above the 65° F at which broiler hatchery eggs are stored. This study thus demonstrates the safety of allowing broiler eggs to go unrefrigerated for the requested period of 120 hours. ^{9/}

2. The Final Rule is Unworkable for the Hatching Egg Industry

Not only is the refrigeration requirement unnecessary for hatchery eggs diverted to breakers, it is entirely unworkable for the hatching egg industry. Broiler companies cannot reliably determine which eggs will be sold to breakers before the eggs are to be placed in incubators. Complying with the Final Rule would require hatching eggs to be refrigerated before the determination of which eggs will be sold to breakers and at a temperature significantly below the threshold at which the eggs will remain viable.

To be in compliance with the Final Rule's 36-hour requirement, hatcheries would have to refrigerate all hatching eggs to 45° F; however, this is not possible because doing so would ruin all of the eggs for potential hatching. Hatcheries refrigerate hatching eggs at approximately 65° because the viability of chicks becomes increasingly compromised as the temperature drops below 65°. As a general rule, eggs maintained below 60° will not be hatched. Eggs may additionally develop conditions more than 36 hours into the holding period that would render them out-of-specification. The number of out-of-specification eggs will, in turn, affect the number of eggs that are surplus.

Hatcheries cannot comply with the refrigeration requirement even as it applies to those hatching eggs that are determined to be out-of-specification prior to 36 hours. Hatcheries do not typically collect hatching eggs from farms within 36 hours. Moreover, NCC is not aware of any farms that have the necessary refrigeration capabilities to comply with the rule. The resources that would be required to outfit farms and hatcheries with adequate refrigeration units, and for hatcheries to collect eggs within 36 hours to make out-of-specification determinations, would not be economically feasible given the price received from breakers for these eggs.

For the reasons set out, the requirements that hatching eggs to be sold to breakers be refrigerated to 45° within 36 hours of being laid is not feasible for hatching eggs. The Final Rule has thus forced hatcheries to abandon the efficient practice of diverting surplus eggs to breakers.

3. The Final Rule Mandates that Millions of Eggs Be Wasted

Prior to enactment of the Final Rule, selling surplus hatching eggs to egg breakers was an important aspect of the broiler production process designed to foster efficiency and reduce waste,

^{8/} J. Chen and H.S. Thesmar, *Populations of Salmonella enteritidis in artificially inoculated chicken eggs as influenced by the temperatures under which eggs might be held from the day of lay until the day of processing*, 71 *Journal of Food Protection* 10, 2073-2077 (2008).

^{9/} Although a statement in the study suggests that chicken eggs should not be held at 22°C from the time of lay to the time of processing, the study's findings are strongly supportive of the safety the 120-hour period proposed in this Petition. The statement in the study appears to be focused on the parameters of the study, which dealt with timelines measured in weeks, not hours.

but now hatcheries must either divert these eggs to renderers, a landfill, or otherwise destroy them, thus wasting acceptable, edible eggs that are now so high in demand. Broiler-type hatching eggs are produced in more than 25 states on about 4,500 farms. ^{10/} USDA calculated that in 2011, there were 12.827 billion chicken hatching eggs produced. ^{11/} Almost 93.5 percent of these eggs (11.989 billion) were broiler-type hatching eggs. ^{12/}

Hatching eggs are primarily produced for incubation to hatch broiler chicks. USDA calculates that of the 11.989 billion broiler-type hatching eggs produced in 2011, 10,309,890,000 eggs were set for incubation for hatching in 19 major poultry states. ^{13/} Conservatively estimating that 3 percent of the eggs were set for incubation outside the 19 major poultry states, NCC estimates that a total of 10,619,187,000 broiler-type eggs were set for incubation.

Given that roughly 10.6 billion broiler-type eggs were set for incubation out of the 11.989 billion produced, 1,369,813,000 eggs, or 11.4 percent of the total broiler-type hatching eggs, were not set for hatching in 2011. A portion of these eggs were intended for use for exports, manufacture of vaccines, or other research needs. The remainder was surplus eggs, eggs that did not meet specifications (“out-of-specification eggs”) or eggs that did not warrant setting due to changing market conditions. ^{14/}

Prior to implementation of the Final Rule, broiler companies diverted surplus and out-of-specification eggs to breakers or for rendering and use in non-human food in order to recoup some of the losses in producing the eggs. Of the 1,369,813,000 broiler-type hatching eggs not set for hatching in 2011, 26.3 percent or 359,670,000 were sent to breakers. ^{15/} In other words, about 3 percent of the 11.989 billion broiler-type hatching eggs produced in 2011 were sent to breakers. The 359.67 million surplus or out-of-specification hatchery eggs sent to breakers in 2011 represented about 1.7 billion grams of protein, or a year’s supply of protein for about 94,000 people. ^{16/}

Extrapolating the 2011 breakdown of broiler-type hatching eggs sent to breakers to the total 11.854 billion broiler-type hatching eggs produced in 2014, NCC estimates that the Final Rule resulted in the industry disposing of roughly 355.62 million eggs in 2014. ^{17/} The broiler industry thus has the potential to provide hundreds of millions of eggs to egg breakers during this period where eggs are in short supply due to the HPAI outbreak. Broiler hatcheries cannot provide this relief, however, because the broiler industry was forced to end the efficient and profitable practice of diverting hatching eggs to egg processors when the Final Rule became effective. ^{18/}

^{10/} *Census of Agricultural 2007* National Agricultural Statistics Service/USDA and National Chicken Council estimate.

^{11/} *Chicken and Eggs, 2011 Summary*, February 2012, National Agricultural Statistics Service/USDA. USDA’s calculations span the twelve months from December 2010 through November 2011.

^{12/} *Id.*

^{13/} *Hatchery Production 2011 Summary*, April 2012, National Agricultural Statistics Service/USDA.

^{14/} For instance, an out-of-specification egg may not meet the size requirements or shell conditions that permit the eggs to be set for incubation.

^{15/} National Chicken Council based on industry contacts.

^{16/} See USDA, National Nutrient Database for Standard Reference, Release 24, *available at* <http://ndb.nal.usda.gov/> (last visited June 26, 2015) (using the value of 4.77 grams of protein for a small egg, whole, raw, fresh); 21 C.F.R. § 101.9(c)(9) (setting 50 grams of protein as the daily recommended value for a 2,000 calorie diet).

^{17/} *Chicken and Eggs, 2014 Summary*, February 2015, National Agricultural Statistics Service/USDA. USDA’s calculations span the twelve months from December 2013 through November 2014.

^{18/} NCC estimates that the industry is losing \$6 million a year in revenue and incurring \$6 million a year in disposal costs, creating a total of \$12 million annual loss to the industry as a result of the Final Rule.

The Final Rule has caused, and continues to cause, the industry to waste hundreds of millions of acceptable, safe eggs without any additional safety benefit. In light of the strain the HPAI outbreak is putting on the nation's egg supply, FDA should revisit the use of the surplus of affordable, quality eggs available in the United States for use by egg breakers and their customers, rather than seeking costly imports of foreign eggs.

4. These Wasted Eggs Could Be Used to Address the Current the Egg Shortage

As the nation's egg supply continues to suffer from the effects of the recent HPAI outbreak, the economic impact of destroying broiler-type hatching eggs is being felt by individuals and companies throughout the supply chain. Since the HPAI outbreak first began in December 2014, more than 48 million chickens, turkeys and other birds have been affected. ^{19/} The nationwide layer hen population has consequently decreased by more than 25 percent, and it will take many months before these flocks can be repopulated. ^{20/}

Meanwhile, the food industry is bracing itself for the egg shortage and subsequent spike in egg prices due to the sharp depopulation of layer hen flocks. Following the 1984 HPAI outbreak, which affected only a fraction of the number of animals already impacted by the current outbreak, retail egg prices rose by more than 30 percent. ^{21/} An even greater increase can be expected as a result of the current outbreak, given how great the scope is in comparison to the 1984 outbreak.

Indeed, market analysts reported that retail egg prices more than doubled in the period following the HPAI outbreak. ^{22/} Notably, the greatest impacts of the egg shortage will be felt by companies that use breaker eggs, eggs that the broiler industry could help supply if the FDA suspends the Final Rule, because the majority of the eggs taken out of production were meant for the egg processing market. ^{23/} Industry experts estimate that the price of a dozen breaker eggs rose dramatically from 63 cents in late April to \$2.15 in early June. ^{24/}

^{19/} Update on Avian Influenza Findings: Poultry Findings Confirmed by USDA's National veterinary Services Laboratories, Animal and Plant Health Inspection Service, http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3Apath%3A/aphis_content_library/sa_our_focus/sa_animal_health/sa_animal_disease_information/sa_avian_health/sa_detections_by_states/ct_ai_pacific_flyway (last visited June 26, 2015).

^{20/} Stephanie Strom, *Egg Farms Hit Hard as Bird Flu Affects Millions of Hens*, New York Times (May 14, 2015), available at http://www.nytimes.com/2015/05/15/business/bird-flu-outbreak-chicken-farmers.html?_r=0.

^{21/} 17 million birds died or were euthanized following the 1984 outbreak. Veterinary Services, World Organisation for Animal Health (OIE), *Highly Pathogenic Avian Influenza* (Feb. 2002), available at <http://www.oie.int/doc/ged/D246.HTM>.

^{22/} Stephanie Strom, *Egg Farms Hit Hard as Bird Flu Affects Millions of Hens*, New York Times (May 14, 2015), available at http://www.nytimes.com/2015/05/15/business/bird-flu-outbreak-chicken-farmers.html?_r=0; Lydia Mulvany, *Are We Headed for an Egg Shortage?*, Bloomberg Business (May 14, 2015), available at <http://www.bloomberg.com/news/articles/2015-05-14/bird-flu-leaves-record-high-u-s-egg-prices-alongside-dead-hens>. USDA more conservatively estimates that prices have increased by 28 cents for Jumbo eggs, 31 to 44 cents for Extra Large eggs, 28 to 44 cents for Large eggs, and 8 to 45 cents for Medium and Small eggs, still a very significant increase and a shock to the egg supply. USDA, Egg Market News Report, Vol. 62 No. 25 (June 22, 2015), available at <http://www.ams.usda.gov/mnreports/pybshelllegg.pdf>.

^{23/} *Poached! Bird flu leads to egg shortage, higher prices*, CNN Money (June 10, 2015), available at <http://money.cnn.com/2015/06/10/investing/egg-prices-shortage-bird-flu/>.

^{24/} *Id.*

These price spikes and supply disruptions are putting tremendous strain on the shell and egg products industries, and the impact has already begun to trickle down and impose hardships on restaurants and industries producing products with egg ingredients. Companies reliant upon breaker eggs have begun stockpiling supplies before prices escalate further. ^{25/} Some grocery stores have even begun limiting egg purchases per customer, while others have sold out of eggs entirely. ^{26/} Despite their best efforts, many restaurants have also removed egg dishes from their menus, and many are debating the need to increase their prices. ^{27/}

Meanwhile, as companies scramble to find alternative sources for egg supplies and brace themselves for further price hikes, the Final Rule continues to force the hatching egg industry to destroy hundreds of millions of perfectly safe eggs. Though exempting the hatcheries industry from the 36-hour refrigeration rule cannot entirely mitigate the egg shortage, allowing the industry to resume selling its eggs to egg breakers as it did before implementation of the Final Rule will certainly help mitigate some of hardship other industries and consumers will face in the coming months as egg prices continue to rise.

In light of the foregoing, we request that the rule be amended so that it does not apply to eggs intended to be sold to breakers (which includes hatching eggs). Alternatively, we request that the agency temporarily delay the refrigeration requirement from 36 to 120 hours as it applies to surplus hatchery eggs sold to breakers, in response to the current and any forthcoming HPAI outbreak.

E. Environmental Impact

The actions requested by this petition are exempt from the requirements for an environmental assessment or an environmental impact statement pursuant to categorical exclusions set out in FDA regulations, including 21 C.F.R. § 25.30(i), 25.30(j), and 25.32(g).

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petition that are unfavorable to the petition.

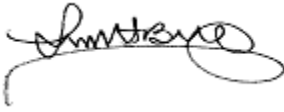
^{25/} Lydia Mulvany, *Are We Headed for an Egg Shortage?*, Bloomberg Business (May 14, 2015), available at <http://www.bloomberg.com/news/articles/2015-05-14/bird-flu-leaves-record-high-u-s-egg-prices-alongside-dead-hens>.

^{26/} Roberto A. Ferdman, *Egg rationing in America has officially begun*, The Washington Post (June 5, 2015), available at <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/06/05/the-largest-grocer-in-the-texas-is-now-rationing-eggs/>.

^{27/} Margery A. Beck, *Egg Shortage: Restaurants raise Prices, Drop Items*, NBC News (June 22, 2015; 10:25 AM), available at <http://www.nbcnews.com/business/consumer/egg-shortage-restaurants-raise-prices-drop-items-n379611>.



Ashley B. Peterson, Ph.D.
Senior Vice President,
Scientific and Regulatory Affairs
National Chicken Council



Leon H. Bruner DVM, Ph.D.
Executive Vice President,
Scientific and Regulatory Affairs
and Chief Science Officer
Grocery Manufacturers Association



Jeannie Milewski
Executive Director
The Association for Dressings & Sauces



cc: Susan Mayne, Director, CFSAN
Steven Musser, Deputy Director for Scientific Operations, CFSAN
John Sheehan, Director, Division of Plant and Dairy Food Safety, CFSAN