NATIONAL CHICKEN COUNCIL

1152 FIFTEENTH STREET NW, SUITE 430
WASHINGTON, DC 20005
PHONE: 202-296-2622

May 8, 2018

Carmen Rottenberg
Acting Deputy Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture
331-E Jamie L. Whitten Federal Bldg.
Washington, DC 20250-3700

Re: Request to Exercise Enforcement Discretion to Allow Surplus Broiler Eggs to be Sent to Egg Breakers

Dear Acting Deputy Under Secretary Rottenberg:

The National Chicken Council ("NCC") respectfully submits this letter requesting that the Food Safety and Inspection Service ("FSIS") coordinate with the Food and Drug Administration ("FDA") to exercise enforcement discretion to allow surplus broiler eggs to be processed into egg products under FSIS jurisdiction. Historically, the broiler industry sent surplus hatching eggs for processing at egg breaking plants (but not into the table egg market), where they were pasteurized under FSIS jurisdiction and oversight. As you may be aware, in 2009 FDA published a final rule requiring that shell eggs, including surplus broiler eggs sent for breaking, be refrigerated shortly after the time of lay. The problem is that the timing of refrigeration under the FDA rule is incompatible with the process broiler eggs must follow. This is because refrigerating broiler eggs prevents them from hatching – that is, they cannot be warm enough for possible hatching yet cool enough for compliance with the FDA rule. Accordingly, since the rule took effect, the broiler industry has been forced to discard surplus eggs instead of sending them to breakers, costing the broiler industry more than $25 million each year and unnecessarily keeping billions of eggs out of the egg breaking market.

Importantly, NCC's request, if granted, would maintain the same high level of public health protection as intended under the FDA rule. The breaking process overseen by FSIS requires a pasteurization step that is proven effective at destroying *Salmonella*. Moreover, under the FDA shell egg rule, the remedy for eggs containing *Salmonella* is to send the non-compliant eggs to the breaker for pasteurization – *i.e.*, the very same step that NCC proposes for surplus broiler eggs. In either case, the FSIS-regulated pasteurization process is sufficient to assure safety for human consumption. We therefore recommend that, as part of the Administration's regulatory reform efforts, FSIS coordinate with FDA to exercise enforcement discretion to allow surplus broiler eggs to be sent for breaking without needing to meet the refrigeration requirement in FDA's shell egg rule.

I. Background

A. Broiler Hatching Eggs and Surplus Egg Uses

NCC is the national trade association representing the vertically integrated United States chicken industry. NCC member companies ("broiler companies") produce and process approximately 95 percent of the chickens in the United States. Broiler chickens are raised for meat production, whereas laying hens are used in the egg production industry. The United States Department of Agriculture ("USDA") calculates that in 2017, there were about 13.6 billion chicken hatching eggs produced.[1] More than 99 percent of these (13.5 billion) were broiler-type hatching eggs.[2]

Broiler hatching eggs are produced primarily for hatching into broiler chicks. USDA calculates that of the 13.5 billion broiler-type hatching eggs produced, 10.8 billion were set for incubation for hatching in 19 major poultry states.[3] (In addition, a very small percentage would have been set for incubation outside of the 19 major poultry states.) Therefore, about 2.7 billion, or about 20 percent, of the total broiler-type hatching eggs were not hatched. Some of these eggs are intended for use for exports, manufacture of vaccines, or other research needs. The remainder are surplus eggs and eggs that do not meet specifications ("out-of-specification eggs"). For instance, an out-of-specification egg may not meet the size requirements or shell conditions that permit the eggs to be incubated.

To be viable for hatching, a broiler egg must be held at the proper temperature. For optimal hatching, broiler-type hatching eggs are maintained at around 65 degrees Fahrenheit prior to placement in the incubators.[4] If a broiler egg is refrigerated, it will not hatch. It can take up to five days to determine which eggs are appropriate for hatching and thus equally as long to determine which eggs should be diverted. Prior to the implementation of the FDA shell egg rule at 21 C.F.R. Part 118 (and in particular the refrigeration requirement at 21 C.F.R. § 118.4(e)), these diverted eggs were then sold to egg breakers and processed as liquid eggs in compliance with FSIS regulations. FSIS's egg-breaking regulations require that liquid eggs be processed to destroy *Salmonella*.

By contrast, dedicated shell egg operations are set up significantly differently than broiler hatcheries. In a typical shell egg laying facility, eggs are collected daily, and sometimes continuously. There is no concern about maintaining viability for hatching, and so the eggs can be placed quickly into dedicated refrigeration facilities or trailers. Grading, sorting, and other steps to determine which shell eggs should be marketed can be done after they are refrigerated. Although some of these eggs may be sent to breaking for various reasons, they are produced primarily with the table egg market in mind. Most table eggs are not processed to destroy *Salmonella*, making *Salmonella* control especially important during harvesting and processing. The FDA shell egg rule was developed with these eggs in mind. Surplus broiler hatching eggs, by contrast, historically were

---

1 *Chicken and Eggs 2017 Summary*, February 2018, National Agricultural Statistics Service/USDA. USDA's calculations span the twelve months from December 2016 through November 2017.

2 *Id.*

3 *Hatchery Production 2016 Summary*, April 2017, National Agricultural Statistics Service, USDA.

4 North & Bell, *Commercial Chicken Production Manual* at 96 (4th ed. 1990). Eggs held longer than five days may be stored at temperatures as low as 51 degrees Fahrenheit, but hatchability is materially reduced for each day over four that an egg is held. *Id.* at 96–97.

not sold into the table egg market and thus present a significantly different production process and timeline.

B. The FDA Shell Egg Rule

In 2009, FDA published a final rule on Prevention of *Salmonella Enteritidis* in Shell Eggs During Production, Storage, and Transportation, codified at 21 C.F.R. Part 118 (the "FDA Shell Egg Rule").[5] Intended to address issues associated with *Salmonella* on shell eggs, the FDA Shell Egg Rule requires that all shell eggs be refrigerated at or below 45 degrees Fahrenheit beginning 36 hours after the time of lay. Although the proposed rule did not mention surplus broiler eggs, the final rule expanded the scope of the requirement to include surplus broiler eggs, even if destined solely for egg breaking operations. Broiler companies therefore are covered by the rule, which means that they must hold and transport eggs at or below 45 degrees Fahrenheit beginning 36 hours after the time of lay if any of the eggs are to be sold into the egg breaking market. This requirement applies even if the eggs are to be sold exclusively for processing into egg products under FSIS jurisdiction. This temperature requirement is incompatible with the necessary conditions for hatching chicks, and renders the eggs useless for hatching. As a direct result, most broiler companies have stopped selling their surplus and out-of-specification hatching eggs to egg breakers.

At the time this rule was being implemented, NCC submitted a letter to the FDA requesting relief. In it, NCC explained that subjecting surplus broiler hatching eggs to the FDA Shell Egg Rule was unnecessary and wasteful. Surplus broiler hatching eggs were sold for processing into egg products, not for consumption as shell eggs, and thus are subjected to a lethality process under FSIS inspection validated to destroy *Salmonella*. As a result of the rule, NCC pointed out, billions of eggs would be needlessly discarded. Moreover, NCC raised procedural concerns with the administrative process, noting in particular that extending the refrigeration requirements in 21 C.F.R. § 118.4(e) to surplus hatching eggs was not a logical outgrowth of the proposed rule, as the FDA had expressly acknowledged in the final rule that the proposal did not address surplus hatching eggs. Ultimately, the FDA determined that the final rule would still nonetheless apply to surplus broiler eggs. We understand FDA to have based its decision in part on theoretical concerns that the FSIS egg inspection process may be inadequate to control *Salmonella* in certain cases involving extreme contamination of the eggs and prolonged opportunity for growth. We address this concern below.

C. Requested Action

FDA's decision to subject surplus broiler hatching eggs to the FDA Shell Egg Rule has resulted in significant cost to American businesses and has needlessly deprived American consumers of millions of servings of high-quality egg protein. NCC welcomes the Administration's focus on reforming regulatory programs to eliminate needless waste and requests that FSIS and FDA collaborate to exempt surplus broiler eggs intended for breaking from the FDA Shell Egg Rule. Specifically, NCC requests that FSIS and FDA work together to exercise enforcement discretion to exempt surplus broiler hatching eggs intended for breaking from the refrigeration requirements in 21 C.F.R. § 118.4(e) and instead rely on the existing processing requirements applicable to egg products processing establishments (and eventually the requirements in FSIS's proposed egg products HACCP

[5] FDA, *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*, 74 Fed. Reg. 33030 (July 9, 2009).

regulations) to control for *Salmonella* in these products.

II. Support for Requested Action

A. Exempting Surplus Broiler Eggs from the FDA's Shell Egg Rule Does Not Create Any Public Health Risks

The public health justification for extending the refrigeration requirement to hatching eggs sold for egg products was never clear from the FDA rulemaking for several reasons. First, because broiler eggs cannot be refrigerated, and because they are not produced with the table egg market in mind, surplus broiler eggs previously sold to egg breakers were pasteurized to achieve at least a 5-log reduction in *Salmonella Enteritidis* pursuant to the Egg Products Inspection Act and FSIS regulations (and often greater reductions).[6] This pasteurization process operates under FSIS inspection, ensuring that egg breakers adhere to strict regulatory requirements.

Moreover, the FDA Shell Egg Rule provides that noncompliant shell eggs testing positive for *Salmonella Enteritidis* are to be diverted to pasteurization at egg breakers, regardless of the levels of *Salmonella Enteritidis* that may be present on those eggs. Importantly, the FDA Shell Egg Rule does not require testing to determine how much *Salmonella Enteritidis* may be present; rather, the rule simply assumes that no matter how large the levels may be, the FSIS pasteurization process will be sufficient. This demonstrates FDA's belief that pasteurization is adequate to protect the public health and notably creates the odd situation of unrefrigerated surplus broiler eggs destined for egg breakers being declared noncompliant even if no *Salmonella* is present while other noncompliant eggs known to have *Salmonella Enteritidis* are diverted to egg breakers as a remedy. If FDA has confidence that the FSIS-inspected pasteurization process would remedy eggs that actually test positive for *Salmonella Enteritidis* regardless of the level of *Salmonella Enteritidis* on the eggs, FDA should be similarly confident in the pasteurization process to control *Salmonella* that may or may not be present on surplus broiler eggs. This oddity reinforces the underlying point that this rule is intended for eggs destined for the table egg market and is not readily applicable to eggs intended for either hatching or liquid egg (pasteurized) products.

As FDA's own shell egg regulations reflect, FSIS has robust regulations in place to ensure that eggs sent for breaking and processing into egg products are safe for consumption. Egg breaking plants operate under FSIS inspection and must meet processing requirements detailed in comprehensive FSIS regulations in 9 C.F.R. Part 590. The processing regulations are designed to ensure that egg products are processed to destroy *Salmonella*. Additionally, most broiler companies vaccinate their breeder flocks (the flocks that produce the eggs for hatching into broiler chickens) against a variety of *Salmonella* strains, including Enteritidis, Typhimurium, and Heidelberg, thereby reducing the risk that these or other strains are present on surplus broiler hatching eggs. Moreover, broiler breeder flocks are extremely important for broiler production operations, and the flocks are held under strict biosecurity protocols typically significantly more intensive than what is feasible at a large-scale commercial shell egg production farm. These measures further reduce the risk of surplus broiler eggs being contaminated with *Salmonella*.

We understand that FDA may have had theoretical concerns about extreme outlier scenarios

[6] *See* 9 C.F.R. § 590.

in which an individual egg might have *Salmonella* growth that would overwhelm the FSIS pasteurization process, extrapolating from models developed in FSIS's 2005 *Risk Assessments of Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Products*.[7] Such concerns are unfounded. First, NCC is not aware of such instances occurring. The FSIS egg products processing requirements are robust and well implemented. In fact, FSIS has a sampling program to identify *Salmonella* in egg products. For the one-year period of April 1, 2017 through March 31, 2018, FSIS collected 1,702 samples of pasteurized egg products in finished form from 58 establishments. None of the samples tested positive for *Salmonella*. The FSIS pasteurization process works. Second, FSIS considers egg products containing *Salmonella* to be adulterated, and these egg products containing *Salmonella* would be handled accordingly. Third, under the FDA Shell Egg Rule, standard shell eggs intended for the table egg market that actually test positive for *Salmonella Enteritidis* may be diverted to FSIS-regulated egg breakers as a remedy.[8] Importantly, these eggs may be diverted without regard for the level of *Salmonella Enteritidis* actually on the eggs. In other words, FDA's egg-diversion remedy for shell eggs does not depend on how much *Salmonella* may be present. There is no reason why broiler surplus hatching eggs should be treated any differently.

Surplus broiler eggs are different than shell egg laying operations in another important way. At a shell egg laying operation, a significant percentage of the eggs produced will be sent to the table egg market, increasing the risk of inadvertent commingling eggs intended for breakers and eggs intended for the table egg market. By contrast, all surplus broiler eggs sold for food use would be sent to breakers – there is no real risk of these eggs ending up in the table egg market.

Moreover, exempting surplus broiler hatching eggs from the FDA Shell Egg Rule's refrigeration requirement and consolidating jurisdiction over these products with FSIS is consistent with FSIS's egg products HACCP proposed rule.[9] In that proposed rule, FSIS announced plans to extend its well-established and effective HACCP requirements to egg breaking plants. HACCP is a scientifically robust, state-of-the-art approach to food processing that ensures plants comprehensively identify, assess, and control all food safety hazards reasonably likely to occur in processing food. The egg product HACCP proposed rule promises to further enhance food safety at egg breaking plants, reinforcing that egg breakers will be able to safely handle surplus broiler hatching eggs without the need for FDA's Shell Egg Rule refrigeration requirements. For example, egg breaking plants would be required to validate that their processes are capable of destroying any *Salmonella* present in the food. Egg breakers presumably would take into account the potential for *Salmonella* on incoming eggs and implement controls as appropriate to reduce and eliminate the potential hazard. Moreover, if a breaker were to conclude that surplus broiler eggs presented a different risk profile, the breaker would be free to adjust the pasteurization process for such eggs to ensure the eggs are pasteurized at a time and temperature shown to destroy *Salmonella*. This type of flexibility and science-based decision making is fundamental to HACCP and would ensure that surplus broiler eggs are handled safely. Subjecting the surplus broiler hatching eggs to prescriptive refrigeration controls is not necessary. In addition, the FSIS proposed rule on egg product HACCP indicates FSIS's intent to exercise jurisdiction over several types of products[10] that the Agency historically had not regulated

---

7 FSIS, *Risk Assessments of Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Products* (2005).

8 21 C.F.R. § 118.6.

9 Egg Products Inspection Regulations, 83 Fed. Reg. 6314 (February 13, 2018).

10 Specifically, FSIS has proposed exercising jurisdiction over egg substitutes and freeze-dried egg products. 83 Fed. Reg. 6314, 6316 (Feb. 13, 2018).

as egg products, indicating that now is an opportune to time for FDA and FSIS to consider efficiencies in their exercise of jurisdiction over egg production. Ensuring that surplus broiler hatching eggs are treated appropriately is consistent with these efforts to rationalize FSIS and FDA jurisdiction.

Finally, the broiler industry is willing to implement any additional reasonable safeguards needed to ensure that surplus broiler hatching eggs are not introduced into the table egg market. For instance, NCC's members could certify all surplus hatchery eggs from a broiler laying operation that enter the food supply are sent only to breakers, use shipping seals, mark containers of surplus hatchery eggs destined for the food supply as "breaking only," and/or insist on agreements that buyers not resell surplus hatchery eggs into the shell egg market. As the industry is not aware of outbreaks resulting from surplus broiler eggs sent to egg breakers, combining the current FSIS regulation scheme with some of these safeguards would adequately address any public health concerns remaining.

B. Current Compliance with the FDA Shell Egg Rule Has Negative Economic and Societal Effects

Selling surplus broiler hatching eggs to egg breakers reflected a modest but nonetheless significant source of revenue to broiler companies, which allowed companies to recoup some of the costs associated with producing eggs and helped make broiler chicken such a price-competitive protein. NCC projects that FDA shell egg rule has cost the broiler industry at least $25 million per year. Broiler companies receive much lower value for surplus and out-of-specification hatching eggs diverted to rendering and non-human food use than for eggs sold for breaking. NCC conservatively estimates that, from 2009 through 2017, broiler companies experienced lost revenue totaling $121.8 million because they could not sell surplus hatching eggs to breakers. Moreover, in many cases broiler companies would actually lose money selling surplus eggs to renderers or for non-human uses because of the costs of handling and transportation. NCC estimates that industry disposal costs, including landfilling, for these eggs from 2009 through 2017 amounted to about $93.4 million. Combined, the lost revenue and added disposal costs add to $215.2 million over the last eight years, or more than $25 million per year. These lost revenue and disposal costs add to the costs of producing chicken and ultimately affect the market price consumers pay at the grocery store. Thus, making this one change would save the broiler industry approximately $25 million dollars per year, or $250 million over the next decade.

Moreover, surplus broiler hatching eggs provide a valuable protein source. As consumers face rising food costs and many Americans continue to struggle to access affordable food, the FDA Shell Egg Rule needlessly removes an affordable, wholesome protein source from the market. NCC estimates that from 2009 through 2017, 4.87 billion surplus broiler hatchery eggs would have gone to egg breaking operations but for the FDA Shell Egg Rule. Those discarded eggs could have provided the equivalent of an egg a day to 13.4 million people for an entire year, roughly the population of the entire state of Pennsylvania. From a nutritional standpoint, those 4.87 billion eggs amount to 29.2 billion grams of protein,[11] which would satisfy the daily protein needs for 584,000 people,[12] or

[11] We assume 6 grams of protein per egg.

[12] Both FSIS and FDA recognize a daily value of 50g for protein. The calculations above are based on adults. The discarded eggs could feed even more children.

roughly the population of Wyoming, for an entire year. There is no societal benefit to discarding these eggs or to depriving consumers access to this safe and affordable protein source.

C. The Current Move Toward Regulatory Reform Offers a Unique Opportunity for FSIS and FDA Collaboration

Exercising enforcement discretion for surplus broiler hatching eggs sent to egg breakers under the FDA Shell Egg Rule, in recognition of existing FSIS regulatory oversight, would provide regulatory cost savings and reduce the regulatory burden on the industry, both outcomes that align with the President's and Secretary's regulatory reform initiatives. The Administration has initiated several regulatory reform measures intended to decrease regulatory burden on industry, eliminate ineffective or unnecessary regulations, and make the federal government more efficient. Executive Order (EO) 13771 on Reducing Regulation and Controlling Regulatory Costs states that it is the policy of the executive branch to be "prudent and financially responsible in the expenditure of funds, from both public and private sources," and it requires that for each new regulation issued, at least two existing regulations must be eliminated to offset the cost of the new regulation.[13] Additionally, EO 13777 on Enforcing Regulatory Reform Agenda calls for each agency to establish a Regulatory Reform Task Force to identify regulations that, among other things, eliminate jobs or inhibit job creation; are outdated, unnecessary, or ineffective; impose costs that exceed benefits; create serious inconsistency; or otherwise interfere with regulatory reform initiatives and policies.[14] As previously discussed, FDA regulation of broiler eggs bound for egg breakers is unnecessary because there is no food safety risk associated with these products given the other safety measures implemented under FSIS inspection. The FDA Shell Egg Rule also imposes costs that exceed any benefits because it imposes both industry and societal costs without any corresponding increase in food safety. Eliminating this unnecessary coverage of broiler eggs under the FDA Shell Egg Rule would remove these unnecessary costs, consistent with the President's prioritization of regulatory reform.

In addition to the Administration's focus on regulatory reform, the FDA and the USDA recently issued a formal agreement committing to collaboration and coordination in an effort to improve efficiency and effectiveness.[15] The agreement specifically explains that "USDA and FDA share the goals of identifying and potentially reducing . . . dual regulatory requirements, bringing greater clarity and consistency to jurisdictional decisions . . ., and decreasing unnecessary regulatory burdens." Given the FSIS regulatory regime encompassing the safety of surplus eggs sold to egg breakers, exercising enforcement discretion to exempt broiler companies from the refrigeration requirements of the FDA Shell Egg Rule would further the goals of the FDA-FSIS agreement. Jurisdiction could be streamlined into FSIS, in order to ensure public safety, and the industry could eliminate the unnecessary costs imposed by the FDA rule.

Finally, consolidating jurisdiction over surplus broiler hatching eggs sent for breaking furthers the general approach of modernizing and streamlining inspection regulations that is motivating many of FSIS's regulatory initiatives, including the proposed rule on egg product HACCP. That proposed

---

[13] Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, 82 Fed. Reg. 9339 (Feb. 3, 2017).

[14] Executive Order 13777, Enforcing the Regulatory Agenda, 82 Fed. Reg. 12285 (March 1, 2017).

[15] Formal Agreement between USDA and FDA Relative to Cooperation and Coordination, available at https://www.fda.gov/Food/InternationalInteragencyCoordination/DomesticInteragencyAgreements/ucm594371.htm (January 30, 2018).

rule reflects a shift away from "command and control" regulatory schemes toward a risk-based, scientifically driven approach to food safety that is fully capable of addressing any potential issues associated with incoming ingredients including surplus broiler eggs. It also marks a modest realignment of jurisdiction between FDA and FSIS. It is appropriate and timely to address surplus broiler hatchery eggs in light of these efforts.

III. Conclusion

For the reasons stated herein, NCC respectfully requests that FSIS coordinate with FDA to provide enforcement discretion to allow surplus broiler eggs to be sent to breakers despite the requirements of 21 C.F.R. § 118.4(e), relying instead on FSIS's egg products regulations to ensure the safety of products derived from these surplus eggs. There would be no increased food safety risk associated with this change, as FSIS regulations will continue to protect public health. Moreover, this deregulatory action would remove a needless regulatory obstacle on businesses, would advance the Administration's objective to reduce unnecessary regulatory burdens, and would prevent needless food waste. In sum, the exemption would create industry and consumer gains without any sacrifices to food safety.

Thank you or your consideration of this petition. Please do not hesitate to contact me if I can provide any additional information.

Respectfully submitted,

Michael J. Brown
President

cc:

Mr. Paul Kiecker, Acting Administrator, U.S. Department of Agriculture, Food Safety and Inspection Service
Ms. Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service
Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine, U.S. Food and Drug Administration
Dr. Susan Mayne, Director, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration