



**NATIONAL CHICKEN COUNCIL**

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**September 12, 2011**

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

**Re: Comments on “Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation.”**

Dear Sir or Madam:

The National Chicken Council (NCC) respectfully submits these comments on the draft guidance entitled “Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation,” published July 13, 2011 [76 FR 41157]. Specifically, NCC urges the agency either to amend the final rule to exempt hatching eggs from its scope, reopen the comment period, or clarify in its final Guidance document that the rule does not apply to surplus hatching eggs destined for further processing.

NCC is a nonprofit member organization representing companies that produce and process over 95 percent of the broiler/fryer chickens marketed in the United States. NCC promotes the production, marketing, and consumption of safe, wholesome, and nutritious chicken products both domestically and internationally. NCC serves as an advocate on behalf of its members with regard to the development and implementation of federal and state programs and regulations that affect the chicken industry.

For the reasons set out herein, the change in the Final Rule to extend the refrigeration requirements in 21 C.F.R. § 118.4(e) to surplus hatching eggs was not a logical outgrowth of the proposed rule, published September 22, 2004 [69 FR 56824] (“Proposed Rule”). Indeed, FDA expressly acknowledges in the Final Rule that the Proposed Rule did not address surplus hatching eggs. Broiler companies had no reason to expect this requirement would be added to the Final Rule, and were effectively denied an opportunity for meaningful comment as required by the Administrative Procedure Act, 5 U.S.C. § 553(b) (“APA”).

Moreover, with respect to the extension of the refrigeration requirement to hatching eggs, the Final Rule is arbitrary and capricious in violation of the APA, in that it is based on an incomplete and inadequate record. Because broiler companies and other affected parties had no reason to comment on the Proposed Rule, FDA did not receive input from directly affected parties. The result is a Final Rule that does not address the significant consequences of the imposed requirement on the regulated industry and does not adequately set out the purported benefits that justify the costs.

The resulting rule would impose a refrigeration requirement on farms and hatcheries that is incompatible with necessary conditions for hatching chicks, and would render the eggs useless for

hatching as eggs will not be viable for hatching if they are maintained below 65 degrees. As a direct result, broiler companies would likely stop selling surplus and out-of-specification hatching eggs to egg processors (“breakers”). This would significantly reduce the income of broiler companies and is potentially devastating to those breakers that rely primarily on surplus hatching eggs for production of egg products. It would also result in the destruction of otherwise useful eggs.

Most critically, the public health justification for extending the requirement to hatching eggs sold for egg products is not clear from the rulemaking. As the agency notes 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.

Because of the significant adverse impact the final rule will have on the broiler industry – and recognizing that the rule as proposed, specifically exempted hatching eggs from its scope – NCC petitioned the agency on February 18, 2010, asking that either the final rule be amended to include the exemption as consistent with the proposal or the comment period be reopened so the industry would have reasonable notice and opportunity to comment. NCC representatives then met with officials from the Center for Food Safety and Applied Nutrition to explain and discuss the reasons set forth in the petition. To date, the agency has failed to respond substantively to NCC’s petition.

### **Background on the Hatching Egg Industry**

Broiler-type hatching eggs are produced in more than 25 states on about 4,500 farms. <sup>1</sup> USDA calculates that in 2008, there were 13.346 *billion* chicken hatching eggs produced. <sup>2</sup> More than 94 percent of these (12,543,000,000) were broiler-type hatching eggs. <sup>3</sup>

The primary purpose for producing hatching eggs is for incubation to hatch a broiler chick. USDA calculates that of the 12,543,000,000 broiler-type hatching eggs produced, 10,876,807,000 eggs were set for incubation for hatching in 19 major poultry states. <sup>4</sup> Conservatively assuming that 3 percent of the eggs were set for incubation outside the 19 major poultry states, we estimate that 11,213,200,000 total broiler-type eggs were set for incubation. <sup>5</sup>

Thus, there were 1,329,800,000 eggs, or 10.6 percent of the total broiler-type hatching eggs, that were not hatched. Some of these eggs are used 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 set for incubation.

An egg may also not be hatched if it is not maintained at proper temperatures for hatching. For optimal hatching, broiler-type hatching eggs are maintained at around 65 degrees Fahrenheit for up to 5 days prior to placement in the incubators. <sup>6</sup> The viability of the chick is compromised if the egg is held at

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<sup>1</sup> *Census of Agricultural 2007* National Agricultural Statistics Service/USDA and National Chicken Council estimate.

<sup>2</sup> *Chicken and Eggs, 2008 Summary*, February 2009, National Agricultural Statistics Service/USDA. USDA’s calculations span the twelve months from December 2007 through November 2008.

<sup>3</sup> *Id.*

<sup>4</sup> *Hatchery Production 2008 Summary*, May 2009, National Agricultural Statistics Service/USDA.

<sup>5</sup> Assumes 3 percent additional eggs set outside the 19 states.

<sup>6</sup> North & Bell, *Commercial Chicken Production Manual* at 96 (4<sup>th</sup> ed. 1990).

lower temperatures. <sup>7</sup> Eggs held longer than 5 days may be stored at temperatures as low as 51 degrees, but hatchability is materially reduced for each day over 4 that an egg is held. <sup>8</sup> The determination as to whether an egg will be hatched is typically made at the time eggs are to be placed in the incubator. As a result, it may be 5 days or longer, depending on the operation, before surplus and out-of-specification eggs are diverted for sale to breakers.

Broiler companies divert all surplus and out-of-specification eggs to breakers for thermal processing or for rendering and non-human food in order to recoup some of the losses in producing the eggs. Of the 1,329,800,000 broiler-type hatching eggs not set for hatching, 28.3 percent or 376,300,000 were sent to breakers. <sup>9</sup> In other words, about 3 percent of the 12,543,000,000 broiler-type hatching eggs produced in 2008 were sent to breakers.

The average price broiler companies received for broiler hatching eggs sent to egg processors in 2008 was 16 cents per dozen. <sup>10</sup> Thus, the total value of broiler hatching eggs sent to egg processors was over \$5.0 million.

Broiler companies receive much lower value for surplus and out-of-specification hatching eggs diverted to rendering and non-human food use. In certain cases, the value will be lower to the company than the cost of handling and transportation, in which case the eggs may be diverted to landfill operations.

### **The Final Rule is not a logical outgrowth of the Proposed Rule**

The APA requires that a “[g]eneral notice of proposed rule making shall be published in the Federal Register, “and that the “notice shall include ...either the terms or substance of the proposed rule or a description of the subjects and issues involved.”<sup>11</sup> A final rule provides inadequate notice if it is not a “logical outgrowth” of the proposed rule.<sup>12</sup> The logical outgrowth test is satisfied where the proposed rule provided interested parties with sufficient information to make them aware of the issues to be addressed by the final rule, and to permit them to comment and provide relevant information.<sup>13</sup> On the other hand, a final rule is not a logical outgrowth if “interested parties would have had to ‘divine [the agency's] unspoken thoughts,’ because the final rule was surprisingly distant from the proposed rule.”<sup>14</sup>

The change in the Final Rule that hatching eggs sold to breakers are subject to the refrigeration requirement is not a logical outgrowth of the Proposed Rule. Indeed, FDA acknowledges in the preamble to the Final Rule that the refrigeration requirement in the Proposed Rule did not encompass hatching eggs sold to breakers:

[T]he refrigeration requirement in the proposed rule only addresses eggs held at the farm for more than 36 hours after time of lay. The proposed requirement does not address ...surplus hatching eggs sent to the table egg market.<sup>15</sup>

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<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 96-97.

<sup>9</sup> National Chicken Council based on industry contacts.

<sup>10</sup> National Chicken Council based on industry contacts.

<sup>11</sup> 5 U.S.C. § 553(b).

<sup>12</sup> *See Ass'n of Battery Recyclers, Inc. v. EPA*, 208 F.3d 1047, 1058-59 (D.C. Cir. 2000).

<sup>13</sup> *See Fertilizer Inst. V. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991). See also *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C.Cir.2004).

<sup>14</sup> *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259-60 (D.C.Cir.2005) (citations omitted).

<sup>15</sup> 74 FR at 33041.

Notwithstanding this acknowledgment that the proposed rule did not address refrigeration of hatching eggs, FDA proceeded in the Final Rule to explicitly state that it was changing the requirement to specifically apply to hatching eggs sold to breakers:

Following are three examples of eggs requiring refrigeration under the final rule, which would not have required refrigeration previously: ... (3) eggs from a hatchery that are more than 36 hours old, were never used for hatching, and are now being transported to a shell egg processing facility.<sup>16</sup>

The refrigeration requirement is the only requirement that applies to hatching eggs in the Final Rule. Since, as FDA acknowledges, the refrigeration requirement in the Proposed Rule did not apply to hatching eggs, broiler companies had no reason to think that any requirement in the Proposed Rule was relevant to them and would have had no reason to comment. The Proposed Rule concerned reduction of SE contamination in table eggs. In a section titled “Rationale for Proposal,” FDA effectively states as much:

Although there are Federal rules requiring refrigeration of shell eggs packed for the ultimate consumer (FSIS) and at retail (FDA) to limit the growth of SE that may be present, there are no Federal requirements to address the introduction of SE into the egg during production.... 3.3 million SE-contaminated shell eggs may be produced annually. Thirty percent of total egg production is used in egg products, leaving an estimated 2.3 million SE-contaminated shell eggs that may reach the consumer.

...  
[W]e have tentatively concluded that a proposal to require that producers of shell eggs for the table market ... comply with all of the proposed SE prevention measures would exclude SE on the farm and, thus, remove sources of SE contamination of shell eggs.<sup>17</sup>

Broiler companies comprise a separate industry from producers of table eggs. The only hatching eggs that may reach consumers are surplus and out-of-specification hatching eggs that are sold to breakers for processing into egg products. Under the Egg Products Inspection Act, all egg products are treated to achieve a 5-log reduction in SE. Presumably this treatment is why egg products are not included in the “2.3 million SE-contaminated shell eggs” that were identified as the focus of the Proposed Rule.

In summary, the purpose of the Proposed Rule did not concern broiler companies, FDA has acknowledged that the refrigeration requirement in the Proposed Rule did not address hatching eggs, and no other requirement in the Proposed Rule applies to broiler companies. For all of these reasons, the change in the Final Rule to encompass hatching eggs sold to breakers is not a logical outgrowth of the Proposed Rule.

**The Final Rule is arbitrary and capricious in that it reflects no consideration or understanding of the effects of the rule on hatcheries**

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<sup>16</sup> *Id.*

<sup>17</sup> 69 FR at 56832.

An agency action violates the APA if it is found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”<sup>18</sup> To satisfy the arbitrary and capricious standard, an agency must “examine the relevant data and articulate a satisfactory explanation for its action including a ‘rational connection between the facts found and the choice made.’”<sup>19</sup> As the U.S. Supreme Court has stated

Normally, an agency rule would be arbitrary and capricious if the agency ...entirely failed to consider an important aspect of the problem [or] offered an explanation for its decision that runs counter to the evidence before the agency,...<sup>20</sup>

In the Final Rule, FDA failed to consider the implications of applying the refrigeration requirement to hatching eggs, a different industry from production of table eggs. Moreover, the agency imposed the requirement on hatching eggs sold for egg products despite acknowledging that treatment of egg products is sufficient to ensure safety.

According to the preamble to the Final Rule, FDA changed the refrigeration requirement to apply to surplus hatching eggs in response to a single comment on the issue. Broiler companies had no reason to think the Proposed Rule applied to them in any respect. Accordingly, the agency does not appear to have considered any information on how the requirement could affect the hatching egg industry. The result is that the Final Rule would require hatching eggs to be refrigerated at a detrimental temperature before the determination of which eggs will be sold to breakers.

The agency cites to the representation in the comment that “most ... hatcheries currently refrigerate these eggs” in support of extending the refrigeration requirement.<sup>21</sup> This representation is not correct to the extent that it does not consider how hatcheries refrigerate eggs.

Broiler companies cannot reliably determine which eggs will be sold to breakers before the eggs are to be placed in incubators. Eggs may develop problems 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. As a result, hatcheries would have to refrigerate all hatching eggs to 45 degrees Fahrenheit to comply with the Final Rule’s 36 hour requirement – rendering them useless to the hatchery.

This result is unworkable for the hatching egg industry, since refrigeration at 45 degrees would ruin eggs for hatching. Hatcheries refrigerate hatching eggs at approximately 65 degrees. As noted above, hatchability of the hatching eggs becomes increasingly compromised as the temperature drops below 65 degrees. As a general rule, eggs maintained below 60 degrees are not hatched.

The refrigeration requirement is unworkable even as 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 be too high given the price received from breakers for these eggs.

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<sup>18</sup> [5 U.S.C. § 706\(2\)\(A\)](#)

<sup>19</sup> *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, [463 U.S. 29, 43 \(1983\)](#) (quoting *Burlington Truck Lines, Inc. v. United States*, [371 U.S. 156, 168 \(1962\)](#)).

<sup>20</sup> *Id.* at 43.

<sup>21</sup> 74 FR at 33041.

For the reasons set out, the requirements that hatching eggs to be sold to breakers be refrigerated to 45 degrees within 36-hours of being laid is unworkable for hatching eggs. Broiler companies would not be able to comply except at great expense for a limited number of out-of-specification eggs. As a result, we expect that most, if not all, broiler companies will decide to stop selling surplus and out-of-specification hatching eggs to breakers if the refrigeration requirement goes into effect. The primary option for these eggs if not sold to breakers is to sell for rendering, which typically yields a much lower price than selling to breakers.

The effect on breakers who buy surplus and out-of-specification hatching eggs could be devastating. NCC is aware that there are a number of breakers who predominantly purchase surplus and out-of-specification hatching eggs rather than table eggs. They stand to lose a significant amount of business if selling to breakers becomes too expensive for hatcheries. In addition, by eliminating from the market surplus hatching eggs, breakers likely will have to pay significantly higher prices for table eggs. Ultimately, the farmer and consumers will bear the burden of these increased costs.

### **The Final Rule does not explain why the benefits of refrigeration of surplus hatching eggs justify the costs**

The Final Rule does not discuss the costs of the change to apply the refrigeration requirement to hatching eggs. As set out above, broiler companies would likely discontinue most, if not all, of their sales of surplus and out-of-specification eggs to breakers. Based on the data available, we estimate broiler companies realized around \$5 million from that business. The alternatives for broiler companies to dispose of these eggs – rendering, use for non-human food or sending them to a landfill – provide much less, if any, value.

The Final Rule also does not set out any benefits of extending refrigeration to hatching eggs sold to breakers to justify the costs. Surplus and out-of-specification hatching eggs sold for use as egg products are treated to achieve a 5-log reduction in SE. This treatment is required by the Egg Products Inspection Act. Neither the Proposed Rule nor the Final Rule suggest that the 5-log reduction treatment is inadequate to render the egg products safe. To the contrary, FDA expressly states 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.<sup>22</sup>

Indeed, 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.

Despite the agency's acknowledgment that treated egg products are safe, the Final Rule does not address the public health justification for extending the refrigeration requirement to surplus and out-of-specification hatching eggs to be sold for egg products.<sup>23</sup> Neither the 5-log reduction or hatching eggs are considered in the discussions in the Final Rule on the legal authority for the refrigeration requirement<sup>24</sup> or in the discussion of economic impacts of the refrigeration requirement.<sup>25</sup> The only justification for the requirement set out in the Final Rule is the agency's agreement with the one unidentified comment that "to maintain maximum benefit of SE illness reduction from refrigeration, eggs

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<sup>22</sup> 74 FR at 33037.

<sup>23</sup> See 74 FR at 33041.

<sup>24</sup> See 74 FR at 33049.

<sup>25</sup> See 74 FR at 33065-67.

should be refrigerated throughout the distribution chain.<sup>26</sup> No support is provided for the assertion. This is not sufficient to satisfy the arbitrary and capricious standard.

Accordingly, we respectfully request that the agency use this comment period on the Guidance to grant NCC's petition asking that the rule be amended so that it does not apply to hatching eggs or, at a minimum, that the agency re-open the comment period for the refrigeration requirement (or re-propose the requirement, as appropriate) to allow the affected industries a meaningful opportunity to explain why extension of the refrigeration requirement is not needed and would greatly disadvantage broiler companies and breakers. In the alternative, NCC requests that the agency's final Guidance document clarify that this requirement does not apply to hatching eggs destined for further processing.

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cc: Michael M. Landa, Acting Director, CFSAN  
John Sheehan, Director, Office of Food Safety, CFSAN

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<sup>26</sup> See 74 FR at 33041.