



United Egg Association

October 30, 2018

Office of Policy and Program Development
Food Safety Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, D.C. 20250

Re: Petition Number 18-06

Dear Sir or Madam:

These comments are submitted by the Further Processors Division of United Egg Association (UEA) in strong opposition to the citizen petition submitted on May 8th, 2018, by the National Chicken Council and posted to USDA petition website on August 9th, 2018. UEA's Further Processors Division represents companies that make a wide variety of nutritious processed egg products for the consumer packaged goods, food service and restaurant industries.

The Egg Safety Rule is clear about its requirements for the refrigeration of eggs. The rule states (at 21 CFR 118.4(e)): "You must hold and transport eggs at 45° F ambient temperature beginning 36 hours after time of lay." Equally clear is the rule's applicability; among other situations, the refrigeration requirement applies "[i]f you transport or hold shell eggs for shell egg processing or egg products facilities." ("Egg products facilities" are specifically defined as USDA-inspected plants [21 CFR 118.3]).

In explaining its reason for implementing the 36-hour refrigeration requirement, FDA stated (74 FR 130 at 33040): "Our proposed requirement that eggs be refrigerated if stored more than 36 hours was based on data indicating that, although fresh shell eggs provide an inhospitable environment for *Salmonella* to multiply, the chemical and physical barriers against bacterial movement and growth in shell eggs degrade as a result of the time and temperature of holding ...The 36-hour limit for unrefrigerated holding is supported by a model, contained in the 1998 joint SE risk assessment [reference omitted], which was developed to examine the relationship among holding time, holding temperature, and yolk membrane breakdown as an indicator of SE risk."

Our present comments are prompted by reports that some companies and trade associations have recently approached both FDA and the U.S. Department of Agriculture seeking to be able to market hatchery surplus eggs to the egg processing industry in violation of the Egg Safety Rule. Among other requirements, the Rule stipulates that eggs bound for further processing must be refrigerated within 36 hours of lay. This requirement applies to all eggs, regardless of origin, because of FDA's concern for food safety.

In the preamble to its final rule in 2009, FDA explicitly rejected pleas from some of the same interests, who had asked the agency to exempt hatchery surplus eggs from the food safety requirements that apply to all other eggs for the purpose of avoiding contamination with *Salmonella* Enteritidis (SE). FDA stated that under its final rule, refrigeration was required for "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." FDA wrote that the absence of refrigeration "allows growth of any SE that may be present in the eggs."

In the final rule, FDA imposed this requirement on all eggs despite the fact that such eggs will subsequently undergo pasteurization. The agency wished to minimize the pathogen load in incoming (unpasteurized) eggs, a view based in part on risk assessments that hypothesized that some SE might survive pasteurization, or that improper procedures at a processing plant might allow survival and growth of the SE.

Nothing prevents hatchery surplus eggs from being marketed to egg processors within 36 hours of lay. They may also be so marketed if they are older than 36 hours post-lay but have been refrigerated within the time required by the Egg Safety Rule. Hatchery companies that supply chicks to the layer industry – and therefore also face decisions about whether or not to incubate eggs -- have made substantial investments in refrigeration equipment in order to comply with the rule, with respect to eggs that will not undergo hatching. These major capital investments would be devalued should FDA grant the petitions.

Some exemption proponents have asserted that the current requirements encourage food waste. We want to minimize unnecessary food waste. However, it is not in consumers' interest to compromise food safety. Reducing waste should not require compromising food safety standards that are intended to protect consumers.

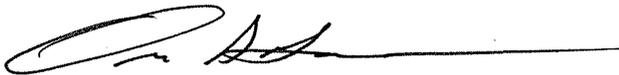
Fundamentally, this is a food safety issue and should be decided on that basis. Toward that end, both the UEP board of directors and the membership of UEA have adopted identical policy positions as follows: "We believe the Egg Safety Rule should be administered on the basis of food safety determinations, and special exemptions should not be provided to particular sectors since food safety risks could be increased. If federal agencies believe that previous food safety-based regulatory determinations may have been incorrect, then a new and robust risk assessment should be conducted prior to any use of enforcement discretion or changes to the Egg Safety Rule. Affected industries should

have the opportunity to participate in the development of the assessment, as well as the chance to comment on it once complete. "

We would respectfully submit that if the agencies decisions, based on a prior FSIS risk assessment, is to be reconsidered, then a new risk assessment is the appropriate way to proceed. We stand ready to work cooperatively with FDA and USDA should the agencies choose to pursue that course.

In the absence of a new risk assessment, USDA and FDA should reject the pending petitions and maintain its current regulations.

Sincerely,

A handwritten signature in black ink, appearing to read "Oscar S. Garrison", followed by a long horizontal line extending to the right.

Oscar S. Garrison
Senior Vice President
Food Safety and Regulatory Affairs
United Egg Association
Further Processor Division