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Comments Received:

The National Association of Egg Farmers is pleased to comment on to the Office of Management and Budget on Docket No. FDA-2013-N-0297 pertaining to regulatory burden of Prevention of Salmonella Enteritidis in Production, Storage and Transportation of Shell Eggs.

On July 9, 2009 the Food and Drug Administration (FDA) issued the final rule [Part 118 (21 CFR part 118) [74 FR 33030] ["Egg Rule"]. This regulation in part 118 requires egg farmers to implement measures to prevent Salmonella from contaminating eggs on the farm and from further growth during storage and transportation and requires these farmers to maintain records concerning their compliance with the egg safety rule.

Sec. 118.7 (a) requires environmental tests of each poultry house. If any environmental sample tests positive, Sec. 118.8 requires four 1,000 egg samples tested at 2-week intervals for a total 4,000 eggs. When it comes to food safety, testing is important, but the lowa State University VDL test results show that Salmonella- positive environmental samples do not necessarily translate into contaminated eggs. From 2011 to 2015, ISU VDL test results showed a dramatic drop (14% to 2.4%) in positive tests of SE from environmental samples taken at egg laying facilities. After testing over 685,000 shell eggs from the summer of 2010 until March of 2016, ISU VDL has found only one positive egg pool, which was during the 2010 national recall.

One suggestion for reducing the burdens of the Egg Rule on farmers while following procedures to maintain the safety of our food supply is to modify the environmental testing of farms by pooling the samples. In the egg safety rule, farmers are required to test the environments of their farms. The cost of environmental sampling for Salmonella these farms are borne by the farmers with single drag swabs being cultured throughout the farm. Pooling the samples will help reduce the cost to farmers and as shown in the 2015 research article (published in Avian Diseases 59:548-553) entitled "Validation of Single and Pooled Manure Drag Swabs for the Detection of Salmonella Serovar Enteritidis in Commercial Poultry Houses" by Dr. H. Kinde et.al., California Animal Health and Food Safety Laboratory System, School of Veterinary Medicine, San Bernardino, CA. This study showed there is no significant difference between the sensitivity of environmental sampling of four-swab pooled together using the National Poultry Improvement Plan culture method compared to the single swabs analyzed by FDA's method, but the costs are significantly less.

Another burdensome requirement is the 4 egg sample tests of 1,000 eggs each if Salmonella is found in the environment. By adjusting the testing protocol to 2 egg sample tests of 1,000 eggs each, it would ensure Salmonella-preventative steps are being taken by the farmers to protect the nation's consumers.

Thank you.

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