United Egg Association

June 8,2001

FSIS Docket Room
Docket #01-014N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, **S.W.**
Washington, D.C. 20250-3700

01-014N
01-014N-1
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Attn: National Advisory Committee on Meat and Poultry Inspection

These comments are submitted in response to the notice in the May 29,2001, ***Federal Register.*** The comments focus on those aspects of the National Advisory Committee on Meat and Poultry Inspection's June ***5-6*** agenda that are relevant to egg producers and egg processors. United Egg Producers (UEP) is a national cooperative representing the interests of 80% of the nation's shell egg production, and United Egg Association (UEA) is a national association representing 95% of all further processed egg products.

Egg Safety Action Plan

Since the Egg Safety Action Plan was first announced on December 10,1999, UEP and UEA have commented extensively on both general and specific aspects of the plan. The action plan included both regulatory actions that had been anticipated – e.g., a HACCP regulation for processed egg products – and actions that broke new ground or raised novel issues – e.g., the Food Safety and Inspection Service's plan to regulate egg packing facilities.

UEP and UEA have long believed that regulations must be national in scope, non-discriminatory in application and efficient in design. Toward that end, the organizations filed extensive comments in response to "current thinking" papers published by FSIS and the Food and Drug Administration on July **3** 1,2000. UEP and UEA reiterate and stand behind these comments, which are attached.

Proposed regulations to implement the Egg Safety Action Plan have not yet been published. **A** final rule has been issued by FDA on labeling and refrigeration of shell eggs. UEP and UEA generally commended FDA's final rule, published December 5,2000, and believe that in most

respects it is a marked improvement from the agency's original proposal. UEP has continued to maintain contact with FDA about questions and issues that have arisen as the agency and the industry prepare for implementation of the rule,

Since publication of the "current thinking" papers, several new issues relevant to FSIS jurisdiction have arisen.

Sanitation Regulations: At a meeting of the National Egg Regulatory Officials (NERO), an organization comprising the agencies that administer State egg laws, there was extensive discussion of whether FSIS should apply sanitation regulations designed for the meat and poultry industries to egg packing and egg processing establishments. Some provisions of these regulations (Part 416 ***(supply full cite)*** **)** may be readily applicable to the egg industry, but others will not be. Several state officials at the NERO meeting voiced concern about applying these regulations wholesale to eggs and egg products, as opposed to preparing sanitation regulations specifically tailored to egg production and processing. UEP and UEA share many of the concerns expressed by the State officials and urge FSIS to consider carefully whether an attempt to apply Part 416 without change may create unnecessary complications, result in a substantial burden on the industry, and lead to unforeseen consequences. The egg industry is not the same as the meat and poultry industries, and its regulatory regime should recognize that reality.

HACCP for Egg Packing Plants

At the NERO meeting, some officials questioned whether it was practical to require HACCP plans in egg packing establishments, expressing a preference for the establishment of sanitation standard operating procedures (SOPs) and/or good manufacturing practices (GMPs) instead. UEP believes these concerns merit FSIS's careful consideration. We have consistently spoken of a "HACCP-like" regulatory structure as potentially more practical and suitable to the production (packing) side of the industry than HACCP per se.

Pre-Pack Refrigeration Requirements

In our August 13,2000, comments on the "current thinking" papers, UEP and UEA noted one aspect of the agencies' plans that could be counterproductive to food safety. Although this issue involves FDA's planned regulations, it is relevant to FSIS as well. FDA is considering a proposal that eggs must be refrigerated to a 45-degree ambient temperature within 36 hours of being laid.

In off-line operations (where eggs are produced in one location and then transported to a different site for packing), this 36-hour rule may make *Salmonella* Enteritidis growth more likely rather than less, because subsequently washing the eggs at a much higher temperature is likely to result in more thermal checks (hairline shell cracks). We provided additional detail in the August **13** comments, attached.

Since the time of these comments, USDA's Agricultural Marketing Service has evaluated new rapid-cooling technology, measuring among other things the difference in thermal checks compared to normal circumstances. We believe AMS's results tend to bear out UEP's concerns about the potential 36-hour rule, and strongly urge FSIS and FDA to consult with AMS about these results before proceeding with this aspect of their plans.

Importance of Agency Coordination

Finally, UEP and UEA wish to reiterate the extreme importance of informed, carefully-considered coordination among the several agencies involved in the Egg Safety Action Plan. Under the regulatory plan described in the "current thinking" papers, the egg industry will continue to be regulated by multiple agencies under separate Cabinet departments. If this regulatory system is to avoid duplication, contradiction, inconsistency and excessive burden, it must be designed with care.

To the maximum extent feasible, UEP and UEA believe FSIS and FDA should utilize the services of agencies that already have a presence in egg production facilities today – chiefly the Agricultural Marketing Service and State agencies with whom it maintains agreements. FSIS's implementation of the 1991 refrigeration statute provides a useful model for how this can be done. For some aspects of the planned regulations, verification by certified, arms-length private entities may also be an option that will allow the agencies' goals to be established within the limits of available personnel.

Finally, it is important that the agencies coordinate their proposed regulations. We believe it is highly desirable that FDA and FSIS publish their proposed and final regulations simultaneously. If one agency's proposal appears without detailed information on the other agency's plans, our organizations will not be able to comment in an informed manner. This is the case because one cannot reasonably predict the effect on an industry of regulations by one agency without knowing what regulations will be forthcoming from another agency that intends to regulate the same industry in similar ways. We would think that separate publication would also limit the ability of consumer, public health and other groups to comment in a comprehensive and thoughtful way.

UEP and UEA appreciate the advisory committee's attention to these comments, and hope FSIS officials will also give them careful consideration.

Sincerely,

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