UEP

United Egg Producers

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

RE: Docket No. 02N-0276
02N-0277
02N-0278
02N-0275

United Egg Producers (UEP), a Capper Volstead Cooperative representing 85% of all the shell eggs produced and United Egg Association (UEA), a national trade association representing 95% of all the further processed egg products produced, appreciates this opportunity to provide comments on the provisions in Title III, Subtitle A (Protection of the Food Supply) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). UEP and UEA will offer comments on four sections to assist the Agency in developing an achievable response on behalf of the egg industry to the authorizing legislation.

Section 305 (Registration) Docket No. 02N-0276

Section 305 (Registration of Food Facilities) requires the owner, operator, or agent in charge of a domestic or foreign facility to register with the FDA no later than December 12, 2003. Facilities are defined as any factory, warehouse, or establishment, including importers. Although the Bioterrorism Act has certain exemptions for registration for food establishments that serve food directly to the consumer, egg production and further egg processing companies are both engaged in packing shell eggs and egg products that enter the distribution network of wholesale, retail and institutions. The egg industry is supportive of the efforts to protect the nation's food supply and enters these comments to contribute so that the process is workable and achievable.

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Shell egg packing stations and further egg processors may be connected directly to the farm facility (inline operation). This advancement in production and processing technology allows for product freshness and quality. It also serves to reduce the likelihood of product tampering.

Shell egg producing companies or corporations may own or manage multiple sites of facilities producing shell eggs and/or further processing egg products in different states. At present, these companies and corporations employ staff with technical expertise for environmental management systems, food safety/quality assurance, grading, humane production certification, and other managerial reporting responsibilities. It would contribute to the uniformity of registration for biosecurity if the proposed regulations would allow each company to manage the registration requirements for all of its facilities whether in one state or a multiple of states. Once a shell egg packing station or further processor of egg products registers identifying information with FDA, a yearly registration would be unnecessary in identifying the producers of those products. Hence, it would lessen the encumbrance of registering an identity, if a one-time registration process were implemented. Furthermore, the basic identity information would only need to be updated should the company add product lines or the basic identity information would change due to mergers or the incorporating of other companies.

Section 306 (Recordkeeping) Docket No. 02N-0277

Section 306 (Establishment and Maintenance of Records) establishes requirements for the creation and maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food, (i.e., one up, one down). Such records will allow FDA to address credible threats of serious adverse health consequences or death to humans or animals. Entities subject to these provisions are those that manufacture, process, pack, transport, distribute, receive, hold or import food.

Records on receipts of products and sales of products must be kept confidential. FDA's requirements for records to address credible threats of serious adverse health consequences or death to humans or animals are intended not divulge confidential information to sources outside the parameters of protecting the public from intentional adulteration. The intent of the authorizing legislation is to safeguard the public health and records investigations must be restricted to that intent.

Section 307 (Prior Notice) Docket No. 02N-0278

Section 307 (Prior Notice of Imported Food Shipments) requires that prior notice of food shipments be given to FDA. The notice must include a description of the article, the manufacturer and shipper, the grower (if known), the country of origin, the country from which the article is shipped, and the anticipated port of entry. Inspection of Eggs and Egg Products Regulations 9 CFR §590.920 addresses the need for an importer to make application for inspection of imported egg and egg products. This regulation is

administrated by the U.S. Department of Agriculture Food Safety Inspection Service through the Technical Service Center Import-Export Egg Products Coordinator in Omaha, Nebraska. The URL for this regulation is www.access.gpo.gov/nara/cfr/waisidx 01/9cfr590 01.html

We recommend that FDA establish a Memorandum of Understanding (MOU) with FSIS to collect this information under existing regulations.

Section 303 (Detention) Docket No. 02N-0275

Section 303 (Administrative Detention) authorizes FDA to order the detention of food if an officer or qualified employee finds credible evidence or information indicating an article presents a threat of serious adverse health consequences or death to humans or animals.

Eggs and egg products are perishable foods that must be kept under 45 degrees F (7.2 degrees C) refrigeration by federal statute (21 USC 1041). Detention of said foods must continue to be kept under refrigeration at federally mandated temperatures until such times as the threat of serious adverse health consequences or death to humans or animals no longer exists and the food can be released to resume its normal flow in the distribution and marketing channels.

We greatly appreciate this opportunity to provide these advance comments in support of FDA's proposed rule on the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Yours sincerely,

Mike Bynum	Elliot Gibber	Al Pope	Ken Klippen
UEP Chairman	UEA Chairman	President	Vice President