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Comments by Patrick O'Connor
On behalf of the
International Warehouse Logistics Association

Proposed Rule for Preventive Controls Current Good Manufacturing Practice and Hazard Analysis and
Risk-Based Preventive Controls for Food for Animals

Food Safety Modernization Act
U.S. Food and Drug Administration
College Park, MD
Nov. 21, 2013

Thank you for the opportunity to comment today on the proposed rule for Preventive Controls for Animal Food. I am speaking today on behalf of the International Warehouse Logistics Association (IWLA).

IWLA member companies are warehouse-based third party logistics (3PL) providers that act as distribution centers for their customers. They offer warehousing; inventory and supply chain management capabilities; and a broad range of value-added services.

A significant number of IWLA members operate food-grade warehouse facilities for the storage, handling and distribution of food products for manufacturers, processors and distributors.

An important factor is that in every instance the 3PL warehouse does not own and never takes title to the products held in the warehouse, nor does the warehouse have the authority to direct the sale or disposition of the product.

Food products in a 3PL warehouse are generally stored in sealed packages, such as cartons, drums, and totes – often in pallet-sized increments. The manufacturer determines the proper packaging and the product is packaged prior to arrival at the warehouse. Food products in the warehouse may be finished packaged products destined for the consumer or packaged ingredients intended for use in the production process.

A 3PL warehouse will typically handle hundreds of SKUs from multiple customers. The preventive control practices used by our members for food storage and handling are based on FDA's warehousing and distribution current good manufacturing practices (cGMP), as well as our customer's specifications.

The 3PL warehouse is contractually required to comply with the specific requirements set by their customer, e.g., a food manufacturer, for their particular product. The warehouse is dependent on its customer to determine the optimal conditions for storage of their products based on the customer's own hazard analysis and preventive control.

Today, I will raise two issues regarding the proposal, which we will explain in more detail in our written comments. We have raised the same issues with respect to the NPRM for human food in a meeting with FDA staff and in written comments to be submitted on Nov. 22.

IWLA strongly supports, with some small modification, the agency's proposed exemptions for warehouse facilities that store non-TCS packaged food and we support the modified exemption for TCS foods.

IWLA was a party to the citizen petition submitted to FDA on July 22, 2011 which requested that FDA exempt food warehouse facilities from the requirements of section 418 of the FD&C Act.

Issue 1 – Clarifying the Meaning of "Solely Engaged": A typical 3PL warehouse maintains up to 400,000 square feet or more of space designed for multiple customers with a range of different products. We believe that "*solely* engaged in the storage of packaged food" is intended to refer only to those activities in the warehouse that trigger registration under the Food Safety Modernization Act ("FSMA") and does not refer to any nonfood activities that are outside the scope of FSMA. For example, this means that a warehouse storing consumer electronics, in addition to unexposed packaged food products, is still considered to be "solely" engaged in the storage of packaged food.

Issue 2 –Responsibility for Determining Time and Temperature Controls: IWLA disagrees with FDA's tentative conclusion that it is "rare" for warehouse operators not to have information on whether temperature controls are required and what specific temperature controls are necessary. In fact, it is rare for the 3PL to have sufficient information to determine this. FDA does not serve the goals of food safety by placing this responsibility on a party that is not in a position to make a substantive determination about the temperature control needs of a product. Certainly, a "Keep Refrigerated" warning label on the package provides notice to the 3PL that it requires temperature control, as it does to a consumer who purchases the product. But what temperature is required for optimal food safety purposes during storage of the product?

FDA references scientific literature as a means for a warehouse facility to discern necessary time and temperature controls, but the literature cannot provide these answers with any precision without appropriate information from the owner of the product. We believe this suggested approach by the FDA oversimplifies the universe of TCS foods and does not account for variations in time and temperature controls among various TCS foods.

FDA should insist that the responsibility for this determination be placed on the party in the best position to know: the product owner; and the agency should require this information to be passed to supply chain participants who store the food.

Thank you for your consideration of our comments.