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Food and Drug Administration
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Reference: Food and Drug Administration Proposed Rule:
Current Good Manufacturing Practice and Hazard Analysis and
Risk-Based Preventive Controls for Human Food
Docket No.: FDA-2011-N-0920

To Whom It May Concern:

The International Warehouse Logistics Association (IWLA) is pleased to submit the following comments in response to the U.S. Food and Drug Administration's Proposed Rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" published on January 16, 2013 (78 FR 3646).

A. Background: International Warehouse Logistics Association

IWLA represents warehouse-based third party logistics (3PL) providers. A large number of IWLA members operate food-grade warehouse facilities for the storage, handling, and distribution of food products for manufacturers, processors, distributors and retailers.

3PL warehouses operate pursuant to Article 7 of the Uniform Commercial Code (UCC), which has been adopted in all 50 states. Article 7 governs the contractual relationship between warehouses and product owners. In short, a 3PL warehouse does not own or take title to the products held in its possession; the 3PL warehouse is simply a service provider who enters into contracts to store goods with the owner or consignee of products (hereinafter referred to as "the product owner"). At all times, the 3PL warehouse does not have authority under the UCC to direct the sale or disposition of the product because it is acting only as a service provider or "bailee" to the product owner.

Food products in these warehouses may be finished products packaged for the consumer or packaged ingredients intended for delivery to another food production facility. Food products are generally stored in sealed packages, such as cartons, drums, or totes -- often in pallet-sized increments. The product owner determines the type of packaging used and is responsible for packaging and labeling prior to arrival at the warehouse.

The 3PL typically handles hundreds of stock keeping units (SKUs) on behalf of numerous product owners. Contrary to some outdated perceptions, modern 3PL warehouses are busy distribution centers that may load and unload hundreds of truckloads of goods, involving thousands of pallets and millions of pounds of freight each year. To illustrate the range of 3PL operations, we offer the following three examples of typical 3PL food warehouses:

- A New Jersey 3PL operates six distribution centers totaling 750,000 square feet. All locations are registered with and subject to inspection by FDA. A majority of the products received at the distribution centers arrive by way of ocean containers from around the globe, with the balance arriving via trailers and rail cars. As the inbound loads arrive, each vehicle is inspected to verify that seals are intact and that there are no breaches of the delivery vehicle. The vehicles typically contain cases, totes or bags of product, either loaded by hand or unitized. The size of these cartons varies from as small as .5 cubic feet to 15 cubic feet or larger. Prior to arrival, the product owner or its service provider informs the 3PL as to the products to be warehoused, including product description, quantity and packaging. In order to track products and maintain inventory, the 3PL affixes each product with a tracking label upon arrival to the warehouse. Subsequent to unloading, the products are transported to a storage location within the warehouse, where they remain until the product owner instructs the 3PL to retrieve the product from storage and deliver it to the next destination, via carriers chosen by the product owner. The food products stored in this distribution facility have all been packaged according to instructions by the product owner prior to arrival at the warehouse. Examples of packaged food products stored in the warehouse include: canned and bottled olives, canned tomato products, bagged and boxed rice, canned vegetables and bottled juices. All of these packaged food products are encased in larger shipping cartons for 3PL handling and storage purposes.

- An Indiana 3PL warehouse handles a variety of different products, including apparel, toys and games, fashion accessories, health and beauty aids, dietary supplements and other packaged food products. The warehouse services two primary food product owners: a candy manufacturer and a popcorn manufacturer. Eighty percent of the food products stored in this warehouse are shipped directly to consumers. The facility is registered with the FDA and is inspected by the FDA and the county Board of Health. In addition, the food product owners conduct annual inspections of the facility to ensure it complies with their requirements for cleanliness, product storage, product packing for shipping, and lot control. The warehouse also undergoes an annual inspection conducted by a well-established third party audit organization. This 3PL primarily picks packaged food products at the direction of its customer and packs them for shipment to the consumer. The 3PL also provides value-added services for the product owner. For example, they assemble “sales kits” for use by volunteers of a well-established non-profit organization for their annual fundraising drive. The kits include small sealed bags of popcorn, sales literature, and order forms. The assembly of the kits does not entail opening the individual popcorn packages, so the packaged food product is never exposed to the environment.

- A 3PL in Kentucky provides logistics support services for a large grocery retailer. Any food manufacturer who sells to the grocery retailer ships their finished food product to the 3PL warehouse for storage. The warehouse is registered and subject to inspection by the FDA. On a 24/7 day operation, as the grocery store sells its goods, via point of sale technology at the checkout lane, the information is downloaded into a database. The food product owner then communicates this information to the 3PL and instructs them to retrieve and assemble goods to replenish inventory at various stores.

The practices that IWLA members follow for food storage and handling are designed to comply with all applicable FDA requirements (e.g., current good manufacturing practices (cGMPs)), as well as any additional requirements that may be specified by contract by the food product owner. The 3PL warehouse is contractually obligated to comply with the specific requirements set by the product owner.

We feel fortunate to have customers who know their products well and have established strict food safety and quality assurance standards to protect those food products. The food product owners determine the optimal conditions for storage of their products based on their own hazard analysis and preventive controls, and they communicate those requirements to us so we can continue to support them while the goods are stored at our location. We work closely with the food product owners to ensure that we are able to maintain those products in the same conditions and with the necessary protections to keep the food safe and of high quality.

B. Current Good Manufacturing Practices

IWLA supports the proposed revisions to the food cGMPs. We know the agency worked extensively with industry to develop these changes, and we appreciate these efforts. The revised cGMPs apply to 3PL warehouses and provide an effective means to protect the safety of food stored in warehouses that are otherwise exempt from subpart C.

We urge the FDA to ensure that requirements for education and training in the cGMPs provide flexibility for the facility to determine the scope and frequency of training, based on the type of facility, the type of products, and the job responsibilities of the employee.

C. Preventive Controls

The proposed regulations are an important step forward in the continuing efforts of the food industry and the FDA to improve the safety of our nation's food supply. The risk-based preventive system, which underlies this proposed rule, is the right approach to address the challenges of today's diverse and complex food supply chain.

IWLA encourages the agency to focus on food safety outcomes, allowing facilities maximum flexibility to achieve the desired outcome. The range of preventive controls in any particular facility should be proportionate to the nature and extent of the risk involved.

To the extent the agency decides to include environmental testing requirements in the final rule as a means to verify the effective implementation of preventive controls, IWLA recommends that such testing should *not* apply to a facility that is exempt from subpart C because it is engaged solely in the storage of packaged food that is not exposed to the environment. Since the food in a food warehouse facility is not exposed to the environment, there is no reasonable basis for applying environmental testing to an exempt facility.

D. Applicability of Part 117 to a Facility Solely Engaged in the Storage of Packaged Food That Is Not Exposed to the Environment

Pursuant to its authority under section 418 of the Federal Food, Drug & Cosmetic Act ("the FD&C Act"), the FDA proposes new section 117.7 which would explicitly exempt from the hazard analysis and risk based preventive control requirements specified in Part 117, subpart C any facility that is "solely engaged in the storage of packaged food that is not exposed to the environment" and would instead require such facilities to comply with the modified requirements specified in new section 117.206 of Part 117, subpart D. Under these modified requirements, the owner, operator, or agent in charge of a facility that is solely engaged in the storage of packaged food that is not exposed to the environment would be required to conduct prescribed activities for any "refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance," including to establish,

implement, monitor, and verify required temperature controls, take corrective action under specified conditions, and maintain various records. These preventive controls would not apply to those packaged foods that are not refrigerated and do not require such time/temperature controls. Under the FDA proposal, facilities that store solely packaged food that is not exposed to the environment and are not subject to time/temperature controls ("non-TCS packaged food") would otherwise be subject to Part 117, including to new cGMP requirements in new Part 117, subpart B.

IWLA strongly supports the agency's proposed exemption in new section 117.7 as it applies to facilities that store non-TCS packaged food and respectfully requests that the agency adopt the proposed exemption with some modifications that we believe will help clarify the scope of the exemption and better account for the range of activities that may occur in food warehouses that handle and store non-TCS packaged food products. 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. We appreciate the agency's readiness to adopt the measured, risk-based approach set out in new section 117.7 and avoid the unduly burdensome application of subpart C requirements to facilities that store packaged foods under conditions that insulate such foods from the environment through the use of protective packaging and containers.
Food warehouse facilities work diligently to ensure that they never jeopardize the food product owner's original packaging and prevent human contact with the unexposed packaged food product in the warehouse. Employees of food warehouse facilities are trained regarding current good manufacturing practices so they are well equipped to identify and guard against the limited routes of contamination for unexposed packaged food. For example, food warehouse facilities work with food product owners and other service providers, such as pest-control providers, to train our associates on how to inspect packaging and to monitor the warehouse to detect possible rodent or insect activity. We believe that by complying with the cGMP requirements that will be codified in Part 117, subpart B, and other applicable requirements, food warehouse facilities will continue to ensure the safety of packaged food products.

While IWLA strongly supports the exemption proposed in new section 117.7, we believe that certain modifications to the proposed language of the exemption would be helpful in clarifying the scope of the exemption as it would apply to facilities that handle and store non-TCS packaged food products.

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 **not to** refer to any nonfood activities that are outside the scope of FSMA. This means that a warehouse storing consumer electronics, for example, in addition to unexposed packaged food products, is still considered to be "solely" engaged in the storage of packaged food.

This interpretation is consistent with the risk-based principles of FSMA. The exemption is based on the relatively low food safety risk presented by unexposed packaged food. This fundamental characteristic does not change when the packaged food is placed in a multi-use 3PL warehouse that is subject to cGMPs.

To deny the unexposed packaged food exemption to a warehouse engaging in activities that would not otherwise be subject to subpart C (e.g., storing non-food products) would result in an overly narrow application of the exemption with no corresponding benefit to public health. We do not think Congress intended to create a distinction based on the type of warehouse storing the unexposed packaged food. We were very encouraged

when, during a meeting to discuss these issues earlier this year, the FDA team agreed that it is not their intent to limit the exemption by such a narrow reading.

To clarify the application of the exemption to a multi-use storage facility, IWLA proposes the revisions to Section 117.7 of the proposed rule shown at the end of this section.

Issue 2 – Applying Exemption to a Food Warehouse Facility Housed within a Mixed-Use Facility: The primary activity of a 3PL warehouse with regard to food products is the storage of unexposed packaged food products. Some 3PLs may, however, operate facilities that store non-TCS packaged food products and in a separate part of the same facility may also engage in other food packaging or other processing activities. For example, one IWLA member company operates a warehouse facility that stores non-TCS packaged food products, and in a separate part of the same facility the 3PL provider selects and blends tea leaves from bulk containers and packages them in accordance with the food product owner's specifications. Clearly, these tea blending and packaging activities would be subject to the proposed preventive control requirements of Part 117, subpart C. IWLA concludes that when such limited food packaging or processing activities as these are conducted within a facility that elsewhere stores solely non-TCS packaged food products, such activity should not serve to disqualify the entire facility from the exemption from subpart C requirements. The fact that a food warehouse facility stores non-TCS packaged food products within a larger mixed-use facility should not remove the exemption altogether.

Issue 3 – Routine Sampling Activities Conducted in Exempt Facilities: Other 3PLs may briefly, at the direction of the food product owner, open a single container of otherwise unexposed packaged food in order to test a sample for quality control or grading purposes. For example, one IWLA member company services a food product owner that instructs the 3PL to periodically sample sugar according to highly specific instructions. As presently written, the rule would arguably remove the exemption altogether from facilities temporarily exposing otherwise unexposed packaged food to the environment for the purpose of sampling. We believe that the rule should make clear that subpart C *only* applies to the sampling activities and that engaging in sampling activities in accordance with subpart C does not remove a warehouse's exemption altogether.

FDA considered similar issues in looking at farm mixed-type facilities. The FDA tentatively concluded that a farm mixed-type facility should be subject to Section 418 *only with respect to its activities that trigger the Section 415 registration requirement* and not with respect to its activities at the same location that are within the exempt farm activity. The FDA reached a similar conclusion relating to the exemption for facilities that are subject to the Seafood and Juice HAACP. The agency determined that the activities of a facility that are subject to the Seafood and Juice HAACP are exempt, regardless of whether the facility manufactures, processes, packs or holds other food.

The same rationale should apply to a 3PL facility that conducts sampling in accordance with subpart C. We agree with FDA's conclusion that the outcome of a hazard analysis for storage of non-TCS packaged food is that there are no hazards reasonably likely to occur. This conclusion is unaffected by the fact that the facility conducts sampling activities subject to subpart C. As such, we have proposed revisions to section 117.7 to provide that a food warehouse facility does not become subject to subpart C by virtue of conducting sampling activities in accordance with subpart C.

IWLA Proposed Revisions

IWLA strongly supports the agency's proposed exemption in new section 117.7 as it applies to facilities that store non-TCS packaged food and respectfully requests that the agency adopt the proposed exemption with the following modifications, which IWLA believes will be helpful in clarifying the scope of the exemption in view of the range of 3PL activities that may reasonably occur in food facilities that principally are engaged in storing non-TCS packaged food products.

"§ 117.7 Applicability of subparts C and D to a ***food warehouse*** *facility* ***that is*** ~~***solely***~~ *engaged* ***solely*** *in the storage of packaged food that is not exposed to the environment.*

(a) Subpart C of this part does not apply to a ***food warehouse*** *facility* ***that is*** ~~***solely***~~ *engaged* ***solely*** *in the storage of packaged food that is not exposed to the environment.*

(b) A ***food warehouse*** *facility* ***that is*** ~~***solely***~~ *engaged* ***solely*** *in the storage of packaged food that is not exposed to the environment is subject to the modified requirements in § 117.206 of subpart D of this part.*

(c) The exemptions in (a) and (b) of this section are applicable with respect to any food warehouse facility that is engaged solely in the storage of packaged food that is not exposed to the environment, notwithstanding that:

(i) such food warehouse facility engages in other activities that do not require registration under section 415, provided those activities are conducted in compliance with part 117, subpart B;

(ii) such food warehouse facility is housed in a mixed-use facility in which other activities are conducted outside of the portion of the facility that is solely engaged in the storage of packaged food that is not exposed to the environment; or

(iii) such food warehouse facility conducts product sampling activities, provided that such sampling activities are conducted in compliance with part 117, subpart C."

E. Modified Exemption Applicable To A Facility Engaged In The Storage Of Unexposed Packaged Food Subject To Time and Temperature Controls (TCS)

In Section 117.206, the FDA is proposing to apply modified requirements if the facility stores refrigerated packaged food requiring time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance.

IWLA agrees with FDA's proposed decision to apply a modified exemption for the storage of packaged food kept at refrigerated temperatures necessary for the maintenance of the food's safety, which includes requirements for temperature controls, monitoring, verification and recordkeeping. We also appreciate that the proposed Section 117.206 applies only to products requiring refrigeration for food *safety* purposes versus those food products that may require "temperature controls," e.g. storage in an air-conditioned facility, in order to maintain the organoleptic qualities of the food. This distinction is important to our members and we agree with FDA's tentative decision not to include foods requiring temperature controls for quality purposes (but that do not pose a safety issue).

Implementation of these requirements, however, raises the following issues for IWLA members:

Issue 1 – Responsibility for Determining Time and Temperature Controls - The preamble to the NPRM states:

"*There are two fundamental questions that the owner, operator, or agent in charge of a facility subject to proposed § 117.206 would need to know the answers to in order to comply with proposed § 117.206 for any given unexposed refrigerated packaged food:*

Is the food a TCS food?
If the food is a TCS food, what is the appropriate temperature for storage of the food?

The two primary ways in which the owner, operator, or agent in charge of a facility subject to proposed § 117.206 can obtain the answers to these questions are: (1) through information provided by the manufacturer, processor, or packer of the food, either in documents exchanged between the parties in the course of business or by label statements placed on the food by the manufacturer, processor, or packer of the food; and (2) through applicable scientific and technical support literature……..

We tentatively conclude that it would be rare for a facility solely engaged in the storage of unexposed packaged food to not have information regarding whether a refrigerated packaged food requires time/temperature control for safety and, if so, what specific temperature controls are necessary for safe storage of the food. We request comment on this tentative conclusion."

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. A 3PL is an intermediary in the supply chain who has the legal duty to provide custody, care and control of the product, in this case unexposed packaged food requiring time/temperature controls, at the direction of the food product owner. A 3PL never holds title to the products in his possession and does not have independent knowledge of the product to make a determination of the time and temperature control needs of the product. Indeed, as explained above, under Article 7 of the UCC, a food warehouse facility does not have the legal authority to make these decisions about the product. Only the food product owner has the knowledge and legal authority to make such determinations concerning the time and temperature control needs of the product. As such, the food product owner should bear primary responsibility for making this critical determination and communicating that information to the 3PL warehouse.

FDA does not serve the goals of food safety by placing this responsibility on a party that is not in a position – practically or legally – 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 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 certainty 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 between 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.

Therefore, IWLA recommends that the FDA 1) require the product owner to provide specific information to downstream supply-chain partners, including 3PL warehouses, as to whether a packaged food requires time/temperature controls, and, if so, what specific temperature controls are necessary; and 2) require the 3PL to adhere to the temperature controls determined by the manufacturer or owner of the product, but specifically state that the 3PL is not responsible for time/temperature control determinations.

Issue 2 – Preventing Product From Entering Commerce: Proposed Section 117.206(a)(3)(ii) requires a warehouse facility to "prevent the food from entering commerce" if the temperature controls have failed and the facility cannot ensure that the affected food is not adulterated. However, as explained above, the 3PL warehouse does not have title to the food and is subject to state law provisions under Article 7 of the UCC. As a "bailee" under the UCC, the 3PL warehouse does not have decision-making authority over the shipment of the food. We have a duty to care for the product while it is in our custody and control, but the 3PL is not legally empowered to make independent decisions about when and where to ship the product, or not to ship it at all.

IWLA Recommends: IWLA recommends that the 3PL warehouse be required to 1) notify the owner of the food if the safety of the affected food is in doubt; and 2) upon the direction of the food product owner, prevent the food from entering commerce. We propose the following revisions to Section 117.206:

IWLA Proposed Revision

§ 117.206

Modified requirements that apply to a facility solely engaged in the storage of packaged food that is not exposed to the environment.

(a) The owner, operator, or agent in charge of a ***food warehouse*** *facility* ***that is*** ~~***solely***~~ *engaged* ***solely*** *in the storage of packaged food that is not exposed to the environment must conduct the following activities for any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance:*

(1) ~~*Establish and i*~~ ***I****mplement temperature controls* ***established by the manufacturer or owner of the food*** *adequate to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance;*

(2) Monitor the temperature controls with sufficient frequency to provide assurance they are consistently performed;

(3) If there is a problem with the temperature controls for such refrigerated packaged food, take appropriate corrective actions ***in consultation with and at the direction of the manufacturer or owner of the food*** *to:*

(i) Correct the problem and reduce the likelihood that the problem will recur;
(ii) Evaluate all affected food for safety; and

(iii) ***Notify the manufacturer or owner of the food*** ~~*Prevent the food from entering commerce*~~*, if the owner, operator, or agent in charge of the facility cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;* ***and upon the direction of the manufacturer or owner of the food, prevent the food from entering commerce****;*

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices;
(ii) Reviewing records of calibration within a reasonable time after the records are made; and
(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within a week after the records are made;

(5) Establish and maintain the following records:

(i) Records documenting the monitoring of temperature controls for any such refrigerated packaged food;
(ii) Records of corrective actions taken when there is a problem with the control of temperature for any such refrigerated packaged food; and
(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

(c) A manufacturer of refrigerated packaged food that is not exposed to the environment shall establish temperature controls to significantly minimize or prevent the growth of, or toxin production by, microorganisms of public health significance and shall provide that information to a subsequent owner or to a third-party intermediary providing storage for the food.

Economic Analysis

The economic analysis accompanying the preventive controls significantly understates the potential impact of the proposal on 3PL warehouse companies. The analysis appears to have looked at just two standard industrial classification codes (SIC): 4221 on farm products, warehouses, and storage, and 4222, refrigerated warehouses and storage. Yet, most 3PL warehouses, including food-grade warehouses, are classified in SIC Code 4225, general warehousing and storage.

According to the 2008 Census Bureau, there are 10,448 facilities in SIC Code 4225. We estimate that approximately 70% of those warehouses, or 7,314, are involved in the storage of food products. These facilities should be factored in to your economic analysis of the impact of this rulemaking. Many, if not most, of these facilities will qualify for the exemption for facilities that are solely engaged in the storage of unexposed packaged food, assuming the FDA accepts the clarifications to the Section 117.7 that we are recommending.

We should also mention that distribution facilities for food wholesalers and retailers are not included in any of the SIC codes mentioned above. Therefore, these represent additional warehouses that should be considered in determining the economic impact of this rule.

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Thank you for your consideration of these comments.

Sincerely,

Steve W. DeHaan, CAE
President and CEO