Guidance for Industry

Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices

DRAFT GUIDANCE

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Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices

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This draft guidance represents FDA's current thinking on the control measures juice processors may need to use to ensure that juice concentrates and certain shelf stable juices do not become contaminated or recontaminated with microbial pathogens during bulk transport. The guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations.

Purpose of guidance

The purpose of this guidance is to provide industry with recommendations for appropriate control measures to use in the bulk transport of:

1) high degree Brix juice concentrate that is transported to a separate facility for final packaging or for dilution to a consumer strength concentrate and final packaging, and

2) shelf stable single strength juice that is transported in aseptic packaging to a separate facility for final packaging.

For the bulk transport of high degree Brix juice concentrate, two container types are considered in the guidance: multi-use or reusable containers (e.g., tankers, reusable drums without liners, and reusable totes without liners) and single-use sanitary containers or liners (e.g., single-use sanitary totes, single-use sanitary drums, bag-in-box containers, totes with single-use sanitary liners, and drums with single-use sanitary liners).

Background

The juice industry produces thermally treated commercial or institutional concentrate that may be transported to a separate facility for further processing and packaging. At the subsequent facility, the commercial concentrate may be repacked or diluted to a consumer strength concentrate and packed in final packaging. This guidance is concerned with the bulk transport of juice concentrates[1] that are put in final packaging or further processed and put into final packaging at a location different than where the juice was produced. Also included in this guidance are recommendations for the bulk transport of aseptically packaged shelf stable single strength juices that are put into final packaging at a location different than where the juice was produced.

The juice HACCP regulation (21 CFR Part 120) requires that a processor of juice evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles.

[1] Commercial concentrate may also be sold to processors making single strength juice, juice blends, or beverages containing juice. However, manufacturing and packaging processes for single strength juice or beverages containing juice differ from processes for concentrated juice products. Single strength juice products made from concentrate are typically treated to control spoilage organisms immediately before final consumer packaging or are made into shelf stable products. In both cases the final heat treatment achieves a 5-log or greater pathogen reduction.

If the evaluation shows that one or more hazards is reasonably likely to occur in the absence of controls, the processor must develop and establish control measures for the hazard(s). For the hazard of contamination with a pathogenic microorganism, the regulation requires the processor to incorporate control measures into its HACCP plan that will consistently produce a 5-log pathogen reduction in the facility where the final packaging is done (120.24(a) and (c)).

A processor of shelf stable or concentrated juice (referred to as "covered products") made at a single facility that includes thermal treatment of all ingredients is exempt from the requirement to include in its HACCP plan a critical control point that achieves the 5-log pathogen reduction. The thermal process that is integral to the manufacture of these products consistently delivers a microbial pathogen reduction that far exceeds the 5-log pathogen reduction standard in the juice HACCP regulation. Under the juice HACCP regulation, to qualify for these exemptions from the 5-log pathogen reduction requirement, the processor must include a copy of the thermal process in its hazard analysis (120.24(a)(2)), the thermal processing step must be accomplished within a single production facility, and the final product packaging must be performed in the facility where the thermal processing is accomplished (120.24(c)).

The requirement in 120.24© that the 5-log pathogen reduction and final packaging occur within a single facility ("single facility requirement") was established because FDA is concerned about post-process contamination of juice. Specifically, the agency is concerned that separating the pathogen reduction steps and final packaging in time and space may compromise the HACCP system, including the pathogen reduction.

FDA received a citizen petition from industry asking the agency to exempt processors of the covered products from the requirement to perform a second 5-log pathogen reduction treatment when the covered product manufactured in one facility is sent to another facility for final packaging because the transportation hazards that 120.24 (c) was designed to address could be adequately controlled as part of a processor's HACCP plan. Although FDA is concerned with the potential for contamination during bulk transport of juice, as noted below, we have decided to consider the exercise of enforcement discretion as to the single facility requirement provided that certain conditions are met.

Scope of guidance

This guidance applies to the covered products, containers used to carry the covered products, and equipment used to load, carry, and unload the covered products.

Covered products

1. High degree Brix juice concentrate that is transported, diluted, and packaged at a separate facility as either frozen juice concentrate for consumer use or as institution concentrate. This guidance does not apply to concentrate processed into single strength juice.

2. Shelf stable juice that is transported in bulk aseptic packaging and repackaged into final packaging at a separate facility.

Containers

1. Multi-use containers used to carry the covered product: after transporting the product, multi-use containers are cleaned, sanitized, and reused. This guidance addresses three types of multi-use containers: 1) tankers, i.e., tankers transported by truck, ship, or railroad, 2) reusable totes without liners, and 3) reusable drums without liners.

2. Single-use sanitary containers and reusable containers with single-use sanitary liners used to carry the covered product; the five types of single-use containers or liners covered in this guidance are: 1) sanitary bag-in-box (BIB) containers, 2) reusable totes with sanitary single-use liners, 3) reusable drums with sanitary single-use liners, 4) sanitary single-use drums, and 5) sanitary single-use totes. The term "sanitary" is used with single-use containers and liners to mean that the containers and liners are produced, handled, dispensed, and disposed of in a manner that protects against the contamination of food and food-contact surfaces.

Other equipment

Equipment other than containers used in bulk transport of the covered product includes equipment used to: 1) load the covered product into an empty container at the producer's facility and 2) unload the covered product at the user's (receiver's) facility. In general, pumps and fittings (e.g., elbows, hoses, gaskets, valves, nozzles, clamps, seals) are the two types of equipment used to perform these tasks. Specific equipment may vary depending on the type of container used.

Conditions for the exercise of enforcement discretion

FDA intends to consider the exercise of enforcement discretion for covered products when the following three conditions are met:

1. The producer and user (receiver) establish appropriate prerequisite programs and sanitation standard operating procedures (SSOPs) for the bulk transport of covered products.

2. The producer and user designate as a critical control point (CCP) in their respective HACCP plans, the bulk transport of covered products from the production facility to a separate facility for further processing and final packaging.

3. The producer and user establish control measures to prevent, reduce to acceptable levels, or eliminate the risk of contamination or recontamination of covered products during bulk transport.

General Recommendations

FDA is providing this guidance to producers and users to aid their development of measures to prevent, reduce to acceptable levels, or eliminate the risk of contamination or recontamination of covered products during bulk transport. The guidance describes five major areas of concern with bulk transport systems, special considerations for tankers, examples of control measures for loading and unloading covered product into tankers, and an example of critical control points a producer could use to include bulk transport in its HACCP plan.

FDA recommends that producers and users evaluate their bulk transport operations (loading, carrying, and unloading covered product) using HACCP principles and implement control measures to ensure that bulk transport does not contaminate or recontaminate the covered product with microbial pathogens. The producer and user may address some hazards with control measures in their prerequisite programs and SSOPs, while other hazards should be incorporated into HACCP plans at critical control points (CCPs) where critical limits, monitoring, and verification will provide additional assurances that the covered product will not become contaminated. An example of when a producer should address the hazard of microbial contamination as a critical control point in bulk transport would be at the receipt of an empty tanker because no subsequent step in transport could eliminate this hazard.

To establish control measures for bulk transport, the producer and user of the covered product should have a thorough understanding of the procedures and equipment used to load, carry, and unload the covered product and the procedures and materials used to maintain and clean such equipment. Additionally, to help ensure that the control measures are effective, the producer, transporter, and user should make communication a high priority.

FDA recommends that the producer and user conduct their hazard analyses focusing on five areas of concern with bulk transport: 1) sanitation operations, 2) equipment design, 3) equipment maintenance, 4) employee practices, and 5) loading and unloading areas. These are areas of concern for both multi-use containers (e.g., tankers) and single use containers (e.g., sanitary bag-in-box) used in bulk transport.

Sanitation operations

Consistent with the juice HACCP regulation, sanitation operations for equipment and containers used in bulk transport must be in accordance with the Current Good Manufacturing Practices (CGMPs) regulation (21 CFR Part 110) and the Sanitation Standard Operating Procedures (SSOPs) as described in the Juice HACCP regulation under §120.5 and §120.6, respectively. Under §110.35 (d) of the CGMPs, food contact surfaces of the equipment must be cleaned as frequently as necessary to protect against contamination of food. Similarly, under §110.35(d)(3), non-food contact surfaces of the equipment should also be cleaned as frequently as necessary.

Cleaning and sanitizing protocols should be tailored to the size and configuration of the container and other equipment and the type of food grade product carried in the previous load. Cleaning and sanitizing systems for multi-use equipment may include both clean-out-of-place (COP) systems for removable components and clean-in-place (CIP) systems for large containers, i.e., tankers. A previous load of an oil-based food in a multi-use container may indicate that an alkaline detergent should be used and that the cleaning and sanitizing protocol should have an additional step to degrease the container before cleaning.

Only sanitizing solutions that are covered by appropriate FDA food additive regulations should be used (21 CFR 178.1010). Sanitizers and cleaning solutions should be used in the concentration recommended by the manufacturer. The temperature, pressure, and

potability of the water used in cleaning, sanitizing, and rinsing should be sufficient to ensure that the equipment is adequately sanitized.[2]

The producer and user should obtain, review, and verify sanitizing protocols used by the transporter. Verification activities may include periodic audits of the transporter's wash station.

Equipment design

Equipment and containers that come in contact with the food being transported should be constructed of food grade materials and designed to have a smooth, easily cleanable, nonabsorbent, corrosion-resistant surface (e.g., stainless steel AISI series 200 and 300 with a minimum chromium content of 16 percent and a No. 3 finish or higher). The surfaces should be clean and sanitary without physical defects or corrosion. Seals used on containers should be uniquely numbered and tamper-evident.

Single-use containers without liners (i.e., bag-in-box containers, single-use totes, and single-use drums) and liners should be clean and sanitary with inner surfaces compatible with food materials and should present no physical defects or abnormalities. Single-use containers with liners, i.e., totes with liners and drums with liners, should be designed for use with liners. Single-use liners and their closures should be of sufficient structural

[2] Adequately sanitized means treated by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer

integrity to prevent food materials from contacting outer containers. Liners should be produced in a manner that results in clean, sanitary inner surfaces.

Like single-use containers, multi-use containers (e.g., tankers, reusable totes without liners, and reusable drums without liners) should be designed with inner surfaces clean and sanitary, compatible with food materials and should present no physical defects or abnormalities. Unlike single-use containers, multi-use containers will be reused and should be adequately cleaned and sanitized before they are used again. Multi-use containers should be designed to be easily and adequately cleanable. Seams on the food contact surfaces should be smoothly bonded and maintained to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for the growth of microorganisms.

Preventive maintenance

Preventive maintenance programs should be established to ensure the proper functioning of the equipment and integrity of the food contact surfaces. Periodic inspection of containers and equipment and periodic replacement of gaskets and flexible hoses are examples of preventive maintenance programs.

Employee practices

Employee practices must be in conformance with the CGMPs and the SSOPs as described in the Juice HACCP regulation under sections 120.5 and 120.6, respectively. In accordance with the Juice HACCP regulation, all employees working in the loading

and unloading areas in direct contact with the covered product must employ hygienic practices to protect against microbiological contamination of the covered product.

Employees responsible for the loading and unloading of the covered product should be trained about the measures to prevent contamination of the covered product. Competent supervisory personnel should oversee employee practices.

Loading and unloading areas

In addition to the equipment used in bulk transport, the loading and unloading areas should be designed and maintained in accordance with the CGMPs in 21 CFR Part 110. The areas should be maintained in sanitary condition and in good repair to prevent contamination of the covered product.

Special Considerations for Tankers

Because of the complexity, size, multiple configurations and accessories, and the potential for contamination from previously transported product, the producer and user should carefully scrutinize tanker operations, i.e., cleaning, sanitizing, loading, carrying, and unloading, to ensure that sufficient control measures are in place to adequately safeguard against contamination of the juice concentrate.

FDA recommends that a producer use tankers dedicated to carrying only treated juice products. If it is not feasible to use a dedicated tanker, the producer should demonstrate in its hazard analysis that the cargo permitted as a load prior to carrying the juice concentrate does not add to the risk of microbial contamination of the concentrate. An

example of cargo that would have a similar low level of risk would be a treated food or food grade product that is easily cleanable, e.g., citric acid.[3] The producer should demonstrate that the permitted cargo offers the same low level of risk of microbial contamination, as does a treated juice product.

Producers and users should have written agreements between each other and with the transporter as a means of control. To make such controls effective, producers and users should perform verification activities such as periodic inspection of the hauler and cleaning stations, environmental testing of containers, product testing, periodic inspection of employee practices, e.g., handwashing, and periodic inspection of the condition of the equipment.

An example of an agreement with a transporter that both the producer and user should consider is an agreement regarding the transporter's cleaning and sanitizing protocol. The provisions of a cleaning and sanitizing protocol will depend on the configuration of the container and the previous load. A cleaning and sanitizing protocol for a complex container such as a tanker that has many removable parts and a venting system will differ from a cleaning and sanitizing protocol for a 55-gallon reusable drum. A cleaning and sanitizing protocol for a tanker with a previous load that was oil-based should include a degreasing step, but if the previous load was a water-based food, the degreasing step

[3]Although this guidance is focused on microbial contamination in bulk transport, a producer should also consider the potential for chemical contamination if cargo in prior loads could cause allergic reactions (e.g., milk and eggs) or could be carcinogenic or toxic (e g., non-food grade dyes, inks, pigments).

should not be used. An example of a cleaning and sanitizing protocol for a tanker is set out below:

Recommended protocol for cleaning and sanitizing a tanker

1 Before cleaning and sanitizing

- Determine previous load and cleaning and sanitizing protocol. Protocol should eliminate pathogenic microorganisms and other hazardous contaminants
- Drain completely
- High-pressure rinse or scrub interior surfaces if residue is still present

2 Pre-rinse interior of tanker

- Rinse with potable water.
- Degrease if previous load was oil-based material
    - Use degreaser/detergent in accordance with manufacturer's recommendations.
- Drain

3 Clean primary interior tanker surfaces

- Use appropriate cleaner in accordance with cleaner manufacturer's recommendations.
- Drain completely

4 Clean--removable components (COP)

- Hand clean (or use automatic COP system) rear valve, gaskets, and other removable parts.
- Use appropriate cleaner in accordance with the cleaner manufacturer's recommendations.

5 Rinse (if required) interior of tanker

- Rinse with ambient, potable water until completely clear.
- Test by measuring pH of rinse water (pH=neutral)
- Drain thoroughly

6 Inspection of tanker interior

- Visually inspect from exterior with inspection light
- Verify removal of residues and excess liquids.

7 Sanitize—interior of tanker and removable parts

- Sanitize all food contact surfaces and all removable parts and components.
- Use food-grade sanitizer diluted with potable water according to sanitizer manufacturer's recommendations for concentrations and time/temperature of use.

8 Rinse (if required) interior of tanker

- Rinse with ambient, potable water until completely clear
- Test by measuring pH of rinse water (pH=neutral)
- Drain thoroughly

9 Seal

- Immediately after draining, seal all points of entry and discharge
- Use numbered, tamper-evident seals.

10 Record information about the wash

- Include date and time, seal numbers, trailer number, and cleaning and sanitizing protocol on the current wash ticket.
- Maintain copies of wash records for period of time agreed upon by customer.

11 Clean exterior of tanker only after sealing tanker.

Examples of control measures for tanker transport of covered product

The producer and user should each establish control measures for bulk transport of covered products. The producer and user should determine where each of its control measures should be incorporated, i.e., into prerequisite programs or as a critical control point in its HACCP plan.

Examples of control measures that may be appropriate for the producer in loading a covered product into a tanker and for the user in unloading a covered product from a tanker follow:

Recommended control measures for loading a tanker

1 Inspect the empty tanker upon arrival to verify that--

- The tanker is marked for food grade use.
- The tanker access points were sealed at the wash station with numbered, tamper-evident seals at all major points of entry and discharge. (Sealing points may include the dome cover, tank outlet, vent cap, pump inlet, pump outlet, and hose tube covers)
- The hoses and pump outlets were capped and sealed after cleaning and sanitizing
- The integrity and cleanliness of the tanker and its component parts are apparent.
    - The interior of the tank is clean, dry, and free of cracks, corrosion, and residues from the prior load
    - The seals, gaskets, pumps, valves, hoses, and hose tubings are clean and free of cracks, corrosion, and residues from prior load
    - There is no presence of off-odors when opening the dome cover of the tanker

2. Review and verify that the wash ticket from the transporter contains--

- Certification of the last load
- Cleaning and sanitizing protocol used for the last load
- Seal identification. (Seal numbers should be recorded on the wash ticket and verified by the producer)

3 Prior to loading the tanker, producer should verify that--

- The loading facility is maintained according to CGMPs
- The employees follow CGMPs and SSOPs
- The integrity and cleanliness of the transfer equipment (i e , pumps, hoses, and associated equipment) are apparent

4 Immediately after loading the tanker, the producer should verify that--

- The tanker is closed and numbered, tamper-evident seals are affixed to any access ports that were unsealed during inspection.
- The bill of lading contains correct seal numbers and cargo identification
- A copy of the wash ticket is provided to the outbound tanker for the user

Recommended control measures for unloading a tanker

1 Review and verify documentation from the transporter, including--

- Bill of lading from the producer containing security seal numbers and identification of cargo.
- Wash ticket.

2 Inspect the loaded tanker to verify that--

- The tanker is marked for food grade use
- The tanker access points were sealed at the producer's facility with numbered,

tamper-evident seals at all points of entry and discharge.

- The numbers of the tamper-evident seals match those listed on the bill of lading
- The integrity and cleanliness of the transfer equipment are apparent.
- The integrity and cleanliness of the tanker and its component parts are apparent

3 Conduct periodic review of these activities performed upstream to verify that appropriate controls are in place and effective

An example of tanker transport: a producer's critical control points, conditions to be monitored and verified, and critical limits

Some hazards in tanker transport may be addressed adequately in SSOPs, while others may require additional assurances in the form of critical control points in the processor's HACCP plan. In the following example, a producer of a high degree Brix juice concentrate determines that tanker transport in his facility can be divided into three separate processes, two of which are critical control points:

Recommended critical control points and critical limits for a producer

Product description

High degree Brix juice concentrate transported by tankers

Tanker transport processes

1 Receipt of empty tanker (critical control point).

2 Loading of empty tanker (controlled by prerequisite programs and SSOPs).

3. Preparation of loaded tanker for shipping (critical control point)

CCP 1—Receipt of empty tanker

For the first CCP, the producer should have a written agreement from the transporter that the empty tanker has been adequately sanitized The agreement should identify the transporter's cleaning and sanitizing protocol and provide assurances that the cleaning and sanitizing protocol has been followed. The producer should monitor and verify the following three conditions:

1. Intact seals on empty tanker.
2. Presence of complete wash ticket, including –
    a Certification of last load
    b. Cleaning and sanitizing protocols used for last load.
    c. Seal numbers that match seals on the tanker.
3. Integrity of the tanker and its component parts

Critical Limit for CCP 1

The critical limit for the three conditions is that the conditions must be satisfied, i.e , the tanker seals must be uncompromised, the wash ticket must be complete and correct, and the tanker and its component parts must be without corrosion or cracks If any one of these three conditions is not met, the tanker should be rejected.

CCP 2—Preparation of loaded tanker for shipping

For the second CCP, the producer should provide assurances to the user that a clean, intact, properly sanitized tanker was used to carry the product, the tanker was adequately sealed, and the documentation accompanying the tanker is correct and complete, i.e , the seal numbers listed in the documentation match those on the tanker The producer should monitor and verify the

following three conditions.

1. Seals are applied correctly on the loaded tanker.
2. Complete and correct wash ticket accompanies loaded tanker.
3. The current bill of lading has correct product identification and seal numbers on loaded tanker.

Critical Limit for CCP 2

As with CCP 1, the critical limit for the conditions in CCP 2 is that the conditions must be satisfied, i.e., the seals must be applied properly and the appropriate documentation, the wash ticket and bill of lading, must accompany the loaded tanker. Until all of these conditions are met, the tanker should not be shipped to the user.