Juice HACCP and the FDA Food Safety Modernization Act: Guidance for Industry

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Table of Contents

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I. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) (FSMA) enables the Food and Drug Administration (FDA or the Agency) to better protect public health by helping to ensure the safety and security of the food supply. It requires FDA to promulgate food safety rules that focus on preventing food safety issues rather than relying on detecting issues and reacting to them after they occur. FSMA recognizes that FDA has previously established preventive control type regulations for juice (Title 21, Code of Federal Regulations (21 CFR) part 120, the Juice HACCP regulation) based on the Hazard Analysis and Critical Control Point (HACCP) concept. See FSMA §§ 103(a), 103(f), 105(d), and 301 (§§ 418(j) and 805(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 350g(j), 350g note, 350h note, and 384a(e))). The juice HACCP regulation requires juice processors to identify food safety hazards that are reasonably likely to occur with the products they process[2] and to develop plans for the control of those hazards. In addition, the juice HACCP regulation requires importers of certain juice products to comply with requirements designed to help ensure that these imported products are processed in accordance with the juice HACCP regulation.

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] 21 CFR 120.3(j)(1), *"Processing means activities that are directly related to the production of juice products (2) For the purposes of this part, processing does not include: (i) harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and (ii) The operation of a retail establishment."*

Importantly, several of the regulations that FDA has issued under FSMA provide exemptions that are related to the juice HACCP regulation. This guidance addresses those exemptions, and also provides information about the juice HACCP regulation in connection with the FSMA regulations.

Though not the subject of this guidance, we also note that some juice products are also subject to 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers). Certain FSMA regulations provide additional exemptions related to part 113.

This guidance summarizes how the following FSMA regulations affect processors and importers covered under 21 CFR part 120, the Juice HACCP regulation:

- 21 CFR part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (the CGMP & PC Regulation)
- 21 CFR 1, subpart L, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the FSVP Regulation)
- 21 CFR part 112, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Safety Regulation)
- 21 CFR part 121, Mitigation Strategies To Protect Food Against Intentional Adulteration (the IA Regulation)
- 21 CFR 1, subpart O, Sanitary Transportation of Human and Animal Food (the ST Regulation).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

The CGMP & PC regulation contains 7 subparts which address key areas associated with a comprehensive food safety program. Below is a brief summary of the content of each subpart:

Subpart A: General Provisions

This subpart provides definitions, identifies exemptions, defines applicability of subparts, and specifies training requirements.

Subpart B: Current Good Manufacturing Practice

Subpart B contains most of the provisions previously in 21 CFR part 110. The changes include modifications that either delete or make previously recommended practices into requirements and provide explicit regulatory text to address allergen cross-contact.

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

Subpart C describes the requirements for a food safety plan, including hazard analyses and preventive controls for facilities subject to this subpart.

Subpart D: Modified Requirements

Subpart D describes the modified requirements for qualified facilities and facilities solely engaged in the storage of unexposed packaged food (for food that requires time/temperature control for safety).

Subpart E: Withdrawal of a Qualified Facility Exemption

Subpart E addresses the withdrawal of a qualified facility exemption and the appeal and reinstatement procedures.

Subpart F: Requirements Applying to Records that must be Established and Maintained

Subpart F establishes the requirements that apply to all subparts for the records required to be kept.

Subpart G: Supply-Chain Program

Subpart G requires the establishment of written risk-based supply-chain programs for receiving facilities (manufacturers/processors) for raw materials and other ingredients when a hazard associated with the raw material or other ingredient has been controlled before receipt. It further describes the requirements for supply-chain programs, supplier verification activities, and recordkeeping for those programs.

Subpart A – General Provisions

1. Are juice processors subject to the Current Good Manufacturing Practice and Preventive Controls Regulation (21 CFR part 117)?

Juice processors must meet the requirements of specific subparts of the CGMP & PC Regulation. The exemption in 21 CFR 117.5(c) applies to the activities that are subject to 21 CFR part 120, i.e., activities of persons that meet the definition of "processor" in 21 CFR 120.3(k), if the facility is in compliance with 21 CFR part 120 with respect to such activities. 21 CFR 117.5(c) specifically exempts the processing activities of juice processors from the requirements of 21 CFR 117 subpart C, *Hazard Analysis and Risk-Based Preventive Controls*, and subpart G, *Supply-Chain Program*. Juice processors still must meet the applicable requirements of 21 CFR 117 subparts A, B, and F (for the records required by subpart A).

2. What if the facility is not in compliance with 21 CFR part 120?

We expect that situations in which enforcement actions to ensure compliance with the juice HACCP regulation in 21 CFR part 120 are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and G, will be rare and will depend on very specific circumstances.

In general the appropriate action for us to take when a facility is out of compliance with the juice HACCP regulation will be to employ existing enforcement tools to bring the facility into compliance with the juice HACCP regulation. However, there may be circumstances where an added food safety benefit could be achieved by requiring compliance with the CGMP & PC regulation when a facility does not comply with the juice HACCP regulation. For example, a juice processor that has ongoing problems with microbial contamination of fruit it receives for processing may be better able to address its supply of fruit by complying with the specific requirements of the human preventive controls regulation for a supply-chain program (subpart G).

3. Which definitions in part 117 apply to my facility and process?

The definitions of terms in 21 CFR 117.3 apply to juice processors and importers subject to 21 CFR part 120 except that the definitions of the terms "facility," "hazard," and "manufacturing/processing" in 21 CFR 117.3 do not apply when used in the context of the juice HACCP regulation.

4. What additional training requirements apply to juice processors under 21 CFR part 117?

In addition to the training requirements listed in 21 CFR 120.13, the management of an establishment must also ensure that their employees meet the training requirements listed in 21 CFR 117 subpart A. The workers who are engaged in manufacturing, processing, packing or holding juice (including temporary and seasonal personnel) must have the necessary combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties ("qualified individual") and must receive training in the principles of food hygiene and food safety (21 CFR 117.4(b)). In addition, supervisory personnel must have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food (21 CFR 117.4(c)). Juice processors must maintain records of the training in the principles of food hygiene and food safety, including health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties (21 CFR 117.4(d)). The requirements of subpart F apply to these training records.

5. When do I need to comply with the relevant provisions in 21 CFR part 117 that apply to me, including the records requirements?

Compliance dates for businesses are staggered over several years.

- Very small businesses, which means, for purposes of part 117, a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee), must be compliant by September 17, 2018.

(This is also the compliance date for grade ''A'' milk and milk products covered by the Pasteurized Milk Ordinance.)

- Small businesses, which means, for the purposes of part 117, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees, must be compliant by September 18, 2017.
- All other businesses must be compliant by September 19, 2016.

For the purpose of determining your compliance date for the relevant provisions, e.g., the CGMPs in 21 CFR part 117 subpart B and the training requirements in subpart A, the definitions of ''small business'' and ''very small business'' established in 21 CFR part 117 apply, not the definitions in the Juice HACCP regulation in 21 CFR part 120.

Subpart B – Current Good Manufacturing Practice

6. Are the Current Good Manufacturing Practices provisions in 21 CFR part 117 different from those in 21 CFR part 110?

The CGMP requirements in 21 CFR part 117 (mostly in subpart B) generally align with the requirements of 21 CFR part 110, with the non-binding provisions in 21 CFR part 110 removed or made binding. In addition, 21 CFR 117 subpart B addresses allergen cross-contact explicitly in the regulatory text. In addition, training, which was recommended in 21 CFR part 110, is now mandated in 21 CFR 117 subpart A (refer to question 4).

7. How does 21 CFR part 117 change what procedures and controls FDA requires that juice processors have and implement to control allergen cross-contact and control for undeclared food allergens?

Juice processors would address allergens through the application of CGMPs as required by 21 CFR 117.10, 117.35, 117.40, and 117.80, which mandate that personnel, plant equipment and utensils, and other activities must not lead to allergen cross-contact.

The juice HACCP regulation in part 120 requires that a juice processor consider the presence of undeclared ingredients that may be food allergens as part of its hazard analysis (21 CFR 120.7(c)(8)), and several sections in our guidance entitled "Juice HACCP Hazards and Controls Guidance (First Edition)" http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm072557.htm also make recommendations for the control of food allergens.

8. Does 21 CFR part 117 require juice processors to have written sanitation procedures?

No. The updated CGMPs in 21 CFR 117 subpart B do not require sanitation procedures to be written. Although subpart C would require sanitation controls to be written if they are applicable, subpart C does not apply to juice processors who are in compliance with 21 CFR part 120. The juice HACCP regulation does not require written Sanitation Standard Operation Procedures (SSOPs). Juice processors are required to implement sanitation

monitoring procedures and to maintain written sanitation monitoring records and records of corrections as defined by 21 CFR 120.6.

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

9. What additional 21 CFR part 117 risk-based preventive controls, if any, do juice processors in compliance with 21 CFR part 120 need to implement for the non-juice raw materials and ingredients they use in their juice?

Juice processors in compliance with 21 CFR part 120 are exempt from 21 CFR 117 subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program). However, as well as complying with 21 CFR part 120, juice processors must comply with 21 CFR 117 subparts A, B, and F (for the training requirements of subpart A). Non-juice raw materials and ingredients that are part of a 100 percent juice product (and thus subject to the juice HACCP regulation) must be evaluated for hazards in a juice processor's hazard analysis and controlled for in a juice processor's HACCP plan (21 CFR 120.7).

10. What controls are required if a facility is producing juice subject to the juice HACCP regulation in 21 CFR part 120 and products not subject to the juice HACCP regulation?

When a facility manufactures, processes, packs, or holds both exempt (juice produced under 21 CFR part 120) and non-exempt products (for example, juice beverages or juice cocktails that are not covered by 21 CFR part 120), the activities that apply to non-exempt products and their raw materials or ingredients must meet the requirements of 21 CFR part 117 (including subparts C and G), unless an exemption applies. Juices that are exempt from subparts C and G of 21 CFR 117 are subject to subparts A, B and F (for the training requirements of subpart A) of part 117.

11. Are juice processors required to collect and test environmental samples?

No. Juice processors who are in compliance with the juice HACCP regulation are exempt from the requirements in 21 CFR 117 subpart C, which includes, when appropriate, environmental monitoring through the testing of environmental samples.

12. Do I have to establish a written recall plan for my juice?

No, juice processors in compliance with 21 CFR part 120 are exempt from 21 CFR 117 subpart C, which mandates that you must establish a written recall plan for a food with a hazard requiring a preventative control.

Subparts D and E – Modified Requirements and Withdrawal of a Qualified Facility Exemption

13. Do the requirements applicable to a qualified facility in subparts D and E apply to juice processors subject to the juice HACCP regulation?

No. A "qualified facility" is eligible for an exemption that enables very small businesses to comply with modified requirements in 21 CFR part 117. A qualified facility is exempt from the requirements of subparts C and G, but is subject to the provisions of 21 CFR 117.201 in Subpart D, *Modified Requirements*, and could be subject to subpart E, *Withdrawal of a Qualified Facility Exemption.* However, these do not apply to juice processors as defined in 21 CFR 120.3(k). The activities subject to 21 CFR part 120 are already exempt from subparts C and G; the juice processor does not have to comply with modified requirements nor is there a provision to withdraw the exemption that applies to juice processors.

However, if a facility also conducts activities that are not covered under the juice HACCP regulation, then that portion of the operations may be subject to subparts D and E if the business meets the definition of a qualified facility.

Subpart F - Requirements Applying to Records that must be Established and Maintained

14. Do the records requirements listed in subpart F apply to my juice HACCP program?

No. The record requirements in Subpart F only apply to the training records discussed in question 4 and required by 21 CFR 117.4(d). Records that are intended to meet the requirements of the juice HACCP regulation must comply with the requirements in the juice HACCP regulation (21 CFR 120.12).

III. Foreign Supplier Verification Program (FSVP)

The *Foreign Supplier Verification Programs (FSVP) for Food Importers of Foods for Humans and Animals* (FSVP regulation) is found in 21 CFR 1, subpart L (21 CFR 1.500-1.514). The FSVP regulation requires importers to create and follow procedures to ensure the safety of the food they import. FSVP does not apply to (1) juice products that are imported from a foreign supplier that is required to comply with and is in compliance with 21 CFR part 120; or (2) raw materials or other ingredients that an importer uses in manufacturing or processing juice subject to part 120, provided that the importer is in compliance with the requirements in part 120 with respect to the juice product manufactured or processed from the imported raw materials or other ingredients.

15. Will the FSVP regulation impact my importation of juice products?

Importers of juice are exempt from the FSVP regulation, provided that the juice is imported from a foreign supplier that is required to comply with, and is in compliance with, 21 CFR part 120 (21 CFR 1.501(b)(1)). Importers of juice products that are processed in accordance with 21 CFR part 120 are subject to the requirements of 21 CFR 120.14, *Application of requirements to imported products.*

It is important to note that the FSVP regulation requires all importers subject to that rule to identify themselves as the FSVP importer upon entry. As a consequence, all food imports will be prompted for an additional data code at entry. Because importers of juice products are exempt from the FSVP regulation, they should transmit the Affirmation of Compliance code, "FSX" (designating that the food is exempt from the FSVP regulation or that compliance with the FSVP regulation is not required), for each entry. Without a code, the entry will be rejected. An incorrect code could result in the importer being listed in the FSVP inventory for inspection. The Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation provides information on how importers exempt from FSVP may comply with FDA's requirements for entries. See: https://www.fda.gov/food/guidanceregulation/fsma/ucm556661.htm.

16. Does the definition for importer in 21 CFR 120.3 of the juice HACCP regulation still apply to juice importers?

Yes. Since juice products that are imported from foreign suppliers that are subject to the juice HACCP regulation and in compliance with the juice HACCP regulation are not required to comply with the FSVP regulation, importers of juice products that are subject to the juice HACCP regulation must comply with the requirements applicable to importers of those products under 21 CFR 120.14. Consequently, the definition of an importer in 21 CFR 120.3 applies to such importers, and the definition of importer in 21 CFR 1, subpart L, 1.500 (regarding FSVP) does not apply.

17. How does FSVP affect my importation of raw materials or ingredients for juice products?

If an importer imports raw materials or other ingredients for use by the importer in manufacturing or processing juice subject to 21 CFR part 120, the FSVP regulation does not apply to those raw materials or ingredients, provided that the importer complies with 21 CFR part 120 in manufacturing or processing the juice product made from the imported raw materials or other ingredients (see 21 CFR 1.501(b)(2)).

IV. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

18. Must a juice processor purchase produce that was produced in compliance with 21 CFR Part 112?

No. 21 CFR part 112 applies only to certain farms and their produce. It does not apply to activities of juice processors subject to 21 CFR part 120. For farms and their produce that would otherwise be subject to part 112, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from part 112 (21 CFR 112.2(b)(1)). Processing in accordance with the requirements of 21 CFR part 120 is an example of processing that adequately reduces the presence of microorganisms of public health significance for purposes of this exemption. However, for the produce to qualify for the exemption from part 112, the farmer must

disclose in documents accompanying the produce that the food is "not processed to adequately reduce the presence of microorganisms of public health significance" (21 CFR 112.2(b)(2)). To qualify for the exemption, the farmer must also obtain written assurance annually from the customer (e.g., the juice processor) that performs the commercial processing that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance or that an entity subsequent to it in the food chain will do so (and in such cases, the farmer must also obtain certain additional assurances from the customer) (21 CFR 112.2(b)(3)). The compliance date for such written assurances has been extended (see 81 FR 57784 at 57786).

V. Mitigation Strategies to Protect Food Against Intentional Adulteration

19. Must a juice processor also comply with 21 CFR part 121 – Mitigation Strategies to Protect Food Against Intentional Adulteration (IA)?

Domestic and foreign juice processors required to register with FDA (21 USC 350d) must comply with 21 CFR part 121 unless an exemption applies to the facility. Facilities must be in compliance by the dates established by the IA final regulation.

- The IA regulation does not apply to a very small business (i.e., a business, including any subsidiaries or affiliates, averaging less than $10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee), except that the facility is required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption.
- This regulation does not apply to the holding of food, except the holding of food in liquid storage tanks.
- This regulation does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- This regulation does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- This regulation does not apply to the manufacturing, processing, packing, or holding of food for animals.

See 21 CFR 121.5 for exemptions.

VI. Sanitary Transportation of Human and Animal Food

20. Is the shipment of packaged juice covered under 21 CFR 1 subpart O – Sanitary Transportation of Human and Animal Food?

Transportation operations for food completely enclosed by a container are not subject to this regulation unless the food requires temperature control for safety. For example, the transportation of pasteurized acidic fruit juice (pH 4.6 or less) packaged in a sealed container is not subject to this regulation because the juice will only spoil, and not become unsafe if temperature control is not maintained.