Alignment of FSMA with Existing Food Safety Programs

International Citrus & Beverage Conference

Donald Kautter
US Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety

September 22, 2016

Overview

- Juice HACCP regulation and the Food Safety Modernization Act (FSMA)
- The FSMA Technical Assistance Network (TAN)
  - Questions and Answers received to date that may impact juice and beverages
  - Other Questions and Answers from Regulation(s) preamble with citations to assist in review
  - Draft Guidance Documents – impact juice and beverages/human food by-products to animal food products
- Planned Guidance(s)
- Additional support for the implementation and understanding of the FSMA regulations

FSMA Regulations - Background

- The FDA Food Safety Modernization Act (FSMA) enables the FDA to better protect public health by helping to ensure the safety and security of the food supply.
- It enabled FDA to promulgate food safety and food defense rules that focus on preventing food safety and food defense issues rather than relying on detecting issues and reacting to them after they occur.
- FSMA acknowledges that FDA has previously established preventive control type regulations for juice (21 CFR part 120) based on a Hazard Analysis and Critical Control Point (HACCP) concept and requires juice processors to identify significant food safety hazards associated with the products they process and to apply preventive controls to reduce or eliminate the identified hazard(s).
- The FSMA regulations provide exemptions from certain sections of FSMA where pre-existing FDA regulations require HACCP principles for the processing and importing of juice.

FSMA Regulations - Questions

- The FDA FSMA Technical Assistance Network (TAN) has been operational since September 9, 2015 and provides technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation.
- The TAN addresses questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final.
- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

FSMA Regulations - TAN

- Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. Complicated questions may require more time for a response. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive.
- Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.
- Questions will be tracked and trended using a Knowledge Management System (KMS) to assist FDA in prioritizing, in part, FSMA policy, guidance, and training. Additionally, many questions will be addressed through guidance documents posted on FDA's website.

FSMA TAN – Q/A

Question:

How does the FSMA PC rule apply to an alcohol production facility?

FSMA TAN – Q/A

Answer:

- An alcoholic beverage is a food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 USC § 321(f)). If your company is engaged in the bottling of alcoholic beverages for consumption in the United States, then your company must register with FDA as a food facility because you manufacture/process, pack, or hold food for consumption in the United States (see 21 CFR § 1.225). If you are required to register, then you are subject to the requirements of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117) (PC rule), unless an exemption applies (see 21 CFR § 117.5 Exemptions; 80 Fed. Reg. 55907 at 56148).
- Section 116 of FSMA provides an exemption for certain facilities engaged in the manufacturing, processing, packing, or holding of alcoholic beverages. Alcoholic beverages at a facility that is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business and is required to register with FDA are exempt from subparts C and G of the PC rule.

FSMA TAN – Q/A

Question:

Does FSMA require pasteurization or irradiation of spreads, butters, beverages or milks made from almonds, hemp, pumpkin seeds, or other nuts, seeds and grains?

FSMA TAN – Q/A

Answer:

- The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117; 80 Fed. Reg. 55909)(PC rule) creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food.
- Unless an exemption applies (see 21 CFR 117.5), a facility that manufactures a food is required to conduct a hazard analysis (see 21 CFR 117.130) and implement preventive controls for identified hazards (see 21 CFR 117.135). Heat treatments such as pasteurization may be an appropriate preventive control if hazards such as pathogens are identified as hazards requiring a preventive control in such foods.

FSMA TAN – Q/A

Question:

The plant I work at falls into Juice HACCP as we produce fruit purees. We have one line of non puree products (formulated fruit sauce for the food service industry). Since the "facility" falls under Juice HACCP, is the fruit sauce line exempt from FSMA Preventive Control rule if we have a HACCP plan for that line as well?

FSMA TAN – Q/A

Answer:

- Fruit purees fall within the definition of Juice (see FDA's Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition and therefore must be produced in compliance with 21 CFR part 120 (FDA's regulations covering Hazard Analysis and Critical Control Point (HACCP) Systems). The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117; 80 Fed. Reg. 55908)(PC rule) establishes an exemption applicable to fruit purees in 21 CFR § 117.5(c) which provides that subparts C (Requirements for Hazard Analysis and Risk-Based Preventive Controls) and G (Requirements for a Supply-Chain Program) of 21 CFR part 117 do not apply with respect to a facility's activities that are subject to 21 CFR part 120 if the facility is required to comply with, and is in compliance with, part 120 with respect to those activities.
- Fruit sauce does not fall within the definition of Juice, and, therefore, its manufacture is not required to be in compliance with the HACCP regulations of 21 CFR part 120). Thus, the fruit sauce manufacturing operation at your facility is not covered by the exemption in 21 CFR § 117.5(c), and your facility will be subject to the PC rule with regard to the manufacturing of the fruit sauce product.

FSMA TAN – Q/A

Question:

If we switched from (juice) HACCP to HARPC (FSMA PC rule) for 100% juice products would we still meet the agency's requirements?

FSMA TAN – Q/A

Answer (part 1):

- The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117; 80 Fed. Reg. 55907)(PC rule) creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for human food. In general, the PC rule applies to facilities that have to register under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- There is insufficient information provided as to the nature of your juice product to determine which regulation your juice products currently are subject to such as the low acid canned juice (21 CFR Part 113), juice subject to acidified foods regulation (21 CFR Part 114) or the Juice HACCP regulation (21 CFR Part 120).
- FSMA included certain exemptions which have been provided in 21 CFR § 117.5 of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food final rule (80 Fed. Reg. 55908 at 56148), including:

FSMA TAN – Q/A

Answer (part 2):

- 21 CFR § 117.5(c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities, and
- 21 CFR § 117.5 (d)(1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities. (2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.
- Foods subject to the Acidified Foods regulation (part 114) are not exempt from the PC Rule. Depending on your food operation, you also may be subject to FDA's final rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals published in the Federal Register on November 27, 2015.

FSMA TAN – Q/A

Question:

Does FSMA make any changes in regards to pasteurization of juices or beverages?

FSMA TAN – Q/A

Answer:

For any of the products you produce that are regulated by FDA (e.g., pasteurized juices), you are subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117) unless an exemption applies. See 21 CFR § 117.5 (b) and (c) for exemptions for foods subject to 21 CFR part 120). Your HACCP program and the existing records can be used to demonstrate compliance with the requirements of subparts C and G (21 CFR part 117) and may be supplemented as necessary to include all of the required information.

FSMA TAN – Q/A

Question:

My question is regarding exemptions to this rule. Our beverage company has one manufacturing plant that is FSSC 22000/ISO 9001 certified and will follow all rules regarding the FSMA. My question is regarding our 13 Distribution Centers. Our beverages are non-refrigerated, shelf stable and completely contained within it's packaging, no product is exposed in our warehouses. Are our Distribution Centers exempt from FSMA PC Regulation?? Any information regarding soft drink beverage distribution would be extremely helpful.

FSMA TAN – Q/A

Answer:

- In general, a facility that has to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act and that manufactures, processes, packs, or holds food is subject to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR Part 117; 80 Fed. Reg. 55908)(PC rule), unless subject to an exemption.
- An exemption is provided in 21 CFR § 117.7(a) which states that subparts C (Hazard Analysis and Risk-Based Preventive Controls) and G (Supply-Chain Program) of 21 CFR part 117 do not apply to a facility solely engaged in the storage of unexposed packaged food. Because your unexposed packaged beverage products are non-refrigerated and shelf stable (and do not require time/temperature controls during storage), the modified requirements of 21 CFR § 117.206 do not apply to your distribution centers. However, your distribution centers are subject to other provisions of the PC rule, such as training requirements (21 CFR Part 117, subpart A) and requirements for current good manufacturing practice (21 CFR part 117, subpart B).

FSMA TAN – Q/A

Question:

In the Webinar conducted on June 21 on the intentional adulteration FSMA regulation, one of the exemptions briefly mentioned were alcoholic beverages under certain conditions. Is there any clarification on this exemption? What are the circumstances that allow this exemption (i.e. Processes, Nature of Alcohol itself, safe product)? Any answers provided would be greatly appreciated. As a production brewery, we try to adhere to a fairly novel Food Defense plan, but the extent of our plans is definitely hindered by design of an older facility.

FSMA TAN – Q/A

Answer:

The FSMA Mitigation Strategies To Protect Food Against Intentional Adulteration rule (IA rule) contains an exemption for certain food and alcohol at certain alcohol-related facilities (21 CFR 121.5(e)). The following two conditions must be met for alcoholic beverages at a facility to be exempt from the IA rule: (i) Under the Federal Alcohol Administration Act or chapter 51 of subtitle E of the Internal Revenue Code of 1986 the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and (ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages (21 CFR 121.5(e)(1)). The conditions for a food at such a facility to be exempt are addressed in 21 CFR 121.5(e)(2).

Selected FSMA Regulation(s) Preamble Information for Beverages

FSMA Preamble

Question:

What if the facility is not in compliance with the applicable regulation (Juice HACCP regulation)?

FSMA Preamble

Answer:

- We expect that situations in which enforcement actions to ensure compliance with an applicable HACCP regulation 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. (Federal Register Vol. 80, No. 180, Page 55977).

FSMA Regulations-Preamble PC

- (Comment 382) Some comments ask us to recognize that existing HACCP plans, such as those developed in accordance with the EU 2004 Food Hygiene law and GFSI-compliant food safety plans, can satisfy the requirements for what must be in a food safety plan.
- (Response 382) To the extent that an existing HACCP plan or GFSI-compliant food safety plan includes all required information, a facility can use such plans to meet the requirements of this rule. We expect that many existing plans will need only minor supplementation to fully comply with these requirements. Relying on existing records, with supplementation as necessary to demonstrate compliance with the requirements of the human preventive controls rule, is acceptable (see § 117.330).

FSMA Regulations-Preamble PC

- (Comment 496) Some comments ask whether we will endorse certification under GFSI as satisfying the requirements for validation.
- (Response 496) GFSI was established to support improvements in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide (Ref. 83). GFSI has developed a guidance document that specifies a process by which food safety schemes may gain recognition by GFSI, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation), in relation to food safety (Ref. 83). We have no plans to endorse certification under GFSI (or any other standard setting organization) as satisfying the requirements for validation. However, to the extent that scientific and technical information available from GFSI or another standard setting organization provides evidence that a control measure, combination of control measures, or the food safety plan as a whole is capable of effectively controlling the identified hazards, a facility may use such information to satisfy the validation requirements of the rule.

FSMA Regulations – Preamble PC

Question:

Are juice processors subject to the Current Good Manufacturing Practice and Preventive Controls Rule (21 CFR 117)?

FSMA Regulations – Preamble PC

Answer:

Juice processors must meet the requirements of specific subparts of the CGMP/PC Rule. 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 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). (Federal Register Vol. 80, No. 180, Page 56148.)

FSMA Regulations – Preamble Produce Rule

Question:

Must a juice processor covered by the Juice HACCP regulation purchase produce that is in compliance with 21 CFR Part 112 (The Produce Safety Rule)?

FSMA Regulations – Preamble Produce Rule

Answer:

- No. Produce that receives a commercial process that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from 21 CFR Part 112 (21 CFR part 112.2(b)(1)). (Federal Register Vol. 80, No. 228, Page 74549).
- 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. However, 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" and the farmer must obtain written assurance annually from the customer (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.

FSMA Regulations – IA Regulation

Must a juice and/or beverage processor also be in compliance with 21 CFR 121 – Mitigation Strategies to Protect Food Against Intentional Adulteration (IA)?

FSMA – IA Regulation

Yes, domestic and foreign juice processors must be in compliance with 21 CFR 121 unless an exemption applies to the facility. Facilities must be in compliance with the IA regulation by the dates established by the IA final regulation.

- The 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.

FSMA Draft Guidances – Human Food By-Products for Use as Animal Food

- Human food by-products sent to animal food use must comply with CGMPs – however, they may only be subject to limited holding and distribution CGMPs IF the human food facility meets two conditions
  - Human food facility must be subject to and in compliance with applicable human food safety regulations and
  - Human food facility must not further manufacture or process the human food by-products for use as animal food
- If the facility meets these two conditions – then once the by-product for use as animal food is separated from the human food – the human food by-product for use as animal food is only subject to the limited requirements found in 507.28 for holding and distribution.

FSMA Draft Guidances – Human Food By-Products for Use as Animal Food

- Section 507.28 (Animal Food PC Rule) – limited requirements IF conditions are met:
  - Holding requirements (507.28(a))
    - Protect from contamination
  - Labeling requirements (507.28(b))
    - Identify the material through labeling
  - Shipping containers and bulk vehicles (507.28(c))
    - When facility is responsible for the transport of the human food by-products or arranges with a 3rd party - examine prior to use to protect against contamination
- http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM499201.pdf

FSMA Draft Guidances – Human Food By-Products for Use as Animal Food

- The guidance also notes that as part of FDA's implementation of FSMA, FDA issued a final rule on the Sanitary Transportation of Human and Animal Food on April 6, 2016.
- That rule establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. Human food facilities engaging in transport operations for human food by-products for use as animal food must be in compliance with applicable requirements in that rule.

FSMA Guidance Documents

Planned Guidance Documents:

- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (1st 5 Chapters out for comment) (August 2016)
- Draft Guidance for Industry: Human Food By-Products for Use as Animal Food (August 2016)
- Small Entity Compliance Guides (future)
- Draft Guidance for Industry: Juice HACCP and the Food Safety Modernization Act (future)
- MANY MANY other guidances (future)
- http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance