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Regulatory Alert: FDA Takes Numerous FSMA Actions

FDA Delays Compliance Dates for Produce Safety Rule, FSMA Exemption Guidance Provides Helpful Insights, Food Safety Plan Builder Released, Small Entity Compliance Guides Summarize Compliance Requirements for Several Rules

October 17, 2017

FDA has released a multitude of FSMA resources, announcements and guidance documents in August and September including:

Constituent Update: Produce Safety Rule Compliance Dates Delayed, September 12, 2017
Compliance Guide for Small Entities on the Produce Safety Rule, September 2017
Sixth Chapter of Guidance for the Human Food Preventive Controls Rule, August 30, 2017
Small Business Compliance Guide for Food Defense Rule, August 24, 2017
FDA Food Safety Plan Builder, August 22, 2017
Major Sampling Study of Sprouts, August 18, 2017
Guidance Clarifying Retail Waivers for the Sanitary Food Transportation Act, August 14, 2017
FDA Guidance Documents Explaining Exemptions for FSMA, August 7, 2017

This Regulatory Alert reviews or summarizes the key aspects of each release.

FDA Takes Action to Delay Produce Safety Rule Water Standards

On September 13, 2017, FDA published a proposed rule in the Federal Register that extends the compliance dates for the agricultural water requirements in the Food Safety Modernization Act (FSMA) Produce Safety Rule for produce other than sprouts. For sprouts the agricultural water compliance dates remain unchanged. Note the proposed rule does not impact compliance dates for the other requirements of the Produce Safety Rule. FDA Commissioner Gottlieb announced the delay along with other FDA planned actions related to the Produce Safety Rule at the National Association of State Departments of Agriculture annual conference. His remarks may be found here.

Compliance Dates

If the proposed rule is finalized, the new compliance dates for the agricultural water standards will be as follows:

Business Category	Old Compliance Date	New Compliance Date
Very small businesses ($25k-$250k annual produce sales)	January 26, 2022	January 26, 2024
Small businesses ($250,001-$500k annual produce sales)	January 26, 2021	January 26, 2023

All other businesses ($500,001 + annual produce sales)	January 26, 2020	January 26, 2022

Enforcement Discretion

In addition to announcing the compliance date delay for the water standards, Commissioner Gottlieb also announced that the agency does not intend to take action to enforce the agricultural water requirements for produce other than sprouts while the rulemaking to extend the compliance dates is underway.

Produce Farm Inspections

Farms that are not small or very small businesses will be expected to meet all produce safety requirements set by the rule for produce other than sprouts, except those related to agricultural water, by the original January 26, 2018, compliance date. Commissioner Gottlieb announced however that inspections to assess compliance with the non-water requirements for produce other than sprouts will not begin until 2019.

Produce Safety Rule Compliance Guide for Small Entities

In September FDA released a compliance guide for small entities on the Produce Safety Rule. The compliance guide distills the requirements of the Produce Safety Rule into a 35 page document and may be helpful to not only small growers, but large ones as well. It also is a helpful reference for Foreign Supplier Verification Program (FSVP) importers.

Preventive Controls for Human Food Guidance Draft Guidance: Chapter 6 Published: Use of Heat Treatments as a Process Control

On August 30, 2017, FDA published the sixth chapter of the Draft Guidance on Preventive Controls for Human Food. The chapter covers the use of heat treatments as a process controls. The chapter contains sections on:

- Design and Validation of the Heat Treatment
- Developing a Strategy for Preventive Control Management Components
- Establish and Implement Monitoring Procedures Including What to Monitor, How to Monitor, How Often to Monitor and Who Performs the Monitoring
- Corrective Actions
- Verification
- Recordkeeping
- Examples of Heat Treatment Controls Including in:
    - Cookie Production
    - Soup Production
    - Salsa Production
- Summary Process Control Tables

Small Business Compliance Guide for Food Defense Rule

On August 24, 2017, FDA released a compliance guide for small businesses on the Food Defense Rule. The compliance guide summarizes the Food Defense Rule into 23 pages and may be helpful to businesses of all sizes.

The compliance guide covers:

- Who must comply with the rule
- When compliance is required
- Food defense measures
    - Food defense plan
    - Vulnerability assessment
    - Mitigation strategies for actionable process steps
    - Reanalysis
- Recordkeeping
- Education, training and qualifications

Note that the Food Defense Rule does not apply to facilities only engaged in the holding of food such as the typical grocery distribution center. Compliance is required for the rule as early as July 26, 2017. Small businesses have additional time to comply.

FDA Launches Food Safety Plan Builder

On August 22, 2017, FDA released the Food Safety Plan Builder (FSPB). The FSPB is a free software application, developed by FDA, that businesses can download from the FDA's website to guide them, step-by-step, through the creation of a food safety plan, as required by FSMA.

The user is taken through a series of sections in the application that prompt them to answer questions and/or fill in information specific to their business and facility. Once all the tabs have been completed, the file may be saved or printed, and the firm will have a food safety plan to use in its operations and to provide when FDA conducts an inspection.

FDA Concludes Major Sampling Study of Sprouts

On August 18, 2017, FDA announced it had concluded a major sampling study of sprouts.

The agency's testing program was designed to estimate the prevalences of *Salmonella*, *Listeria monocytogenes* and *Escherichia coli* (*E. coli*) O157:H7 in sprouts, and to identify patterns in hopes of preventing these pathogens from contaminating sprouts.

The FDA collected 825 samples from 37 states, Puerto Rico and the District of Columbia, and found that most of the positive samples came from a small number of sprouting operations: A total of 14 positive samples were found at eight of the 94 growers, and ten of these samples came from just four growers. The FDA tested samples collected at three points in the production process (seeds, finished product and spent irrigation water) to gain insights into the sources of contamination in sprouts.

The agency found:

- *Salmonella* on 2.35 percent of seed samples.
    - Studies have identified *Salmonella*-contaminated seed as the most likely source of most sprout-associated salmonellosis outbreaks. The prevalence of *Salmonella* in finished sprouts was 0.21 percent and in spent irrigation water was 0.53 percent.
- *Listeria monocytogenes* on 1.28 percent of finished sprouts.
    - In contrast to FDA's findings regarding *Salmonella*, there was no significant difference in the prevalence of *Listeria monocytogenes* by point in the production process. The similarity of findings at different steps of production indicate that the contamination most likely occurred as a result of environmental transmission, which is similar to findings in other studies indicating that this pathogen is most often transmitted to produce via the production environment.
- None of the finished sprout or spent irrigation water samples tested positive for *E. coli* O157:H7.
    - The FDA did not test seed for *E. coli* O157:H7 due to limitations with the test method.

Guidance on Clarification on Food Establishment Waiver from Requirements of the Sanitary Food Transportation Act

In August 2017, FDA released guidance on the food establishment waiver under the Sanitary Food Transportation Act Rule (SFTA Rule).[1] FDA issued a waiver from the SFTA Rule to retail food establishments that provide food directly to consumers, such as the typical retail supermarket.

The agency issued this guidance to respond to questions as to whether the waiver can encompass establishments that only sell animal food or sell both human and animal food. The agency stated the waiver applies to establishments that (1) sell human food and (2) sell human and animal food. **The waiver does not apply to establishments that sell only animal food.**

The agency stated:

> We are issuing this guidance to clarify that the retail food establishment waiver applies to establishments that are permitted or otherwise authorized by the regulatory authority to sell human food, We are also clarifying that these establishments that are permitted or otherwise authorized by the regulatory authority to sell human food, that sell both human and animal food also fall under the retail establishment waiver. The retail food establishment waiver does not extend to establishments that sell food for animals and do not sell food for humans . . . With regard to such retail establishments that also sell food for animal consumption, the waiver would cover any animal food that they handle.[2]

[1] 81 Fed. Reg. 20091.
[2] P. 4-5

FDA Guidance Documents Explaining FSMA Exemptions for Foods Subject to HACCP Regulations

In August 2017, FDA issued a series of guidance documents explaining FSMA exemptions for foods subject to the Low-Acid Canned Foods (LACF) HACCP Rule, the Seafood HACCP Rule, and the Juice HACCP Rule. The guidance documents address questions and answers. Key questions and answers for each rule are summarized below:

Foods Subject to the LACF HACCP Rule (21 CFR part 113)

Are manufacturers of LACF subject to the Current Good Manufacturing Practice and Preventive Controls Regulation for Human Food (21 CFR Part 117)?

Yes. They are subject to certain provisions and generally exempt from others. They are exempted from the main provisions: subpart C (Preventive Controls) and subpart G (Supply Chain Program) in most circumstances; however, in certain circumstances they are subject to these subsections (more details follow). They are subject to subparts A (General Provisions), B (Current Good Manufacturing Practices) and F (Recordkeeping).

Note that manufacturers of acidified foods (21 CFR part 114) are not specifically exempt from any provisions of the Preventive Controls for Human Food Rule.

What additional training requirements apply to manufacturers of LACF under part 117?

LACF manufacturers are required to comply with the new training requirements in 21 CFR § 117.4 which require that individuals engaged in the manufacturing, processing, packing or holding of food and the supervisors who oversee their activities (1) be qualified individuals and (2) receive training in the principals of food hygiene and food safety. LACF manufacturers must also maintain related training records.

Under what circumstances are LACF manufacturers subject to subparts C and G of part 117?

LACF manufacturers are subject to subpart C (Preventive Controls) and subpart G (Supply Chain Program) if they identify chemical hazard or physical hazards as hazards for which they must establish preventive controls (i.e. they are only exempt from subparts C and G with respect to biological hazards). For physical and chemical hazards, LACF manufacturers must comply with subparts C and G.

What procedures and controls does FDA require manufacturers of LACF to have and implement to control allergen cross contact?

Food allergens, which are considered chemical hazards and are thus not covered by the LACF exemption are a hazard that must be addressed in the food safety plan required under subpart C (Preventive Controls). If a LACF manufacturer identifies food allergens as a hazard they must establish preventive controls.

Does part 117 require manufacturers of LACF to have written sanitation controls?

Written sanitation controls for microbiological hazards are not required because manufacturers of LACF are exempt from subpart C with regard to microbiological hazards regulated under part 113 (21 CFR § 117.5(d)). However, sanitation controls may be required to prevent cross contact if the firm has identified food allergens.

Do the records requirements listed in part 117 subpart F apply to manufacturers of LACF?

Yes, the recordkeeping requirements in 21 CFR part 117 subpart F apply to manufacturers of LACF with respect to applicable preventive controls (physical and chemical hazards), as well as to training records required by 21 CFR 117.4(d)(2).

Does subpart G (Supply Chain Program) of part 117 apply to manufacturers of raw materials and ingredients?

If a manufacturer of LACF identifies non-biological (i.e. chemical and physical) hazards associated with raw materials and ingredients received by the facility and the hazards are controlled by the supplier, the manufacturer would be subject to the supply chain program requirements under subpart G.

How does FSVP impact importation of LACF?

Importers of LACF not subject to further manufacturing and processing are subject to the FSVP Regulation (21 CFR part 1, subpart L (21 CFR § 1.500-1.514).

With respect to microbiological hazards that are controlled by part 113, importers of LACF must verify that their suppliers produced the LACF products in accordance with part 113. With respect to non-biological hazards (i.e. chemical and physical hazards) in these products, importers must have an FSVP.

How does FSVP affect my importation of raw materials or other ingredients used in LACF?

With respect to microbiological hazards that are controlled by part 113, importers are not required to comply with the FSVP regulation for raw materials or other ingredients that the importer uses in manufacturing or processing of LACF provided that the importer is in compliance with part 113 with respect to the LACF manufactured or processed from the imported raw materials or other ingredients. With respect to all hazards other than microbiological hazards, the importer must have an FSVP for the imported raw materials and other ingredients that the importer uses in the manufacture or processing of LACF.

Must a manufacturer of LACF also comply with 21 CFR part 121 (the Food Defense Rule)?

Yes. Domestic and foreign LACF manufacturers required to register with FDA as food facilities must comply with the Food Defense Rule unless an exemption applies.

Is the shipment of LACFs covered under the Sanitary Food Transportation Act (SFTA) Rule?

Transportation of food completely enclosed by a container is not subject to the SFTA regulation unless the food requires temperature control for safety. LACFs are thus not subject to the regulation.

Foods Subject to the Seafood HACCP Rule (21 CFR Part 123)

Are seafood processors subject to the Current Good Manufacturing Practice and Preventive Controls Regulation for Human Food (21 CFR Part 117)?

Yes. They are subject to certain provisions and generally exempt from others. They are exempted from the main provisions: subpart C (Preventive Controls) and subpart G (Supply Chain Program). They are subject to subparts A (General Provisions), B (Current Good Manufacturing Practices) and F (Recordkeeping).

What additional training requirements apply to seafood processors under part 117?

Workers who are engaged in the manufacturing, processing, or holding of seafood (including temporary and seasonal personnel) must have the necessary combination of training, education and/or experience necessary as appropriate to their roles (i.e. they must be qualified individuals) and must receive training in the principals of food safety and food hygiene. Supervisory personnel similarly must be qualified individuals. ***Note that the existing Seafood HACCP Rule***

does not contain such a requirement, we advise businesses subject to part 123 to review and edit their seafood HACCP plans accordingly.

What additional part 117 risk-based preventive controls, if any, do seafood processors in compliance with part 123 need to implement for the non-seafood raw materials and ingredients they use in their fishery products?

None. There are no additional requirements when seafood processors are in compliance with part 123.

Does the exemption part 117 subpart B (CGMPs) for establishments solely engaged in the holding of raw agricultural commodities apply to seafood processors?

Yes. Examples of seafood items that are considered raw agricultural commodities are whole, raw uneviscerated fish, whole raw crabs or lobsters, and raw head-on, shell-on shrimp.

Are radiological hazards relevant to the hazard analysis under part 113?

Yes, radiological hazards are a type of chemical hazard and must be considered.

Do the records requirements listed in subpart F of part 117 apply to a seafood HACCP program?

No.

Do the part 117 subpart G supply chain program requirements apply to seafood processors?

No. Activities that are subject to part 123 are exempt from subpart G of part 117.

Does the FSVP regulation impact the importation of fish and fishery products?

No. Fish and fishery products are exempt from FSVP.

How does FSVP impact the importation of raw materials or ingredients for seafood products?

It does not. Such raw materials and ingredients are exempt from FSVP requirements.

Are seafood facilities subject to the Food Defense Rule?

Yes.

Is the shipment of seafood covered under the Sanitary Food Transportation Act (SFTA) Rule?

Yes, except for businesses that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program (NSSP). These businesses are waived from the requirements of the SFTA regulation, only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

Foods Subject to the Juice HACCP Rule (21 CFR Part 120)

What juice products are exempt from most FSMA requirements?

One hundred percent (100%) juice products. Products that are not 100% juice (i.e. blends of juice and sugar or other ingredients (for example nectar drinks)) are subject to FSMA requirements as other processed foods are.

Are juice processors subject to the Current Good Manufacturing Practice and Preventive Controls Regulation for Human Food (21 CFR Part 117)?

Yes. They are subject to certain provisions and generally exempt from others. They are exempted from the main provisions: subpart C (Preventive Controls) and subpart G (Supply Chain Program). They are subject to subparts A (General Provisions), B (Current Good Manufacturing Practices) and F (Recordkeeping).

What additional training requirements apply to juice processors under part 117?

Workers who are engaged in the manufacturing, processing, or holding of juice (including temporary and seasonal personnel) must have the necessary combination of training, education and/or experience necessary as appropriate to their roles (i.e. they must be qualified individuals) and must receive training in the principals of food safety and food hygiene. Supervisory personnel similarly must be qualified individuals. ***Note that the existing Juice HACCP Rule does not contain such a requirement, we advise businesses subject to part 120 to review and edit their juice HACCP plans accordingly.***

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

Juice processors would address allergens through the application of CGMPs as required under part 117. Part 120 requires that a juice processor consider the presence of undeclared ingredients that may be food allergens as part of its hazard analysis.

Does the FSVP Regulation apply to the importation of juice products subject to part 120?

No.

How does FSVP impact the importation of raw materials or ingredients for juice products subject to the part 120?

Such raw materials and ingredients are exempt from FSVP requirements.

Does the Food Defense Rule also apply to facilities subject to part 120?

Yes.

Is the shipment of packaged juice subject to part 120 covered under the Sanitary Food Transportation Act Rule?

Generally no. Transportation operations for food completely enclosed by a container are not subject to the Sanitary Food Transportation Act regulation unless the food requires temperature control for safety.

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