

# Ready to Eat & Not Ready to Eat Produce

May 9, 2019

# Overview

- Definitions
- Regulations
  - Produce Safety Rule (PSR) (21 CFR 112)
  - CGMP & Preventive Controls for Human Food (PCHF) Rule (21 CFR 117)
- Enforcement discretion
- Guidance

# Raw Agricultural Commodity (RAC)

*Raw Agricultural Commodity (RAC)* means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing. (201(r) of the FD&C Act)

# Processed Food

*Processed food* means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling. (201(gg) of the FD&C Act)

# Ready-to-Eat Food

*Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. (21 CFR part 117.3)

# Farms

- A farm is exempt from FDA's food facility registration requirement
- Depending on certain factors, farms may be subject to the Produce Safety Rule (PSR)
- The CGMP & PCHF rulemaking revised the farm definition to reflect modern farming practices

# Covered Produce

- “Covered produce” is produce that is a raw agricultural commodity and within the scope of the Produce Safety Rule. (21 CFR 112.1).
- Produce that is not covered under the Produce Safety Rule includes that which is:
  - Rarely consumed raw;
  - Produced for personal or on-farm consumption; or
  - Not a RAC.

# Rarely Consumed Raw Produce

- “Rarely consumed raw” (RCR) produce includes those commodities that FDA determined are almost always eaten only after being cooked and thus not subject to the provisions of the Produce Safety Rule.
- Consumption of the commodity in any form – raw, processed, or other – had to be reported by at least 1% of weighted survey respondents to be included in the RCR list.

# Commercial Processing Exemption

- Produce is eligible for exemption from the PSR if it will be commercially processed to adequately reduce the presence of microorganisms of public health significance.
- Must disclose that the food is “not processed to adequately reduce the presence of microorganisms of public health significance.” (21 CFR 112.2(b)(2)).

# Who is Covered by the CGMP & PCHF Rule?

- Facilities that manufacture, process, pack or hold human food
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

# Manufacturing/Processing

- *Manufacturing/processing* means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding (21 CFR part 117.3).

# Farms, RACs, and Manufacturing/Processing

- Manufacturing/processing activities do not always transform a RAC into a processed food.
  - e.g., coloring, washing, waxing
- Manufacturing/processing permitted under the PSR:
  - Drying/dehydrating RACs to produce a distinct commodity
  - Treatment to manipulate ripening
  - Packaging and labeling RACs

# Food Safety Plan: Hazard Analysis

- Hazard identification must
  - Consider known or reasonably foreseeable biological, chemical and physical hazards.
  - Include an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging...

# Environmental Pathogens

- A pathogen capable of surviving and persisting with the manufacturing processing, packing, or holding environment...
  - *Listeria monocytogenes*
  - *Salmonella*

# Food Safety Plan: Preventive Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan

# Sanitation Controls

- Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards.

# Enforcement Discretion for Certain Entities

- We are exercising enforcement discretion for:
  - The PC requirements for facilities that would qualify as secondary activities farms except for the ownership of the facility.
  - The written assurance requirements of the CGMP & PCHF Rule, the CGMP & PCAF Rule, the Produce Safety Rule, and the FSVP Rule.



# The Federal Food, Drug, & Cosmetic Act

Regardless of our intent to exercise enforcement discretion, the statutory prohibition in the FD&C Act against the introduction or delivery for introduction into interstate commerce of adulterated food applies.

# Guidance

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry (Draft)
- Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities: Guidance for Industry (Draft)
- Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry

# Guidance, cont'd

- Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry (Draft)
- Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry (Draft)
- Guide to Minimize Food Safety Hazards of Fresh-cut Produce (Draft)

# Draft Guidance

- RTE/NRTE draft guidance for industry
  - Draft Chapter in “Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry”
- Draft *Listeria monocytogenes* Compliance Policy Guide (CPG)
  - Guidance to FDA field staff on how to address the presence of Lm in FDA-regulated foods and facilities
- Will be published as drafts for public comment

# Summary

- Enforcement discretion: PC requirements for facilities that would qualify as secondary activities farms except for the ownership of the facility.
- Both produce RACs and processed produce can be RTE or NRTE.
- RTE/NRTE draft guidance for industry is in development.
- Designation of a food as NRTE does not excuse lack of GMPs leading to insanitary conditions in a facility.