



Marc C. Sanchez, Esq.
Contract In-House Counsel & Consultants, LLC



FSMA Update

Produce Safety Rule
HARPC Rule

IMPACT



FDA analysis found 131 outbreaks associated with contaminated produce between 1996 and 2010, causing more than **14,000 illnesses** and **34 deaths**.

FDA estimates that close to **1,000,000 illnesses** each year are attributable to food that would fall under the scope of the HARPC rule.

All prior outbreak litigation occurred under *voluntary guidance documents*

Once finalized, produce safety rule & HARPC (preventative controls rule) provides plaintiff's lawyers and FDA with **enforceable regulations** **NOT** **guidance documents**

COMMENTS

Draft
Rule



Comment
Period



Hearings



Final
Rule

FDA issues proposed rule along with economic analysis (total 2,000+ pages)

120-days to submit comments on the proposed rule

Public hearings held offering further opportunity to comment

60-days after comment period closes final rule issued

COMPLIANCE DATES

Produce Safety Rule

"Very Small"

No more than
\$250,000 in
annual sales
during previous 3
years

"Small"

No more than
\$500,000 in
annual sales
during previous 3
years

"All Others"

Not "very small" or
"small"

COMPLIANCE DATES

Produce Safety Rule

"Very Small"

4-years
✓ most provisions

6-Years
✓ some agricultural
water provisions

"Small"

3-years
✓ most provisions

5-Years
✓ some agricultural
water provisions

"All Others"

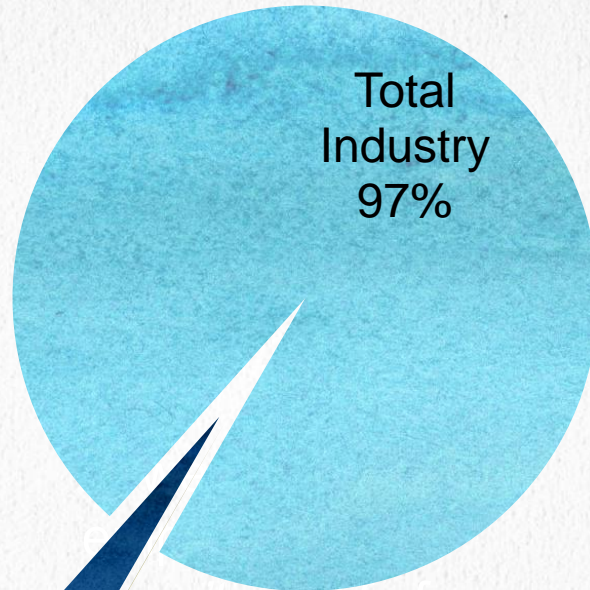
2-years
✓ most provisions

4-Years
✓ some agricultural
water provisions

COMPLIANCE DATES

HARPC Rule

"Very Small"



3 proposals based on total annual sales

All options combined

3%

Not "very small" or "small"

WHICH RULE?

1. Produce Safety Rule
(generally)

2. Preventative Controls Rule
(generally)

3. If “Low Risk” then may be
exempt under on farm risk
assessment

1. Only pack your own produce

2. Pack your own produce *and*
another farm’s produce *or*
other processing *and* not
“small” or “very small”

3. “Very small” or “small” and
pack your own produce and
another farm’s produce or
other processing

EXEMPTIONS

Produce Safety Rule

- * Specified commodities that are rarely consumed raw;
- * Produce that is used for personal or on-farm consumption or that is not a raw agricultural commodity (RAC);
- * Produce that received commercial processing that adequately reduces the presence of microorganisms (e.g. a "kill step") as long as certain documentation records are kept;

EXEMPTIONS

Produce Safety Rule

- * Farms that have an average annual value of food sold during the previous three-year period of \$25,000 or less;
- * Qualified exemption and modified requirements for farms that meet two requirements:
 - (a) farm must have food sales averaging less than \$500,000 per year during the last three years, and
 - (b) farm's sales to qualified end users must exceed sales to others.

EXEMPTIONS

HARPC Rule

- * Foods subject to the low-acid canned food regulation (limited exemption);
 - * Seafood and Juice facilities subject HACCP
 - * Dietary Supplements, and alcoholic beverages;
- GMP Revisions in the Rule still apply!!**

EXEMPTIONS

HARPC Rule

- * Modified requirements for a facility with food sales averaging less than \$500,000 per year during the last 3 years. In addition, sales to qualified end users must exceed sales to others (qualified end user defined in the reg.)
- * Very small facilities and activities within the definition of “farm” (both defined in the reg.);

GMP Revisions in the Rule still apply!!

FOOD SAFETY PLAN



A **Hazard analysis** that identifies and evaluates known or reasonably foreseeable hazards...

Preventive controls, required to be identified and implemented to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented.

Preventive controls would be required to include, as appropriate: (1) process controls, (2) food allergen controls, (3) sanitation controls, and (4) a recall plan.

Supplier approval and verification program is a risk-based and appropriate control to significantly minimize or prevent hazards from raw materials and ingredients...

FOOD SAFETY PLAN



Also includes monitoring, corrective actions, verification, and record keeping.

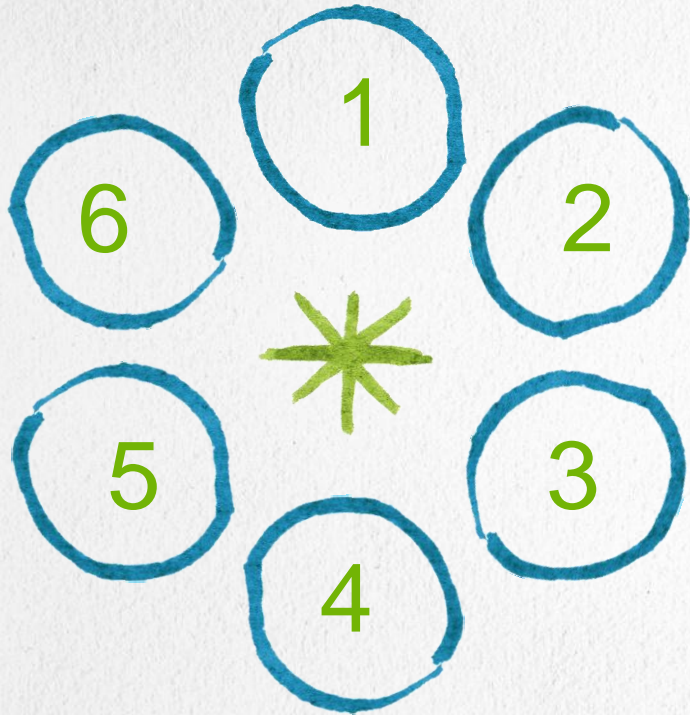
The FDA proposes a definition and description of a qualified individual to complete the four activities above. To be qualified, an individual must have "successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA" or "be otherwise qualified through job experience to develop and apply a food safety system." The person performing these tasks doesn't need to be an employee.

RECALL PLANS



- ✓ Preventive controls include a recall plan along with details about what should be included (notifications, effectiveness checks, etc.)
- ✓ The rule also lays out new recordkeeping requirements for all corrective actions
- ✓ Remember FDA's new mandatory recall authority. A recall plan is a means to comply during grace period before mandatory recall ordered.

PRODUCE SAFETY



Produce safety rule sets new standards for

1. Agricultural water;
2. Biological Soil Amendments
3. Equipment/Tools/Buildings
4. Domesticated and Wild Animals
5. Health/Hygiene
6. Sprouts

ENFORCEMENT

Open Secret
FSMA unfunded

Look at Margaret
Hamburg's statements
since FSMA passed

New authority still
quickly used

See Sunland for speedy
use of facility registration
suspension
See Chetak for quick use of
administrative detention
authority

Are the
consequences
worth it?

Risks include fees,
suspension, and high risk
facility designation and
litigation under new
mandatory standards

MORE DETAIL

Comment

Understand the impact
Chime in on FDA
assumptions

In, out, exempt, partially exempt?

Get an analysis of how
the rule applies to your
operations

Plan ahead

Compliance takes time
Impacts operations (or your
suppliers)

HEALTH & HYGIENE



Requires training including principles of food hygiene and food safety, health and personal hygiene, and other topics as applicable (proposed §§ 112.21 and 112.22).

Requires measures to prevent contamination of covered produce and food-contact surfaces from any person with an applicable health condition, such as a communicable illness, infection, open lesion, vomiting, or diarrhea (proposed § 112.31)

Requires personnel who work in operations in which covered produce or food-contact surfaces are at risk of contamination with known or reasonably foreseeable hazards to use hygienic practices to the extent necessary to protect against contamination.

SOIL



Biological soil amendments of animal origin, such as composted manure, are identified as a source of pathogens.

The rule proposes three types of measures to reduce the risk:

- ✓ types of treatment;
- ✓ methods of application, and
- ✓ time intervals between the application of a biological soil amendment of animal origin and crop harvest.

The proposed rule also has provisions pertaining to the handling and storage of biological soil amendments of animal origin.

EQUIPMENT/TOOLS



Equipment and tools must be stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards...

Must inspect, maintain, clean and sanitize, when necessary and appropriate, all food-contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce

Instruments or controls used to measure, regulate, or record temperatures, (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination must be accurate and ...