
Regulatory Update: What's up in Washington?

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Five FSMA Proposed Rules

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Animal Feed
- Foreign Supplier Verification
- Third Party Accreditation
- And more to come...

Part 112: Standards For The Growing, Harvesting, Packing, And Holding Of Produce For Human Consumption

- 142 pages, as published in Federal Register
 - First 124 pages are “preamble”
 - Explains FDA’s thought process
 - Asks specific questions, soliciting comment on what they have/have not proposed
- Actual proposed rule is last 18 pages
 - 15 Subparts

What's covered, what's not

- Applies to raw agricultural commodities, including fruits and vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables
 - Applies to domestic and imported produce
 - Covers the edible portion (including peel) but not the rest of the plant
 - Exhaustive list of “rarely consumed raw” not covered
 - Does not apply to produce that is commercially processed (must have records of who processed it)
- No mention of “high risk” commodities

***Subpart A**

Rarely Consumed Raw

arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussel sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams

Commercially Processed

“The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products”

Who's covered, who's not

- Applies to “farms”, domestic and foreign, as defined in 21 CFR part 1.227
 - Including “farm” portion of mixed-type operations
- Does not apply to operations <\$25,000 total food sales (3 year average)
- Small or very small operations, with majority of food sold to consumers (retail) in-state/275 miles, qualify for exemption from most requirements
 - Package or Point-of-Service labeling of “where grown” required
 - Qualified exemption can be withdrawn

***Subpart A**

First, the good...

- Addresses the same 5 likely sources and vectors of fresh produce contamination in the field, during and post-harvest, as in the 1998 FDA GAPs Guide and most fresh produce guidances:
 - Agricultural water
 - Soil amendments (manure/compost)
 - Animals
 - Workers' health and hygiene, and
 - Equipment and food contact surfaces

First, the good...

- Takes a “risk based” approach that does not create a list of “high risk” commodities based on outbreaks, recalls
 - Allows for different practices = different risk
 - Once high risk, always high risk?
 - Recognizes produce “rarely consumed raw”
 - Recognizes low risk of water, soil amendment use that does not contact the produce
 - No prescriptive requirements for the uncontrollable; e.g., wildlife in the field

First, the good...

- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
 - Agricultural water used during growing
 - Microbiological quality of compost
 - Interval between compost use and harvest
- No need for FDA “approval” until requested by FDA on-farm

First, the good...

- Less recordkeeping than anticipated
 - Mostly monitoring, corrective action records
 - No written hazard analysis, food safety plan required
 - Records already kept for other purposes need not be duplicated
- But...
 - Records must be reviewed, dated, signed by supervisor, and retained on-site (off-site) and accessible for 2 years

Then, the bad...

- “Tester Amendment” exemptions
 - Operations with less than \$500,000 annual food sales
 - Selling majority of foods direct to consumers (including store door delivery)
 - In-state or within 275 miles
- These would otherwise be considered “small” and “very small” operations, covered by the rule
- Pathogens don’t know what size operations they’re on or where the produce is going

Then, the bad...

- Provides no recognition of commodities (and their practices) that are normally eaten raw and have never been implicated in an outbreak or illness
 - Science hasn't explained why tree crops like citrus and stone fruit have not been associated with illnesses, despite being grown in the open and handling practices that the proposed rule considers "risky"
 - Proposed rule does not provide for adding to "exempted" produce in the future

Then, the bad...

- Variances can only be applied for by state and foreign governments
- Variances and alternatives not permitted for all standards, e.g.,
 - Which microorganisms to test for in water or compost
 - The frequency of water testing
 - All non-numerical standards

Then, the bad...

- Comment period closes May 16, 2013
- We've only seen the first two proposed rules of the FSMA "suite"
 - Preventive Controls for Animal Feed
 - Foreign Supplier Verification
 - Third Party Certification
- Difficult (impossible?) to provide complete comments to first two rules without seeing the others

And then, the details...

- Exempted “rarely consumed raw” list is “exhaustive” – no way to add in the future
- A farm that packs its own produce is a “farm”, but if it packs its neighbor’s produce, it is a “mixed-type facility”, subject to the Preventive Controls rule
- Washing and packing are “harvesting”, but waxing is “processing”
- Numerical standards in the rule can’t be changed
- Untreated surface water subject to runoff: must be tested every 7 days

Worker health and hygiene

- Training
 - All personnel, including temporary, part time, seasonal and contracted, who handle covered produce or food-contact surfaces
 - Principles of food hygiene and food safety; recognizing symptoms; and the standards in this rule
 - Additional requirements for harvest crew
 - “At least one supervisor or responsible party” standardized curriculum recognized by FDA
 - Records of training

***Subpart C**

Worker health and hygiene

- Health
 - “Excluding any person...”
 - “Instructing personnel to notify their supervisor...”
- Hygiene
 - Personal cleanliness
 - Avoiding contact with animals
 - Washing hands (gloves)
- Visitor policies, access to toilets, hand washing

Agricultural water

- Inspect entire water system “under your control”: water source, distribution system, facilities and equipment
 - At beginning of growing season and “maintain”
 - “Immediately discontinue use” until...
- Testing:
 - Everyone: Beginning of growing season and every 3 months
 - Untreated surface water subject to runoff: every 7 days
 - Untreated surface water NOT subject to runoff: monthly

***Subpart E**

Agricultural water standards

- No E. coli in 100 mL, for
 - Directly contacts produce during/after harvest
 - Used to make treated “agricultural tea”
 - Food contact surfaces
 - Washing hands
- <235 E. coli/100 mL (single sample) and <126/100 mL (5 samples rolling geometric mean)
 - Direct water application during growing
- Option for alternative standards
- No standard for non-direct water application (drip)
- No testing if public water source or treated water
- Records of test results required

***Subpart E**

Animal-derived soil amendments

- Human waste prohibited, unless in compliance with 40 CFR part 503 (biosolids)
- 9 month “interval” for use of untreated amendment that contacts produce
- Compost standards for *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7 and fecal coliform
 - No interval if meets all standards
 - 45 day if meets *Salmonella*/fecal coliform standard and may contact produce
 - No interval if does not contact produce
- Option for alternative standards

***Subpart F**

Animals (wildlife and domestic)

Domestic/working animals

- “Adequate waiting period” after allowing animals to graze
- “Measures to prevent” if animals allowed where crop has been planted

Animal intrusion

- “Must monitor” during growing season and immediately prior to harvest
- If intrusion occurs, evaluate whether to harvest

Other

- “Drops” prohibited
- Do not contact soil unless...
- Transport, buildings, tools, equipment, other food contact surfaces, sanitation, plumbing, toilet/handwashing facilities, trash, pests
- Recordkeeping
 - Reviewed, dated, signed by supervisor
 - Retention: 2 years
 - Accessible: on-site, off-site after 6 months if retrievable within 24 hr

***Subparts K, L and O**

Meanwhile, what about facilities?

Part 117 — *Current Good Manufacturing Practice And Hazard Analysis And Risk-based Preventive Controls For Human Food*

- 178 pages, as published in Federal Register
- Actual proposed rule pages 3798-3811
- Many specific requests for comment, but entire document is open for comment

Six subparts:

A: Applicability, definitions and exemptions

B: cGMPs (replaces part 110)

C: Hazard Analysis and Risk-Based Preventive Controls (written food safety plan, hazard analysis, monitoring, corrective actions, validation...)

D: Modified Requirements (for qualified facilities and for facilities solely engaged in storage of packaged food not exposed to the environment)

E: Withdrawal of an Exemption

F: Records and Recordkeeping

Subpart B: cGMPs

- Includes almost everything in current 21 CFR part 110, current Good Manufacturing Practices
- Adds prevention of “cross contact” and other allergen controls.

Subpart C: Preventive Controls

- Written food safety plan
- Written hazard analysis
- Written preventive controls for identified hazards
- Written monitoring procedures and frequencies
- Written corrective actions
- Written verification procedures, including validation of most preventive controls

It could have been worse...

- Mandatory microbiological testing of raw materials, finished product
- Mandatory environmental monitoring for pathogens
- Mandatory supplier approval and verification program

117.5 Exemptions

- (j) Subpart C of this part does not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

117.5 Exemptions

- (k) Subpart B of this part does not apply to ‘ ‘farms’ ’ ..., activities of ‘ ‘farm mixed-type facilities’ ’ ... that fall within the definition of ‘ ‘farm,’ ’ or the holding or transportation of one or more ‘ ‘raw agricultural commodities,’ ’ as defined in section 201(r) of the FFDCA.

117.3 Definitions

- *Mixed-type facility* means an establishment that engages in both activities that are exempt from registration under section 415 of the FFDCA and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

117.5 Exemptions

- (g) Subpart C of this part does not apply to on-farm packing or holding of food by a small or very small business if the only packing and holding activities ...are the following low-risk packing or holding activity/food combinations on food not grown, raised, or consumed on that farm mixed-type facility or another farm or farm mixed-type facility under the same ownership— i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- (1) Hard candy, fudge, taffy and toffee;
- (2) Cocoa beans and coffee beans (raw and roasted);
- (3) Cocoa products;
- (4) Grains and grain products;
- (5) Honey (raw and pasteurized);
- (6) Intact fruits and vegetables (for purposes of paragraph (g) and paragraph (h) of this section only, ‘ ‘intact fruits and vegetables’ ’ refers only to fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts);
- (7) Jams, jellies and preserves;
- (8) Maple sap for syrup and maple syrup;
- (9) Peanuts and tree nuts;
- (10) Soft drinks and carbonated water;
- (11) Sugar beets, sugarcane, and sugar;

117.5 Exemptions

- (h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FFDCA that the business conducts are the following:
 - (1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) of the FFDCA (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:

- (i) Artificial ripening of intact fruits and vegetables;
- (ii) Boiling/evaporation of maple sap to make maple syrup;
- (iii) Chopping raw peanuts and raw tree nuts;
- (iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);
- (v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);
- (vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);
- (vii) Grinding/milling/cracking/ crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);
- (viii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);
- (ix) Making sugar from sugar beets and sugarcane; and
- (x) Salting raw peanuts and raw tree nuts.

117.5 Exemptions

- (h) Subpart C of this part does not apply to on-farm low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the FFDCA that the business conducts are the following:
 - (2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:
(i-xxiv)

- (i) Artificial ripening of intact fruits and vegetables;
- (ii) Chopping peanuts and tree nuts;
- (iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
- (iv) Cooling intact fruits and vegetables using cold air;
- (v) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
- (vi) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);

- (vii) Fermenting cocoa beans and coffee beans;
- (viii) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
- (ix) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

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- (x) Making hard candy, fudge, taffy, and toffee;
 - (xi) Making cocoa products from roasted cocoa beans;
 - (xii) Making honey;
 - (xiii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);
 - (xiv) Making maple syrup;
 - (xv) Making soft drinks and carbonated water;
 - (xvi) Making sugar from sugar beets and sugarcane;
 - (xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;

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- (xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
- (xix) Salting peanuts and tree nuts;
- (xx) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
- (xxi) Sifting grains and grain products;

Rulemaking Process

- FDA publishes proposed rule in Federal Register (January 16, 2013)
- Public comment period: 120 days (May 16; subject to extension)
- FDA publishes final rule within 1 year after comments close (2013-'14)
- Two year implementation (2016 likely first year of enforcement)
- Dates to be staggered for small (3 years) and very small (4 years) operations
- Plus 2 years for some water requirements

Commenting On Proposed Rule

- Federal Register notice and 3 public meetings in March
- FDA expects to receive hundreds of responses
- Everyone has the right to comment, but...
 - “I hate it” not likely to work
 - provide alternative and why it’s better

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Questions?

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