I. Introduction

On January 4, 2013, FDA issued its proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption to implement the FDA Food Safety Modernization Act (FSMA) section on Standards for Produce Safety. FDA requests feedback on the proposed approach and provisions, and comments are due to FDA by November 16, 2013.

The proposed rule applies to fruits and vegetables for human consumption that are raw agricultural commodities, and sets standards for the growing, harvesting, packing and holding of such produce to minimize the risk of serious adverse health consequences or death. Produce that is (1) rarely consumed raw, (2) grown for personal or on-farm consumption, or (3) destined to undergo commercial processing to reduce microorganisms are exempt from these requirements. Very small farms are not covered by the proposed rule, while others would be eligible for a partial exemption, which could be withdrawn due to specified safety concerns.

For raw produce, the FDA specifies standards for the regulation of:

- Water that is intended or likely to contact produce;
- Personnel qualifications, training, health;
- Biological soil amendments of animal origin;
- Domesticated and wild animals in the growing area; and
- Equipment, tools, building, and sanitation

The proposed rule includes specific standards for sprouts, and for each area of the rule there are recordkeeping requirements. Importantly, the proposed rule would not require a farm (defined as a facility in one location devoted to the growing and harvesting of food) in general to conduct operational assessments or to develop written food safety plans such as are required for food facilities that manufacture processed foods. And, under this proposal, farms are still excluded from the “one up/one back” recordkeeping requirements applicable to registered food facilities, which are used to track and trace food.

The proposed rule covers only microbiological hazards, not specific standards for chemical, physical, or radiological contamination of produce.

FDA notes that product testing for microorganisms can be problematic given that
contamination events typically result in low level, intermittent, non-homogeneous pathogen presence. Accordingly, negative product test results, even with a reasonable sampling plan, do not necessarily indicate the absence of a hazard. And such testing may significantly impact the shelf-life of products if done on a test and hold basis. Thus, FDA did not include product testing as a required component of the science-based standards (except under certain conditions for sprouts).

The effective date for the regulations would be 60 days from publication of the final rule (not this proposal), but the general compliance date would be two years after the effective date, with additional time for small businesses (three years after the effective date) and very small businesses (four years after the effective date). In addition, FDA proposes additional time for certain provisions about water safety/quality.

This proposed rule does not address intentional adulteration. FDA plans to issue a rulemaking in the future to cover produce hazards that may be intentionally introduced, including by acts of terrorism.

II. Food Subject to the Proposed Rule

Raw Produce Regulated: Unless excluded, food that is produce, raw, and for human consumption is subject to the proposed rule, whether it is grown in the United States or imported into the United States (including Puerto Rico).

The proposed rule sets out a list of examples of fruits and vegetables that are covered, such as:

- Almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon;

- Mixes of intact fruits and vegetables (such as fruit baskets)

- Tree nuts (defined as fruits), unless they meet the criteria for exemptions

Produce to be Cooked or Processed Not Regulated: Produce that is not a raw agricultural commodity (such as some tree nuts) or rarely consumed raw is not covered. The proposed rule lists those commodities FDA has determined are not typically consumed raw: Arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas,
bok choy, brussels 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.

Produce that is covered by the proposed rule is eligible for an exemption when it receives commercial processing that adequately reduces the presence of microorganisms to the extent sufficient to prevent illness. Examples include low-acid canned foods, acidified foods, produce treated with a validated process to eliminate spore-forming microorganisms, and produce processed under HACCP systems or by methods such as refining or distilling produce into products such as sugar, oil, spirits, or similar products.

Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership is also not covered by the proposed rule.

III. Persons/Entities Subject to Proposed Rule

Very small farms exempted: The proposed rule applies to farms or farm mixed type facilities with an average monetary value of food sold each year during the previous 3-year period of more than $25,000. A covered farm must comply with all applicable requirements of the proposed rule when it grows, harvests, packs, or holds raw produce that is covered by the proposed rule. Some farms grow but also have processing that is covered by the accompanying food facilities rule (preventive controls) and must follow the rules applicable to the different parts of their operation.

Small, direct or local farms may get exemption: An otherwise covered farm is eligible for a qualified exemption in a calendar year if:

- During the previous 3-year period, the average annual monetary value of the food sold directly to consumers or sold to restaurants or retail that are within the same state or within 275 miles exceeded the average annual monetary value of the food sold to all other buyers during that period; and

- The average monetary value of all food sold each year during the 3-year period was less than $500,000, adjusted for inflation.

This qualified exemption, the so-called Tester amendment, applies to non-U.S. and U.S. farms.

If a farm qualifies for this exemption, it must include its complete business address with the food. When the food must carry a label, the farm’s name and address must be prominently and conspicuously visible on the label. When a food packaging label is not required, the name and complete business address of the farm must be must prominently and conspicuously displayed at the point of purchase.
Withdrawal of the qualified exemption: FDA may withdraw a qualified exemption:

- In the event of an active investigation of a foodborne illness outbreak that is directly linked to the farm in question; or

- If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the farm

IV. General Requirements

Covered farms must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. This includes those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce. And the farms must provide reasonable assurances that the produce is not adulterated.

The proposed rule allows covered farms to establish alternatives to the following specific requirements:

- The requirements for testing, and taking action based on test results, for specified agricultural water;

- Composting treatment processes;

- The minimum application interval for untreated biological soil amendments of animal origin; compost agricultural teas; and biological soil amendment of animal origin treated by a composting process

These alternatives are permitted only if adequate scientific data exists to prove that the alternative would provide the same level of public health protection as the requirement established in the proposed rule, and would not increase the likelihood that the covered produce will be adulterated.

V. Standards Regarding Personnel

All personnel who handle covered produce or supervise such activities must receive training that, at a minimum, includes (1) the principles of food hygiene and food safety; (2) the importance of health and personal hygiene; and (3) the standards established by FDA in the proposed rule that are applicable to the employee’s job responsibilities. At least one supervisor must have completed food safety training using a curriculum that FDA recognizes as adequate.

Personnel who conduct harvest activities for covered produce must also receive training that includes (1) recognizing covered produce that should not be harvested; (2) inspecting harvest containers and equipment to ensure they do not become a source of
contamination; and (3) correcting or reporting problems with harvest containers or equipment.

VI. Standards Regarding Health and Hygiene

The proposed rule imposes requirements regarding health and hygiene, including:

- Measures to prevent contamination of covered produce and food contact surfaces from any person with an applicable health condition;

- Require hygienic practices, including washing hands, maintaining adequate cleanliness, avoiding contact with nonworking animals, and minimizing the likelihood of contamination from working animals;

- Measures that apply to visitors to a covered farm

VII. Standards Regarding Agricultural Water

Agricultural water means water used in the growing, harvesting, packing or holding of produce where water is likely to contact produce or food-contact surfaces. All agricultural water must be safe and of adequate sanitary quality for its intended use.

Covered farms must manage the water to maintain adequate sanitary quality and minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards. Such management may include water change schedules, measures to minimize hazards, visual monitoring, and temperature controls.

**Inspection and Maintenance:** At the beginning of each growing season, the entire agricultural water system under a covered farm’s control (including water source, water distribution system, facilities, and equipment) must be inspected to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of the circumstances.

In addition, agricultural water distribution systems must be adequately maintained to prevent the water distribution system from being a source of contamination to: covered produce, food-contact surfaces, areas used for a covered activity, or water sources. Agricultural water sources that are under control of the covered farm (such as wells) must be adequately maintained by regularly inspection and keeping the source free of possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

**Discontinuing use if unsafe and treatment:** If a covered farm has determined or has reason to believe that its agricultural water and/or its distribution system is “not safe and of adequate sanitary quality for its intended use,” its use must be discontinued immediately and it must not be used until either:
The entire agricultural water system is inspected, any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces are identified, necessary changes are made, and the water is tested to determine whether the changes were effective and to ensure that the agricultural water is safe and of adequate sanitary quality for its intended use; or

- The water is treated

If it is known or there is reason to believe that agricultural water is not safe and of adequate sanitary quality for its intended use, it must be treated (such as with an EPA-registered antimicrobial pesticide product). Any method used to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use and such safety must be confirmed through monitoring at an adequate frequency.

**Testing for E. Coli:** The quality of agricultural water must be tested using a quantitative, or presence-absence method of analysis to ensure there is no detectable generic E. coli in 100 milliliters (mL) of agricultural water when it is:

- Used as sprout irrigation water;
- Directly contacts covered produce during or after harvest activities (for example, for washing or cooling or to prevent dehydration before cooling), including when it is used to make ice that directly contacts covered produce during or after harvest;
- Used to make a treated agricultural tea;
- Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or
- Used for washing hands during and after harvest activities

If there is any detectable generic E. coli in 100 mL of water, use of that source of agricultural water and/or its distribution system must be immediately discontinued for uses listed above.

The proposed rule does permit the use of water that is found to contain specific, low amounts of E. coli under certain conditions.

If the water source or distribution system exceeds these E. coli levels, it may be used again if the water is treated or if:

- The entire agricultural water system under the covered farm’s control is re-inspected;
- Any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces are identified;

- Necessary changes are made; and

- The water is retested to determine that the changes were effective

**Testing Frequency:** Any agricultural water used for sprout irrigation, direct contact with covered produce or food-contact surfaces, agricultural tea, or hand washing must be tested: at the beginning of each growing season and every three months thereafter during the growing season. *Except* that there is no requirement to test agricultural water when the covered farm

- Receives water from a public water system that furnishes water that meets specified microbial requirements;

- Receives water from a public water supply that contains no detectable generic E. coli level and can demonstrate that the water meets that requirement; or

- Treats water under the requirements of the proposed rule

Untreated surface water used for sprout irrigation, direct contact with covered produce or food-contact surfaces, agricultural tea, or hand washing must be tested every seven to 30 days during the growing season, depending on the source and storage site of the water and how much runoff may be contained therein.

**VIII. Standards for Biological Soil Amendments of Animal Origin**

A biological soil amendment of animal origin (such as manure, or non-fecal animal byproducts, or table waste) must be handled, conveyed, and stored so that it does not become a potential source of contamination to: covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems. Any biological soil amendment must be handled/stored to minimize the risk of contamination by a different biological soil amendment of animal origin that is as yet untreated or in-process. Under the proposed rule, the regulation of biological soil amendments differs on whether and how the soil amendment is treated.

A biological soil amendment of animal origin is treated if it has been processed to adequately reduce microorganisms of public health significance or, if it is an agricultural tea, the biological materials used have been processed as above and the water used in the tea satisfies the testing requirements for agricultural water. Treatment processes that are acceptable for these amendments that are applied in the growing of covered produce are either a scientifically valid controlled physical or chemical process (or a combination of the two) or a composting process. Whichever process is used, it must meet specified microbial standards.
A biological soil amendment of animal origin is untreated if it:

- Has not been processed;
- Has become contaminated after treatment;
- Has been recombined with an untreated biological soil amendment of animal origin or untreated waste that the covered farm knows or has reason to believe is contaminated with a hazard or has been associated with foodborne illness; or
- Is an agricultural tea that contains an agricultural tea additive

The proposed rule sets forth time intervals between the application of these amendments and crop harvest. Depending on the soil amendment used and how it is applied, the time interval is zero days, 45 days, or nine months. Human waste may not be used for growing covered produce, except sewage sludge biosolids used consistent with EPA standards.

**IX. Standards Regarding Domesticated and Wild Animals**

The standards regarding domesticated and wild animals apply only when a covered activity takes place in an outdoor area or a partially enclosed building and when there is a reasonable probability that animals will contaminate covered produce.

If animals are permitted to graze or they are used as working animals in fields where covered produce is grown, and there is a reasonable probability that the animals will contaminate covered produce, a covered farm must:

- Establish an adequate waiting period between grazing and harvesting for covered produce to ensure the safety of the harvested crop; and
- Establish measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce (when working animals are used in a field where a crop has been planted)

If there is a reasonable probability that animal intrusion will contaminate covered produce, areas used for a covered activity must be monitored for evidence of animal intrusion. If intrusion occurs, a covered farm must evaluate whether the covered produce can be harvested.

**X. Standards Regarding Growing, Harvesting, Packing, and Holding Activities**

The proposed rules set out requirements related to growing, harvesting, packing, and holding of covered produce. Covered farms must:

- Keep covered produce and excluded produce separated (if the excluded produce is not grown, harvested, packed or held in accordance with the proposed rule);
- Take all measures reasonably necessary to identify and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard;

- Handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards;

- Not distribute covered produce that drops to the ground before harvest unless it is destined for commercial processing (this does not apply to root crops that grow underground, crops that grow on the ground, or produce that is intentionally dropped to the ground as part of the harvest method);

- Package covered produce in a manner that prevents the formation of Clostridium botulinum toxin if it is a known or reasonably foreseeable hazard;

- Use food-packing material that is adequate for its intended use and reuse food-packing material only if steps are taken to ensure that food-contact surfaces are clean;

**XI. Standards Regarding Equipment, Tools, Buildings, and Sanitation**

The proposed rule imposes requirements on:

- Equipment and tools;

- Fully or partially enclosed buildings used for covered activities and buildings used to store food-contact surfaces;

- Instruments or controls used to measure, regulate, or record temperatures, hydrogen ion concentration (pH), sanitizer efficacy, or other conditions;

- Equipment used to transport covered produce;

- Design and construction of buildings;

- Domesticated animals in and around fully enclosed buildings;

- Pest control used in buildings;

- Toilet facilities;

- Hand washing facilities;

- Control and disposal of sewage;
• Disposal of trash, litter, and waste in areas used for covered activities;
• Plumbing systems; and
• Control of animal excreta and litter from domesticated animals

XII. Standards Regarding Sprouts

The proposed rule imposes additional requirements on sprouts, including:

• Requirements for beans and seed used to grow sprouts;
• Required measures for growing, harvesting, packing, and holding sprouts;
• Testing required during the growing, harvesting, packing, and holding of sprouts;
• Requirements applicable to environmental testing for Listeria species or L. monocytogenes;
• Required actions if the growing, harvesting, packing, or holding environment tests positive for Listeria species or L. monocytogenes; and
• Requirements regarding the collection and testing of spent sprout irrigation water or sprouts

XIII. Analytical Methods

The proposed rule imposes requirements regarding the analytical methods that must be used for required testing. Those interested in specifics on these methods should consult this section in the proposed rule.

XIV. Recordkeeping Requirements

The proposed rule imposes general recordkeeping requirements on covered farms, including:

• Records must include basic information such as the name and address of farm, observations monitored, description of covered produce, location of growing area, and date and time. Records must also be contemporaneous, accurate, legible, indelible, signed, and dated;
• Records may be stored offsite if they are older than six months (counted from the date the record was made), provided they can be retrieved and onsite within 24 hours of a request for review. Electronic records are considered onsite if accessible from a location at the covered farm;
• The proposed rule clarifies that duplication of existing records is unnecessary if the existing records contain all required information;

• Generally, records must be kept for 2 years past the date the record was created. However, records related to the general adequacy of the equipment or processes being used by a farm (e.g., scientific studies and evaluations), must be retained for at least 2 years after the use of such equipment or processes is discontinued;

• Acceptable records formats;

• Requirements applicable to making records available and accessible to FDA. Onsite records must be “readily available and accessible” to FDA for inspection and copying upon oral or written request, except 24 hours is permitted to obtain records kept offsite; and

• FDA’s records disclosure policies and protection of confidential information

In addition to the above, a covered farm must establish and keep documentation of actions taken when a standard in one of the following subparts is not met:

• Standards Directed to Personnel Qualifications and Training;

• Standards Directed to Agricultural Water;

• Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste;

• Standards Directed to Equipment, Tools, Buildings, and Sanitation; and

• Standards Directed to Sprouts

XV. Variances

A state or a non-U.S. country may request a variance from one or more requirements of this part, where the state or non-U.S. country determines that:

• The variance is necessary in light of local growing conditions; and

• The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Act and to provide the same level of public health protection as the requirements of this proposed rule

To request a variance, the regulatory authority for food safety for a state or a non-U.S. country must submit a petition to FDA.