

## PROPOSED PRODUCE SAFETY RULE

The U.S. Food and Drug Administration's (FDA's or the Agency's) proposed rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Rule), will establish science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms. When finalized, the proposed rule will be the first national standard for on-farm practices related to produce safety.

### Who would be covered by the rule?

- Fresh (raw) produce that is sold commercially as human food. Food grains are not covered.
- Fruits, vegetables, nuts, herbs, mushrooms, and sprouts that are typically eaten raw or crops that are generally cooked or further processed are excluded (not covered by the rule) – see other side for details.
- Partial exemptions are provided to farms with produce sales averaging less than \$500,000 and if the more than 50% of the produce is sold directly to the consumer of the food or to a restaurant or retail food establishment that is located in the same state as the farm or not more than 275 miles away.
- If a crop is mostly sold through wholesale outlets, such as through distributors, warehouses, or fresh-cut processors and the yearly total food sales is over \$25,000, the farm IS covered under the rule and exemptions do not apply.
- FDA can cancel exemptions if they determine that a farm may be a source of contaminated produce.
- Certain activities, namely on-farm manufacturing/processing that is not consumed on the farm, would result in a "mixed-type facility and the processing activity would be subject to the proposed preventative controls rule.

### The proposed rule would establish science-based minimum standards in the following major areas:

- Worker Training and Health and Hygiene
- Agricultural Water
- Biological Soil Amendments
- Domesticated and Wild Animals
- Equipment, Tools, and Buildings
- Sprouts
- Growing, Harvesting, Packing and Holding Activities

The proposed rule would allow farms to establish alternatives to certain requirements related to water and biological soil amendments of animal origin if the alternative is scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration.

### How do I comment on the proposed rules?

These are **proposed draft rules** and not final regulation. Stakeholders are encouraged to comment on aspects of the rules they object to or do not understand. **Comments must be submitted by May 16, 2013.**

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Insert the docket number into the "search" box and follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

All submissions received must include the Agency name and Docket No. FDA-2011-N-0921 and Regulatory Information Number RIN 0910-AG35 for this rulemaking.

## Where can I go for more detailed information?

The FDA website is frequently updated with new information on the Produce Safety Rules:  
[www.fda.gov/Food/FoodSafety/FSMA/ucm304045.htm](http://www.fda.gov/Food/FoodSafety/FSMA/ucm304045.htm)

FDA Summaries include:

- [Overview of the Proposed Rules](#)
- [Preventive Controls for Human Food: Fact Sheet on the Proposed Rule](#)
- [Standards for Produce Safety: Fact Sheet on the Proposed Rule](#)

The following chart can be used in conjunction with the proposed rule to help understand coverage and exemptions:

Proposed Standards for Produce Safety - Coverage and Exemptions/Exclusions for Proposed 21 PART 112		
Does your farm grow, harvest, pack or hold produce? Sections 112.1 and 112.3(c)  YES ↓	NO →	You are NOT covered by this rule.
Is your produce rarely consumed raw? Section 112.2(a)(1)  NO ↓	YES →	This produce is NOT covered by this rule.
Is your produce for personal/on-farm consumption? Section 112.2(a)(2)  NO ↓	YES →	This produce is NOT covered by this rule.
Does your farm manufacture/process, pack, or hold produce that is not a *Raw Agricultural Commodity (RAC)? Section 112.2(a)(3)  NO ↓	YES →	Produce that is not a RAC is NOT covered by this rule.
Is your produce intended for commercial processing with a "kill step"? Section 112.2(b)(1)  NO ↓	YES →	This produce is NOT covered by this rule, EXCEPT as per Sections 112.(b)(2) and (3)
Does your farm on average (in the previous 3yrs) have < \$25k annual food sales? Section 112.4(a)  NO ↓	YES →	You are NOT covered by this rule.
Does your farm on average (in the previous 3yrs) as per Section 112.5: <ul style="list-style-type: none"> <li>● have &lt; \$500k annual food sales, AND</li> <li>● a majority of the food (by value) sold directly to "qualified end-users"?</li> </ul> "Qualified End-User" Section 112.3(c) means: <ul style="list-style-type: none"> <li>● the consumer of the food ("consumer" is not a business) OR</li> <li>● a restaurant or retail food establishment that is located—                (i) in the same State as the farm that produced the food; OR                (ii) not more than 275 miles from such farm.</li> </ul> NO ↓	YES →	You are EXEMPT from this rule except as per Section 112.6
You are COVERED by this rule.		

Questions? Contact Gwendolyn Wyard

OTA Regulatory Director, Organic Standards and Food Safety (gwyard@ota.com | 503-798-3294)