



# Sprouts - Subpart M Fact Sheet

## Background

As part of the Food Safety Modernization Act (FSMA), the FDA developed “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (CFR 21 Part 112). These standards are referred to as the Produce Safety Rule. The rule sets forth procedures, processes and practices that minimize the risks for consumers of eating raw fruit and vegetables that could be contaminated with bacteria, viruses or parasitic organisms that cause food borne illness.

While sprout producers are subject to the entire Produce Safety Rule, sprout production is specifically addressed under subpart M. These specific requirements are established for sprouts because they present a unique risk because the warm, moist, and nutrient-rich conditions required to produce sprouts are the same conditions that are also ideal for the growth of pathogens. The requirements of subpart M apply to the growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

Compliance dates for sprout producers are based on annual produce sales and are as follows:

<b>Very Small Farms (More than \$25,000 but less than \$250,000*)</b>	<b>January 28, 2019</b>
<b>Small Farms (More than \$250,000 but less than \$500,000*)</b>	<b>January 26, 2018</b>
<b>Large Farms (More than \$500,000*)</b>	<b>January 26, 2017</b>

\*Amounts are annual monetary values averaged over a 3-year period, adjusted for inflation. Inflation is calculated using 2011 as the baseline year.

## License (REQUIRED FOR FRESH SPROUTS PROCESSING FACILITY)

- (1) Prerequisite for Fresh Sprout Operation. A person may not operate a Fresh Sprouts Processing Facility falling under Code of Federal Regulations, Title 21 Part 112, Subpart M without a valid food sales establishment license to operate issued by the Department.
- (2) Form of Submission. A person desiring to operate a Fresh Sprouts Processing Facility must submit to the Department a written application for a license on a form provided by the Department.
- (3) License.
  - (a) The Commissioner will charge a license fee of \$300 for the food sales establishment license issued, pursuant to O.C.G.A 26-2-25.
  - (b) The license must be renewed annually on July 1. License fees will be increased by fifty percent (50%) for the renewal of a license not renewed by September 1.
- (4) Qualifications and Responsibilities of Applicants. To qualify for licensing, an applicant must:
  - (a) Be an owner of the establishment or an officer of the legal ownership;
  - (b) Comply with the requirements of these regulations, and the Current Good Manufacturing Practices (CGMP) found in 21 CFR Part 117 - Subpart B, adopted by reference in Department rule 40-7-18-.12(2); and
  - (c) Agree to comply with directives of the Department including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the Department regarding the license holder's Fresh Sprout Processing Facility. Further, a license holder must, at the time of inspection, correct a critical violation of these regulations and/or implement corrective actions.
- (5) License Not Transferable. A license may not be transferred from one person to another person, from one processing plant to another, or from one type of operation to another. Authority O.C.G.A. Secs. 26-2-34, 26-2-441.

## Requirements

Unless specifically exempt or excluded, such as by annual produce sales and/or sales and market channels, sprout growing operations are subject to the sprout-specific requirements in subpart M. They are also subject to all other requirements of the Produce Safety Rule.

Specific requirements that apply to the growing, harvesting, packing, and holding of sprouts include:

- Sprouts must be grown, harvested, and packed in fully enclosed buildings and have established written and implemented sampling plans to test water or sprouts for pathogens, as well as corrective actions if pathogens are detected. (21 CFR 112.143)
- Using a valid testing method to test of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch (if testing water is not practical), for E. coli O157:H7, Salmonella species and any other pathogen meeting the criteria in 21 CFR 112.144(c). (21 CFR 112.44)
  - Validated testing methods for the growing, harvesting, packing, and holding environments and spent sprout irrigation water (or sprouts) can be found in 21 CFR 112.152 and 112.153.
- Testing the growing, harvesting, packing, and holding environment for the presence of Listeria species or L. monocytogenes. (21 CFR 112.44)
- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive. (21 CFR 112.146 and 112.148)
- Establishment of the following records:
  - Documentation of treatment of seeds; or documentation from seed supplier verifying that seeds have been treated
  - Written environmental monitoring plan (21 CFR 112.145)
  - Written sampling plan for each production batch (21 CFR 112.147)
  - Other documentation as required by 21 CFR 112.150

## Training

All personnel who handle (contact) sprouts must receive training that includes:

- Principles of food hygiene and food safety
- The importance of health and personal hygiene for all personnel and visitors
- Other training as applicable to the employee's job responsibilities (21 CFR 112.22)

At least one supervisor or responsible party for your operation must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA. The current standardized training recommended for sprout producers is offered by the Sprout Safety Alliance. Course dates and locations can be found at <http://www.ifsh.iit.edu/ssa/resources/ssa-training>

## Resources

FDA – Produce Safety Rule Summary

<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

FDA – Guidance Document for Sprout Operations

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM537031.pdf>

Sprout Safety Alliance

<https://www.ifsh.iit.edu/ssa>

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Georgia Department of Agriculture – Produce Safety Program  
[www.GeorgiaProduceSafety.com](http://www.GeorgiaProduceSafety.com)

If you have any additional questions or concerns regarding sprouts or the Produce Safety Rule, please contact the Produce Safety Program at (229)-386-3488.

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