REGULATORY CONSIDERATIONS FOR MARKETING SPROUTS, MICROGREENS AND BABY GREENS IN TENNESSEE

Megan Bruch Leffew, Extension Specialist, Center for Profitable Agriculture Rachel Painter, Extension Specialist, Center of Farm Management Brooke Emery, Produce Safety Extension Assistant, Department of Plant Sciences Annette Wszelaki, Professor and Commercial Vegetable Extension Specialist, Department of Plant Sciences

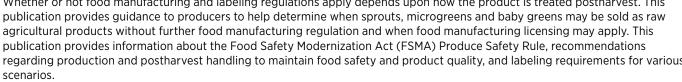
Introduction

Tennessee producers interested in growing sprouts, microgreens and baby greens often have questions regarding the application of food manufacturing regulations to the sale of these products. Sprouts include the underdeveloped leaves, stems and roots of germinated or partially germinated seeds.1 Microgreens are small plant shoots, typically 1-4 inches tall and are often harvested by cutting when one to two true leaves are formed. With optimal conditions, microgreens can often be grown from seed and harvested in 10 to 14 days. Baby greens have true leaves and are harvested from older, larger plants than microgreens but still not at full maturity. ²

Sprouts, microgreens and baby greens may come from a variety of plants such as arugula, kale, lettuce, spinach, beets, sunflower, radish, broccoli, cauliflower, peas, basil, fennel, dill, cilantro, parsley and more. While sprouts are sold and consumed with roots intact, microgreens and baby greens are sold in various forms such as:

- · Harvested with a single cut fresh from the plants at the production site and sold either segregated or mixed with other microgreens or baby greens from bulk containers or in packages;
- Harvested with a single cut fresh from the plants in trays at a retail location or farmers market and sold from bulk containers or in packages;
- · Harvested and washed:
- · Harvested and further cut or chopped;
- · Rooted plants in a growing tray or package;
- Dehydrated and ground into a powder.

Whether or not food manufacturing and labeling regulations apply depends upon how the product is treated postharvest. This regarding production and postharvest handling to maintain food safety and product quality, and labeling requirements for various



¹The Handbook for Small and Direct Marketing Farms: Regulations and Strategies for Farm and Food Business (2019 Edition). Washington State Department of Agriculture. Accessed online December 20, 2023 at agr.wa.gov/departments/business-and-marketing-support/small-farm/thegreen-book/regulations-for-specific-products.

²Bumgarner, Natalie and Rosalie Metallo. The Tennessee Vegetable Garden: Small Scale Microgreen Production (W346-J). University of Tennessee Extension. February 2017. Accessed online December 11, 2023 at https://tiny.utk.edu/W346J.







Questions often arise as to when sprouts, microgreens and baby greens are considered raw agricultural products or processed food products. This section will help producers determine when sprouts, microgreens, and baby greens are considered raw agricultural products and what regulations require for the sale of these products.

Unprocessed fruits and vegetables in their raw or natural state with only a minimal amount of cutting or trimming necessary for harvest are regulated under the FSMA Produce Safety Rule, and no food manufacturing license is needed. Under this definition, microgreens and baby greens harvested with a single cut from the plants without any further cutting are considered raw agricultural products and are subject to inspection in Tennessee through joint efforts from the Tennessee Department of Agriculture (TDA) and Food and Drug Administration (FDA) if the operation is covered by FSMA (more information provided below).

Washing is allowable for greens sold as raw agricultural products; however, it can impact product quality and foodborne illness pathogen growth. (See section titled Managing Risks of Producing and Marketing Sprouts, Microgreens, and Baby Greens.)

Sprouts, microgreens and baby greens as raw agricultural products may be sold without a food manufacturing license either as single species or as a mix of species. These products can be sold in bulk or in smaller packages or containers. For example, sprouts, microgreens or baby greens are often sold in clam shells that can protect them against bruising and crushing.

Microgreens or baby greens harvested with a single cut fresh from a tray at the point of sale, such as at a farmers market, would also be considered the sale of a raw agricultural product. Food manufacturing licensing is not required in these cases in Tennessee.

The Tennessee Department of Agriculture has regulations regarding the allowable units of sale for produce and has adopted

guidelines from the National Institute of Standards and Technology (NIST) Handbook 130. Leafy vegetables, such as herbs and loose greens, may be sold by weight, bunch or dry measure.

When sprouts, microgreens, or baby greens are prepackaged and sold by weight, the net quantity of product in terms of the largest whole unit must be listed on the principal display panel of the consumer package. For example, a mix of microgreens packaged in a clam shell container would need to include either the net weight of the product in pounds/ounces and grams or a dry measure such as a pint. A product's net weight is the weight of the product alone and does not include the weight of the packaging or label.

The National Institute of Standards and Technology (NIST) from the U.S. Department of Commerce issues Handbook 130 each year with uniform laws and regulations and is adopted by the Tennessee Department of Agriculture Consumer and Industry Services Division for weights and measures regulations. NIST Handbook 130³ defines a package as:

- · Enclosed in a container
- · Wrapped in any manner in advance of wholesale or retail sale
- · Weight or measure has been determined in advance of wholesale or retail sale

In addition, "an individual item or lot of any commodity on which there is marked a selling price based on an established price per unit of weight or of

measure shall be considered a package (or packages)."

Scales used to weigh product for sale in Tennessee are required to be National Type Evaluation Program (NTEP) approved and legal for trade. Scales used to weigh product for sale must be tested and permitted by the Tennessee Department of Agriculture (TDA) Consumer and Industry Services Division, Weights and Measures for accuracy. In recent years though, TDA has not provided inspection or permitting of scales for use at farmers markets in the state. Products sold by weight at farmers markets, however, must be weighed on an accurate legal-for-trade scale. Questions about weights and measures regulations or scales requirements and licensing can be directed to the Tennessee Department of Agriculture Consumer and Industry Services, Weights and Measures staff at (615) 837-5109.





Managing Risks of Producing and Marketing Sprouts, Microgreens and Baby Greens

Sprouts, microgreens and baby greens can have a high risk of microbial contamination, as the same food reserves in the seed that help it to germinate can also 'feed' plant and foodborne illness pathogens that are introduced into the system. Producers should complete educational training and implement practices to ensure safe growing, harvesting, packing and storage. For farms covered by FSMA, one person from each farm must complete a standardized curriculum, such as training through the Produce Safety Alliance or sprout specific training offered through the Sprout Safety Alliance.

The Food and Drug Administration provides a <u>decision tree</u> to help producers determine if their operation is subject to the rules of FSMA. Further details of the FSMA regulations are available on the <u>FDA's website</u>.

The ideal growing environment for sprouts, microgreens and baby greens is also the ideal growing environment for both

human and plant pathogens; therefore, sanitation is of utmost importance. Thorough recordkeeping to be able to trace any food safety issue back to the production lot is necessary to reduce and mitigate risks. Specifically for sprouts, growers must test the growing, harvesting, packing and holding environments for generic *Listeria spp.*, and spent irrigation water for both generic *Salmonella* and *E. coli.* Sprouts must be grown in a fully enclosed building and all food contact surfaces must be cleaned and sanitized before contacting the sprouts. For microgreens and baby greens, consider the potential risks associated with harvesting in an outdoor or off-site environment, such as a farmers market and document steps or practices implemented to reduce such risks.

Sprouts are a higher food safety risk than microgreens or baby greens because sprout seeds are typically fully submerged in water for the first 12 to 16 hours of growth and grown without light, and the final product includes semi-germinated seed and root. Seeds can carry pathogens, and when put in water can easily spread pathogens to an entire lot of sprouts. Due to the increased risks posed by sprouts, the FDA provides special guidance for growing, harvesting, packing and holding sprouts through these guidelines.

Microgreens and baby greens are generally a lower food safety risk because, if harvested following proper food safety protocols, any pathogens present in the seed will remain in the soil after harvest, rather than travel with the product. However, similar risks for sprouts remain for microgreens and baby greens grown hydroponically if leaves and stems come into contact with recirculating water.

A food manufacturing permit is not needed to wash sprouts, microgreens or baby greens prior to sale; however, washing creates a humid environment, which can contribute to decay and foodborne illness pathogen growth and can decrease shelf-life. Therefore, producers should not wash these products unless absolutely necessary and should instruct the end-user to wash them before consuming.

In order to help manage risk, producers also should consider sharing some important information with consumers. It may be helpful to provide signage, for example to indicate which species of greens are available or included in any mixture in case a particular consumer has a known food sensitivity or allergy. Again, producers may want to remind consumers to wash the product thoroughly before consumption. Consumers may not realize the need to wash sprouts, microgreens or baby greens purchased directly from the farm before consumption with many pre-washed, ready-to-eat products available in grocery stores.

Sprouts, Microgreens and Baby Greens as Processed Foods

Producers may cross a line from selling raw agricultural products into the realm of processed or manufactured foods when they go beyond making an initial harvest cut for sprouts, microgreens and baby greens. This may include chopping, dehydrating or other processes. Food manufacturing regulations apply to the processing and sale of these products. Processing and sales under very limited, specific circumstances may be allowable without a licensed kitchen under the Tennessee Food Freedom Act. Other processes and sales situations require processing be done in a licensed commercial food manufacturing facility.

When sprouts, microgreens or baby greens are processed beyond the initial cut of harvest by further trimming, cutting or chopping to be sold fresh, then processing, packaging, labeling and storage must be conducted in a licensed commercial food manufacturing facility. Similarly, if the greens are made into a product that requires time/temperature controls such as a frozen product, a licensed commercial food manufacturing facility is necessary.

Is plant certification required when selling plants with roots for human consumption?

Since sprouts and sometimes microgreens and baby greens are sold with roots attached either in trays or other containers, some producers may question whether a Plant Certification License from the Tennessee Department of Agriculture is required. Since the product is being sold for human consumption and not to be planted, plant certification is not needed. To learn more about plant certification requirements in the state, visit the *Tennessee Department of Agriculture*.

If sprouts, microgreens or baby greens are processed into a shelf-stable product such as by being washed, dehydrated, or dehydrated and ground into a powder, then producers may be eligible to process at a private residence without licensing and inspection under the Tennessee Food Freedom Act, depending upon some additional factors. Products manufactured under the TFFA can only be sold within the state of Tennessee, but products to be sold across state lines must be manufactured in a licensed facility. In addition, food service establishments, such as restaurants and caterers, are not allowed to use or serve products manufactured under the TFFA. Therefore, if products are intended for sale to food service establishments, producers should process in a licensed food manufacturing facility. TDA staff are available to help determine if a product is eligible for manufacturing under the TFFA or whether it would require a food manufacturing license by calling 615-837-5150.

To ensure food safety of products and reduce liability risk, producers manufacturing products in a private residence should follow current Good Manufacturing Practices (GMPs). Dehydrated products should be tested for water activity levels to make sure the process used is drying greens enough

to inhibit the growth of potentially dangerous microorganisms such as bacteria and fungi. Contact the University of Tennessee <u>Department of Food Science</u> Extension staff to learn more about current GMPs and water activity level testing.

Food manufacturers in Tennessee are licensed by the TDA Consumer and Industry Services Division. To learn more about the requirements for commercial food manufacturing facilities, visit the <u>TDA website</u> or call the Manufactured Food Coordinator at (615) 837-5150.

The <u>Tennessee Food Freedom Act</u> allows non-Time/Temperature Control for Safety (TCS) foods to be manufactured in a private residence without a food manufacturing license or inspection. Examples of allowable products typically include shelf-stable baked goods, canned fruits and vegetables, freeze-dried produce, dehydrated produce, dehydrated and ground produce, and spice blends. Any finished product requiring temperature control (refrigeration, freezing, etc.) is not allowable under this act. Likewise, meat, poultry, fish, egg, dairy products and fresh garlic in oil are not allowable. Products manufactured under the Tennessee Food Freedom Act may only be sold within the state of Tennessee and must follow specific labeling rules as described below.

Labeling Processed Foods

Sprouts, microgreens or baby greens as processed foods must be properly packaged in food grade containers and labeled in accordance with food manufacturing and labeling regulations.

Basic Label Requirements

Labels for products manufactured in a licensed commercial facility must include these six items:

- 1. Common or usual name of the product
- 2. Ingredient name(s) in descending order of predominance by weight (include individual plant names)
- 3. Farm or manufacturer name
- 4. Farm or manufacturer address (can be a P.O. Box)
- 5. Quantity (net weight in standard and metric units or dry measure)
- 6. Allergen declaration, if needed

Labels on products manufactured under the Tennessee Food Freedom Act must include:

- 1. Common or usual name of the food product
- 2. Ingredients of the food item in descending order of predominance by weight
- 3. Producer name
- 4. Producer home address (not a P.O. Box)
- 5. Producer telephone number
- 6. The following statement: "This product was produced at a private residence that is exempt from state licensing and inspection. This product may contain allergens."





Suggested Label Information

Labels are not required to include a date; however, producers may choose to add one as part of their risk management strategy. Producers may want to include a lot code or date in the event a product recall is necessary. Producers may also consider adding a "Harvested On" or "Best if Used By" date in order to communicate how long customers can expect fresh quality. Producers covered by FSMA are now required to include lot codes in accordance with the traceability section of FSMA.

For marketing purposes, some buyers such as distributors or grocery stores may request a UPC code be included on the packaging as well, although a UPC is not required by food manufacturing regulations. Producers may learn more or reserve barcodes on the GS1 standards website.

Nutrition Facts Panels

Nutrition fact labeling is required for packaged foods under the Federal Food, Drug and Cosmetic Act unless the manufacturer qualifies for an exemption. Many small businesses will qualify for one or more exemptions. Some product buyers, however, may require nutrition facts panels even if a business is exempt by the Federal, Food, Drug and Cosmetic Act.

A producer employing fewer than 100 full-time equivalent employees and selling fewer than 100,000 units of product in the United States within a 12-month period would qualify for a low-volume product exemption. In this case, the producer must file a notice of exemption with the Food and Drug Administration annually.⁴ Note that products that include health or nutrition claims or include nutrition content information on the label or in labeling or advertising are not eligible for the small business exemptions for nutrition labeling.⁵

Special Claims

Producers sometimes want to include special claims on product packaging or in marketing materials to communicate messages to consumers. It is important to note that special claims may not be used for products manufactured under the Tennessee Food Freedom Act. For products made in a licensed food manufacturing facility, the use of many claims related to production methods, health and nutrition is regulated by a variety of agencies including the United States Department of Agriculture or the United States Food and Drug Administration. Depending upon the particular terms, using special claims on product labels or marketing materials can require manufacturers to seek a premarket review and authorization, submit scientific evidence that a claim is truthful, or even undergo an inspection or certification.

Producers may learn more about some example special claims and requirements on the following websites:

- USDA National Organic Program
- FDA Label Claims for Conventional Foods and Dietary Supplements

Summary

Sprouts, microgreens and baby greens are grown, harvested, processed and packaged in a variety of ways. As shown in Table 1, some methods maintain a raw agricultural product state and no food manufacturing facility or license is needed. Other methods, such as when greens are further cut or chopped, are considered processing and must be completed in a licensed commercial food processing facility. Processing into shelf-stable products such as dried greens or a dehydrated powder may be conducted at a producer's private residence without inspection if being sold within the state of Tennessee, does not include any special claims, and is not intended for food service establishments. In all cases, food safety is of the utmost importance, and producers should take care to implement Good Agricultural Practices, Good Handling Practices and Good Manufacturing Practices.



4U.S. Food and Drug Administration. Small Business Nutrition Labeling Exemption. November 23, 2023, Accessed online October 3, 2023 at https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption.

⁵U.S. Food and Drug Administration. Small Business Nutrition Labeling Exemption Guidance. May 2007. Accessed online October 3, 2023 at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-business-nutrition-labeling-exemption-guidance.

Table1. Example Harvest and Postharvest Handling Scenarios, Requirements for Food Manufacturing License, and Requirements and Recommendations for Product Labeling

Example Harvest and Post- harvest Handling Scenarios	Requirements for Food Manufacturing License	Requirements (*) and Recommendations (**) for Product Labeling
Harvested with a single cut fresh from the plants at the farm and sold either segregated or mixed with other greens from bulk containers or in packages Harvested with a single cut fresh from the plants in trays at the farmers market and sold from bulk containers or in packages	Raw agricultural product (no food manufacturing license needed)	**Indicate species of greens and remind customers to wash the product thoroughly before consuming *If packaged, products must be labeled with: 1. Common or usual name of the product 2. Ingredient name(s) in descending order of predominance by weight (include individual plant names) 3. Farm or manufacturer name 4. Farm or manufacturer address (can be a P.O. Box) 5. Quantity (net weight in standard and metric units or dry measure) 6. Allergen declaration, if needed
Harvested and washed	Raw agricultural product (no food manufacturing license needed). (Producers should not wash unless absolutely necessary as it degrades quality and can introduce food safety risks.)	
Entire plants in a growing tray or package	Raw agricultural product (no food manufacturing license needed); Consumable product (no plant certification licensing needed)	
Harvested and further cut or chopped microgreens	At the Farm or Other Facility: Cutting or chopping beyond the initial harvest cut is considered processing and requires a licensed food manufacturing facility and proper packaging and labeling. Contact the Tennessee Department of Agriculture Consumer and Industry Services Division for licensing and inspection information at (615) 867-5150. At the Market for Food Service: If microgreens, baby green or sprouts are prepared and used as an ingredient at a market to be served to customers, then a Tennessee Department of Health Food Service Establishment permit (either regular, mobile or Farmers Market Food Unit) would be required. Contact your local health department for more information.	*Labels for products manufactured in a licensed commercial facility must include: 1. Common or usual name of the product 2. Ingredient name(s) in descending order of predominance by weight (include individual plant names) 3. Farm or manufacturer name 4. Farm or manufacturer address (can be a P.O. Box)
Harvested, washed, dehydrated and (optionally) ground	At the Farm or Other Facility: Dehydrating and grinding are considered processing. Since the final product does not need to be temperature controlled for safety (non-TCS), however, product sold within Tennessee could be processed at a private residence without licensing or inspection under the Tennessee Food Freedom Act. Products produced under the TFFA are not approved for use by food service establishments licensed by the Tennessee Department of Health. If products were going to be sold to food service establishments or outside of Tennessee, a food manufacturing license from the Tennessee Department of Agriculture would be required. Contact the Tennessee Department of Agriculture Consumer and Industry Services Division for licensing and inspection information at (615) 867-5150. At the Market for Food Service: If microgreens, baby green or sprouts are prepared and used as an ingredient at a market to be served to customers, then a Tennessee Department of Health Food Service Establishment permit (either regular, mobile or Farmers Market Food Unit) would be required. Contact your local health department for more information.	*Labels on products manufactured under the Tennessee Food Freedom Act must include: 1. Common or usual name of the food product 2. Ingredients of the food item in descending order of predominance by weight 3. Producer name 4. Producer home address (not a P.O. Box) 5. Producer telephone number 6. The following statement: "This product was produced at a private residence that is exempt from state licensing and inspection. This product may contain allergens." *Labels for products manufactured in a licensed commercial facility must include: 1. Common or usual name of the product 2. Ingredient name(s) in descending order of predominance by weight (include individual plant names) 3. Farm or manufacturer name 4. Farm or manufacturer address (can be a P.O. Box) 5. Quantity (net weight in standard and metric units or dry measure) 6. Allergen declaration, if needed

Disclaimer

This publication is for educational purposes only and does not constitute legal advice nor is it intended to be a substitute for the services of a competent legal professional.

Acknowledgements

The authors greatly appreciate the efforts of the following people who contributed to the development of this publication.

Reviewers

- Natalie Bumgarner, University of Tennessee Extension, Plant Sciences Department, Associate Professor and Residential and Consumer Horticulture Extension Specialist and Tennessee Extension Master Gardener Coordinator
- Carlo Gerstenfeld, Tennessee Department of Agriculture, Consumer and Industry Services Division, Manufactured Foods Coordinator
- Mark Hanes, Tennessee Department of Agriculture, Consumer and Industry Services Division, Weights and Measures Program Director
- · Lori LeMaster, Tennessee Department of Health, Environmental Health Program, Director
- · Mark Morgan, University of Tennessee Extension, Food Science Department, Professor and Extension Specialist
- · Catherine Rubin, Tennessee Department of Agriculture, Consumer and Industry Services Division, Produce Coordinator
- Danny Withers, Tennessee Department of Agriculture, Consumer and Industry Services Division, Food Safety Program Director

Online Resources Referenced and Linked in This Publication (not contained in footnotes)

Plant certification requirements, Tennessee Department of Agriculture: tn.gov/agriculture/businesses/plants.html

Produce Safety Alliance, Cornell University's College of Agriculture and Life Sciences: cals.cornell.edu/produce-safety-alliance/ training/grower-training-course

Sprout Safety Alliance, Illinois Tech: iit.edu/ssa

Decision tree, Food and Drug Administration: fda.gov/media/94332/download

FSMA regulations, Food and Drug Administration: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods.

UT Department of Food Science: foodscience.tennessee.edu/food-science-extension/

 $Consumer \ and \ Industry \ Services \ Division, \ Tennessee \ Department \ of \ Agriculture: \ \underline{tn.gov/agriculture/consumers/food-safety/ag-farms-food-manufacturing-and-warehousing.html}$

Tennessee Food Freedom Act: tn.gov/agriculture/consumers/food-safety/tennessee-food-freedom-act/

Traceability records: fsma-final-rule-requirements-additional-traceability-records-certain-foods

GS1 Standards: gs1us.org/

USDA National Organic Program: ams.usda.gov/about-ams/programs-offices/national-organic-program

FDA Label Claims for Conventional Foods and Dietary Supplements: fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements

Local health department listings: tn.gov/health/health-program-areas/localdepartments.html



UTIA.TENNESSEE.EDU

Real. Life. Solutions.™