2016 Addition to the Handbook for Small and Direct Marketing Farms

Regulations and Strategies for Farm and Food Businesses
A Message from the Director

I’m honored to have been appointed director of the Washington Department of Agriculture. As a sixth generation native Washingtonian, I’m proud to serve this state’s second largest industry that has been a vital segment of our economy since statehood.

Washington has one of the most widely diverse agricultural industries of any state. The array of farm operations and variety of crops and products offer consumers choices for nearly every taste imaginable. From dairy and eggs to herbs and vegetables, or meats, honey and mushrooms – we are fortunate to enjoy a cornucopia of edible options.

And much of this diversity comes from small farm operations that make up 90 percent of all farms in Washington. These businesses are essential to the goal of keeping agriculture viable and sustainable for the state’s economy. As consumers increasingly demand fresh, seasonal and local food products, small farms and producers are uniquely positioned to tap this market.

At the same time, emerging developments require all agricultural operators to stay nimble and evolve. Population growth, farming demographics, consumer concerns, and new technologies create a continually shifting environment. In response, best practices and government regulations also adjust to new conditions.

The Handbook for Small and Direct Marketing Farms: Strategies and Regulations for Farm and Food Businesses in Washington State provides information to help farmers and food processors stay current. We’ve created this insert with new and additional information on, for instance, selling juice products and answering question about the Federal Food Safety and Modernization Act Produce Safety Rule.

The fact sheets in this pamphlet reflect the most current information available at the time of publishing. To find up-to-date information, please use the online resources listed in each fact sheet.

WSDA’s mission is to support the viability and vitality of state agriculture. We’re committed to sustaining and growing markets by connecting producers with consumers and assuring you have the information you need to be successful. I hope you find these resources helpful.

Derek Sandison
Director, Washington State Department of Agriculture

About This Pamphlet

This pamphlet is an addition to the 7th Edition of the Handbook for Small and Direct Marketing Farms: Regulations and Strategies for Farm Businesses. Commonly known as “The Green Book,” the handbook has become a trusted resource for Washington’s diverse and innovative farm and food businesses.

We strive to keep the information in the handbook as current as possible by publishing new editions every several years. However, the agricultural and food business landscape changes quickly. We hope this pamphlet helps bridge that gap with new information that was not available when the last handbook was published.

This pamphlet includes two fact sheets on food safety and specific product regulations:

22. FAQ on the Food Safety Modernization Act
42. Selling Juice

An additional fact sheet has been updated online to reflect rule changes that went into effect in 2016.
20. Cottage Food Permit agr.wa.gov/Marketing/smallfarm/greenbook/20.aspx

All the fact sheets in the 2014 handbook are available on WSDA’s website www.agr.wa.gov/farmfoodbiz. The online fact sheets contain web links to the original information sources referenced in each sheet. We encourage you to use the links to find the most up-to-date information since fees, regulations, and contact information may have changed since the handbook was published in 2014.

On the website, you will also find links to our series of farm wisdom videos that illustrate the topics in the handbook with real-world examples from direct marketing farms and food businesses across Washington.

We aim to continue providing this resource with up-to-date information and in user-friendly formats for years to come. As we prepare to create the next full edition, we are considering ways to make it an even more useful and relevant resource. Please share your feedback on how to improve content or format to make this a better resource for you.

Send your suggestions to us at smallfarms@agr.wa.gov or 206-256-6157
FAQ on the Food Safety Modernization Act

What is “FSMA”?
The Food Safety Modernization Act (FSMA) was signed into law in 2011. This sweeping law is the first comprehensive update to federal food safety laws since 1938. It sets new standards for food handling across the entire food chain with rules for businesses ranging from farms and food processors to food shippers, importers, retailers, and others. It is the first federal food safety law that includes specific rules for produce farms.

What is the intent of FSMA?
FSMA represents a change in the Food and Drug Administration’s (FDA) approach to ensuring a safe U.S. food supply. Rather than reacting to instances of food borne illness or contaminated products as they occur, FSMA shifts the focus toward preventing contamination in food.

What’s the difference between FSMA and “GAPs”?
FSMA is a law and the rules are mandatory for farmers and food businesses to follow, with some exemptions that are explained below.

Good Agricultural Practices (GAP) and Good Handling Practices (GHP) are sets of best practices for reducing food safety hazards for produce on the farm. GAP/GHP are voluntary, market-driven standards. Many farms choose to have a voluntary GAP/GHP audit at the request of their buyers. A GAP/GHP audit is a way that farms can provide their customers with a third-party assurance of their on-farm food safety practices.

Many of the basic principles for reducing food safety risks are similar between GAP and FSMA. Farms that are familiar with GAP/GHP will be well prepared to comply with FSMA.

What are the key areas of FSMA?
The law itself is broken down into several different rules that apply to different sectors of the food system including farms, food processors, food transporters, etc. The sections of the law that are most relevant for most people using this fact sheet are the Produce Safety Rule for farms and the Good Manufacturing Practices (GMP)/Preventive Controls Rule for processing facilities.

I’ve been hearing about FSMA for years. What’s the status now?
After the law passed in 2011, the FDA developed initial drafts of the rules which it released in 2013. Over the next two years, the FDA solicited input from farmers, food processors, and food system advocates throughout the country. You may have submitted comments yourself during this period. After several rounds of comment and revisions, the rules were finalized in 2015 and 2016. The good news is that the FDA heard many of the concerns from small farms that are reflected in the final rules. Now the final rules are being implemented. See below for specifics on the deadlines for compliance.
The Produce Safety Rule for Farms

Aren’t some farms exempt from the Produce Safety Rule?
The rule covers produce, but some types of produce and several categories of farms are exempt:

- If your farm’s average annual sales of produce over the last three years are $25,000 or less, your farm is exempt. To claim this exemption, keep records of your **produce sales**.

- Produce used only for personal or on-farm consumption is exempt

- Produce that is defined by the FDA as “rarely consumed raw” is exempt, such as potatoes. The FDA has developed a specific list of produce that they include in that category, [www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2005](https://www.federalregister.gov/articles/2015/11/27/2015-28159/standards-for-the-growing-harvesting-packing-and-holding-of-produce-for-human-consumption#p-2005). Food grains such as barley, wheat, quinoa, rapeseed, etc. are also exempt.

---

**Does FSMA Apply to Me?**

**Do you have a produce farm?** If you operate a farm business that grows, harvests, packs, or holds produce, the **Produce Safety Rule likely applies to you**.

**Do you process a food product?** If you operate a business that processes, packs, manufactures, or holds food, the **Good Manufacturing Practices (GMP) and Preventive Controls for Human Foods Rule likely applies to you**.

If you grow and process food you may be covered by both rules.

**Are you a food hub or farmer cooperative?** For the purposes of FSMA, FDA has written a specific definition of a “farm.” Food hubs and cooperatives may also be considered a “farm” depending on their ownership structure and sourcing model.

**The following resources can help you determine which rules apply to you:**


---

Most diversified farms grow and handle a mix of produce, some on the exempt list, others not. Depending on the specific circumstances of your own farm operations, you may find it is most practical to manage all your produce crops in compliance with the Produce Safety Rule rather than using different practices for crops covered by the rule and those that are exempt.
In addition, your farm may be eligible for a qualified exemption if:

- Your total annual **food sales** averaged less than $500,000 over the past three-year period;  
  AND
- The majority of all of your combined sales over the past three-year period were made directly to “qualified end-users.” Qualified end-users are end consumers, restaurants, or retail food establishments located in the same state or Indian reservation as your farm or within 275 miles of your farm.

Farms with qualified exemptions still need to meet modified requirements of the rule, such as prominently displaying the farm name and address on all packaging labels or at the point of sale and complying with the record keeping, compliance, and enforcement provisions of the rule. A farm may lose its qualified exempt status if there is an FDA investigation of a food borne illness or other food safety concern.

To demonstrate that your farm is eligible for the qualified exemption, you must keep good sales records and make them available upon request. This recordkeeping requirement went into effect in January 2016.

**What are the key requirements of the Produce Safety Rule?**

The Produce Safety Rule sets standards for farms to meet in six key areas. The intent is to reduce food safety risks by limiting microbial contamination – and cross contamination – from hygiene, water, soil, animals, and surfaces on your farm.

The Produce Safety rule sets the standards but does not always define the specific actions you must take. This is to allow flexibility for farms to meet the standards in ways that work for your particular operation. Over the coming years, WSDA and other organizations will provide trainings, guidance, and other resources to help Washington farms implement the Produce Safety Rule standards.

This is a very brief summary to give you a sense of the key elements of the Produce Safety Rule. Please use the resources at the end of this section to learn specifics about the standards in each section and how they might apply to your operation.

- **Worker Health and Hygiene** sets requirements for reducing food safety risks with good training and appropriate hygiene practices for farmers and employees who are in contact with produce.
- **Agricultural Water** must meet specific water quality standards depending on the water source and how it is used on the farm. Irrigation water and post-harvesting handling water (including water used for washing produce, hands and contact surfaces) must meet specific testing criteria for generic *E. coli*. Required testing frequency depends on your specific water quality, source, and use.
- **Biological Soil Amendments** section defines how raw manure and stabilized compost may be used as soil amendments to minimize the risk of contaminating produce. At this time, the recommendation is to follow the National Organic Program Standards for raw manure.
- **Domesticated and Wild Animals** section recognizes that animals are a part of farms but requires farmers to have crop monitoring and corrective action practices to minimize contamination or damage to crops caused by animals.
- **Equipment, Tools and Buildings** section addresses storage, maintenance, and sanitation of surfaces that can come into contact with produce. For example, things to consider include hand washing facilities, packing sheds, tractors and harvesting bins.
- **Record Keeping** – FDA has included specific recordkeeping criteria related to different parts of the rule to increase accountability, traceability, and transparency of practices. Sales records, water-testing results, stabilized compost treatments, and equipment cleaning schedules are some of the activities that may need documented recordkeeping.
Sprouts have special requirements because of their susceptibility to contamination. If you grow sprouts, please see the Sprout Safety Alliance for more details, [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293429.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm293429.htm)

Where can I find key information for farmers to help me understand the Produce Safety Rule?
WSDA has partnered with the Federal Food and Drug Administration (FDA) to establish a Produce Safety Program that is responsible for promoting the understanding of and compliance with the FDA Produce Safety Rule. Questions regarding the development or implementation of this program can be sent to Roger Beekman at producesafety@agr.wa.gov or he can be reached at 360-742-8472.

The National Sustainable Agriculture Coalition has an excellent set of blog posts, recorded interviews, and charts to help farmers understand the specific requirements of rules and how they apply to small farms, [sustainableagriculture.net/blog/produce-rule-analysis-part-1/](http://sustainableagriculture.net/blog/produce-rule-analysis-part-1/)

FDA overview and guidance, [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm)


The Good Manufacturing Practices (GMP) and Preventive Controls Rule for Processors

I already have a WSDA Food Processor License. Does the GMP and Preventive Controls Rule apply to me?
Yes. How it applies depends on your products. WSDA’s Food Processor License requirements are designed around the basic criteria of Good Manufacturing Practices (GMP). This means if you are licensed by WSDA, you are already following GMP for your product.

FSMA updates GMP by adding the Preventive Controls Rule. With the updated GMP, products that are considered to be at a higher risk (due to a presence of allergens or likelihood of pathogens for example) fall under the new regulation. For Preventive Controls, processors must do a hazard analysis of their process to determine the potential points where risks of contamination exist and create a Food Safety Plan that outlines the steps or “preventive controls” they will use to reduce the risks of contamination.

Where can I find key information for food processors about the Preventive Controls Rule?
The FDA Overview of the FSMA Proposed for Preventive Controls for Human Food is an excellent resource, [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm)


Where can I get training on Preventive Controls?
The Food Safety Preventive Controls Alliance (FSPCA) provides training and information, [www.iit.edu/ifsh/alliance/](http://www.iit.edu/ifsh/alliance/)

WSU Food Processing Extension and Research offers trainings and resources on Preventive Controls for food processors. [foodprocessing.wsu.edu](http://foodprocessing.wsu.edu/) Dr. Girish Ganjyal, girish.ganjyal@wsu.edu or 509-335-5613.

Northwest Food Processors Association, [www.nwfpa.org/nwfpa-events/training](http://www.nwfpa.org/nwfpa-events/training)
Are there any exemptions to the Preventive Controls Rule?
Under the Preventive Controls Rule from FDA, there are some exemptions. WSDA is currently reviewing those exemptions as part of the process of identifying exactly how the new FDA FSMA regulations will be implemented in Washington State.

Compliance Timeline and Enforcement
When do farms and processors have to comply with FSMA?
Both the Produce Safety Rule and the Preventive Controls Rule are being implemented now. The specific timelines for implementation and compliance vary by the different parts of the rules and based on the size your business and type of market. The tables below provide an overview of the compliance timelines for the Produce Safety Rule and the Preventive Controls Rule.

### TABLE 1. SUMMARY OF PRODUCE SAFETY RULE COMPLIANCE DEADLINES

<table>
<thead>
<tr>
<th>Category</th>
<th>Produce Safety Compliance Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Keeping Requirements for sales of food and produce*</td>
<td>January 2016</td>
</tr>
<tr>
<td>General Compliance (more than $500,000 in annual produce sales)</td>
<td>January 2018</td>
</tr>
<tr>
<td>Small Businesses (between $250,000 and $500,000 in annual produce sales)</td>
<td>January 2019</td>
</tr>
<tr>
<td>Very Small Businesses (less than $250,000 in annual produce sales)</td>
<td>January 2020</td>
</tr>
</tbody>
</table>
| Water Requirements                                                      | All farms have an additional two years from the applicable deadline above, though some testing and recordkeeping prior to this deadline may be advised.
| Labeling Requirements*                                                  | January 2020                      |

*These deadlines also apply to Qualified Exempt farms.

### TABLE 2. SUMMARY OF PREVENTIVE CONTROLS RULE COMPLIANCE DEADLINES

<table>
<thead>
<tr>
<th>Category</th>
<th>Preventive Controls Compliance Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Record Keeping Requirements*</td>
<td>January 2016</td>
</tr>
<tr>
<td>General Compliance</td>
<td>September 2017</td>
</tr>
<tr>
<td>Small Businesses (less than 500 full-time equivalent employees)</td>
<td>September 2016</td>
</tr>
<tr>
<td>Businesses subject to Pasteurized Milk Ordinance</td>
<td>September 2018</td>
</tr>
<tr>
<td>Very Small Businesses (Less than $1 million market value of annual food produced and/or sold)</td>
<td>January 2019</td>
</tr>
</tbody>
</table>

*Applies to all businesses.
**How will the rules be enforced?**
The exact way the rules will be enforced is not yet defined. FDA has directed individual states to determine specifically how the new regulations will be adopted and enforced in each state.

WSDA is currently working on how the regulations will be adopted in our state and has begun state rulemaking procedures. WSDA is seeking engagement from stakeholders, including farms and food processors regarding this rulemaking. You can learn more about rulemaking and track activity, like public hearings, for specific rules on WSDA’s website, agr.wa.gov/lawsrules/.

**Where can I find information about all the FSMA Rules?**
The FDA has developed web pages for each rule in FSMA that include fact sheets, guidance, and links to the final rule as they were published in the Federal Register.

- Complete FSMA, [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm)
- Produce Safety Rule, [www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm](http://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm)
- GMP / Preventive Controls for Human Food Rule, [www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm)

---

**Recommended Fact Sheets**

18. Good Agricultural Practices (GAPs)
19. WSDA Food Processor License and Facilities

*For further information, to provide comments, or suggest a resource to add to this fact sheet, please email smallfarms@agr.wa.gov or call (206) 256-6157.*
Selling Juice

Some farms are seeing opportunity in juice and juice products as a way to add value to their fruits and vegetables, allowing farms to expand into different marketplaces. Shelf-stable juices can be sold year-round. Bars, restaurants, and shoppers seeking new flavors or health-oriented products are all among potential customers for unique juice products.

Your licensing and marketing options depend on whether your juice is raw or treated. This fact sheet deals with 100% juice products and beverages that include juice as an ingredient such as juice added to sparkling water, teas, kombucha, etc.

Raw Juice

Raw juice and beverages containing raw juice may only be sold in a retail environment where the juice is provided directly to the customer, such as a farmers market, juice bar, or restaurant. It cannot be sold or distributed to other businesses. Raw juice cannot be sold wholesale in Washington State.

To sell raw juice, or a product containing raw juice, you must contact your county health department for specific permitting information. Specific requirements may vary from county to county.

Pasteurized and Treated Juice

If you would like to sell your juice product wholesale for example, to a local restaurant, bar, local grocery or co-op, or if you would like to sell and ship online, you need a WSDA Food Processor License.

If your product is 100% juice you must pasteurize or appropriately treat your juice and follow the FDA’s rules for Juice Hazard Analysis and Critical Control Point (HACCP) regulation as part of your WSDA licensing. If you produce and sell a juice beverage that has juice or puree as an ingredient along with other ingredients, for example, sugar or water, the juice ingredient itself must be treated according to the same FDA Juice HACCP regulations.

**TABLE 1. SUMMARY OF JUICE MARKETING OPTIONS AND LICENSING REQUIREMENTS**

<table>
<thead>
<tr>
<th>Product</th>
<th>Direct Retail</th>
<th>Wholesale</th>
<th>License/Permit Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Juice and Raw Juice Beverages</td>
<td>YES</td>
<td>NO</td>
<td>Local Health Jurisdiction Permit</td>
</tr>
<tr>
<td>Pasteurized Juice and Treated Juice Beverages</td>
<td>YES</td>
<td>YES</td>
<td>WSDA Food Processor License</td>
</tr>
</tbody>
</table>
Production of the final beverage product will need to follow FDA’s Preventive Controls rules to obtain WSDA licensing. Large firms need to follow Preventive Controls rules now. Small firms will be required to do so starting by 2019. Under FDA’s Preventive Controls rules, your juice beverage needs to be appropriately treated.

WSDA Juice Licensing for 100% juice and juice beverages is described below.

**WSDA Food Processor License for Treated Juice**

For general information on the WSDA Food Processor License, please see fact sheet 18, “WSDA Food Processor License and Facilities.” Obtaining a WSDA Food Processor License for juice or a beverage containing juice involves meeting additional juice-specific requirements.

**Juice Hazard Analysis and Critical Control Point (HACCP) Plan for 100% Juice**

As part of obtaining a WSDA Food Processor License for juice, you will need to develop and follow a Juice HACCP Plan. The HACCP Plan is a preventive way of managing food safety that focuses on analyzing and controlling biological, chemical, and physical hazards to reduce them in advance, rather than reacting to them. In your HACCP Plan, you will identify key points in the process where a food hazard is reasonably likely to occur and apply measures to reduce or eliminate those food hazards.

The first step in creating a HACCP Plan is doing a Hazard Analysis to identify all the potential hazards in your production process. This includes identifying the pertinent microorganisms, such as *E. coli* or *Salmonella*, that pose a risk in your product. When you conduct a Hazard Analysis, you assess the likelihood of each hazard happening, how severe the health consequences would be, and how you will address the hazard. Then you identify the critical points in your production process where you can control for the hazards.

**Pasteurization and 5-Log Reduction**

Juice HACCP regulation requires that pertinent microorganisms be controlled with a treatment that results in a “5-log reduction.” This means that the number of the target microorganism present in the juice is 100,000 times smaller after the treatment than before. Essentially, this means juice needs to be pasteurized. The regulation does allow the use of other treatment processes, such as UV radiation. No matter which treatment process you use, you must consistently demonstrate that your process results in a 5-log reduction in the pertinent pathogens for your juice. Pasteurization times and temperatures vary depending on the type of product, process, the target microorganism, and the pH for the product.

**Juice HACCP Training**

To develop and implement your specific Juice HACCP Plan you need to have HACCP training or equivalent on the job experience that gives you the knowledge to identify hazards and the appropriate critical controls for your specific product and process. You may choose to consult with an expert trained to evaluate the effectiveness of your process and control measures. A Juice HACCP expert can determine the pasteurization practices that will work for your particular juice product.

Washington State University (WSU) Food Processing Extension and Research offers trainings for food processors and resources for product and process development. Their food lab can also do pathogen testing. For information, visit [www.foodprocessing.wsu.edu](http://www.foodprocessing.wsu.edu) or contact Dr. Girish Ganjyal at girish.ganjyal@wsu.edu or (509) 335-5613.
Visit the WSDA Food Safety Program webpage www.agr.wa.gov/foodanimal/foodprocessors/haccp for resources to help with HACCP planning, including links to HACCP training opportunities.

Visit www.fda.gov/Food/GuidanceRegulation/HACCP/ for detailed information about Juice HACCP, including an example of a good juice HACCP plan.

Preventive Controls for Beverages Containing Juice
If your product is a beverage containing juice as an ingredient but is not 100% juice, your product falls under the Preventive Controls regulations. Juice ingredients will need to be processed according to Juice HACCP described above before they are added to your product. However, the final product may not need to be treated for a 5-log reduction. Instead, to obtain a WSDA Food Processor license you will need to develop an appropriate Food Safety Plan that identifies the preventive controls, such as heat treatment or acidification, that you will use to ensure your product is safe and “shelf stable.” You must show with valid scientific studies that the treatment process you are using will destroy the food borne microorganisms that cause illness or spoil food.

For training and resources to develop a food safety plan with preventive controls visit www.iit.edu/ifsh/alliance for information from the Food Safety Preventive Controls Alliance.

Resources

In addition to the resources listed above, visit the Northwest Food Processors Association at www.nwfpa.org for training and other resources for food processors.

Recommended Fact Sheets

4. Licensing
18. WSDA Food Processor License and Facilities
22. FAQ on the Food Safety Modernization Act (FSMA)

For further information, to provide comments, or suggest a resource to add to this fact sheet, please email smallfarms@agr.wa.gov or call (206) 256-6157.