



A GUIDE FOR FOOD HUBS ON FOOD SAFETY COMPLIANCE

USDA Photo by Lance Cheung

COMPLIANCE & RISK STRATEGY

To reduce food safety risk and liability, food hubs should adhere to relevant laws and regulations and be aware of liabilities and risk. This can be challenging because food hubs have a wide array of functions, they interact with many parts of the food system, and the applicable rules and regulations are not necessarily written with food hubs in mind. This short guide for decision-makers at food hubs or those advising a food hub will address common considerations for compliance and risk management related to food safety. **We suggest that the best way to use this guide is with the advice of a lawyer and/or food safety consultant.**

The United States Department of Agriculture (USDA) defines a food hub as “a centrally located facility with a business management structure facilitating the aggregation, storage, processing, distribution, and/or marketing of locally/regionally produced food products.”¹ Food hubs range tremendously depending on what parts of the food system they interact with and how they are structured. The content of this guide is the same regardless of whether your food hub is a cooperative, nonprofit, or other entity/tax structure.

All enterprises, including for-profit and nonprofit, must consider the legal landscape or set of laws and regulations that apply to them. These rules, which might be laws or regulations or a combination of the two, can be federal, state, or municipal.² Food hubs must follow the rules of every jurisdiction they work in, even if that just means they have simply driven food through another state. Generally, if an enterprise does not comply with these rules, fines may be assessed or licenses may be revoked. Fines can range tremendously from just a few dollars in interest to millions of dollars, depending on the type, scale, and culpability of the organization’s leadership. If the state or federal government revokes necessary licensure, an organization might have to materially alter or abandon certain business practices or revenue streams.

Another source of rules businesses must be aware of comes from court decisions issued to resolve litigation. Litigation is generally when one party sues another party because someone infringed on someone else’s rights, for example when a customer sues a manufacturer because the manufacturer’s product made the customer sick. The penalties assessed for infringing on someone else’s rights vary from “actual damages,”³ which are the costs to return someone to the condition as if the infringement never happened, or “liquidated damages,”⁴ which are defined in contracts between the parties. An important part of business risk mitigation is a “dispute resolution clause,” which is a contract term that sets out the rules and/or procedures to follow if the parties have a dispute; however, such clauses are beyond the scope of this document.⁵

The way a business builds its operations to conform to legal and regulatory requirements and obligations laid out in contracts is called a **compliance strategy**.⁶ This guide will help walk you through various considerations when developing your food safety compliance strategy. In this resource, we address a broad set of legal considerations in the hopes of providing legal information that is useful to most food hubs. However, it is impossible to definitively address all the legal questions a food hub might have, since many of the answers are specific to each food hub’s unique operations.

In addition to strict compliance and risk mitigation, you might also weigh other factors, such as consumer preferences, supplier relationships, environmental impact, labor availability, necessary space, and equipment upgrades, in developing your entire business strategy. This guide will help you consider what steps you need to take to comply with relevant food safety laws; however, you should consider all the above factors in making the right decisions for your food hub—legal and otherwise.

FOOD SAFETY

All food establishments—including farms, distributors, and food hubs—must adhere to food safety rules. Food safety rules are a tapestry of federal, state, and local law. They are complex and specific. This guide focuses on food safety requirements because they are one of the most likely places for non-compliance, and food safety is not well-suited for a poorly planned compliance strategy.

The federal food safety landscape dramatically changed in 2011, when Congress signed the Food Safety Modernization Act (FSMA) into law.⁷ FSMA governs the food system and directed the federal Food and Drug Administration (FDA) to create standards for food safety through seven “foundational” rules:

1. **Preventive Controls for Human Food:** Requires that food facilities have safety plans that set forth how they will identify and minimize hazards
2. **Preventive Controls for Animal Food:** Establishes Current Good Manufacturing Practices and preventive controls for food for animals
3. **Produce Safety:** Establishes science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms
4. **Foreign Supplier Verification Program:** Requires importers to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as that required of U.S. food producers
5. **Third Party Certification:** Establishes a program for the accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities producing food for humans or animals
6. **Sanitary Transportation:** Requires those who transport food to use sanitary practices to ensure the safety of food
7. **Intentional Adulteration:** Requires domestic and foreign facilities to address vulnerable processes in their operations to prevent acts intended to cause large-scale public harm⁸

For the purposes of this resource, we will only cover food holding and processing. Therefore, we are only covering Preventive Controls for Human Food, which we believe to be the most relevant for food hubs. We are specifically

excluding farms—even if they hold, transport, or process food—because farms are regulated by the Produce Safety Rule. Please see our publications at Extension Legal Services Initiative for more information on the Produce Safety Rule.⁹

This guide should serve as a tool for food hubs to develop compliance goals and a high-level strategy. To that end, this guide provides a series of questions and answers to help direct users to the best routes for compliance.



USDA Photo by Bob Nichols

What type of food hub activities do you engage in?

Most food safety laws do not mention food hubs by name, so it may be challenging to get a quick answer to this question. The first step is to work through all your operations and list the specific activities of your food hub to better understand which laws might apply.

One way to categorize these activities is to separate them by their function in the food supply chain. For example, activities could fall into the following categories: farms/harvesters, aggregators/warehouses, distributors, processors, transporters, retailers, and food service. Many food hubs will fall into more than one category, and the FDA regulates them all differently. So, when building your compliance strategy, be specific about which activities you are considering and be sure to consider all of them.

Relatedly, you'll want to have a clear understanding of how far up you are in the value chain or, put another way, **to whom are you selling**. If you are selling to the end consumer (i.e., the person who will eat the food), you are engaging in direct-to-consumer sales. This is true even if the way you would categorize the majority of your operations is farming, transporting, or aggregating. However, if you are selling to other organizations that will then process or re-sell the product before it is eaten—for example distributors, restaurants, and retailers—you are a wholesaler. Below, this guide will address certain exemptions that apply to food hubs which are engaged in local wholesale.

The law presumes that wholesalers, because of the volume of product they deal with, are more able to adhere to strict food safety rules and, therefore, constitute an important intervention point for public health protection. Wholesalers also are generally understood to have greater resources in determining if they are exempt from certain rules. Therefore, the burden is on wholesalers to identify their own exemptions. Your enterprise may be engaged in both wholesale and direct-to-consumer sales. If this is the case, you should document what percentage of your sales are attributable to each type of buyer, as this is often the deciding factor in what rules you must adhere to and which you are exempt from.

Another way to categorize these activities is by the **kind of food you are buying or selling**. Whether the food is processed or not is one important distinction. There are also important distinctions between forms of processing, for example, fermented, acid preserved, canned, baked, heat treated, frozen, etc.¹⁰ There are also different regulations for unprocessed foods, depending on whether the food is produce, meat, fish, dairy, etc.¹¹

Is there a difference between the food safety rules that the government requires me to follow and those required by a distributor that buys from our food hub?

Yes, rules from the government are generally compulsory, while expectations in your contracts with other organizations might be flexible, at least until you sign the contract. Then they also become compulsory. While one is imposed by government and one is imposed by a private party, both can constitute legal obligations. It is important to understand which rules are inflexible and which you can negotiate.

Major distributors may require certain food safety safeguards to work with your food hub. Some of these might be processes that you already follow, and some might require new systems and/or equipment. If possible, you should consult with an attorney when you are signing any supplier agreements. These agreements will likely contain food safety provisions that you must comply with; otherwise you will be in **material breach** of those agreements and could owe those distributors a lot of money.

Agreements with distributors will often include “indemnification” language. Indemnity means that if the distributor is liable for any damages, fines, or other penalties, the distributor can bring a lawsuit to recover against your food hub if you were ultimately responsible for the harm. For example, if your food hub sold 20 pallets of melons to Sodexo, and those melons were contaminated with E. coli because your food hub's food safety preventive controls failed, and Sodexo sold those melons to a school, and hundreds of children got sick, Sodexo could bring a lawsuit against your food hub for any payments Sodexo had to make to the parents of the injured children. This would be a “material breach” or a failure to perform necessary obligations under the contract.

To avoid this, you should ensure you fully understand and are able to comply with all obligations included in these contractual agreements before signing them. If you are unable to comply with or do not fully understand any of the food safety provisions that are mandated in a supplier agreement, do NOT sign that agreement. You should either try to identify a different distributor or wait to sign the agreement until you can meet all the requirements. If you are uncertain what the requirements mean, you should consult a food safety professional and/or an attorney.

Does my facility need to follow the Preventive Controls for Human Food Rule (PCR)?

The FSMA rule with which most food hubs must comply is the Preventive Controls for Human Food Rule (PCR).¹² The PCR establishes food safety requirements for food facilities that manufacture, process, pack, or hold food for consumption in the United States.^{13,14} If your food hub is an intermediary, meaning that you neither grow food nor sell to the end consumer, you may also find our resource, *Understanding When a Produce Market Intermediary is Subject to FSMA, useful*.¹⁵ This guide has additional resources in the Appendix, including *Demystifying the Food Safety Modernization Act's Preventative Controls Rule*, which has several helpful flowcharts.

Prior to FSMA, all facilities were required to comply with current good manufacturing practices (cGMPs). In addition, certain higher-risk facilities (e.g., juice and seafood facilities) were required to create food safety plans called hazard analysis and critical control point (HACCP) plans.¹⁶ Post-FSMA, facilities must comply with updated cGMPs and must now create food safety plans based on a Hazard Analysis and Risk-Based Preventive Controls (HARPC) framework.¹⁷

These rules apply to certain activities and parties. There are two ways an organization can avoid necessary compliance with those rules, either by not engaging in activities or with parties covered by the rule or by meeting one of the exemptions included in the rule. An exemption is when a party or activity that would normally be subject to the rule is not because the law excludes specific parties or activities. For example, food hubs may not have to follow the requirements of the PCR because they are not engaged in covered activities with covered parties or because they fall within an exemption. Sometimes, resolution of these questions depends on how the language of the regulations is interpreted by regulators and/or courts. The following sections will discuss these issues.

Is my food hub regulated under the PCR?

The PCR only applies to “a facility that manufactures, processes, packs, or holds food for sale in the United States.”¹⁸ Importantly, “facility” is a defined term under the rule and does not have a standard, plain language meaning but instead means a “facility that is required to register [as a food facility with FDA].”¹⁹ The retail food establishments and nonprofits serving prepared food directly to consumers do not have to register as food facilities and are, therefore, not regulated by the PCR.²⁰ A retail food establishment is

one that “sells food products directly to consumers as its primary function.”²¹ Sale of food direct-to-consumer is an establishment’s “primary function” if their annual revenue from those sales exceeds their revenue from sales of food to all other buyers (e.g. sales to other distributors, sales to restaurants, or institutions).²² For example, a retail food establishment can be a grocery store or restaurant, and a nonprofit serving to customers might be a soup kitchen or food bank.²³ Essentially, the PCR only applies to wholesalers.

Does my facility fall within an articulated exemption?

Exempt Facilities: If you have identified that you are a food facility and must register, there are some other factors that may exempt your organization from the rest of the requirements under the PCR. Some examples of exemptions from the PCR are facilities that are regulated under different food safety regulatory systems, such as fish and fishery products, dietary supplements, and activities regulated by the Produce Safety Rule.²⁴ If you believe that you would fall under these exemptions, we recommend that you internally document your exempt status and work with an attorney if your operations fall within an ambiguous area.

Is my facility subject to a qualified exemption (“Qualified Facilities”)?

Some facilities will be subject to what is called a qualified exemption, meaning that they must follow less stringent food safety rules.²⁵

The first type of facility that receives this exemption is a “local and regional market participant.” These facilities must have less than \$500,000 in average annual sales of food over the past three years, and more than half of those sales must be to qualified end-users.²⁶ Qualified end-users are defined as being either an individual human consumer of the food (not a business), a restaurant, or a retail food establishment.²⁷ However, the restaurant or retail food establishment must be located “in the same State or the same Indian reservation as the qualified facility” or no more than 275 miles away from the qualified facility.²⁸ This rule is identical to the qualified exemption for farms from the Produce Safety Rule. Additionally, the restaurant or retail food establishment must be purchasing the food for sale directly to consumers at their establishment.²⁹

The second type of facility that receives a qualified exemption is a “very small business.” A very small business is one with less than \$1 million in annual sales, based on average sales over the last three years and adjusted for inflation.³⁰

A qualified exempt facility is exempt from the requirement to create and implement Hazard Analysis and Risk-Based Preventive Controls. However, a qualified exempt facility must still do the following:

1. Register with FDA as a food facility.
2. Follow updated cGMPs.³¹
3. Submit two attestations to FDA, one attesting to the status as a qualified facility, and the other attesting that the facility either is identifying potential hazards and implementing and monitoring preventive controls for those hazards, or is in compliance with any applicable non-federal (e.g., state or county) food safety law.³² Attestations can be submitted online or by mail and do not require the business to send in records of sales or compliance, but the business should maintain such records.³³

The FDA can withdraw this qualified exemption but must follow certain procedures for doing so. If this occurs and the party unsuccessfully appeals, the facility must come into compliance with all the applicable provisions of the PCR within 120 days of the withdrawal order.³⁴

(NOTE: There is a similar, but different, qualified exemption for farms that also have food storage and food processing functions, called Farm-Mixed Type Facilities. To avoid confusion, we do not cover them here. For more information on that please see the National Sustainable Agricultural Coalition's flowchart on the subject.)³⁵

My facility is covered by the PCR and doesn't fall within an exemption. Now what?

Unless an exemption applies (see above), all establishments that manufacture, process, pack, or hold food for consumption in the United States are fully covered under the PCR and must abide by all its requirements.

Covered facilities are required to comply with the following requirements:

1. Register as a food facility with FDA.
2. Follow updated cGMPs.³⁶
3. Follow HARPC standards, which include (in addition to recordkeeping) identifying manufacturing and processing activities that might pose a food safety risk, creating a food safety plan to prevent those risks, monitoring the processes, fixing any problems, keeping records of manufacturing and processing activities, establishing a risk-based supplier

verification program for raw material and ingredients identified as a significant hazard when controlled by the supplier, identifying corrective actions a facility will take in the event controls are inadequate or fail, and performing various verification measures.³⁷

4. Create and implement a Supply-Chain Program.³⁸

How do I register as a food facility?

The first step to complying with the PCR is to register as a food facility.³⁹ The FDA registration requirements apply to establishments engaged in the “packing or holding of food for consumption in the United States[.]”⁴⁰ The FDA's regulations define “holding of food” as “including activities performed as a practical necessity for the distribution of that food.”⁴¹

The process of registering for a food facility is extremely straightforward. The goal of this registration is merely to provide the FDA with a contact in case there is a food safety concern. To register as a food facility, you will need to create an account on the FDA's website and follow the steps on the platform.⁴²

I have determined that I must comply with the Preventive Control Rule, and I have registered my food facility. Now what?

If you meet a qualified exemption, you need only comply with cGMPs. Subpart B of the PCR provides all cGMPs.⁴³ Many of these requirements are the same as those in your local health code and are likely what a health inspector will also require of your facility. However, you should go line-by-line with your attorney or food safety consultant to ensure that your facility is compliant.

If you do not fall within any exemption to the PCR, your facility must comply with cGMPs and follow the HARPC standards. Subpart C of the PCR includes all the requirements to comply with HARPC standards.⁴⁴ Developing your compliance strategy to meet the HARPC standards is extremely technical. To assist in this process, FDA has developed a tool called a Food Safety Plan Builder.⁴⁵ Food Hubs have said that the Food Safety Plan Builder might be too technical and difficult to use for most food hubs. You should connect with other food hubs in your area to understand how they are complying with FSMA; you might also find a food safety consultant helpful especially in some specific areas, such as seafood.

What is a Supply Chain Program, and does my food hub need one?

Subpart G of the PCR regulates Supply Chain Programs. These programs establish the requirements that a food facility, which receives food from other sources, must impose on its suppliers.⁴⁶ If your facility is fully covered by the PCR, meaning neither exempt nor qualified exempt, then you must also create a risk-based Supply Chain Program.⁴⁷ However, a large distributor may require that you participate in its supplier verification as part of their Supply Chain Program for you to sell to them or may also require your food hub to verify its suppliers.

In contrast, FSMA does not currently require purchasing businesses to ensure a farm's compliance with the Produce Safety Rule.⁴⁸ However, if your food hub does business with a large third-party distributor, they may require you to certify that the farms you purchase from comply with a food safety standard (like USDA GAPs or GroupGAP, for example).⁴⁹ This is true even if some of the farms you purchase from are exempt from FSMA.⁵⁰

Compliance with the Supply Chain Program is a function of contract and supplier's operations. This is not about what your food hub does, but rather, it considers the actions of your suppliers, i.e., those who are in your supply chain. To comply with this requirement, you must establish operations protocols to prevent a potential hazard from being hazardous. You will also need a well-drafted agreement and enforcement of that agreement if you know one of your suppliers is not adhering to the agreement. See below Appendix B for an example of an Attestation used by a food hub for their suppliers to ensure compliance with the necessary food safety standards.

How does my food safety compliance strategy integrate with my organic certification?

If you are a certified organic handler, you already have an organic system handling plan in place regarding commingling product, record keeping, labeling, permitted sanitation, etc.⁵¹ Your plan to comply with relevant food safety regulations is in addition to your obligations under your organic plan. Note that new organic rules, finalized in March of 2023, will come into effect in March of 2024.⁵² If you anticipate that you will be impacted by the new rules, you must ensure that your food safety compliance strategy is consistent with the new organic requirements. The new organic enforcement rules apply to: (1) anyone considering organic certification; (2) existing certified organic producers,

handlers, or processors; (3) importers and brokers of organic products; and (4) retailers selling organic products. These changes will impact organizations (especially importers, brokers, and retailers) who have never been regulated under the USDA organic regulations.

Subject to several exemptions, which are beyond the scope of this guide, after March 2024, many food hubs will require more specific recordkeeping, a more detailed organic production and handling system plan, and labeling of non-retail containers.⁵³ Most importantly, each handling facility will be subject to annual unannounced inspections by their certifying organization.⁵⁴ All of these requirements are in addition to your other food safety obligations.

My facility handles dairy. Do I need a license?

Dairy across the United States is heavily regulated by a patchwork of state laws. If your facility handles dairy in any way, you will likely have additional licensing requirements. These state licenses do not exempt your food hub from compliance with the PCR.⁵⁵ However, if a dairy transporter is licensed to transport Grade A milk, that transporter may be exempt from certain transportation requirements, which are beyond the scope of this guide. If you sell or transport any dairy products across state lines, you may need a different license for each state you do business in or travel through.

Check with your state's Department of Agriculture to determine if you need additional licensure for your dairy program. For example, the Vermont Agency of Agriculture Food and Markets has a dedicated Dairy Section available to answer questions.⁵⁶ Vermont food hubs who sell dairy will likely need to obtain a Vermont Milk Handler License.⁵⁷

My facility handles meat. Do I need a license?

In many states, the responsibility for ensuring the safety of animal meat products is shared between the state department of agriculture and the Food Safety and Inspection Service (FSIS) of the USDA.⁵⁸ In most states there is also a requirement that facilities get a license and inspections to handle meat. For more information on state programs for meat processing, please see The National Agricultural Law Center's *Meat Processing Laws in the United States* resource.⁵⁹

Any meat or poultry products offered for sale, provided the meat is not sold on-farm, must be slaughtered in a USDA inspected facility.⁶⁰ If your facility processes animals, you will need to comply with this rule by ensuring USDA

inspection. Even if your food hub does not process meat, you may still have specific licenses and requirements for selling meat. You should contact your local health department for more specific requirements, which may include refrigeration, freezing, and thawing requirements and particular equipment for cooking, such as a ventilation hood system and fire suppression system (i.e., Ansel system).⁶¹ Your food hub should ensure that all meat it sells is processed in a USDA facility.

Occasionally, your food hub may encounter meat labeled “Custom NOT FOR RESALE.” This is meat that is slaughtered by the farmer or another uninspected processor and may only be consumed by the person who owned the livestock. If you have more questions about on-farm slaughter, see our report on the topic.⁶²

My facility handles or packages eggs. What do I need to consider?

Federal regulations require that eggs be refrigerated as soon as possible and kept at 45°F in sanitary surroundings, and that records of transactions related to eggs be kept and made available on site.⁶³ Common ways to comply with these regulations include keeping a thermometer and a temperature log in fridges used to store eggs and implementing a protocol for checking the fridge temperature periodically, which should already be part of your overall food safety compliance strategy. While many of the labels on eggs, i.e., “pasture-raised,” “local,” and “fresh,” are unregulated in most jurisdictions, you are obligated to tell the truth in your labeling, advertising, and marketing. USDA does have requirements for certain labels, such as “cage free” and “free range,” but these label rules only apply to eggs graded by the USDA as A or AA.⁶⁴ For more questions on specific labeling, please see our resource [Labels Unwrapped](#).⁶⁵

Does my facility have to register with a state agency as a warehouse?

Several states have requirements to register as a warehouse or hold a warehousing license.⁶⁶ Consider whether your food hub is renting temperature-controlled warehouse space (e.g., a farmer is paying you to store produce at your facility that your food hub does not own) or if the food hub is purchasing product to resell, as these could trigger different compliance requirements. States require different things, so make sure to consult with a licensed lawyer in your state, and/or call your state agriculture department. In our experience, many state departments of agriculture have staff dedicated specifically to answering compliance questions.

Does my facility require any state-level health licensing? Do any state- or municipal-level health department regulations apply?

Yes, every state except for California, which has its own food regulation, has adopted a version of the FDA’s Food Code.⁶⁷ The Food Code regulates the types of practices and infrastructure that must be in place to handle food, for example, requirements for three-bay sinks and “Employees Must Wash Hands” signage. Each state’s food code will empower either state or municipal health departments to enforce that state’s food code. You have likely already made contact with your health inspector. Though rules and regulations vary by state and municipality, the common thread is that these regulations tend to cover prepared and/or processed foods and foods served for immediate consumption.

CONCLUSION

Ultimately, in the United States, food is a relatively heavily regulated industry. You, in conjunction with your attorney and/or food safety consultant, should have a plan to ensure you will comply with the many laws, regulations, and legal obligations affecting food enterprises. As described in this guide, you may be exempt from compliance with the most onerous of the FSMA requirements. If you are exempt from any rules, an important part of your compliance strategy is to document the reasons you are exempt from that rule, should a regulator ask at any point in the future. This documentation can be as simple as a couple of sentences.

If you have questions that are unanswered in this guide, contact an attorney. If you do not have an existing relationship with a food business attorney, there may be specialized referral networks, such as the Legal Food Hub in New England, to help connect you with an attorney. If there are no such networks in your community, you can always contact your state bar association for an attorney referral. You should also connect with other food hubs. They are the best resources for on-the-ground experiences, especially with your local regulators.

About the Center for Agriculture and Food Systems at Vermont Law and Graduate School



Vermont Law and Graduate School's Center for Agriculture and Food Systems (CAFS) uses law and policy to build a more sustainable and just food system. With local, regional, national, and international partners, CAFS addresses food system challenges related to food justice, food security, farmland access, animal welfare, worker protections, the environment, and public health, among others. CAFS works closely with its partners to provide legal services that respond to their needs and develop resources that empower the communities they serve. Visit vermontlaw.edu/cafs to learn more.

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Disclaimer

The information provided in this guide does not, and is not intended to, constitute legal advice; instead, all information, content, and materials available on this site are for general informational purposes only. Information on this website may not constitute the most up-to-date legal or other information.

Useful Resources for More Information on Food Safety for Food Hubs

General Resources

Farm Commons Resource Library:

Has some free resources. Several require a membership.

<https://farmcommons.org/library/resources/>

See the “Checklist for Managing your Food Safety Liability” free resource here:

<https://farmcommons.org/resources/articles/checklist-for-managing-your-food-safety-liability/>

Produce Safety Rule Resources

FDA’s website on the PSR:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety>

CAFS and UVM collaboration on PSR:

<https://elsi.necafs.org/>

Rhode Island Department of Environmental Management (RI-DEM) tool for PSR applicability determination:

<https://ridem.wufoo.com/forms/psr-coverage-determination-tool/>

National Sustainable Agriculture Coalition (NSAC) flowchart on whether PSR applies:

http://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf

NSAC’s “Understanding FDA’s FSMA Rule for Produce Farms”:

<http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-PRODUCE-RULE-FINAL.pdf>

Cornell College of Agriculture and Life Sciences website for the Produce Safety Alliance:

<https://cals.cornell.edu/produce-safety-alliance/food-safety-modernization-act/produce-safety-rule>

Pennsylvania State University Extension Service video on the PSR:

<https://extension.psu.edu/the-produce-safety-rule-video>

Demystifying the Food Safety Modernization Act’s Preventive Controls Rule:

Supplier Verification Requirement:

<https://caff.org/wp-content/uploads/2021/04/FSMA-Supplier-Verification-Final-0326-21.pdf>

Appendix B: Sample Attestation



[Producer/Farm Name as a letterhead]

[Date]

To Whom It May Concern:

This document certifies that the product(s) sold to the Food Connects Food Hub (FCFH) from [Vendor Name], are safe for human consumption, free from any adulterations or unlabeled additives, in compliance with applicable defect levels, and have been handled in a manner to minimize contamination from biological, chemical, and physical hazards.

PLEASE INITIAL IN EACH BOX BELOW:

I acknowledge, as an authorized representative on behalf of [Vendor Name], that:

	We are responsible for maintaining compliance with all applicable federal, state, and municipal regulations.
	We are responsible for upholding applicable FSMA law, and to maintain proper documentation and certifications.
	We are responsible for the safety and integrity of the food that we produce and sell, regardless of FSMA status.
	We are responsible for ensuring our product is in compliance with all applicable labeling laws.
	We understand, pending regulatory status, that we may be required to maintain a recall plan and conduct annual mock recalls. Regardless of our regulatory status, we understand it is strongly recommended to maintain a recall plan and conduct annual mock recalls.
	If there is a recall connected to my product, we may: <ul style="list-style-type: none">○ Be subject to additional review and/or inspection by the regulating agency pertaining to the product.○ Experience liability, fines, civil suit(s), and or criminal charges.
	We guarantee that in the event of a significant food safety issue, FCFH will be informed as soon as possible. This includes reporting any issue at hand, the severity, details on the affected product lots and any recalls.
	Food Connects is not responsible for our enterprise's regulatory compliance, policies or record keeping.

All products will be sold and shipped in compliance with FCFH requirements:

- If delivered, products will be transported in a covered truck.
- If delivered, products will NOT be transported with other potentially contaminating materials.
- Products will be packaged in clean boxes or bags, and arrive packaged as sold, per FCFH's Purchase Order.
- If products are processed, all ingredients will be clearly labeled.
- Products will be labeled with vendor name, item name, and quantity (weight or count), using Food Connects supplied labels, or Vendor supplied labels.
- Products will be transported, received or delivered within required temperature zones.
- Products will be accompanied by an invoice matching the pricing per FCFH's Purchase Order.
- Vendor will invoice Food Connects for all orders, and Food Connects will remit payment on 30 day net terms. We prefer that a paper invoice accompany each order, along with an emailed invoice sent to procurement@foodconnects.org and bookkeeper@foodconnects.org.

Signature:

Name & Title:

Date:

Business Name:

ENDNOTES

- 1 Jim Barham, *Getting to Scale with Regional Food Hubs*, USDA (Dec. 14, 2010), <https://www.usda.gov/media/blog/2010/12/14/getting-scale-regional-food-hubs>.
- 2 As a refresher, laws are drafted by legislators (or sometimes voters), and regulations are drafted by agency regulators, a part of the executive branch. Typically, laws are more general and define goals, whereas regulations are more specific and created by people with industry expertise.
- 3 *Actual Damages*, BLACK'S LAW DICTIONARY (11th ed. 2011).
- 4 *Liquidated Damages*, BLACK'S LAW DICTIONARY (11th ed. 2011).
- 5 *Dispute Resolution Clauses*, THOMAS REUTERS: PRACTICAL LAW COMMERCIAL LITIGATION (last visited Oct. 8, 2023), <https://us.practicallaw.thomsonreuters.com/w-027-6352>.
- 6 Stephen Martin & StoneTurn, *Compliance Programs*, LEXIS: PRACTICAL GUIDANCE (updated Jan. 2023).
- 7 Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011).
- 8 *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)* CONGRESSIONAL RESEARCH SERVICE REPORT (2016), <https://www.everycrsreport.com/reports/R43724.html>.
- 9 You can access the Extension Legal Services Initiative here: <https://elsi.necafs.org>.
- 10 Food for Human Consumption, 21 C.F.R. §§ 109.3-189.301 (2023) (presenting a visual example to understand how the FDA subdivides its regulation into food types and activity types).
- 11 *Id.*; see also USDA, *Food Safety Inspection Service: Policy*, <https://www.fsis.usda.gov/policy>.
- 12 *Key Facts about Preventive Controls for Human Food*, FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/files/food/published/Key-Facts-about-Preventive-Controls-for-Human-Food.pdf>.
- 13 *Id.*
- 14 21 C.F.R. § 1.227(b)(2) (2014) (current definition of “facility”).
- 15 *Understanding When a Produce Market Intermediary Is Subject To FSMA*, NECAFS & VERMONT LAW AND GRADUATE SCHOOL: CTR. FOR AGRIC. AND FOOD SYS. (Jun. 2021), <https://elsi.necafs.org/sites/default/files/uploads/Produce%20market%20intermediary%20factsheet.pdf>.
- 16 *Seafood HACCP*, FDA (Jun. 2022), <https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/seafood-haccp>; see also *Juice HACCP*, FDA (Dec. 2021), <https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/juice-haccp>.
- 17 21 C.F.R. § 117.126 (2019).
- 18 21 C.F.R. § 117.1(b) (2016).
- 19 21 C.F.R. § 117.3 (2016).
- 20 21 C.F.R. 1.226(a)-(g); see also 21 C.F.R. 1.227 (2016) (defining relevant terms).
- 21 21 C.F.R. § 1.227.
- 22 *Id.*
- 23 *Id.*
- 24 21 C.F.R. § 117.5.
- 25 21 C.F.R. § 117.3.
- 26 21 C.F.R. § 117.5.
- 27 21 C.F.R. § 117.3.
- 28 *Id.*
- 29 *Id.*
- 30 *FSMA Inflation Adjusted Cut Offs*, FDA (May. 2023), <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs>.
- 31 21 C.F.R. § 117.
- 32 *Qualified Facility Attestation*, FDA (Aug. 2022), <https://www.fda.gov/food/registration-food-facilities/qualified-facility-attestation>.
- 33 *Id.*
- 34 21 C.F.R. § 117.251.
- 35 *Am I affected by new Food Safety Rules under the Food Safety Modernization Act?*, NAT'L. SUSTAINABLE AGRIC. COAL. (2016), https://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf.
- 36 *Understanding FDA's FSMA Rule for Food Facilities*, NAT'L. SUSTAINABLE AGRIC. COAL. (2016), <http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-FACILITIES-FINAL-.pdf>.
- 37 *Id.*
- 38 21 C.F.R. § 117, subpart G.
- 39 21 C.F.R. §§ 1.225-1.245 (2019) (general enforcement regulations).
- 40 21 C.F.R. § 1.225, C.F.; c.f. 21 U.S.C.A. § 350d (a)(1).
- 41 21 C.F.R. § 1.227 (“Holding facilities include warehouses. . .”).
- 42 You can access the Food Facility Registration page here: <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>.
- 43 Current Good Manufacturing Practice, 21 C.F.R. § 117, subpart B.
- 44 Hazard Analysis and Risk-Based Preventive Controls, 21 C.F.R. § 117, subpart C.
- 45 *Food Safety Plan Builder Download*, FDA, <https://www.cfsanappsexternal.fda.gov/scripts/foodSafetyPlan-Builder/>.
- 46 21 C.F.R. § 117, subpart G.
- 47 21 C.F.R. § 117.405.
- 48 *Understanding FDA's FSMA Rule for Produce Farms*, NAT'L. SUSTAINABLE AGRIC. COAL. 11 (2016), <http://sustainableagriculture.net/wp-content/uploads/2008/08/FSMA-PRODUCE-RULE-FINAL.pdf>.
- 49 *Id.*
- 50 *Id.*
- 51 7 C.F.R. § 205.201 (noting that a new Food Traceability Rule may require certain record keeping for certain foods. The Traceability Rule does not come into effect until January 20, 2026, and is beyond the scope of this guide. You can learn if you are exempt from the Food Traceability Rule by visiting <https://collaboration.fda.gov/tefcv13>).
- 52 *National Organic Program (NOP); Strengthening Organic Enforcement*, 88 Fed. Reg. 3548 (Jan. 19, 2023) (to be codified at 7 C.F.R. § 205).
- 53 *Id.*
- 54 7 C.F.R. § 205.403(b) (2023).
- 55 *Frequently Asked Questions on FSMA*, FDA (Jan. 2023), <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma>.
- 56 *Registration & Licensing*, VERMONT AGENCY OF AGRICULTURE FOOD AND MARKETS (last visited August 22, 2023), <https://agriculture.vermont.gov/>

- food-safety-consumer-protection-0/
milk-dairy/registrations-licensing.
- 57 6 V.S.A. § 2721(a).
- 58 Federal Meat Inspection Act, 21 U.S.C. §§ 601–695; *see also* 9 C.F.R. §§ 300–381; *see also* Federal Poultry Products Inspection Act, 21 C.F.R. §§ 451–472.
- 59 Elizabeth R. Rumley & James Wilkerson, *Meat Processing Laws in the United States*, THE NAT'L AGRIC. LAW CTR., <https://nationalaglawcenter.org/state-compilations/meatprocessing/>.
- 60 21 U.S.C. 610.
- 61 *See 2022 Food Code, FDA (Jan. 2023)*, <https://www.fda.gov/media/164194/download?attachment>.
- 62 *Building Resilient Local Meat Supply Chains: How On-Farm Slaughter Fits Into the Federal Meat Inspection Act*, VERMONT LAW AND GRADUATE SCHOOL: CTR. FOR AGRIC. AND FOOD SYS., <https://www.vermontlaw.edu/academics/centers-and-programs/center-for-agriculture-and-food-systems/reports/on-farm-slaughter>.
- 63 21 C.F.R. § 115.50.
- 64 *See, Shell Egg Labeling Guidelines for Producing Bearing the USDA Grademark*, USDA: AGRIC. MARKETING SERV. (2018), <https://www.ams.usda.gov/sites/default/files/media/ShellEggLabelingUSDAGrademarkedProduct.pdf>.
- 65 *Labels Unwrapped*, CTR. FOR AGRIC. AND FOOD SYS. <https://labelsunwrapped.org/>.
- 66 6 V.S.A. § 891; *see also* 94 M.G.L. § 305C.
- 67 *Adoption of the FDA Food Code by State and Territorial Agencies Responsible for the Oversight of Restaurants and/or Retail Food Stores*, FDA 4 (2022), <https://www.fda.gov/media/107543/download>.