Center for Agriculture & Food Systems
VERMONT LAW & GRADUATE SCHOOL

VALUE-ADDED FOOD SAFETY COMPLIANCE GUIDE
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GLEANING ORGANIZATIONS AND VALUE-ADDED PRODUCTS

MANAGING FOOD SAFETY LIABILITY RISKS

OLIVIA BURTON AND ERIKA DUNYAK

OVERVIEW

Value-added products, such as processed food items, provide additional value to consumers and added revenue for the processor. Some examples of value-added production include processing berries into jam or vegetables into soup.[1] Many gleaning organizations are turning to value-added products to capture increased returns, extend the season of their gleaned produce, and reduce waste. Fruits and vegetables that are not visually perfect or are past peak freshness can find new purpose as ingredients in jams, jellies, soups, sauces, or dried goods like leathers and jerkies.

Creating a value-added food product requires the coordination of volunteers and staff; ensuring sanitary and, typically, inspected kitchens; and an understanding of the liabilities and protocols involved in production. There are many types of liability to consider before entering into a new product line, including:

- increased risk of workplace injuries,
- OSHA compliance and workers' compensation;
- new tax burdens;
- new contractual relationships with landlords, suppliers, and buyers; and
- food safety and liability for food-borne illness.

Like other food businesses, gleaning organizations may have to implement new procedures to comply with federal and state food safety and labeling laws.

This guide will help gleaning organizations understand and manage some of the food safety liability risks of value-added production. Specifically, this guide discusses the federal food safety obligations of gleaning organizations in value-added production and the implications of value-added production on the enhanced food safety liability protections gleaning organizations enjoy through the Bill Emmerson Good Samaritan Act, discussed below. Other risks associated with value-added production, such as the increased risk of employee or volunteer injury, are beyond the scope of this guide and require a fact-intensive analysis. If a gleaning organization's management team does not feel equipped to navigate these other risks, they should contact an attorney licensed in their state.

COMPLYING WITH FOOD SAFETY MODERNIZATION ACT'S PREVENTATIVE CONTROLS RULE

All food growers and processors must adhere to the federal Food Safety Modernization Act (FSMA) unless the law exempts them from coverage.[2] Gleaning organizations may already deal with FSMA in their processes in the field. Generally, FSMA is organized into seven major rules that regulate food safety at all levels of the food system.[3] For example, farm-level activities are generally covered by the Produce Safety Rule (PSR).[4] Congress enacted FSMA in 2011, but the rules have only recently been applied to all food and farm firms, regardless of size.[5] This section provides an overview of the Preventive Controls for Human Food Rule (PCR), which covers food processing procedures for safe food processing. Gleaning organizations have an obligation to ensure compliance with the federal laws and regulations; therefore, this guide provides a high-level overview of these rules.

Because many gleaning operations process food in a food hub or other rented commercial kitchen, please also see CAFS' recent guide, Food Safety Compliance for Food Hubs.[6]


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FOOD HUB FOOD SAFETY COMPLIANCE GUIDE
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A GUIDE FOR FOOD HUBS ON FOOD SAFETY COMPLIANCE

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

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,

Registering as a Food Facility

Owners of facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States must register with the federal Food and Drug Administration (FDA), even if they may be otherwise exempt from FSMA and its PCR.[7] This includes commercial kitchens and similar facilities. Only the facility must be registered, not users of the facility. For example, if a gleaning organization is renting kitchen space from another entity, the gleaning organization does not need to be registered. However, if the gleaning organization has its own kitchen, it must be registered. The process of registering a food facility with the FDA is straightforward and is intended to provide the FDA with contact information if there is an outbreak of foodborne illness from the facility.[8]

Qualifying for FSMA PCR Exemptions

Many gleaning organizations qualify for an exemption from the most onerous provisions of the PCR. There are two types of PCR exemptions: fully exempt facilities and qualified exempt facilities.

Fully Exempt Facilities

Facilities that are completely exempt from the PCR are those which fall under different regulatory schemes, including fish and fishery products, dietary supplements, retail food establishments, restaurants, and farms covered by the PSR. The PCR does not apply to on-farm activities, which are covered in more detail in the *Complying with the Produce Safety Rule and On-Farm Processing* section below.

Qualified Exempt Facilities

By contrast, facilities that are qualified exempt ("Qualified Facilities") must comply with some, but not all, of the PCR requirements. The FDA outlines two pathways to be Qualified Facilities.

1. **Local and regional market participant**: The facility 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.[9] A qualified end-user is an individual human consumer of the food (not a business), a restaurant, or a retail food establishment.[10] 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.[11] This rule is identical to the qualified exemption from the PSR for farms. Additionally, the restaurant or retail food establishment must purchase the food for sale directly to consumers at their establishment.[12]
2. **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.[13] This type of Qualified Facility is exempt from the most onerous PCR requirements, namely the Hazard Analysis and Risk-Based Preventive Controls (HARPC) requirements, but still must: (1) register as a food facility; (2) adhere to Current Good Manufacturing Practices (cGMPs); and (3) submit attestations to the FDA regarding its exempt status.

Adhering to the PCR as a Qualified Exempt or Covered Facility

Current Good Manufacturing Practices

Both Covered Facilities, which are those that do not qualify for an exemption, and Qualified Facilities must adhere to the current good manufacturing practices ("cGMPs"). The cGMPs are standard protocols for food processing and handling, such as allergen education, handwashing, and temperature taking.[14] The cGMPs are the same for all types of food except for a few particularly high-risk food categories, such as infant formula[15] and low-acid canned foods.[16]

Covered Facilities have heightened compliance requirements under the PCR. They must have a Food Safety Plan that includes HARPC compliance, supply chain programs, and recall plans. If a gleaning organization is using a Covered Facility, it should familiarize itself with and adhere to the Covered Facility's Food Safety Plan.

Hazard Analysis and Critical Control Points and Hazard Analysis and Risk-Based Preventive Controls

Hazard Analysis and Critical Control Points (HACCP) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) are food safety standards that are, at minimum, best practice. For Covered Facilities, they are required when producing value-added products. While both HACCP and HARPC are food safety standards, they differ in their execution and enforcement and are designed to be used in conjunction with one another.

HACCP is a globally recognized framework for controlling biological, chemical, and physical hazards while in production stages. HACCP plans are required by both the FDA and USDA and provide guidelines for specific types of products, including seafood, juice, and meat products. HACCP plans are also likely required by local or state health departments.

By contrast, **HARPC** is a preventative control framework that is mandated by FSMA and must be implemented by all Covered Facilities. HARPC has specific mechanisms for monitoring food at points that are critical for ensuring food safety and has specific required processes. Gleaning organizations should use the FDA's Food Safety Plan Builder to explore which HARPC protocols apply to their products.[17] Even if a gleaning organization is not a Covered Facility, reviewing the Food Safety Plan Builder can help the organization prepare for state and local health inspections and identify best practices.

Photo by Alan Levine

COMPLYING WITH FSMA'S PRODUCE SAFETY RULE FOR ON-FARM PROCESSING

Rather than processing at a production kitchen, some gleaning organizations process value-added products on-farm. Some of these on-farm activities are covered by the Produce Safety Rule (PSR), rather than the Preventative Controls for Human Food Rule (PCR). Gleaning organizations are likely already familiar with the PSR when it comes to produce washing, fencing, and other on-farm obligations.

The PSR covers all produce except produce that is "rarely consumed raw" because contaminants are likely eliminated in the cooking process.[18] In addition, produce which will be further processed off-farm does not need to adhere to the PSR. However, some on-farm processing that does not happen in a separate facility is covered by the PSR. This includes washing, slicing, and bagging bell peppers on-farm.

The PSR has specific requirements for farms to maintain sanitary conditions of food that is typically consumed raw.[19] These requirements relate to staff hygiene, such as handwashing, sanitation of agricultural water, soil amendments, sanitary condition of tools and equipment, requirements for sprouts, and animal contamination of row crops.[20] Some specific requirements may apply to certain operations. For example, if an operation is sprouting crops almost all the on-farm operations are affected by the employee hygiene and sanitary water rules. If a gleaning organization's activities are on-farm, management should ensure: (1) workers have access to necessary sanitation facilities; and (2) the operations are in compliance with the most up-to-date requirements for agricultural water, especially for water used to clean produce.

LIABILITY PROTECTION AND INSURANCE

All businesses face three types of liability:

- **Regulatory:** Government agencies enforce regulatory liability through fines, license conditions, withdrawal, or other penalties. Failure to comply with the Food Safety Modernization Act could result in regulatory liability like fines or revocation of the entity's qualified exempt status.
- **Civil:** Enterprises are also exposed to civil liability, where the business could get sued by a private actor for violating a contract, acting negligently, or otherwise harming another.
- **Criminal:** Individual managers and decisionmakers of an enterprise may be held criminally liable for certain harms.

Bill Emerson Good Samaritan Food Donation Act

Gleaning organizations benefit from the Bill Emerson Good Samaritan Food Donation Act.[21] The Bill Emerson Act does not protect against any regulatory liability, meaning that gleaning organizations must still comply with FSMA and other applicable laws, including labor and tax laws, but it does insulate organizations from certain civil and criminal liability as long as they act in good faith and without gross negligence or willful misconduct.[22] Importantly, the Bill Emerson Act only provides civil liability protection in the case of donated food causing foodborne illness; it does not insulate gleaning organizations from civil liability in other contexts, such as breach of contract with a landlord.

More specifically, the Act insulates organizations that donate food. To receive this protection, the food must be apparently wholesome, and the donation must be made in good faith by individuals, gleaners, or nonprofit organizations. The Act also does not cover instances where illness or death result from intentional tampering or mishandling or extraordinary carelessness. This civil liability protection applies regardless of whether the food is processed or not. However, the food must be donated—if the food is sold, then it is not protected by the Bill Emerson Act.[23]

Importantly, this guide only addresses federal liability protection; gleaning organizations may not have similar protections under state law, particularly state consumer protection laws. Gleaning organizations should review the laws in their state to understand under what conditions, if at all, they are insulated from civil liability.

USDA Photo by Preston Keres

Liability Insurance

It is best practice for all organizations to have their own liability insurance, even those covered by the Bill Emerson Act. Liability insurance typically covers the organization, its volunteers, and the gleaned food (and in some cases value-added products) that is distributed or sold. Additional product liability insurance that provides added protections for certain value-added food processes that have a higher risk of bacterial growth, such as canning or meat processing, can be obtained. It is important for a gleaning organization to discuss all the activities it regularly participates in with its insurance provider, so the provider can recommend the right policy and coverage.

CONCLUSION

Gleaning organizations will have new regulatory hurdles to navigate as they pursue value-added production. These hurdles are not insurmountable, and gleaning organizations should feel empowered to make the right decisions for their enterprises. If a gleaning organization does not feel properly equipped to navigate this landscape, it should work with an attorney licensed in the organization's state.

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Disclaimer

This guide provides general legal information for educational purposes only. It is not meant to substitute, and should not be relied upon, for legal advice. Each gleaner's circumstances are unique, state laws vary, and the information contained herein is specific to the time of publication. Accordingly, for legal advice, please consult an attorney licensed in your state.

ENDNOTES

1 Other examples of value-added products include physical segregation (such as separating gluten-free products from other products), alternative production methods (such as grass-fed beef), and local foods marketing (such as local sweet corn, which can be sold at a higher price). *Value Added Producer Grant*, USDA (Mar. 17, 2023), https://www.rd.usda.gov/sites/default/files/Value-Added-Fact-Sheet-3-17-23.pdf.

2 *Food Safety Modernization Act*, 21 USC §§ 2201-2252 (2023).

3 The FDA Food Safety Modernization Act, Pub. L. 111-353, 124 Stat. 3885 (2011).

4 21 C.F.R. § 112 et seq. (2016).

5 *FSMA Compliance Dates*, FDA, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-compliance-dates (last visited Mar. 18, 2024).

6 *Food Hub Safety Compliance Guide*, Ctr. for Agric. & Food Sys. (Nov. 2023), https://www.vermontlaw.edu/sites/default/files/2023-11/guide-for-food-hubs-on-food-safety-compliance.pdf.

7 FDA General Enforcement Regulations, 21 C.F.R. §§ 1.225-1.245 (2019).

8 *Registration of Food Facilities and Other Submissions*, FDA, https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions (last visited Mar. 18, 2024).

9 21 C.F.R. § 117.5. (2015)

10 21 C.F.R. § 117.3.

11 21 C.F.R. § 117.3.

12 21 C.F.R. § 117.3

13 *FSMA Inflation Adjusted Cut Offs*, FDA, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs (last visited Mar. 18, 2024).

14 21 C.F.R. § 117 et seq.

15 21 C.F.R. § 106 (2016).

16 21 C.F.R. § 113 (1979).

17 *Food Safety Plan Builder*, FDA, https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder (last visited Mar. 18, 2024).

18 21 C.F.R. § 112.2(a)(1).

19 21 C.F.R. § 112 et seq.

20 *Id.*

21 42 U.S.C. § 1791(c)-(d).

22 *Id.*

23 *See Federal Liability Protection for Food Donation*, Harvard Law School (June 2023), https://chlpi.org/wp-content/uploads/2013/12/Emerson-Act-Legal-Fact-Sheet.pdf (explaining the general structure of the Bill Emerson Act).