**Wisconsin Farmers' Guide to Food Safety Liability Management**

**Introduction**

**Taking food safety seriously—from responsibilities to opportunities**

Food safety and liability issues on the farm can be a tough topic. The details seem overwhelming and the worst-case scenarios are scary. So many questions! Do the Food Safety Modernization Act (FSMA) Produce Safety Rule rules apply to my farm? What do I need to do if they do? What about other state and local food regulations? What do I have to do to comply with those? Most significantly, what should I do to actually prevent an incident? After all, no farmer wants to get anyone sick, regardless of what the law says.

Farmers’ concerns about food safety are justified. A bad incident can leave a farmer emotionally and financially devastated. What’s more, a single negative incident can damage the reputation of the entire sustainable farming community. Nobody wants consumers to doubt the safety of locally grown food. Farmers owe it to each other to take food safety seriously.

On the bright side, food safety concerns also present opportunities for sustainable farmers to educate the communities they serve. With food-borne illness outbreaks making headlines, consumers are ever more aware of and concerned about the safety of their food. These sentiments impact their food choices. By taking food safety seriously, farmers have a huge opportunity to attract these diligent, committed customers. In this way, prioritizing food safety is an opportunity as well as a responsibility.

Bottom line, every farmer should prioritize producing the safest food, first and foremost. Although there are always risks involved in producing and distributing food, careful and conscientious farmers can show their customers that they’re taking food safety seriously, and their customers will surely appreciate it.

**Understanding food safety liability risks and developing an overall food safety strategy**

Still, attention must be paid to the legal aspects of a food safety incident. Accidents can happen to anyone. How can these risks be mitigated? This guide serves to help farmers better understand what the legal risks of a food safety incident are, how to reduce the legal risks, and how to increase the chance of recovery if a food safety incident happens.

The good news is that farmers can take tangible, cost effective steps to minimize their legal risks. This guide is not meant to be a scare tactic, rather it’s a way for farmers to move out of overwhelm and into making informed decisions and taking strategic, practical steps to address their food safety concerns.

**Moving from thinking about food safety to taking action**

Equipped with a deeper understanding of the legal risks of a food safety incident, farmers can better develop an overall food safety strategy that’s suited to their farm. Such a strategy might include getting a food safety plan in place, having a recall protocol, exploring insurance options, learning about and following Good Agricultural Practices (GAP) standards, perhaps even getting GAP certification, looking into and complying with the FSMA rules, researching and following product-specific regulations, such as safety regulations for processed products, and so on.

**Having a food safety plan is strongly recommended**

It’s incredibly important from a legal perspective to at least have a food safety plan in place. Fundamentally, farms with thorough food safety plans are less likely to have an incident in the first place. If customers happen to get sick, having a food safety plan puts the farm in a good position for any impending lawsuits and enforcement actions.

With the plan and implementation records in hand, a farmer is better able to convince a court that the problem occurred elsewhere, not on the farm. Similarly, the government is less likely to compel an expensive and cumbersome recall or initiate an enforcement action if the farm has records to show that a robust food safety plan was being followed.

If an incident is tied to the farm, the food safety plan will help the farmer isolate the problem, conduct a recall if necessary, and minimize the spread and overall impact. Finally, having a food safety plan makes it easier for the farm to prepare for and adapt to changing circumstances—whether they be increasing regulatory obligations, fluctuating insurance options, or shifts in the terms of a contract.

**Actually implementing and regularly evaluating the overall food safety strategy is even more essential**

Taking food safety seriously means more than thinking about it. A food safety plan that is not followed is worthless. It must be implemented with care with records to prove it. And, the food safety plan must be updated as circumstances change: as the farm grows, offers new products, sells into new market channels, adapts to new legal requirements or regulations, and so on. Insurance policies also need to be kept up to date, as coverage may shift or adjustments may need to be made from year to year.

Farmers are well-advised to carve out some time each year to revisit, improve, and adapt their overall food safety strategy for their farm. What’s working and what’s not? Are systems being followed? A call to the farm’s insurance agent should be part of this annual review.

**What you decide to do is up to you**

**In the end, the right risk management strategy regarding food safety is a personal decision that depends on you and your farm. Your own financial, emotional, and business considerations all factor into the appropriate strategy for you.** This resource can help you understand and assess those factors, and then take action accordingly. With this in mind, specific action points are highlighted after the discussion of each legal risk to help you understand the context, or why taking the suggested steps is significant from a legal perspective. It’s then up to you to decide whether taking that step is relevant or appropriate for your farm.

**Limitations of this guide**

This guide does not cover the substantive details of food safety practices such as specific GAP standards, FSMA rules, and product-specific regulations. Instead, it offers the broader context of food safety liability and illustrates how taking certain action steps and following specific food safety practices can mitigate a farm’s overall legal risks.

In addition, this guide is not an exhaustive discussion of the legal aspects of a food safety incident. It is by no means a substitute for the counsel of a qualified attorney. Rather, it introduces a selection of relevant legal issues and serves as a launching pad for exploring individual risks and management options in more detail. Farmers should take steps to learn more, including discussing their situation with an attorney and an insurance agent.

Now, let’s get started.

**The Story of Farmer Alexi and Farmer Sally**

Legal concepts are often better understood through stories. We’ll be referring to the following hypothetical stories of Farmer Alexi and Farmer Sally to highlight key legal points.

Farmer Alexi has a large orchard that produces a wide variety of delicious apples. She sells her apples directly from the farm and wholesales apples in bulk to a local grocery store. In addition, she runs a small on-farm cider operation and has started making caramel apples and dried apple rings to sale at her farm stand.

Alexi hires young people to work at her orchard each summer. This year, things get a little frantic as Alexi manages her new caramel apple and dried apple rings sales and increasing wholesale sales. With the harvest and packing shed in full swing, Alexi decides to promote one of the high school students to manager. However, the young manager doesn’t make sure the new employees understand food safety procedures before they begin. A new employee harvests apples off the ground. Unfortunately, several deer had recently visited the orchard and deer feces had contaminated the ground-harvested apples. A few crates of those apples get processed into caramel apples for sale on the farm stand, while others get bagged for sale to a local grocery store. A few other crates get processed into cider. To make matters worse, another new employee forgets to refrigerate the cider made from the contaminated apples and later puts the cider out for sale on the farm stand.

This is the story of what happens to farmer Alexi as a result:

* **A person is injured.**
* **Contract damages are owed.**
* **Product is recalled.**
* **State officials investigate the farm.**
* **Federal officials investigate the farm.**

This is also the story of how Farmer Sally, Alexi’s neighbor, changes her operation to avoid the same problems. Here are Farmer Sally’s action points:

TAKING ACTION TO REDUCE FOOD SAFETY LIABILITY RISKS

* Adopt and implement a food safety plan and keep records of how food safety measures are being followed
* Check insurance policies for food safety incident coverage and update insurance policies as circumstances change
* GAP: Explore the option of GAP certification, learn about GAP standards, and commit to incorporating them when feasible
* Educate customers about food safety, including adding storage and preparation instructions and “best by” dates for high-risk products
* Draft or negotiate sales contracts that limit indemnification and set achievable production standards
* Check the farm’s insurance policy to see it provides coverage for indemnification
* Implement product tracking and traceability
* Consider recall insurance
* Learn about and follow all product-specific state and local food code regulations
* FSMA: Find out whether FSMA applies, learn about FSMA standards, and commit to incorporating them when required and/or feasible
* Schedule an annual review of the farm’s food safety strategy

**Legal Risk 1: Injuries to People**

**[Farmer Alexi Icon]**

Billy and Betty get sick: On the same day that the contaminated apples and caramel apples are set out on the farm stand shelves, Billy and Betty arrive with their parents at the farm ready to enjoy late summer in the country. Billy and Betty convince their parents to take some caramel apples home for dessert that night while their parents buy cider at the farm stand and drink it on-farm while exploring with the kids. When morning comes, the entire family is feeling very sick. Their condition worsens quickly, and their parents take them to the hospital.

After taking samples, the doctors determine that *Listeria monocytogenes* bacteria are the source of the illness. Three other individuals were admitted to the hospital in the region with similar symptoms the same day. Tests show that all seven people were infected with the same strain of *Listeria*. All seven people had also been to Alexi’s farm two days prior and five of the seven drank cider while on the farm. Only Billy and Betty seem to have gotten sick from eating caramel apples.

Billy and Betty’s parents hire a lawyer and begin discussing a possible lawsuit. The numbers show a high probability that Alexi’s apples are the source, and the lawyer thinks the case might be sound.

**“I might be sued if someone gets sick.”**

This is the first thing that comes to mind when farmers think about the legal implications of a food safety incident. In the legal lingo, this type of case is often called a “personal injury” case. In fact, you might see billboards advertising the services of lawyers by screaming out the phrase, “Have you been injured?” Their clients may have slipped on an icy sidewalk, suffered an auto accident, lost a finger in a farm implement, or suffered a different type of injury.

Perhaps because of those dramatic advertisements and the media stories of million-dollar pay-outs, personal injury lawsuits (also called “tort claims”) don’t have the finest reputation. That may not be entirely deserved. The premise behind a personal injury lawsuit is this: if one person acts irresponsibly and a second person gets hurt as a result, the first person should compensate the injured person for their damages. The premise seems fair. The same applies to property damage. If you buy a toaster that malfunctions and burns your house down, you’d likely want the toaster manufacturer to pay you back for your loss. Likewise, if someone sells you contaminated food and you get really sick, you’d likely want to be compensated for things like medical bills, lost wages, and so on.

Not every person who suffers an injury gets money for it. Although the line between eating contaminated food and becoming sick may be straightforward, the line between getting sick and winning a lawsuit against the source is not. Food poisoning cases can be incredibly complex, time consuming, and costly with very uncertain outcomes. They often involve multiple claims or ways to argue that the source is liable or responsible for compensating anyone who’s injured. For our purposes, we’ll focus on the two main ways that farmers might find themselves liable: negligence and strict liability.

**Negligence**

**Farmers must act with reasonable care—like the average farmer would act—to prevent the food they sell from being contaminated**

Negligence is a legal concept that basically states, “You owe a duty to act with reasonable care not to get others hurt. If you act with less care than the average person in your circumstances would act, and someone gets hurt as a result, you are at fault. You must then pay for the resulting damages.”

The message for farmers is this: “**Farmers owe their customers a duty to act with reasonable care, or like the average farmer would act, in each circumstance to prevent the food they sell from being contaminated**.” If someone gets sick and a lawsuit ensues against the farmer, the court will determine whether the farmer is at fault by asking: did the farmer act reasonably in these circumstances?

**Farmers who follow a food safety plan—and, better yet, abide by Good Agricultural Practices (GAP) and even the Food Safety Modernization Act (FSMA)—have a better chance of showing they acted with reasonable care**

This begs the question, “How does an average farmer act in these circumstances?” Much time and money will be spent determining whether the individual farmer in question met that standard. There is no one-size-fits-all answer to this question, as each case will depend on the specific facts and circumstances. Ultimately, it’ll be up to a jury to decide whether the farmer acted with reasonable care or was negligent and thus at fault. **The farmer’s best defense may be the implementation of a food safety plan.**

Having a food safety plan in place—and perhaps following GAP standards or complying with FSMA rules—is what an average farmer would do, right? Whether this was true in the past, it’s becoming the trend as farmers increasingly take food safety more seriously. What does this mean? As more farmers become GAP certified, or at least follow GAP standards, and comply with the FSMA rules, the standard of care that a farmer will be held to in a personal injury lawsuit might increase. In other words, **courts might turn to GAP standards and FSMA rules in a negligence case when determining whether the farmer acted reasonably. This is all the more reason for farmers to pay attention to these standards, regardless of whether they have to.**

**Farmers who are in fact required to follow specific food safety laws will automatically be held to these standards in a negligence case**

If a farm is in fact required to comply with the FSMA rules or other product-specific regulations under the state or local food code, the farm will certainly be held to these standards in a negligence case. That’s because under the legal doctrine of “negligence per se,” a court will automatically conclude that the farmer acted negligently if they violated a relevant food safety law that they were supposed to follow. This makes sense as, generally speaking, violating the law is not exactly acting with care.

**If the injured person also failed to act reasonably, the damages the farmer owes in a negligence case might be reduced or eliminated**

When a negligence lawsuit ends in favor of the injured person, they may receive money for their medical bills, lost wages, and future loss of earning potential, among other losses. However, in many states, the farmer can reduce or entirely eliminate the damages if the farmer can show that the injured person was also at fault or somehow contributed to their own injury.

The question then becomes, did the injured person act reasonably (i.e., like an average person would act in those circumstances)? If, for example, the person who got food poisoning failed to properly store the food, follow “best by” dates, cook the food at the recommended temperature, or thoroughly wash it as instructed, a court may find them partly or even entirely at fault and reduce the damages that the farmer must pay out accordingly.

**Contributive Fault Rules**

Wisconsin follows comparative fault rules for negligence cases, which would reduce the farmer’s share of damages as follows:

An injured person may not recover anything if they are 51% or more at fault for the injury. If the injured person is less than 51% at fault, they may recover damages, but damages may be reduced according to the percent to which the injured person is at fault. If more than one person contributed to the injury, each person may be liable for damages according to their percentage of fault, but any person who is 51% or more at fault may be individually liable for the entire amount of damages.

Here’s the takeaway message: **Farmers can help mitigate their damages, and better yet prevent anyone from getting sick in the first place, by having a food safety plan, following FSMA rules, and educating customers on how to properly store and prepare the foods they sell**. This can be as simple as putting basic instruction notes in CSA boxes, posting signs at farm stands and farmers’ markets, posting food safety information on the website and referring customers there, distributing handouts along with invoices to wholesalers, and so on. The bonus is that with proper storage, consumers will likely be happier as their products will stay fresher and even last longer!

**[Farmer Alexi icon]**

Billy and Betty’s parents sue Alexi: Facing large medical bills and expenses for the family’s hospital bills, Billy and Betty’s parents go forward with the lawsuit. The attorney gets right to work building the case. She needs to show that Alexi negligently caused the family to get sick. The attorney might say that average farmers make sure their employees are trained thoroughly and understand the fundamental safety aspects of the job. In response, Alexi might claim that average farmers cannot monitor their employees all the time, and that an average farmer could easily fail to notice when food safety practices are occasionally missed among all the different activities on the farm. The two sides will attempt to convince a judge or jury of what average farmers do under Alexi’s circumstances. Then, the attorney will argue that Alexi fell below the standard, while Alexi will argue that she met the standard.

**Strict liability**

**Farmers might automatically be on the hook if they sell a contaminated product that is “unreasonably dangerous” and someone gets sick as a result**

Under some circumstances, a farmer might automatically be on the hook simply by having sold a contaminated product that results in someone getting sick, regardless of whether the farmer acted reasonably. This is what’s called strict liability.

Rather than focusing on the behavior of the producer, strict liability lawsuits focus on the product itself. Strict liability in food-borne illness lawsuits basically means: **If you sell a food product that was contaminated when it left the source—whether it be the farm, the warehouse, the restaurant, and so on—and that product is “unreasonably dangerous” by its nature, you are automatically liable for any resulting damages.** There is no inquiry as to whether the producer or seller acted with reasonable care.

**A product is “unreasonably dangerous” if it includes something that the ordinary consumer would not reasonably expect**

You might be asking, what constitutes unreasonably dangerous? In most states, whether a product is unreasonably dangerous is based on what “an ordinary consumer might reasonably expect.” In other words, **a food product might be considered “unreasonably dangerous” if it includes an ingredient or pathogen that an ordinary consumer would not reasonably expect to find in that food product.**

This begs the question: Would ordinary consumers expect some level of risk from eating green salads, sprouts, or melons—some of the most common carriers of food-borne pathogens? Would ordinary consumers expect a level of risk of *Salmonella* when eating raw or lightly cooked eggs? Would ordinary consumers expect the risk of *Listeria* when eating unrefrigerated caramel apples? As you can see, two minds may disagree! Ultimately, this is a factual question that would be up to the jury to decide on a case-by-case basis.

The reality is the law often presumes that the ordinary consumer is relatively unwitting. This is one reason why we see “warning” signs on particularly dangerous products. The law often requires it. If the manufacturer doesn’t include a warning when required, they will likely automatically be on the hook if someone gets hurt.

Some states have specific laws that require food producers to include warnings on certain products, such as raw milk or undercooked foods like eggs, poultry, and meat products. Even if the law doesn’t require warning signs, in certain circumstances, a food product may be considered “unreasonably dangerous” because adequate warnings or instructions were not provided.

**If the injured person did not act reasonably (i.e., properly store or prepare the food as instructed, follow “best by” dates, etc.) the damages the farmer owes in a strict liability case may be reduced or eliminated**

Just as for negligence, contributory fault rules apply in strict liability lawsuits in most states. In other words, if a farmer is found strictly liable in a food safety lawsuit, they can reduce or maybe even eliminate the damages they are responsible for if the farmer can show that the injured person somehow contributed to their own injury. Did they cook the eggs well enough, wash the greens and sprouts, refrigerate their caramel apples—as an ordinary consumer would? Did they follow any explicit instructions provided by the farmer? This is yet another reason why including proper storage and preparation instructions and “best by” dates can be helpful.

When it comes to strict liability, here’s the takeaway message for farmers: **Take food safety seriously. In addition, be sure to include warnings and instructions for proper storage and preparation, including “best by” dates when selling high-risk products!**

**[Farmer Alexi Icon]**

Were the caramel apples unreasonably dangerous? The caramel apples that Billy and Betty ate sat in the hot car for several hours on their ride home, and then on the kitchen counter for a few more hours before it was time for dessert. They didn’t think they had to refrigerate them, as they often see unrefrigerated caramel apples in candy stores.

Billy and Betty’s attorney will argue in court that caramel apples are by nature unreasonably dangerous. She’ll point to scientific studies showing how apples punctured with dipping sticks that are then coated with caramel and left unrefrigerated pose a huge risk for the spread of *Listeria*.

The question for the court might then become, should Alexi have included a warning or instruction to refrigerate the caramel apples? Were the caramel apples without such an instruction “unreasonably dangerous”? Alexi will argue that ordinary consumers should know to refrigerate caramel apples. She will also argue that Billy and Betty were partly if not entirely at fault because they didn’t refrigerate them, and that she shouldn’t be responsible for all the damages. The result is uncertain, as it’ll be up for the jury to decide!

**What can farmers do to limit their legal risks from personal injury lawsuits?**

No matter how much care the farmer takes, the reality is that accidents can and do happen. In addition, many food contamination cases involve a number of potential sources up and down the supply chain—the farmer, distributor, wholesaler, restaurant, retailer, and so on. Even if the farmer is not ultimately at fault, there’s nothing stopping the injured person from bringing the farmer into a complex and costly lawsuit.

Whether under claims of negligence or strict liability, fault in a personal injury lawsuit involving food contamination often hinges on causation, or exactly where in the food production or distribution chain the contamination occurred. If the consumer sues the grocer, the grocer will point the finger at the processor or distributor, and they will in turn point the finger at the supplier or farmer. Ultimately, it'll be up to the jury to decide after hearing all the facts.

**Bottom line, to prevail against a farm in a personal injury lawsuit—whether negligence or strict liability—the injured person must prove that the food was contaminated *when it left the farm*.** The farmer needs to show that the contamination occurred elsewhere, or at least raise enough doubt in the minds of the jury that it occurred on the farm. How does the farmer do that?

**Take food safety seriously**

Farmers can take proactive steps to protect themselves in case they get caught in such messy litigation. A farmer's best defense may be having a food safety plan in place. Following certain GAP standards or complying with FSMA could also help, to the extent that doing so is reasonable and practical for the farm.

By taking such reasonable food safety precautions, the farmer may raise enough doubt in the minds of the jury that the contamination occurred on the farm. It must have occurred elsewhere! But the farmer will need a paper trail to prove it. The takeaway message is: **adopt and implement a food safety plan, follow GAPs and FSMA standards where feasible, and keep records of how food safety measures on the farm are being implemented*.***

**Are the FSMA standards and GAP standards the same?**

The short answer is no. Both are based on best practices to prevent foodborne illness associated with growing, packing and storing fresh produce. The standards in the FSMA produce rule are minimum legal requirements that some fresh produce growers must adhere to unless they qualify for a full or partial exemption from the rule. It’s up to farmers to demonstrate that they are complying with the FSMA standards when required via records. Good recordkeeping practices and a documented farm food safety plan are the best ways to do so, even though a food safety plan is not required by the FSMA Produce Safety Rule.

GAP audits are not a law or a regulation, but are voluntary verification of your practices via an audit that you pay for. The need for GAP certification may be driven by your buyer, but GAP audit standards are driven by proven food safety practices. There are numerous GAP-certification standards, out there, each with a slightly different set of standards and record requirements It’s entirely up to the buyer to decide which audit to require. The most common is a USDA basic GAP audit or a USDA Harmonized audit.

The good news is that there are ongoing efforts to harmonize the GAP standards and to make the GAP and FSMA standards compatible. The Produce GAPs Harmonized Food Safety Standards were released in 2011, out of an initiative by stakeholders to “harmonize” 14 of the major GAP standards into one audit standard. The USDA Harmonized GAP audit is one of the audits offered by the USDA, along with the more basic GAP/GHP audit. Both are most often conducted by a staff member from the state department of agriculture in your state, but there are also private companies that will offer audits for a fee. The audit you get may depend on which is required by your buyer.

In 2018, USDA issued new Harmonized GAP audit standards to align the audit standards with the FSMA Produce Safety Rule. That’s good news for farmers, because they can feel confident that if they pass a Harmonized Gap audit, they will generally be complying with FSMA. A Harmonized GAP certification is not a substitute for a FSMA regulatory inspection, but it can help demonstrate that you are complying with the Produce Safety Rule if you do get inspected. Likewise, even if a farm complies with FSMA they may still need one or more GAP certifications to sell to certain buyers.

**Look into insurance options**

**When it comes to personal injury suits, the best risk management option is insurance (assuming farmers are following the best food safety practices already)**

Insurance is important for two reasons. First, the insurance company will provide an attorney to defend the insured person or business against the claim. The attorney will know all the ins and outs of personal liability and should provide expert representation. Second, if the farmer is at fault, the insurance company should pay the resulting liability up to the coverage limit.

[Farmer Alexi Icon]

Alexi gets an attorney: Alexi has insurance for her apple orchard and farm stand operation, so she immediately calls her insurance company as soon as she receives notice that she is being sued by Billy and Betty’s family health insurance company. Alexi’s insurance company works closely with her to get an attorney in place and investigate the claim. Alexi works with the attorney and provides as much information as needed. It certainly takes a lot of time, but at least Alexi isn’t dealing with the lawsuit herself. Alexi also sleeps a little better knowing that her policy should cover the resulting claim if it is successful.

**Finding insurance coverage for food poisoning injuries can be challenging**

It’s important for farmers to know whether their insurance policy covers the contamination risks they are most likely to experience. This can be quite challenging.

**Farm liability policies provide limited, if any, coverage for food poisoning injuries**

What we call “farm policies”—also called “farm liability insurance” or a few other names—cover damage to farm property from certain risks like fires and tornados. Many of those policies also cover injuries to farm guests, although they often exclude injuries resulting from hazardous activities. Most farm liability policies will cover a food poisoning injury only under select circumstances. Some policies will not cover food contamination at all, while others will only cover injuries that occur on the farm. If a policy does cover on-farm food poisoning injuries, that still means that if a contaminated product was purchased from a wholesaler or at the farmers’ market, the farmer is probably not insured. Also, generally speaking, farm liability policies will not extend to contamination of value-added products or injuries occurring at an agritourism event.

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[Farmer Alexi Icon]

Alexi deals with insurance: Early on, while dealing with the personal injury lawsuit, Alexi receives a letter from her insurance company. It tells Alexi that the insurance company isn’t entirely certain that the claim made is covered under Alexi’s policy. Although the insurance company continues to provide service as if the claim is covered, the company reserves their right to cease if they conclude the claim is not, in fact, covered. Alexi panics. She was under the impression that buying a farm liability policy would cover her for all the risks encountered on the farm. After a few hours of frantically searching for the 30-page document she received 10 years ago when she purchased the policy, Alexi reads the contract language. She finds a vague endorsement in the back of the policy that discusses bacterial and fungal contamination. It seems like it’s meant to eliminate coverage for grain lost to rot, so it’s hard to tell if it would cover bodily injury from ingesting bacterial contamination. Alexi feels very stressed. She thought she was doing the right thing and now she’s not sure.

**Business endorsements and commercial liability policies might provide more extended coverage for food poisoning injuries**

Instead, many farms will need to modify the standard farm liability policy to address food safety incidents. A “business endorsement” may do the trick if the farm wants coverage for a small value-added operation or a few agritourism events. If the farm wants broader coverage, a commercial liability policy may be the best choice. Commercial policies provide coverage across many marketing channels—wholesale, value-added, processing, and direct-to-consumer. In Farm Commons’ experience, policies vary widely, and some even contradict themselves as to whether food safety outbreaks are covered.

**Don’t assume you’re covered: Read your policy or talk to your agent to be sure your policy provides the coverage you need and expect**

There’s nothing worse than paying insurance premiums only to find out later that the policy doesn’t provide coverage for the actual incident that occurs. The hard reality is that it can be difficult to determine if a specific insurance policy will cover a specific risk. Farmers might go straight to the source and read the policy document, but this can be quite intimidating. Making it additionally difficult, the actual policy language may not have been delivered. Farmers may have to call the agent, who then contacts the underwriter, and a long game of phone tag develops. Even after getting a copy of the policy, farmers may be stumped as to what is means. Many attorneys are stumped as to what insurance policies cover.

If you do get your hands on your entire policy be sure to pay very close attention to the exclusions, which are usually found at the end. This will list items that are not covered. Sometimes it will explicitly say, “Food-borne illness outbreaks are excluded.” There’s obviously no coverage there. If it has a reference to mold or pathogenic or biological contaminants, be careful, as this will likely be interpreted to exclude food contamination incidents.

A shortcut is simply to ask the insurance agent whether specific risks are covered. Admittedly, this is not a bulletproof strategy. The agent may not have an accurate impression of how the policy applies to a non-traditional farm operation. (In other words, the agent might be wrong.)

**Finding an insurance agent familiar with diverse farms is an excellent first step to getting good coverage**

The best way to find that agent is to talk to other farmers in the community who run operations similar to what you do or are planning to do. As a secondary strategy, it’s always a best practice to get things in writing. When talking with an insurance agent about whether a risk is covered (or when talking with a bank about a loan, a credit card company about a payment plan, or any other conversation with serious implications), create a paper trail. Communicating via email is one way to establish a written record. Where that isn’t possible, an office log containing the time of the call, identity of the person called, and the content of the discussion can go a long way toward establishing potential recourse if you are misinformed.

**Dealing with uninsurable situations**

A second hard reality is that insurance may not be available for certain farms as discussed previously. If the insurance industry sees a specific practice or production method as exceptionally risky, they may refuse coverage. If there aren’t a lot of farmers asking for certain coverage, the insurance company doesn’t see any opportunity to make money by offering such coverage. And when one insurance company turns a farmer down, many others are likely to follow suit.

This puts farmers in a very difficult position. In the short term, the best answer is to ask other farmers for a reference to an amenable agent. If that doesn’t yield results, farmers may need to adapt their operations to become insurable. Over the long term, farmers can work with other farmers and farming advocates to convince the insurance industry to cover more unique farm and sales operations. This may be a slow (and frustrating) process, but over time, with enough voices, things can change.

[Farmer Alexi Icon]

Alexi finds her records: Alexi is struggling with figuring out if her policy covers bacterial contamination. Then, she remembers that back in 2008, when the spinach scare occurred, she had emailed her insurance agent about her coverage. Alexi goes back to her email records and searches for a copy of the conversation. Fortunately, she finds an email from her agent saying that Alexi would be covered if folks visiting her orchard consumed contaminated apples while on the farm and became ill. Alexi breathes a sigh of relief. If the insurance company denies the claim, the lawsuit goes forward, and Alexi ends up responsible, she might be able to recover some of her losses from the insurance agent (via the agent’s errors and omissions insurance coverage).

**TAKING ACTION ON INJURY LAWSUITS**

* Adopt and implement a food safety plan and keep records of how food safety measures are being followed
* Check insurance policies for food safety incident coverage and update insurance policies as circumstances change
* GAP: Explore the option of GAP certification, learn about GAP standards, and commit to incorporating them when feasible
* FSMA:Find out whether FSMA applies, learn about FSMA standards, and commit to incorporating when required and/or feasible
* Educate customers about food safety, including adding storage and preparation instructions and “best by” dates for high-risk products

**Farmer Sally Takes Action [Sally Icon]**

Farmer Sally lives just down the road from Alexi. Alexi has been her mentor for a few years now. Although this isn’t the mentorship scenario either had hoped for, Sally is trying to learn from Alexi’s experience. Here are the actions she’s decided to take:

**Food safety plan**: Farmer Sally sets aside a day over the winter to put together a food safety plan. She visits onfarmfoodsafety.org for resources and templates that explain the process.

**Insurance:** Farmer Sally wants insurance for food safety incidents so she takes the following actions:

* Checks her insurance policy to see if personal injury from bacterial contamination is covered.
* Emails her insurance agent to double-check, as the policy is very confusing.
* When her insurance agent calls back with a response, Sally makes a note in her phone log that the agent assures her she is covered.
* Reminds herself to update her insurance policy every time she adds a new enterprise (like value-added) to make sure she doesn’t accidentally go beyond her insurance policy.

**GAP standards**: Farmer Sally looks into getting her produce GAP certified, but decides it’s too expensive, and given that none of her buyers require it, she decides against it. Instead, she decides to learn about the foundations of the USDA’s GAP/GHP standards by registering for a local workshop and commits to incorporating certain standards as best she can.

**FSMA standards**: Farmer Sally has been hearing a lot about FSMA and keeps meaning to look into what it all means for her farm. She’s decided to set aside an hour to find out. Her first step is to read the last section of this guide on FSMA. She then takes 15 minutes to walk through Farm Commons’ resource *Whether and When Farms Must Comply with FSMA: Flowchart* to understand if and how her farm should comply.

**Customer education:** Farmer Sally sells fruits and veggies, including bagged lettuce, at the farmers’ market and through a CSA. She decides to prepare a notecard that provides preparation and storage recommendations for all the produce she sells to include as an insert in her CSA membership packet and to hand out at the farmers’ market. She also decides to include “wash before consuming” and “best by” stickers on the bagged lettuce she sells.

**GroupGAP: A potentially cost-effective way for small farms to get GAP certified as a group**

GroupGAP is a USDA food safety program that allows produce growers to join together as a group and secure a collective GAP certification that covers every farm in the group. GroupGAP allows certification in GAP/GHP, Harmonized GAP, and Harmonized Plus standards. For small growers, GroupGAP certification may be more cost-effective than certifying farms on an individual basis, but the organizational requirements to form and maintain a group can be challenging. A GAP group needs to develop a collective Quality Management System (QMS) that establishes policies for maintaining food safety and quality along with corrective action plans for any nonconforming activities. The group also needs to appoint a group leader, a management group, and one or two internal auditors responsible for making sure that all member farms are following USDA policies and the group QMS policies. Although GroupGAP may work best for growers producing the same type of crops, some states already have statewide GroupGAP organizations in place that can help small farmers get GAP certification without the need to organize a group from the ground up.

You can find more information about GroupGap at the following links:

USDA: <https://www.ams.usda.gov/services/auditing/groupgap>

National Good Food Network: <http://www.ngfn.org/resources/food-safety/food-safety>

Wisconsin Food Hub Cooperative: <https://wifoodhub.com/>

**Legal Risk 2: Contract Damages**

Although personal injury lawsuits are a common point of reference for food safety liability, it’s not the only legal action that can result. Contract laws also play an important role in the legal effect of a food safety incident. We are going to discuss just two of the potential ways contracts can come into play: indemnification clauses and agreements to maintain specific standards.

[Farmer Alexi Icon]

Alexi signed a contract: In addition to selling apples at her own farm stand, Alexi also sells bagged apples to the grocery store up the road. Alexi and the grocery store began working together two years ago after Alexi had a surplus of apples in one successful year. It was so successful Alexi decided to quickly expand and make grocery sales a regular part of her overall business. Two years ago, the grocery buyer asked Alexi to sign a sales agreement. She was keen to unload her apples, and it didn’t look like a very extensive contract—just basic terms about invoices and payment plus some fine print. Alexi signed. When the same contract came up again this year, Alexi signed again. Having already worked with the grocery store, Alexi didn’t see any reason to question the contract.

As it turns out, the fine print at the bottom of the contract said that Alexi agreed to indemnify the grocery store for any damage extending from her apples. It also said that Alexi agrees to maintain GAP (Good Agricultural Practices) certification.

**Indemnification**

Indemnification is a legal concept that basically means if Person A does something that harms Person B, Person A will pay Person B back for their damages. It’s like the negligence concept discussed in the previous chapter. One big difference centers on how a person becomes liable. Negligence relies on an implicit societal responsibility to meet unspoken but commonly accepted standards. For example, you can sue someone for negligence even though they never agreed to be responsible for their negligence. Society assumes we all have that responsibility. Indemnification is a contractual obligation: You are responsible to indemnify someone if you agreed to indemnify them. In other words, if you agree to assume responsibility for a food safety incident, you may have to bear the costs regardless of your own degree of negligence. (Of course, there are always exceptions. In the interest of space, this is a basic distinction.)

Indemnification is a part of many business relationships. Folks all along the supply chain jockey to avoid indemnification themselves while securing it from others. When it comes to food, many people may become potentially responsible for a contaminated product, from producer to warehouse to distributor to retailer. As a result, businesses are especially keen on protecting themselves. Businesses do this by requiring their partners to sign an agreement with an indemnification provision. The indemnification provision may be restricted to specific circumstances (such as negligence of the farmer) or specific claims (such as personal injury lawsuits). Or, indemnification provisions may be very broad by covering all damages, lost sales, degradation of reputation, and more.

[Farmer Alexi Icon]

The indemnification clause haunts Alexi: Contaminated apples made their way into bags, onto the grocery store’s shelves, and into the hands of one individual, Jim. Jim’s compromised immune system takes a hit and he winds up in the hospital for several months. Jim’s health insurance company gets stuck with the hospital bill and is looking for a way for someone else to pay. The insurance company is concerned that Alexi’s insurance may not provide enough coverage for all the injured parties. Instead, the insurance company sues both Alexi and the grocery store. The insurance company argues that Alexi was negligent for allowing her apples to become contaminated and the grocery store was negligent for selling Alexi’s product without having looked into Alexi’s food safety practices more. The grocery store has liability insurance to cover its own negligence and its insurance company takes over to defend the lawsuit. But it loses! Now the grocery store’s insurance company comes looking for Alexi and asks her to pay them back for all the expenses incurred, including attorney fees. Alexi takes a closer look at the sales agreement and finds that she agreed to pay the grocery store back if her negligence caused the store losses. If Alexi is found negligent in the lawsuit, her insurance company might cover the costs of Jim’s medical expenses, but Alexi may still have to pay the grocery store for its losses. Alexi will need to review her insurance policy to see if it also covers this kind of loss.

Indemnification can quickly come into play during a food safety incident involving a grocery store or other retailer. A grocery store may suffer loss of sales from all products of the type (all spinach or all apples) regardless of the source. The grocery store’s reputation may be damaged. The store itself may be sued for negligence, perhaps for negligently working with a farmer who did not meet standard safety protocols. If the farmer agreed to indemnify for these damages, the farmer would then have to pay the grocery store back for all these things. Indemnification can pile up fast and quickly put a farmer out of business.

**Managing the risks of indemnification**

Fortunately, many insurance policies will cover liability incurred by indemnification of others. Commercial policies often provide this coverage; however, the precise language of the insurance policy may limit the types of indemnification. For example, the distributor you contract with may require *risk-shifting* indemnification provisions (requiring one party to assume all risks of claims and lawsuits whether that party was at fault or not) rather than *risk-sharing* provisions (requiring one party to indemnify the other only for the first party’s own negligence or fault). It is important to read both the insurance policy and the sales agreement closely to make sure the indemnification offered to the buyer is the type covered through the insurance policy.

**Contract breach risks**

When one party violates a term of a contract to which they have agreed, they have “breached” the contract. The other party can then bring a lawsuit to force the breaching party to pay for damages the non-breaching party suffered. Contract breach is another way farmers may end up with legal consequences from a food safety incident. By contrast, indemnification (discussed just prior to this section) is an example of becoming responsible by agreement without breaking the contract.

**Write down the sales agreement**

Contracts are incredibly flexible. The law gives contracting parties plenty of leeway to come to an agreement that works for them. Many buyers and sellers agree on which damages are available for specific breaches and describe the procedure for recovering from other parties. By writing it down ahead of time, folks know exactly what they agreed to do and how to handle problems. If the contract doesn’t spell out everything, the court will rely on state law to fill in missing details. Of course, that can be unpredictable. So, the best way to manage contracts and control breaches is to write a detailed sales agreement ahead of time. A good sales agreement clearly lays out responsibilities and a procedure for handling problems.

In terms of food safety, many sales agreements obligate farmers to adhere to specific food safety practices or standards. Buyers might want farmers to maintain GAP (Good Agricultural Practices) certification, buy specific levels of liability insurance, follow specific sanitation practices, offer broad indemnification, or even follow vague guidelines like follow the “highest” food safety practices. These provisions seem innocuous enough. Small breaches fly under the radar and no one cares. But, when bad things happen and bills start to pile up, everyone starts looking around for ways to reduce the damage. Even small breaches can end up leading to large damages. When things are already going wrong, farmers don’t need yet another penalty because they didn’t follow the terms of a contract. It’s so important to understand and follow the terms of any agreement.

[Farmer Alexi Icon]

The agreement to be GAP certified haunts Alexi: Before signing the sales agreement with the grocery store, Alexi read it quickly. She saw that the grocery store required GAP certification. Alexi was planning to get the certification a year prior, so she asked if the store would accept her plans to become certified. They agreed, but it wasn’t put in writing and Alexi signed the contract as it was written. Things got incredibly busy and Alexi didn’t have a chance to schedule an appointment with the auditor. Everything just got away from her. Now, the grocery store claims that Alexi’s failure to get GAP certification is a breach. The grocery store wants compensation for that too. Alexi knows she was supposed to get the certification and she did sign a contract saying she had it. She doesn’t have many options at this point.

**Understand the contract terms**

The reality is that from email services to software, insurance, banking, health care, and nearly every other facet of life, we are presented with contracts that we have no opportunity to negotiate and must sign to utilize the service being offered. Despite their ubiquity, it’s a mistake to assume these contracts aren’t binding. A court will enforce many of these contracts. Even if the pages are filled with legal “boilerplate,” we may be held to our agreement.

To state the obvious, farmers should take some time to thoroughly review the terms of any important sales agreement. Even if it seems like an exercise in futility, farmers may have more opportunity to negotiate than they realize. Farmers have product that grocery stores and institutions want to purchase. Many buyers truly want to build effective relationships with farmers. Understanding shared responsibility for food safety is an important part of that relationship. If a farmer thinks proposed sales terms are unfair, that farmer should feel comfortable bringing it to the buyer’s attention. As with any negotiation, having an alternate proposal in one’s back pocket can boost confidence and help everyone find a resolution quickly.

**TAKING ACTION ON CONTRACTS**

* **Draft or negotiate sales contracts that limit indemnification and set achievable production standards**
* **Check insurance policy to see if it covers indemnification**

[Famer Sally Icon]

Farmer Sally Takes Action on Contracts

Farmer Sally is looking at selling her products wholesale, and she wants to avoid the problems plaguing Alexi. Sally realizes that if she’s standing in the receiving area, being asked to sign a contract to complete a sale, she’ll have no time to understand or negotiate the contract. Doing a little homework ahead of time might make it easier. Sally does the following things:

* Writes down exactly how she would like a sale to proceed with each buyer and uses that procedure to create an effective sales contract. She also includes procedures for when things go wrong. Sally plans to use this agreement with buyers who don’t already have an agreement of their own.
* Prepares by getting copies of any buyers’ existing contracts ahead of time (perhaps from other farmers who sell to them?) and reading them thoroughly.
* Reads any proposed contract, looking for an indemnification provision.
* If there is an indemnification clause, will Sally’s insurance cover her for it? Sally may need to ask her agent about this. Her insurance agent may recommend she buy a “contracts and agreements endorsement.”
* What else does the contract obligate Sally to do? Is she prepared to adhere to each clause?
* If not, are there other options Sally could propose to the buyer? Something that might accomplish mutual goals without undue burden on Sally?
* Signs a written contract before making a sale to larger buyers such as grocery stores.

**Legal Risk 3: Recalls**

When a food safety incident occurs, one of the primary ways to control the outbreak is to recall all the potentially affected products. An effective recall removes the product from the shelves and instructs those who purchased the affected product to throw it away. Naturally, this requires some form of an identification and tracking system. Especially when it comes to products with a long shelf life, an efficient tracking system is a legal necessity. Even if a recall isn’t required, performing a voluntary recall may be the wisest decision. If a farmer does not take steps to control the outbreak and more people get sick, the farmer may appear more negligent. As we discuss above, being found legally negligent can require the farmer to pay extensive damages to the injured person and to indemnified parties.

The tracking should be narrow enough to order as narrow a recall as necessary. To use Alexi’s example, she would want the ability to recall only the apples that came from the contaminated batch. So, her ideal system would track apples by location of harvest and date of harvest. The tracking code would then be stamped on bags or cases so consumers can check whether their item is included. The ability to perform a recall effectively is a key way to manage the potential liability of a food safety outbreak.

Recalls are usually voluntary but can be required under some circumstances. As food safety incidents appear to become more serious around the country, federal and state governments are increasing their ability to mandate recalls of fresh fruits and vegetables. Even very small farmers who sell their own product locally may be required to do a recall. If a farmer is required to perform a recall and cannot, several things may happen. The law may impose a fine or the producer may be forced to destroy all products to be on the safe side.

[Farmer Alexi Icon]

With five people sick and bags of potentially contaminated apples on the shelves, Alexi decides she has to do a recall. She doesn’t want to risk more individuals getting sick. Her tracking system isn’t nearly as efficient as she might like. If she had stamped each bag with a lot and date code, she would be able to instruct customers to look for that code. But, with only two years of wholesale history, Alexi hadn’t gotten that far. Instead, she was simply tagging each bulk bin of bagged apples with a sheet of paper including the date, type of apple, and buyer. Alexi can help the grocery store pull any remaining bulk bins from the affected harvest dates. As for the apples on the shelves, Alexi decides she should pull them all. Since she doesn’t know if the bags came from the affected bulk bins, she recalls all apples on the shelves. While this costs more money, hopefully it will keep spiraling costs from truly getting out of control.

**Managing the financial risks of a recall**

Recalls are generally very expensive to perform. The logistics of getting product off the shelves and communicating the recall to the public are very complicated. Aside from carrying out the recall itself, the farm suffers a loss of reputation, lost revenue from not being able to sell, and if the indemnification dominoes fall, the damage quickly escalates.

Insurance is sometimes available to protect against the expense of a recall. Finding such a policy may take some time. Generally, farm liability policies do not cover the losses from performing a recall or losing revenue, and simple business endorsements or liability additions for direct-to-consumer sales usually don’t include recalls either.

The reality is that some insurance companies may only offer recall coverage as part of a commercial liability policy normally designed for larger commercial operations. Such coverage is likely pretty expensive. Fortunately, there are insurance companies that offer recall coverage at a lower cost for smaller farm operations. However, even this coverage can vary: policies may cover voluntary recalls but not government-ordered ones, or vice versa, covering government-ordered recalls and not voluntary ones.

**TAKING ACTION ON RECALLS**

* **Implement product tracking and traceability**
* **Consider recall insurance**

[Farmer Sally Icon]

Farmer Sally Takes Action on Recalls

Sally recognizes that Alexi is balancing a couple of different priorities. She hasn’t done a large volume of wholesaling, so it seems inefficient to sink money into a detailed tracking system. At the same time, Sally knows that recalls are playing a more significant role in food safety regulation. By talking with other farmers, Sally hears about the other advantages of a good tracking system, such as careful monitoring of field productivity and worker efficiency. It sounds like a good investment. Here’s what Farmer Sally does:

* Makes a careful decision on whether recall ability is right for her business and the level of recall accuracy she would like.
* Researches different options for implementing a product tracking system.
* Puts the right system in place for her farm that will offer a reasonable ability to get product back if there is a risk of contamination.
* Asks her insurance agent whether and how she is covered for the expenses of a recall.

**Legal Risk 4: State and Local Enforcement Actions**

Up to now, this guide has addressed legal risks that are purely business-to-business or business-to-customer. With the exception of a brief discussion of the government’s ability to compel a recall, government action has played a small role in the legal outcomes of a food safety incident. However, there are avenues for government involvement in this kind of legal incident.

**Adulterated foods**

In addition to the federal Food, Drug, and Cosmetic Act, most states have food safety laws that prohibit the selling of “adulterated” foods. Back at the turn of the twentieth century, when these laws were passed, that often meant milk with water added or bread made with chalk. The legal definition is actually broader than just products with something adverse added to them. While each state has come up with its own definition of “adulterated” foods, they all pretty much mean the same thing. Most of the laws say something like, “Products are adulterated if they consist in whole or in part of a diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food consumption.” As a rule of thumb, if the unsafe condition of the food makes someone sick, it’s likely adulterated.

In addition, in most states a food product would be considered adulterated merely if it is held or processed under insanitary conditions, even if the food product itself is not adulterated. This begs the question: would a farm with an inadequate or no food safety plan in place be considered insanitary conditions (i.e., all of the farm’s products would thereby be considered adulterated)?

To take Alexi’s example, the government might see her lax oversight of whether apples are being washed as fundamentally unsafe. By deeming all the apples adulterated due to their holding conditions, the government might be able to prohibit the sale of all Alexi’s apples, or even seize all of her apple products. Alexi might also be subject to a fine, and even imprisonment, if she failed to correct the situation.

**Wisconsin food adulteration laws at a glance**

In Wisconsin, the definition of “adulterated” foods includes foods that are produced, prepared, packed, or held under insanitary conditions. It also includes foods containing added substances that may be harmful to health or that diminish the value of the product to consumers. (Wis. Stats. § 97.02; 21 U.S.C. § 342).

Penalties for violations can be steep. A first offense can result in up to six months incarceration or a fine up to $1,000. Additional violations can result in a combination of jail time and fines up to $5,000. (Wis. Stats. § 97.10).

State governments may be motivated to enforce laws prohibiting the sale of product when a food safety outbreak occurs. Of course, they can enforce the laws at any time, but for the sake of efficiency, it’s not common that agencies make investigations without some reason to believe unsafe conditions are present. We might also speculate that an agency will be motivated to use these laws if the farmer isn’t doing enough to deal with the outbreak. To enforce the prohibition on the sale of adulterated products, when necessary, the state government may seize the food products.

**Product-specific regulations**

When it comes to processed and value-added fruits and vegetables, many more regulations apply. For farms turning apples into apple cider, for example, state laws set detailed requirements. Under Wisconsin law, cider may need to be pasteurized depending on where it is pressed and sold and unpasteurized cider must carry a specific warning label. On a farm that also sells other processed foods, like caramel apples, a Retail Food Establishment License may be required for the cider press, even if there is already a separate, licensed kitchen on the farm property. (Wis. Stats. § 97.30(2)(b)).

This guide isn’t intended to discuss the specific rules that apply to processed products; however, the point is that if these rules are not followed, it opens the door to regulatory action. This risk is always present, but when a food safety incident occurs, the motivation to investigate increases. Farms violating the food safety code may be fined and have their license revoked. In some states, repeated and willful violations of the rules can even result in a criminal prosecution. Food safety regulations are not something to mess around with.

**[Farmer Alexi icon]**

So far we’ve only talked about Alexi’s problems relating to her fresh apple sales. But, remembering back to the beginning, we also said that Alexi produces cider on her farm. We know that some of the contaminated apples made their way into the cider production and that the resulting bacterial growth made customers sick. This draws the attention of the local department of public health, the agency that enforces the food code.

Concerned, the agency decides to investigate Alexi’s cider facility. In an extensive, multi-hour investigation of her facility, the team from the department of public health studies monitoring procedures, takes temperatures, tracks product through production, checks the labels, and samples the cider for bacterial contamination. They do a thorough assessment of whether Alexi is following the regulations that apply to cider production. If they find she isn’t, they may revoke her license or impose a fine for the violations.

**TAKING ACTION ON STATE AND LOCAL LAWS**

* Learn about and follow all product-specific state and local food code regulations

**[Farmer Sally icon]**

**Farmer Sally Takes Action on State and Local Laws**

Farmer Sally has been looking at preparing salad mix in a certified kitchen on her farm. The trouble Alexi is going through is causing her to rethink that decision. Her salad mix operation would require careful compliance with the food code, as she certainly doesn’t want to break the rules. Although she was going to wait until the inspector arrived to learn about the rules, Sally decides to be a little more proactive. Maybe if she reads the code herself, she’ll avoid making any accidental mistakes down the road. So, Sally does the following:

* Gets a copy of her state’s food code and reads all the regulations that apply to a food processing operation. Not all of them make sense, but she keeps track of those she has questions about.
* Contacts the local inspector to set up a meeting well ahead of construction on her certified kitchen. Sally wants to make sure she understands the rules correctly and is interpreting them in the same way as the inspector. This also might help their relationship get off to a good start, so Sally has a ready ally when it comes to getting up and running.

**Legal Risk 5: Federal Enforcement Actions, Including FSMA Rules**

**Adulterated food**

Just like state food safety laws, federal food safety laws prohibit the selling of “adulterated” foods. The federal definition of adulterated is quite broad, and includes food that is simply held or processed under insanitary conditions*.*

If a food is adulterated, the Food and Drug Administration (FDA) and the USDA’s Food Safety Inspection Service (FSIS) have a number of enforcement tools. These include seizing and condemning the product, enjoining persons from manufacturing or distributing the product, or requesting a recall. Farmers can also face fines and the risk of criminal prosecution. Enforcement action is usually preceded by a warning letter from the FDA or FSIS.

**The Food Safety Modernization Act (FSMA)**

Most if not all farmers have heard about the Food Safety Modernization Act, or FSMA, by now. FSMA overhauled existing food safety laws and gave the FDA and state regulatory agencies authority to do inspections on covered farms. The goal of FSMA is to give regulatory agencies the opportunity to prevent, instead of just respond, to food safety incidents. It’s a big deal for farmers as, for the first time, the FDA now has authority to regulate on-farm practices.

Congress passed FSMA back in 2011. It’s since taken the FDA quite some time to develop the final rules, or implementing regulations. These rules are now considered “final” and the implementation and enforcement phase has begun.

While FSMA involves seven major rules, two are most relevant to the majority of farmers: the Produce Safety Rule and the Preventive Controls Rule (also known as the Facilities Rule). Now that these laws are officially in effect, farmers will want to pay attention to whether they must comply with them now or in the future, especially as they expand or enter new markets.

**The Produce Safety Rule governs on-farm activities of produce farms**

The Produce Safety Rule sets food safety standards for farms that grow, harvest, pack, and hold fresh produce. The rule sets guidelines and standards in five areas: water quality; employee health and hygiene; wild and domesticated animals; biological soil amendments of animal origin (such as compost and manure); and equipment, tools, and buildings. There’s also a section governing sprouts.

**Farms that engage in value-added processing or handle other farms’ produce might have to comply with the Preventive Controls Rule**

The Preventive Controls Rule sets standards for food processing operations, which could include farms depending on the degree they engage in value-added processing or handle other farms’ produce. This rule basically requires facilities that process and handle raw agricultural products to register with the FDA, follow current good manufacturing practices (GMPs), and implement a food safety plan.

**Small, sustainable farms may be eligible for full or partial exemptions to the FSMA rules**

A number of full and partial exemptions to the Produce Safety Rule and the Preventive Controls Rule exist for small farm operations. For example, farms that average $28,075 or less in all produce sales are entirely exempt from the Produce Rule. Farms that average less than $561,494 dollars in all food sales and sell mostly direct-to-consumer—for example, through roadside stands, farmers’ markets, and community-supported agriculture (CSA) programs—might be eligible for what’s called a “qualified exemption.” This means they don’t necessarily have to comply with the substantive requirements of the rule—such as the water testing requirements and so on—but they will need to follow certain recordkeeping and labeling requirements. Also, the FDA or state regulatory agency can still take enforcement action if an incident is linked to the farm.

Farms that are doing limited processing (e.g., dehydrating grapes to make raisins) are exempt from the Preventive Controls rule. So are farms that mostly sell their products direct-to-consumer, which again includes roadside stands, farmers’ markets, and CSA programs. In addition, partial exemptions are available for farms that perform “low-risk activities” and have less than a million dollars in all food sales. “Low-risk activities” include chopping or slicing fruits and veggies, making maple syrup, making baked goods, and extracting olive oil. These farms must register with the FDA and keep records to support their exemption (i.e., sales receipts, etc.). They must also comply with the updated GMPs and employee training and qualification requirements.

This is just a summary! In reality, it can be challenging for some farms to navigate these exemptions and determine whether they must comply with these rules, and if so, which parts and by when. This is especially the case for diversified farms that either partner with other farmers to offer more variety of products or engage in value-added processing.

As a first action step, farmers can set aside 15 minutes to walk through Farm Commons’ resource *Whether and When Farms Must Comply with FSMA: Flowchart*. By answering a set of questions, farmers can learn whether one or both of these rules apply to them. It also provides a list of resources where farmers can learn more.

**Uncertainty remains about the substantive requirements of the rules and how the FDA will enforce them**

As the implementation process is now underway, farmers are often left with more questions than answers about what certain substantive requirements mean as well as how the FDA will enforce these rules. This can be frustrating!

**FSMA Produce Safety Rule trainings geared toward small producers now available**

The FDA is working with the state Departments of Agricultures in most states to help them offer FSMA trainings and has established four Regional Centers to coordinate FSMA related activities and outreach across the country. The FSMA Produce Safety Rule Grower Training is a full-day training that covers Good Agricultural Practices and the requirements of the FSMA Produce Safety Rule. Any farm that is fully covered by the FSMA Produce Safety Rule must send a representative from the farm to the training, but all farms are welcome to participate.

The FSMA trainings are standard nationwide. They each use a curriculum created by the Produce Safety Alliance, a national organization and partnership between the USDA, FDA and Cornell University. The trainings are available in every state in the US, and in many international locations. They are available in-person or online.

Farmers interested in attending a FSMA training should check with their state department of agriculture or University Extension programs to find out when programs will be held.

To find out more about upcoming local trainings in Wisconsin, contact your local extension agent or the Wisconsin Department of Agriculture, Trade, and Consumer Protection.

**DATCP Safe Wisconsin Produce:**

<https://datcp.wi.gov/Pages/Programs_Services/SafeWisconsinProduce.aspx>

**University of Wisconsin Division of Extension**

<https://extension.wisc.edu/>

**FDA enforcement is now underway**

Early on, the FDA has indicated that it planned to target its inspection resources based on risk, and planned to rely heavily on states to conduct a large portion of on-farm inspections. At this point, 43 states have entered into contracts under the FDA’s Cooperative Agreement Program to conduct inspections and coordinate reporting requirements. In most states, inspections and enforcement will be conducted by the state departments of agriculture or health. Inspections on large scale farms with more than $500,000 in average food sales began in 2019 and small farm inspections were slated to begin in 2020. In states that did not enter into the Cooperative Agreement Program, inspections and enforcement will be conducted directly by the FDA.

In most cases, farms that are not exempt from the Produce Safety Rule will receive advance notice of the initial on-farm inspection by way of a pre-inspection phone call. The inspection will usually be scheduled within five days of the pre-inspection phone call. In most states, the focus of the initial inspection will be to identify corrective actions rather than enforcement. Any corrections that can be made during the inspection will be documented on site. The inspector will establish a time frame for any corrections that cannot be made during the inspection and may make an unannounced follow up inspection to verify compliance. Serious violations that could lead to contamination or public health concerns may result in immediate enforcement actions, including product seizure or a stop sale order.

Farmers also have the option to request an On-Farm Readiness Review before the initial inspection. The review is free and confidential. Participating farms will get direct feedback from agency representatives identifying actions they can take to comply with the Produce Safety Rule. No violations of the rule will be reported to the state or the FDA unless they present an immediate public health concern and the farmer does not have the ability to contain or prevent the threat.

What happens if farmers fail to comply with FSMA when required? The penalties can be steep. Just as with violating federal adulteration laws, farmers face fines and even criminal prosecution for failing to comply with the FSMA rules.

**What can farmers do to manage their legal risks of FSMA enforcement?**

A good approach is to keep good records and document how the farm is complying with the FSMA rules. The better the records, the easier it is to demonstrate that the farm is meeting the legal standard. More importantly, it helps the farm put processes and procedures in place to prevent problems in the first place. Adopting and implementing a robust food safety plan can be an optimal way to do this.

One thing is certain: compliance with FSMA does not affect personal liability potential in any significant way. Similarly, a farm that is entirely or partially exempt from the FSMA rules is not off the hook for food safety liability risks! Regardless of whether FSMA applies, a farmer can still face a personal injury lawsuit if a food-borne illness is linked to the farm. In addition, the state and federal government can still pursue enforcement action under adulteration laws! **When it comes to managing food safety liability risks, FSMA is just a small piece of the puzzle.**

**FSMA and Personal Injury Lawsuits: Refresher**

Whether a farm must comply with the FSMA rules or not, it’s wise to become familiar with what’s required and to proactively follow the rules as closely as possible. As more farmers begin to comply with FSMA, courts might turn to these standards when determining who’s at fault in a food contamination lawsuit. By following these rules, farmers can better prove that they did not act negligently and that they took reasonable precautions to prevent contamination.

**TAKING ACTION ON FSMA**

* **FSMA: Find out whether FSMA applies, learn about FSMA standards, and commit to incorporating them when required and/or feasible**

**[Farmer Sally icon]**

Farmer Sally’s produce sales for the past three years have averaged about $30,000. Most of those sales (i.e., more than $15,000) have been through her CSA and farmers’ market sales.

Sally walks through the Farm Commons resource *Whether and When Farms Must Comply with FSMA: Flowchart* and learns that her farm falls within the “qualified exemption” of the Produce Safety Rule given her gross produce sales fall below the threshold AND most of these sales were directly to consumers.

Sally sets some time aside to make a placard with her farm’s address to post at the farmers’ market and her CSA pick-up sites, as required under the qualified exemption. She also gets systems in place to keep records of her sales to prove that the qualified exemption applies.

Even though Sally does not have to follow the substantive requirements of the Produce Rule, such as water quality testing and so on, she decides to learn about these standards and gradually incorporate them as best she can. She signs up for a local workshop and commits some time over the winter months to decide which aspects of the Produce Rule are most practical and affordable to pursue first, given the needs and limitations of her particular farm. As an extra step, she decides to get systems in place to document how she’s complying with her food safety plan in case a food safety incident ever arises.

When walking through Farm Commons’ flowchart, Sally also learns that the Preventive Controls Rule would apply to her if she pursues her bagged lettuce operation! Putting cut lettuce greens in a bag is considered packaging, and packaging lettuce or any raw produce is not listed as an activity a farm can perform without being subject to the rule. However, she would be eligible for a “qualified exemption” because her average total food sales over the previous three years were less than $561,494 a year and more than half of her sales were directly to consumers or local businesses. She realizes that to sell bagged lettuce she must do the following:

* *Register* with the FDA.
* Keep sales *records* to support her exemption.
* Comply with *updated GMPs* and *personnel requirements* and all *existing local/state food safety laws*.
* Submit two certified statements (“*attestations*”) to the FDA: (1) that she qualifies for the exemption (i.e., based on food sales) and (2) is either complying with the HARPC (“Hazard Analysis and Risk-Based Preventive Controls”) provisions of the rule OR is complying with all applicable state/local food safety laws.
* Provide the farm’s *name and full address* on every label or point of sale (if she chose to comply with option (2), to comply with applicable state/local food safety laws rather than the HARPC provisions).

Sally feels frustrated and intimidated! She decides to play it safe and hold off selling her bagged lettuce until she looks into all that she needs to do to comply with the rule. She writes down a list of questions to ask at the upcoming FSMA training workshop. She also plans to contact her local extension office to see if they can provide some answers.

**Conclusion**

The risk of a food safety incident is a serious one with wide legal ramifications. Growing safe food is the very first priority for managing these risks. Beyond that, there is still plenty a farmer can do to build a strong, resilient farm business that can withstand such an event! By referring to the Taking Action steps in this guide, farmers can begin to develop an overall food safety strategy most suited to their farm operation. **In the end, the right risk management strategy is a personal decision—financial, emotional, and business considerations all factor into what’s most appropriate and feasible for you and your farm.**

**TAKING ACTION: ONGOING**

* **Schedule an annual review of the farm’s food safety strategy**

Whatever is decided as a first step, farmers are well-advised to carve out some time each year to revisit, improve, and adapt their overall food safety strategy, including their food safety plan. What’s working and what’s not? Are systems being followed? Are records being kept? How might systems be improved? Have regulations changed or do new regulations apply? A call to your insurance agent should be part of this annual review. Are new or better policies available?