

# REDUCING FOOD SAFETY LIABILITY RISKS WHEN INTEGRATING LIVESTOCK WITH SPECIALTY CROPS: FSMA AND BEYOND

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## Executive Summary

Animals can readily perform an array of beneficial services throughout the production cycle, including maintaining weeds, scratching and digging to prepare for planting, excreting and spreading nutrients, controlling insects and pests, and cleaning up fallen nuts and fruits. Reaping the benefits of integrating livestock into orchard systems requires farmers to pay close attention to inherent food safety risks. Animals grazing under the canopy and through alleys of nut, fruit, and vegetable bearing trees, shrubs, and plants will naturally excrete waste and on occasion contact crops in ways that raise the vulnerability of contamination. If the farmer isn't careful, a food borne illness could be linked to the farm.

Food safety liability can seem overwhelming and the worst-case scenarios are scary. After all, no farmer wants to get anyone sick. The bottom line is that every farmer should prioritize producing the safest food, first and foremost. Still, attention must be paid to the legal aspects of a food safety incident.

Accidents can happen to anyone. The risks of contamination increase when animals are around produce crops before, during, and after harvest. The good news is that farmers can take tangible, cost effective steps to reduce their risks of a food safety incident and their legal liabilities in the event of a food safety incident. There are a number of steps farmers can take to reduce the risk of product contamination at all stages of production and post-harvest operations, but this guide focuses specifically on reducing risks when integrating livestock into your crop production areas.

Here we outline three strategies farmers can take to reduce their food safety and legal liability risks:

- Follow good agricultural practices, including complying to the best of your ability with the federal Food Safety Modernization Act (FSMA) standards even if you are not required by law to do so.
- Keep detailed records of how good agricultural practices and other food safety measures are being followed, even if you are not required by law to do so.
- Explore insurance options for food safety incident coverage.

The specific steps and precise details for how each farmer ought to implement these strategies will depend on the unique attributes of their agroforestry or mixed crop-livestock farming operation. Farmers who are not exempt under the law are required to follow any FSMA food safety and record keeping regulations, but even those who are exempt can reduce food safety and liability risks by voluntarily adopting the safety and recordkeeping practices required under FSMA's Produce Safety Rule.

We recommend a fourth strategy to build a legal and regulatory environment that preserves the safety of mixed crop-livestock and agroforestry farming systems. This fourth strategy is not simply about reducing liability risks within the current framework of food safety regulations, but about steps farmers can take to help ensure that any future regulations reflect a sensible approach to food safety in integrated livestock operations. This strategy involves three action steps farmers and farming communities can pursue to help advance laws that promote food safety while taking into account the practical needs and limitations of farms of all kinds.

- Work with regulators
- Build community consensus
- Participate in the rulemaking process

We can expect new rules to be proposed sometime in the future. Producers have an opportunity to shape how the law evolves by developing consensus and common practices that protect the safety of produce in mixed crop-livestock operations. The techniques of this fourth strategy will help shape the regulatory destiny of farms that use managed grazing concurrent with specialty crop production.

In the end, the best risk management strategy regarding food safety legal liability is a personal decision that depends on you and your farm. Your own financial, practical, and business considerations all factor into the appropriate strategy for you. With that in mind, let's review some action steps you can take and questions you should ask yourself to develop good food safety practices in your mixed crop-livestock farming operations.

## Three Steps to Reducing Food Safety Legal Liability Risks

1. Follow good agricultural practices, including complying with the FSMA standards regarding animals

First and foremost, farms following good food safety practices are less likely to have an incident. In addition, if customers happen to get sick, a farm that can show that good agricultural practices were being followed will be in a much better position to defend itself against any lawsuits or government enforcement actions.

What are good agricultural practices when it comes to integrating livestock into the crop production cycle?

From a legal perspective, the FSMA standards regarding animals and corresponding good agricultural practices that are now emerging provide a strong, defensible guidepost for farmers

to turn to when adopting best practices for their particular farm, regardless of whether an individual farm is required to comply. That being said, the FSMA Produce Safety Rule (PSR) does regulate when and how covered farms must manage grazing animals, working animals, and animal intrusion before, during, and after harvest of covered produce.

The first question most farmers ask is: Am I covered by FSMA rules? And even if your farm is covered by FSMA, a number of exclusions and exemptions exist. FSMA only applies to covered food products at times and in areas where covered activities occur. Farms that are required to comply could face fines and even criminal prosecution for violating the standards. Some small farms may be eligible for a qualified exemption from the requirements of the PSR, but even those farms will benefit from trying to comply with PSR requirements in order to avoid losing their exempt status.

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 (ATTACHED). By answering a set of questions, farmers can learn whether the either or both the FSMA PSR and FSMA Preventive Controls rule apply to them. It also provides a list of resources where farmers can learn more.

While the threat of fines and criminal prosecution is a compelling reason to comply with the FSMA rules, it's not the only reason. Regardless of whether FSMA applies, a farmer can still face a personal injury lawsuit or an enforcement action under state or federal adulterated food laws if a food-borne illness is linked to the farm. Farmers who can show that they are complying with FSMA standards regarding animals—even when they're not required to—may have a stronger defense if a food safety incident occurs. That's because courts might turn to FSMA standards when determining whether the farmer is at fault. Good recordkeeping can go a long way toward helping your defense against a lawsuit and help narrow the scope of an investigation in the event of a food safety incident, as well.

Another practical reason to comply with FSMA requirements and standards is that existing and prospective buyers and current or future insurance companies might require compliance. Regardless, most if not all customers will certainly appreciate a farmer's efforts to take food safety seriously. Efforts to comply with FSMA may actually be good for business.

This brings us to our next question.

What does FSMA require when it comes to integrating domestic animals with produce production?

When it comes to domestic animals, the main goals of the FSMA regulations are to reduce the risk of contamination from animals, and to ensure that produce contaminated by animals is not harvested. The FSMA PSR requires farmers to take preventive and protective measures if "there is a reasonable probability that grazing animals, working animals, or animal intrusion will

contaminate covered produce.”<sup>1</sup> Farmers are required to “take all measures reasonably necessary to identify and not harvest produce that is reasonably likely to be contaminated.”<sup>2</sup>

It is clear that the rule explicitly requires farmers to assess growing areas for potential contamination before and during harvest. It is also clear that when a reasonable probability of contamination exists, farmers need to take additional steps to ensure such product that is reasonably likely to be contaminated is not harvested. For better or worse, though, the rule and related regulations do not prescribe specific measures, procedures, or steps to further define words like “reasonable” or “likely.” (The PSR requires additional actions to protect food safety, (for example, worker training and storage practices) which are described later in this guide.

FDA has issued a variety of guidance documents explaining how it interprets the current FSMA regulations, but even the guidance documents leave plenty of room for questions about how the rules might apply in different individual situations.<sup>3</sup> Moreover, the guidance documents, unlike the regulations themselves, do not have the force of law. FDA and state regulatory agencies are not legally obligated to follow the guidelines. Compliance with the guideline recommendations may provide compelling legal support for a farm’s food safety practices, but it won’t necessarily prevent a farm being ordered to change its practices.

How do I know if there is a “reasonable probability” that animals will contaminate produce? When is it “reasonably likely” that produce is contaminated?

The answers to these questions are not exactly clear. The FSMA regulations themselves do not offer any definition or explanation of what circumstances might amount to a reasonable probability of contamination. Regardless, farmers are expected to identify crop areas where a reasonable probability of animal contamination might exist and periodically assess those areas to determine whether it is reasonably likely that any crops in those areas actually have been contaminated. Certainly, although knowledge that animals have been present in a crop area is a key factor in assessing the probability of contamination, the mere presence of animals doesn’t automatically mean that a reasonable probability that they will contaminate produce exists.

FDA recommends evaluating land features and structures that could attract animals or influence how close animals get to harvestable produce. Other considerations could include water flow patterns that might carry animal contaminants from one area to another, weather events that influence animal movement patterns and, of course, the type of crop being evaluated. For example, FDA is of the view that there will not be a reasonable probability of contamination by

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<sup>1</sup> 21 CFR 112.83

<sup>2</sup> 21 CFR 112.112.

<sup>3</sup> See “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry”, *Draft Guidance*, U.S. Food and Drug Administration, October 2018. Available at <https://www.fda.gov/media/117414/download>; and “At a Glance: Key Points in the Produce Safety Rule Draft Guidance”, available at <https://www.fda.gov/media/117422/download>.

animals for produce that grows entirely underground. Nonetheless, FSMA still requires taking steps to avoid harvesting underground crops if a visual assessment or other evidence indicates a reasonable likelihood that the produce actually has been contaminated.<sup>4</sup> Although FSMA doesn't require farmers to keep records of efforts to identify a reasonable probability of animal contamination, it is probably a good practice to document observations that support your determination.

The FSMA regulations identify a visual assessment of the growing area and the crops to be harvested as the minimum effort necessary to identify produce that is "reasonably likely" to be contaminated.<sup>5</sup> The details of when, where, and how you conduct your assessments are left up to you to determine. Likewise, it falls to you to decide whether evidence of potential contamination is significant enough to require that you exclude that portion of your crop from harvest.

There is no binding list of factors that you should consider in determining whether a portion of your crop is "reasonably likely" to be contaminated. It's clear that produce that is visibly, directly contaminated by animals should not be harvested, but beyond that, FSMA rules anticipate that you will use common sense and a good understanding of food safety principles to decide whether a product has experienced a reasonable probability of contamination and is reasonably likely to be contaminated.

Above, we discussed the nature of the farmer's obligation to take preventative measures relative to when "there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce." But, that's not the end of the line. Farmers also need to assess when produce is "reasonably likely to be contaminated," such that they can avoid harvest by all measures reasonably necessary. These are two sides of the same coin, but they deserve separate exploration.

#### What measures are "reasonably necessary" to avoid harvesting contaminated produce?

Depending on the specifics of your farm operations, that decision may require taking a number of different factors into consideration, like the type and number of animals involved, the type of crop involved, the proximity of animals to the harvestable portion of the crop, the length of time between harvest and the presence of animals, and environmental conditions like soil characteristics and weather events. In short, there is no simple equation for determining whether your crops are reasonably likely to be contaminated. That makes it all the more important to establish regular assessment practices and keep records documenting the evidence that supports your decision to harvest or not harvest the crops in question.

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<sup>4</sup> See "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry", *Draft Guidance*, pp. 74 – 76.

<sup>5</sup> 21 CFR 112.112.

If you do decide that a portion of your crop is reasonably likely to be contaminated, FSMA requires you take all “reasonably necessary” measures to avoid harvesting that crop. Again, the FSMA regulations and guidelines leave it to you to determine what measures are appropriate for your farm operations. FDA suggests marking non-harvest areas with flags, but alternative methods, such as temporary fencing and additional visual assessments at harvest time may also amount to reasonably necessary measures. Although FSMA requires farmers to keep records documenting processes for treating manure on the farm, FSMA does not require farmers to keep records of measures taken to avoid harvesting contaminated produce. Nonetheless, as always, it is probably a good practice to document the efforts you make to avoid harvesting produce at risk of contamination, including the steps you take to instruct your employees which areas are not to be harvested.<sup>6</sup>

#### What precisely must I do to comply with the FSMA standards regarding animals?

Ultimately, FSMA compliance is going to look a little different from one farm to another. What does it mean, for example, to “maintain a system for control of animal excreta”<sup>7</sup> in an agroforestry context? A fence around a currently-harvested asparagus production area may fit the bill. Farm workers may also need to inspect their boots before stepping in the fenced area or have separate pairs of boots used for working in harvest areas as opposed to areas where animals have been present. The process must also be systematized. What does that mean on a practical level? It may mean that during the weeks of harvest, a task list for asparagus harvest season defines when the fence is erected, when it is inspected, and when it is removed. Another task list for the harvest itself should include inspection or change of one’s boots before entry.

The lack of specificity in FSMA rules and guidelines might be frustrating for some farmers. But there is a bright side. Farmers have a degree of flexibility and leeway to design and implement measures that will most effectively and appropriately manage animals on their farms to minimize food safety risks.

Good agricultural practices are constantly emerging as the farming community grapples with how to interpret and implement the FSMA standards. This provides the farming community, particularly agroforestry or regenerative farmers who are incorporating livestock in their systems, the opportunity to work together to collectively design and implement practical, effective best practices when integrating animals with produce production.

To put it another way: By developing an emerging consensus about best practices, the agroforestry community itself can lead the way to defining best practices. Gaining legitimacy does require a somewhat precise articulation of procedures. And, we need evidence that such practices lead directly to reduced excrement contamination. This is a do-able task.

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<sup>6</sup> See “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry”, *Draft Guidance*, pp. 74 – 81.

<sup>7</sup> 21 CFR 112.134

What else do I need to know about my obligations under the PSR relative to integrating livestock and produce production?

- Handwashing: Workers must wash their hands “as soon as practical” after touching animals or animal waste.<sup>8</sup> Workers having direct contact with animals should wash their hands before leaving any animal enclosure, after handling animals or animal waste, and before beginning any activities involving produce.
- Pre-harvest and harvest assessment: Farmers must identify and not harvest contaminated crop. This includes monitoring and assessing areas where there might be contamination during the growing season and at the time of harvest. During this assessment, farmers must identify areas where there is evidence of potential contamination by animals (e.g. significant amounts of excreta or crop destruction), for example, by placing flags outlining the affected area.<sup>9</sup>
- Restricted access to fully-enclosed buildings: Animals must either be kept out of fully enclosed buildings where produce, food contact surfaces, or food-packing material is exposed or be separated from the produce/surfaces/materials by location, time, or partition.<sup>10</sup>
- Animal excreta control/disposal. Farmers should adopt a systematic method for effectively disposing of or controlling animal excreta.<sup>11</sup> If you compost animal waste on the farm, the compost pile must be maintained properly and you must keep records documenting the composting process, such as composting time periods, pile temperature readings, and dates of pile turnings.<sup>12</sup>
- Water sources: Farmers must take measures to prevent animal excreta from contaminating agricultural water sources or agricultural water distribution systems used for produce.<sup>13</sup>
- Equipment and tools: Equipment and tools used to harvest, pack, or hold covered produce must be cleaned and equipment and tools that contact the edible portions of covered produce must be sanitized “as frequently as reasonably necessary to protect against contamination.”<sup>14</sup>

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<sup>8</sup> 21 CFR 112.32(b).

<sup>9</sup> 21 CFR 112.12.

<sup>10</sup> 21 CFR 112.32(a).

<sup>11</sup> 21 CFR 112.134(a).

<sup>12</sup> 21 CFR 112.54; 21 CFR 112.60.

<sup>13</sup> 21 CFR 112.134(a).

<sup>14</sup> 21 CFR 112.123

- Boots/clothing: Farmers should implement policies to prevent cross-contamination between animal areas and produce areas when appropriate. While the FSMA rule does not compel farmers to provide or require separate boots and clothing for separate work activities, this can be an effective approach when animals are grazing in separate areas from produce fields.
- Worker trainings: Workers must receive training in the principles of food safety, health and personal hygiene, and how to recognize produce that may be contaminated and should not be harvested. At least one person responsible for supervising harvesting and packing activities must complete a food safety training program that meets FDA standards. Farm employers must keep records documenting the date of training, topics covered, and the persons trained.<sup>15</sup> A good practice might include training workers on how to conduct pre-harvest and at-harvest risk assessments in the field—including standard operating procedures and protocols for identifying and marking potential hazards and what to do if contamination is found in the field before or during harvest (i.e., remove or leave). Workers might also need to be trained on how to safely dispose of or control animal waste (what tools/equipment, vehicles to use) and how to clean equipment and tools.<sup>16</sup>
- Intervals between grazing and harvest: The FSMA rule does not require farmers to establish waiting periods between grazing and harvest. The rule simply requires that untreated manure be applied in a manner “that does not contact covered produce during or after application” or in a manner that “does not contact covered produce during application and minimizes the potential for contact with covered produce after application.”<sup>17</sup> Under the FDA’s current interpretation of FSMA rules, the minimum application interval for untreated manure applications that meet either of these standards is zero days, meaning that “harvesting of the covered produce can occur on the same day” that untreated manure is applied in a manner that does not contact the harvested portion of crops during application and minimizes the risk of contact after application. However, the FDA encourages farmers to consider applying such intervals as appropriate and recognizes the 90-day or 120-day application interval established by the National Organic Program as “a prudent step toward minimizing the likelihood of contamination.”<sup>18</sup>
- Buffer zones: While the FSMA rule does not require farmers to establish no-harvest buffer zones around contamination, this can be an effective way to avoid contact with

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<sup>15</sup> 21 CFR 112.22

<sup>16</sup> See “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry”, *Draft Guidance*, pp. 26 – 38.

<sup>17</sup> 21 CFR 112.56(a).

<sup>18</sup> See “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry”, *Draft Guidance*, pp. 66 – 69.; and “At a Glance: Key Points in the Produce Safety Rule Draft Guidance”.

the harvestable portion of crops during grazing and to minimize the potential for manure to contact produce after grazing.

## 2. Keep records of how best practices or other measures are being followed

The importance of documentation cannot be emphasized enough! Food safety standards, practices and protocols that are being followed without records to prove it won't get you very far if a food safety incident were to occur. Maintaining records and documentation can be tedious, but it's absolutely essential when it comes to limiting your food safety liability risks.

In addition, certain buyers might require farmers to have records showing how they're following FSMA standards or food safety best practices. Regardless, most if not all customers will likely appreciate seeing them or at least knowing you're keeping them.

Key records include:

- Animal activity monitoring log: log any notable events and any actions taken.
- Pre-harvest risk assessment log: document results of monitoring assessment and any notable actions taken (e.g., identify, mark, address, prevent further potential hazards).
- Harvest risk assessment log: document results of monitoring assessment and all actions taken to avoid harvesting contaminated produce.
- Worker training log: Document when workers were trained and what was covered.
- Product tracking and traceability system: When a food safety incident occurs, one of the primary ways to control the outbreak, and mitigate damages, is to recall all the potentially affected products. Naturally, this requires some form of a tracking and traceability recordkeeping system. The tracking should be narrow enough to order as narrow a recall as necessary. Newly proposed rules from the Food and Drug Administration may establish minimum requirements for product tracking systems for non-exempt farms.<sup>19</sup>

Going back to the asparagus example, this means that farmers need an actual checklist of harvest activities with a literal checking of the box that boots were in fact inspected. The best

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<sup>19</sup> "Requirements for Additional Traceability Records for Certain Foods", Proposed Rule, Food and Drug Administration, Federal Register Vol. 85, No. 185, pp. 59984 – 60038. Available at: <https://www.govinfo.gov/content/pkg/FR-2020-09-23/pdf/2020-20100.pdf>

legal resilience comes with a paper trail that is time stamped and filed where it can be found if needed.

The law allows great flexibility in terms of exactly how record keeping happens. It can be a paper and clipboard, it can be a digital file, a series of photographs, a project management app or more. If producers can arrive at consensus about what the best practice is, the law allows individual farmers to demonstrate the practice was followed in a wide variety of ways. However, whatever method you choose, be aware that FSMA requires records to be made at the time when an activity is “performed or observed.”<sup>20</sup> To comply with FSMA record-keeping requirements, your records also need to include certain specific information, including the name and location of your farm, the crop type and the location of the growing area or other activity area, the date and time of the activity or observation documented, the signature of the person who performed the activity or made the observation, and the signature of a reviewing supervisor where applicable.<sup>21</sup> If the FDA’s proposed food traceability rules are adopted as written, covered farms may even need to go a step farther, down to providing GPS coordinates for fields where crops have been harvested.

### 3. Explore insurance options for food safety incident coverage

Having liability insurance is critical to protect your farm should it become entangled in a foodborne illness lawsuit. If an incident occurs, the decision to sue is not up to your customers. It’s up to third-party insurance companies who are financially motivated to place the burden of damages elsewhere, regardless of whether the farmer is at fault. If you have insurance coverage, your insurance company should defend your case and pay out any damages up to your policy limit.

The hard reality is that finding insurance coverage for food poisoning injuries can be 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. Some farm liability policies will cover a food poisoning injury under select circumstances. Some farm liability policies only cover injuries that occur on the farm. This means if the contaminated product was purchased from a wholesaler or at the farmers’ market, the farmer is not insured. Some farm liability policies cover food poisoning injuries only if the contamination was the result of a fire, tornado, or other natural risk, but not farmer negligence. Farmers never intend to be negligent, but accidents happen. Business endorsements, product liability policies, and product recall policies might provide more extended coverage for food poisoning injuries than a basic farm policy. Nevertheless, in Farm Commons’ experience, policies vary widely, and some even contradict

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<sup>20</sup> 21 CFR 112.161(a)(2)

<sup>21</sup> 21 CFR 112.161; See also, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: Guidance for Industry”, *Draft Guidance*, pp. 131 – 138.

themselves as to whether food safety outbreaks are covered. Understanding the limits of your insurance policy coverage is critical to managing legal risks in your farming operations.

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. Unfortunately, it can be quite difficult to determine if a specific insurance policy will cover a specific risk. Farmers might read the policy document itself, but this can be 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 it 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 your 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.) Be sure to ask your agent to provide an answer to your questions in writing and keep notes of any verbal conversations you have with your agent or underwriter.

A second hard reality is that insurance coverage for food borne illnesses may not be available for certain farms. 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.

As a starting point, here's what you can do:

- Find an insurance agent: If you don't already have an insurance agent, or if you're wanting to shop around to see what else is out there, 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.

- Determine whether your existing or prospective insurance policy includes food safety incident coverage: Read your policy or ask your insurance agent. If you find out that the answer is NO, or if it's ambiguous (which is most likely), explore your options under a product contamination liability policy.
- Consider recall insurance: Insurance is sometimes available to protect against the expense of a recall. Finding such a policy may take some time. Recall coverage may only be available as part of a commercial liability policy. It's worth asking your insurance agent what options are available to you.
- Revisit your policy each year: 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.

When talking with an insurance agent about whether a risk is covered 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.

## Action Steps for Achieving Regulatory Consensus

### 1. Work with regulators

As we've talked about, there's a lot of ambiguity in food safety regulations, especially when it comes to integrated livestock operations. That means that it falls to state and local regulators to decide how they will interpret and apply those ambiguous rules generally, or even on a case-by-case basis. Understanding how and why your state and local regulators interpret food safety rules can give you a helpful framework for understanding what considerations might go into future regulations. Moreover, evidence of an agency's longstanding interpretation of a regulation can carry a lot of weight when legislators are trying to decide how to shape new rules.

With that in mind, consider starting a dialogue with your state or local regulators to find out whether food safety rules are being applied the same way to other farms with similar operations, whether the interpretation of the rules comes from agency policy or your local regulator's judgment, and what your regulators would like to see in terms of new, more specific rules.

When talking with your regulators, don't forget that your regulators are required to follow the regulation and directives from above (i.e., agency supervisors or the legislative branch), whether they agree with it or not. In some cases, your regulators may be very reluctant to provide any guidance at all, particularly if there are ambiguities in the regulation. All the same, as

representatives of the agency or the legislative branch, your regulator is acting as a voice for the agency or government as a whole and must act consistently or else it may be subject to challenges in court. Having conversations to identify or help achieve consistencies within the regulatory agency can be a good step toward negotiating future regulations that address the interests and concerns of everybody involved.

Sometimes, discussion about how a regulator interprets or applies existing regulations can be a touchy subject. Try to be professional, yet friendly. Remember that your regulators are people. Although it helps to set a tone of professionalism, including demonstrating that you've done your homework and that you know a thing or two about the regulation, it's generally not in your favor to come off as defensive or a know it all. Try to identify the points you can agree upon, and respectfully agree to disagree on points where you have differences of opinion.

While it's important to have a civil conversation with representatives of your regulatory agencies, it's also fair to respond to unclear or unsatisfactory answers by asking if there is anybody else you can talk with to better understand the agency's position. Most regulatory agencies have staff assigned to program lead or policy analyst positions whose job it is to interpret regulations and ensure that they are consistently applied across the agency. If you have the chance to talk with someone responsible for coordination agency policies, consider following up with a letter or email summarizing your understanding of the conversation and asking for a reply to confirm your understanding.

Finally, remember to thank your regulators for taking the time to answer your questions, listen to your concerns, and give you feedback regarding their own positions on the law. Although it is certainly part of your regulators' responsibilities to respond to public inquiries, they are often tasked to do a big job with limited resources. When you show that you value their time, your regulators will be more likely to spend time addressing your concerns and to value the time you've spent bringing those concerns to their attention.

## 2. Build community consensus

When regulations are vague, community consensus can be a powerful tool in achieving greater clarity. When a community approaches a regulatory body with a single proposed objective that many individuals stand behind, it's simply more persuasive. But, the reasons to develop community consensus run deeper than having a stronger muscle to flex in front of regulatory bodies.

Community consensus takes on the force of law in a variety of contexts that often go unnoticed. In a litigation environment, attorneys and judges will often cite broad-based community practices when explaining their reasoning behind their conclusions. For example, let's say a farmer is part of a lawsuit alleging he or she was negligent in having caused a food safety incident. Attorneys on both sides would be very busy gathering evidence about broad-based community practice regarding food safety. The farmer in question will be more likely to win the

lawsuit if that farmer can show that his or her practices were in line with what other famers do. It's difficult to prove that a farmer's specific practices are in line with community custom if we have no community customs! It's also very difficult to win these lawsuits if as a community, we have no evidence to support our claims as to community customs.

A community with consistent and documented customs is in a better position if and when members of that community get pulled into litigation. Published documents, conference presentations, and working documents are all possible sources of consistent and documented customs. Where the agroforestry community is able to discuss and document their practices through white papers, research summaries, and conference presentations, they are in a much better position to defend themselves from lawsuits.

Community consensus also helps shape regulatory interpretation. If the regulatory interpretation is handled by means of litigation, the process explained in the previous paragraph becomes important. During litigation, attorneys for both sides will try to explain why community consensus supports their preferred interpretation of the law. The side with the stronger demonstration of consensus, when it is supported by evidence and in line with the regulation's intent, is more likely to win. But at the same time, regulatory interpretation usually happens through policy, as discussed next.

Regulatory interpretation is more often solidified outside the courtroom. Enforcement bodies and regulatory agencies often adopt policies that memorialize their preferred interpretation of the law, and then they follow those policies internally. These policies don't receive any judicial stamp of approval (assuming a lawsuit is never brought) and may change as elected administrations change, but they serve as "the rule" all the same. When setting their interpretation policies, enforcement bodies often turn to community practice. Although of course, the enforcement body is centrally focused on a policy that will fulfill the intent of the law, they look to the community to discover a reasonable process for fulfilling that intent. A community that can easily and quickly show an enforcement body what their community is already doing (and why!) is in a much better position to influence the interpretation process. This ability is the strongest when a community can support its position with robust evidence about why and how their practices, for example, protect the safety of our food supply.

Consensus isn't just about going along with whatever our peers want to support. Consensus is about having a robust dialogue about why and how a community chooses to adopt a practice. Strong consensus is supported by interrogating our options, researching choices, engaging in debate, and pursuing an authentic agreement about what should be done. The process isn't necessarily neat or smooth. It also requires support from industry supporters, associations, and advocates. These are the organizations that often facilitate the dialogue and help to document the process.

However it occurs, community consensus is something we want and need in the agroforestry community to help shape regulatory interpretations that protect the food supply while

encouraging innovative production methods that protect the environment and build community wealth. Each farmer plays a role in stewarding that process.

### 3. Participate in the rulemaking process

One really meaningful and important thing you can do to help shape future regulation is to participate in the rulemaking process. Every new piece of regulation has to go through a formal rulemaking process that typically includes a public comment period. Every individual comment becomes part of the record of that rulemaking process and agencies are required to address those questions as part of the process and explain why they did or did not choose to modify the rule to address those comments. In most cases, you can submit comments to a proposed rule online with an opportunity to attach supporting documents, such as research articles, or records like soil or water test results that demonstrate that your food safety practices work.

At the state government level, the rulemaking process also often includes one or more public hearing sessions. As with the public comment process, testimony offered at public hearings becomes part of the rule-making record that the regulatory agency must consider before finalizing a proposed rule. Public hearings can provide a great opportunity for you and other like-minded farmers to have your voices heard. Unfortunately, regulatory agencies are not required to hold public hearings in locations that are easily accessible to every region of the state. If you become aware of a public hearing that you can't easily attend in person, check the public hearing notice or contact the regulatory agency to see if it allows alternate ways to participate, such as by telephone, video conferencing, or pre-recorded testimony.

Although public comment periods and public hearings offer a meaningful way to contribute to the lawmaking process, don't feel that you need to wait until the formal rulemaking process begins to introduce your opinions. You can express your interests to your state or federal legislative representatives at any time by letter, telephone, or email, or through the online comment form on your representative's personal website. If you've already built a consensus among other farmers in your community, consider working together to craft a joint statement you can collectively send to all your legislative representatives.

Although it can sometimes seem as though laws and regulations are created in a vacuum that doesn't appreciate the practical difficulties imposed on different people in different situations, the law is designed and intended to make the regulatory process transparent and participatory. That process only works when the people being regulated play an active role. Against a backdrop of special interests and industry lobbying groups, the voices of independent farmers matter as much, if not more, than ever before.

## Practical Examples to Move Forward

One thing we know is that mixed crop-livestock farms come in a wide variety of different shapes and forms. From orchards to vegetable growers, different farms introduce livestock in different ways and for different reasons. Certainly, every farmer appreciates the nutrient value and soil health improvement that can result from introducing livestock into production areas. For some farmers, though, one of the main benefits livestock delivers is simply to clean up after harvest by scavenging dropped fruit or standing crop residues. These farmers value the time saved in cleanup and preparation for the next growing season, not to mention the added nutrition and dietary variety enjoyed by their livestock. Other farmers introduce livestock prior to harvest with an eye toward pest control benefits, including cleanup of dropped fruits to reduce the attraction of wild animals.

Different farmers use different methods for keeping livestock away from harvestable crops depending on the types of crops involved and the resources available to the individual farmer. Those methods might look very different, for example, on an orchard where fruit is harvested by hand as compared to a machine-harvested berry farm or a specialty crop producer.

First, let's compare and contrast approaches to harvest and worker training in two real-life examples.<sup>22</sup>

#### Farmer Alexi's Orchard

Farmer Alexi raises hogs, sheep, and chickens on her orchard where she grows a mix of hand-harvested apples and several different kinds of berries. If Alexi were to describe her operation's food safety practices she might say:

"I allow the hogs and chickens into production areas at different times during the growing season, but only after harvest to clean up drops. I use sheep to mow around field edges, but I never allow the sheep into production areas. I conduct regular visual assessments to avoid stepping in manure and I instruct my employees to use the siderails of ladders, rather than put their hands on the same rungs that have been contacted by their boots during harvest. I also train my staff to recognize and not harvest visibly contaminated fruit, but I have no written policies and no formal record keeping system."

Farmer Alexi wants to know how her practices align with the PSR in terms of integrating livestock with production. What might a knowledgeable person say about Alexi's situation relative to the PSR? Here's a possible response:

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<sup>22</sup> Note: The examples in this guide are based on farmer interviews conducted by Farm Commons and the Savanna Institute, but names have been changed to protect participants' privacy and some details have been added or changed to promote discussion and critical inquiry. Even where the real farms in these examples are exempt from FSMA requirements, the examples are intended to highlight common practices and differences between farms to examine what questions those practices raise in the context of FSMA compliance.

"Even though Alexi says sheep stay outside production areas and hogs/chickens are allowed in only after harvest, we still have the possibility of contamination. Alexi has both apples and berries, so if chickens or hogs go in to clean up after the berries, they are present before the apples are harvested. Alexi didn't mention using any physical exclusion like fencing that might keep the hogs and chickens out of the apple areas, so there may still be a reasonable probability that the chickens and hogs will contaminate the apples. It looks like Alexi has already anticipated that possibility because she's given instructions to her staff about how to avoid transfer of animal fecal matter via the ladder. This is good, but did Alexi and her staff conduct a visual assessment? It does help show compliance to have taken this step, like flagging locations where fecal matter might be present. Just having a plan isn't enough- Alexi will want to be sure she is specifically training her staff in assessing the presence of fecal matter in the area of harvest, too, in addition to the staff training she's already doing on ladder usage. Where this potential for contamination exists, Alexi is also obligated by the PSR to take "all measures reasonably necessary to identify and not harvest" apples that are potentially contaminated. Is a visual inspection of the apples on the tree and not handling the rungs of the ladder enough? We don't know. Conversation and consensus with other producers are essential steps in building her legal resilience. Do other farmers feel this is enough? What evidence does the community have that this is protective of food safety? Alexi should also pay close attention to documenting each of her steps and to making sure she is complying with the other elements of the PSR, as well."

### Farmer Sally's Orchard

Farmer Sally raises hogs and chickens on her orchard where she grows several different cider apple varieties, mulberries, nut trees, and other tree fruits including pears and persimmons. Many of her apple varieties are double-grafted and drop forage fruits before the harvestable fruits ripen. If Sally were to describe her operation's food safety practices she might say:

"I use temporary fencing to keep animals at least two feet away from tree trunks but I do allow them to forage under the drip line of the trees. I harvest all of my orchard crops using a tree shaker that catches fruit as it falls. My orchard crops are never touched by human hands until they get delivered to the packing shed. I rely a lot on visual observations and weather patterns to assess whether there's a risk of contamination and I am really diligent in monitoring field conditions. After all, there are plenty of reasons apart from food safety why I don't want to step in hog manure. I keep records of when livestock are allowed into different crop areas, but I have no written policies instructing employees how to comply with good food safety practices."

Farmer Sally wants to know how her practices align with the PSR in terms of integrating livestock with production. What might a knowledgeable person say about Sally's situation relative to the PSR? Here's a possible response:

"Even though Sally grows tree crops that are mechanically harvested, the fact that animals are allowed in the orchards and under the drip lines of the trees before harvest suggests a reasonable probability that the chickens and hogs could contaminate her crops. It's also possible for tree crops to have been contaminated by birds or other wild animals. Sally can't skip past the PSR's obligation to determine if there is a reasonable probability that domestic or wild animals have contaminated the produce. Sally says she's doing this by monitoring weather patterns and field conditions, which may be enough to determine if contamination has potentially made its way into the harvest process (for example, a rain event washing fecal matter into a location where the harvest equipment is staged). Where a reasonable probability exists, are Sally or her employees visually inspecting produce or taking any other measures before harvest to assess potential contamination? Sally doesn't say, necessarily. Has Sally trained her employees to recognize contaminated produce after harvest? It's good that Sally keeps records of when animals are present in different crop areas, but she should start documenting worker trainings and documenting when, where and how workers are assessing the reasonable probability of contamination (such as documenting the process of monitoring weather patterns) if she wants to meet FSMA record keeping requirements."

Now, let's explore the implementation of exclusion periods. How do exclusion periods help meet the obligations of the PSR within different farm operations? Before we dive into examples, let's explore how farmers are making decisions about exclusion periods.

Exclusion periods are the amount of time that a farmer allows between the introduction of livestock and crop harvest activities. Some farmers, whether organic certified or not, choose to follow the guidelines of the National Organic Program and exclude animals from production areas for 90 to 120 days before harvest. Others choose to be more flexible. They rely more on the FSMA requirement to determine whether a "reasonable probability" of contamination exists, and they determine exclusion periods based on their own experience and individualized risk assessments.

Farmers' choices about exclusion periods tend to reflect their preferences toward the structure of any new regulations. Those who prefer to make individual determinations of appropriate exclusion times tend to say that they have good relationships with local regulators. They feel that they have good opportunity to justify their practices, negotiate changes if necessary, and come to a mutual consensus with their agency representatives. Nonetheless, they worry that those relationships could change at any time if, for example, their local regulators were to change jobs or receive new directives from agency supervisors. If any new regulations come into place, these farmers would prefer to see rules that provide more security in their own ability to self-assess risks and define food safety practices that are tailored to their individual operations.

In contrast, farmers who choose to follow organic program standards tend to appreciate the predictability of a clearly defined time limit. They would prefer to see rules that offer the same level of certainty in compliance, but they also express concerns about the potential for new rules to be drafted with a "one size fits all" approach. These farmers would prefer to see rules based

on science that account for individual differences across different integrated livestock operations, like crop types, livestock types, climate regions and soil health. They would also want any future regulations to consider practical impacts, accounting for conditions like short growing seasons in northern climates, record keeping burdens, and a meaningful cost-benefit analysis of what it would take – especially for small farms – to implement those rules.

Let's take another look at some real-life examples.

### Farmer Sally's Orchard

Let's take another look at farmer Sally, who raises hogs and chickens on her orchard. If asked about her approach to exclusion periods, Sally might say:

"I believe that scientific research supports the safety of shorter exclusion periods, so I do not observe any hard-and-fast exclusion periods when it comes to introducing livestock into production areas before harvest. I allow hogs into orchard areas both after harvest and prior to harvest depending on when early fruit drops. I allow chickens into orchard areas as early as 30 days before harvest. I've had a good relationship with my local agricultural department agent, who has been satisfied that my system represents good food safety practices. If I had to follow a 90-day exclusion period, I would probably have to completely change the genetics of my orchard crops."

What might a knowledgeable person say about Sally's approach to exclusion periods? Here's a possible response:

"As it stands now, the Produce Safety Rule doesn't require any exclusion period between a raw manure application and harvesting, as long as the manure doesn't contact produce during 'application' and the farmer takes steps to minimize the risk of contact after harvest. But that doesn't necessarily mean that there isn't a reasonable probability that her livestock will contaminate her crops. Whether Sally's practices satisfy PSR requirements probably also depends on the measures she takes to assess and identify potentially contaminated produce before harvest and the steps she takes to avoid contamination after harvest."

### Farmer June's CSA

Farmer June raises sheep and runs a successful CSA focused on vegetable crops. She rotationally grazes her sheep to mow down spring cover crops and fertilize fields for harvest crops. If asked about her approach to food safety, June might say:

"I'm not certified organic, but I strictly follow the National Organic Program 90 to 120-day exclusion periods because I believe my customers value knowing that I follow organic

standards. I use maps with aerial photographs to identify different farm fields and I keep records of when sheep are rotated into different fields and when produce is harvested from each field. I don't have any written employee policies, but I do require workers to change boots between animal areas and crop fields and I have a weekly employee meeting to discuss grazing rotations and harvest plans."

Farmer June wants to know how her practices align with the PSR in terms of integrating livestock with production. What might a knowledgeable person say about June's situation relative to the PSR? Here's a possible response:

"FDA views the National Organic Program exclusion periods as a 'prudent step' toward minimizing the risks of contamination, so June's decision to follow those rules probably helps with satisfying the PSR standards. Documenting when her sheep rotate through different fields is a good practice, but we don't know for certain whether the FDA's statement that it 'does not object' to farmers following NOP rules also means that FDA thinks there is no reasonable probability that animals will contaminate produce if NOP standards are followed. To feel more confident about whether June's practices satisfy the Produce Safety Rule, it would help to know what other steps she is taking to assess produce for contamination before harvest and to minimize the risks of contamination after harvest. In short, the exclusion period doesn't absolve June of the obligation to follow the PSR's requirement to assess the reasonable probability of contamination and to not harvest produce reasonably likely to be contaminated. June might also consider working with a community of on-farm scientific researchers to establish that the exclusion periods achieve the desired goal of reducing the risk of contamination. June might also coordinate and work towards consensus with other farmers on whether the 90-day period is an appropriate regulatory goal. To what extent do other farmers see a 90-day period as practical and reasonable for their operations? Community consensus at the beginning could help drive regulatory consistency. Lastly, while FSMA doesn't require farmers to have formal employee policies, like an employee handbook, June should make sure she is giving her employees the type of food safety training required under the PSR, and she should keep records to document those trainings."

Some farmers are using many techniques to protect food safety: fencing, exclusion periods, and detailed planning. Let's explore through one real life example how we might still reinforce these good practices with strong recordkeeping.

### Farmer April's Permaculture Plan

Farmer April raises hogs and chickens on her permaculture farm where she grows orchard fruits and vegetable crops for CSA and farm market sales. If asked about her approach to food safety, June might say:

"I am not organic certified, but I observe National Organic Program exclusion periods. My fruit crops are selected to ripen at different times and are planted in rows sequential to

their ripening dates. I allow hogs and chickens into the orchard rows prior to harvest, but never less than 90 days before the fruit in each orchard row ripens. Rows that will ripen in less than 90 days are sectioned off with temporary fencing. During harvest, I visually inspect fruit for evidence of potential contamination. After the last fruit harvest, I introduce the hogs again to cleanup drops, followed by the chickens to help break up the hog droppings. I also allow the hogs and chickens into the market garden plots, but only after harvest to clean up crop residues. During the growing season, the market gardens are fenced off with hog panels and chicken wire. I have taken FSMA training courses and I'm very conscientious about food safety practices, including changing boots between animal chores and crop chores. I don't have any employees, so I have not formally documented systems for food safety and manure management. My fruit crops ripen consistently at the same time each year, so I rely exclusively on calendar dates to decide when to exclude animals from orchard rows and I don't keep real-time notes documenting livestock rotations or harvest dates."

Farmer April wants to know how her practices align with the PSR in terms of integrating livestock with production. What might a knowledgeable person say about April's situation relative to the PSR? Here's a possible response:

"Just as with farmer June's situation, April's decision to follow National Organic Program standards is probably a good step toward satisfying the Produce Safety Rule. But, again, that alone might not rule out a reasonable probability that her animals will contaminate her produce. She should also consider talking with other farmers and advocates, as well as with researchers to solidify consensus on the 90-day exclusion period as effective and practical on the farm. Taking a look at April's practices overall, though, we know that she is also using temporary and permanent fencing to exclude animals during the growing season, and that she visually inspects all her produce before harvest. Looking at her practices as a whole, we can probably say that even if there is a reasonable probability of animals contaminating her produce, she is taking reasonable measures to identify and avoid harvesting potentially contaminated crops. If April wants to take extra steps to try to be fully compliant with the PSR, she should probably start keeping real-time records about when she introduces animals into different fields and when she harvests each crop fields, rather than just relying on calendar dates."

Now, let's explore the practices of a different farm operation that prefers a more flexible approach. How can flexibility be preserved within the confines of the PSR's obligations?

#### Farmer August and May's Orchard

August and May raise hogs, chickens, and sheep on a popular orchard that produces hand-harvested apples for on-farm and grocery store sales, as well as cider apples for on-farm cider production and sales to other local cider makers. If asked about their approach to food safety, August and May might say:

"The entire perimeter of our farm is surrounded by deer fencing to keep out wild animals with a secondary fence inside that creates a ring pasture allowing animals to be moved from one plot to another without crossing through other production areas. We don't follow any formal livestock rotation, but instead we introduce hogs as needed during the growing season to clean up drops. Sometimes we follow the hogs with chickens, but not always. Different orchard plots may see livestock introduced in different years. Not every plot will see livestock in any given year. When livestock are introduced to orchard plots, they will be excluded at least a few weeks before harvest. We occasionally introduce sheep to the orchard plots, but we are only introducing sheep in small groups for short time periods as we continue to work out how to keep them from browsing on tree trunks. Most of the time, our livestock rotate through dedicated grazing fields, rather than through production areas. We keep records of our livestock rotations and crop harvest dates, but we haven't felt the need to prepare any formal livestock or manure management plans because we have had a good relationship with our local agricultural department agent. We would be more likely to prepare a formal plan with more clearly defined rules and exemptions, but we also believe that any new rules should allow farmers to develop their own best practices based on the particular circumstances of individual farm operations. We do have formal written employee food safety policies for harvest and retail sales operations, as well as training records for new and returning employees."

August and May want to know how their practices align with the PSR in terms of integrating livestock with production. What might a knowledgeable person say about their situation relative to the PSR? Here's a possible response:

"August and May are taking a variety of different approaches to reduce the probability of contamination by both wild animals and their livestock. Since they raise tree crops, manure from their livestock most likely does not contact their produce before harvest, meaning that FSMA does not require any exclusion period between the application of manure and harvest activities. As with farmer Sally, though, meeting the requirements for no exclusion period doesn't necessarily mean that there isn't a reasonable probability that their animals will contaminate produce. We don't know what steps August and May take to assess produce for potential contamination before harvest or what steps they take during harvest to avoid introducing contamination from areas where animals have been present. It's good that August and May have written food safety policies, documentation of worker trainings, and documentation of livestock rotations and harvest dates. It would be even better if they also kept records of pre-harvest inspections for potential contamination and if we knew what steps they take to minimize the risk of contact with animal manure after harvest."

As we can see from these real-life examples, there are a variety of both common practices and differences between the ways different farms manage food safety for integrated livestock operations. Still, with all the differences between farm operations, integrated livestock management practices, and attitudes toward future regulations, it's fair to ask whether any community of farmers can actually come to a consensus about what to support in the rulemaking process. Don't get discouraged. Rather than being an obstacle to consensus, it's

those very differences that can help define an advocacy position that can be widely accepted among mixed crop-livestock farmers of all stripes. There is also a real need for evidence that farmer practices support the objectives of the PSR by resulting in decreased likelihood of contamination. Particularly with exclusion periods, the organic rules are a reasonable default but need scientific support. Coordinated advocacy can help develop the evidence needed to establish the safety of farmer practices. The sooner that conversation begins, the better prepared your community will be to play a meaningful role in the rulemaking process.

## Conclusion

Regardless of whether your operation is subject to the FSMA PSR, following the FSMA requirements and standards regarding animals may provide a strong line of defense should a food borne illness be linked to your farm. Essentially, when integrating animals with crop production, FSMA requires farmers to take reasonable steps to reduce risk. That means using common sense and following good agricultural practices including complying with FSMA rules where possible or required by law. Keeping records of how and when these and other food safety measures are being taken can help farmers set systems in place to encourage and confirm implementation. In addition, the records will help support the farmer's case if a food borne illness is linked to the farm. A farmer who follows the protocols but has nothing to prove so is left with little to no defense in court. Exploring insurance options for coverage related to food borne illness is another way that farmers can minimize their food safety liability risk.

Finally, remember that you and your community members have a voice in shaping the regulations that guide your food safety practices. Make a plan to have discussions with your regulators, participate in the rulemaking process and, most importantly, keep the conversation going among farmers in your community.

## Does the PRODUCE RULE apply to my farm?

Start here: Does your farm operation grow, harvest, pack, or hold "produce"? (see pg.6 for definition of produce)

YES

The PRODUCE RULE applies but exemptions or modified rules may be available. Proceed.

NO

- Do you gross \$25K or less per year in all produce sales (averaged across 3 yrs)?
- Do you grow/harvest/pack/hold only produce that's rarely consumed raw (before answering see exhaustive list on pg. 6)?
- Do you grow/harvest/pack/hold produce only for personal/on-farm consumption?
- Do you grow/harvest/pack/hold only produce that's destined for commercial processing?

If you can answer "yes" to any of these questions, follow the YES path. If the answer is "no" to all of them, follow the NO path.

YES

NO

You are not required to comply with the PRODUCE RULE. At the same time, you must keep full and complete records establishing that you meet the exemption options above. Proceed below.

You're eligible for a **Qualified Exemption**, which involves:

- *Labeling*: If your produce requires a food packaging label, the label must include the farm's name & complete address. For produce without a label, you must clearly display this info at every point of sale.
- *Records*: You must keep sales records to prove you meet the requirements for a qualified exemption.
- *Enforcement*: If an incident is linked to your farm, enforcement action can still be taken.
- *Withdrawal of Exemption*: FDA may withdraw your qualified exempt status—after giving notice and an opportunity to rectify—if a foodborne illness is directly linked to your farm or they learn of unsafe conditions/conduct. It can be reinstated later on.

### Qualified Exemption Compliance Dates:

- *Labeling*: If a packaging label is required, you must comply with the name & address requirement by Jan 1, 2020. Otherwise, by the general compliance dates (see far right).
- *Records*: The FDA expects you to keep sales records as of the effective date of the rule—Jan 26, 2016. You'll need to do an annual review and verification at the end of each year to demonstrate that you continue to satisfy the qualified exemption.

**All farmers are still legally obligated to sell only safe food under various federal and state laws.** Plus, safe food is what your customers want!

**Reduce your risk of liability overall by learning about and complying with the PRODUCE RULE standards and requirements, including adopting a food safety plan.**

The PRODUCE RULE does not apply to you. But you may be subject to the PREVENTIVE CONTROLS RULE. Proceed to the next page.

1. Do you gross less than \$500K/yr in all food sales? AND
2. Is more than 50% of the value of those sales to "qualified end users"?  
A "qualified end user" is:
  - » An individual consumer of food (not a business) or
  - » A restaurant or retail food establishment that is either in the same state as the farm or within 275 miles.

If you answer "yes" to BOTH 1 and 2, follow YES. If the answer is "no" to either, follow NO.

YES

NO

You have **No Exemption**. You must comply with the full PRODUCE RULE which addresses standards for the following:

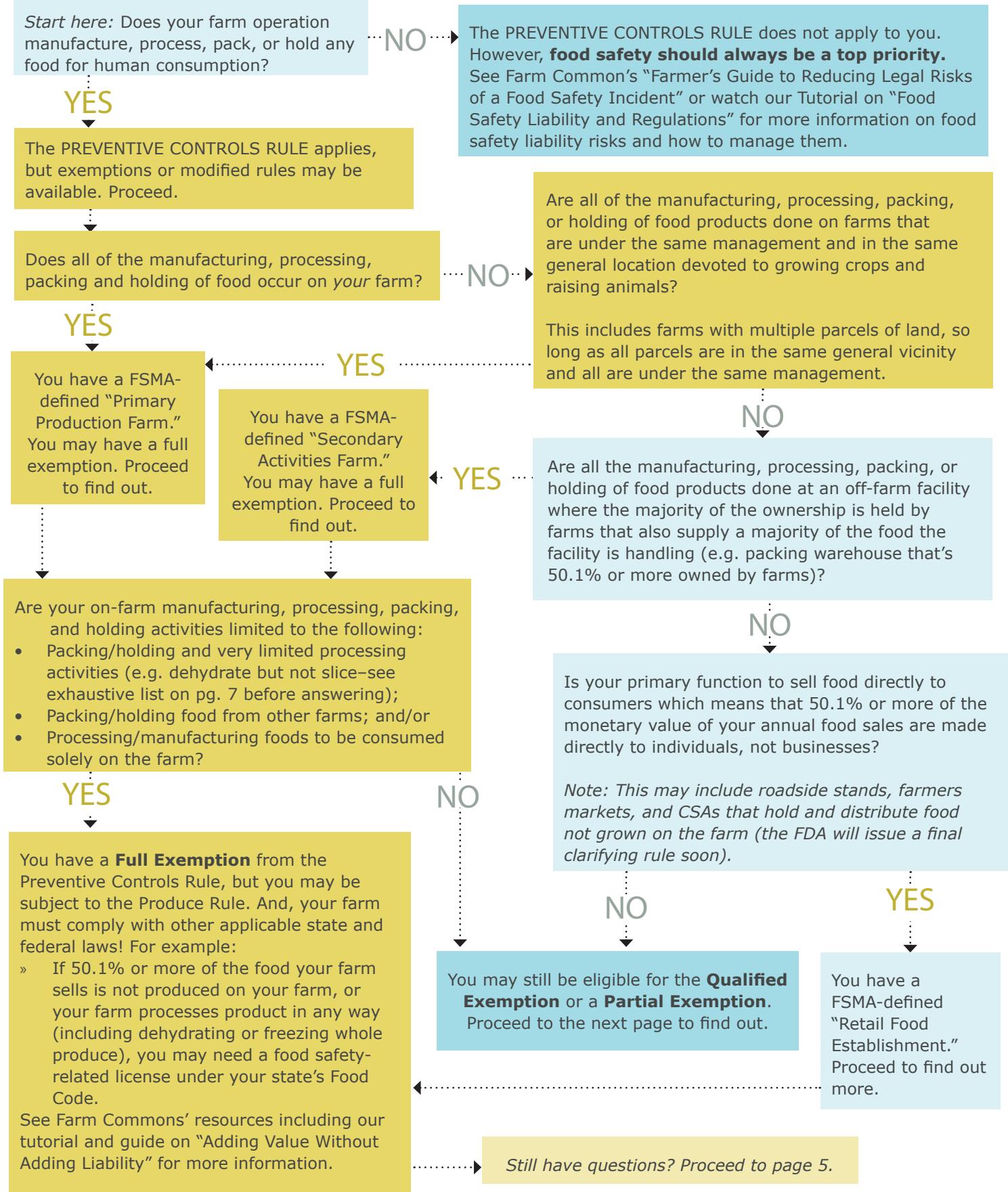
- Agricultural water (irrigation, washing)
- Biological soil amendments (raw manure, compost)
- Domesticated and wild animals
- Personnel qualifications and training, and health and hygiene
- Equipment, tools, and building sanitation.
- Growing sprouts

### General Compliance Dates:

- Very Small Farms: If you gross \$250k or less/yr in all produce (avg 3 yrs), you must comply by Jan 26, 2020.
- Small Farms: If you gross \$500k or less a year in all produce (avg 3 yrs), you must comply by Jan 26, 2019.
- Everyone else: By Jan 26, 2018.
- Agricultural Water testing: You have 2 additional years to comply.
- Sprouts: 1 less year to comply.

Proceed to next page to determine if the PREVENTIVE CONTROLS RULE applies.

## Does the PREVENTIVE CONTROLS RULE apply to my farm?



## Does the Preventive CONTROLS RULE apply to my farm (cont'd)?

If you've gotten here, you're a FSMA-defined "Farm-Mixed Type Facility." You're going to have to comply with all or part of the PREVENTIVE CONTROLS RULE. In a nutshell, this rule:

- Updates and requires facilities to follow *current good manufacturing processes (GMPs)*;
- Establishes a new set of prevention-oriented food safety requirements referred to as *Hazard Analysis and Risk Based Preventive Controls* or "HARPC", which require facilities to implement a food safety plan, analyze potential hazards, establish risk-based preventive controls, and follow a *supply chain program*.
- Requires *training and qualification of employees*; and
- Requires facilities to *register with the FDA* and follow certain *labeling and recordkeeping requirements*.

The following will help you determine which parts of the rule you'll have to comply with and by when.

Is your answer yes to *both* of the following:

- » Does you perform "low-risk on farm processing activities" to make value-added products (see exhaustive list on pg. 8 before answering) AND
- » Do you either have less than 500 full-time employees or less than \$1 M/year in all human food sales (avg 3 yrs)?

YES

NO

Do you gross less than \$1 M/year in all human food sales (avg 3 yrs)?

NO

YES

You have **No Exemption**. You must comply with the full rule (i.e. register with FDA and follow HARPC provisions, GMP standards, personnel qualifications and training requirements, etc.)

Do you produce only juice, seafood, dietary supplements, or alcoholic beverages?  
-OR-  
Are you a facility that just packs and holds human foods that aren't fruits & veggies (e.g. grain elevator)?

YES

You have a **Qualified Exemption**:

- You must *register* with the FDA.
- You must *keep sales records* to support your exemption.
- You don't have to comply with the HARPC provisions, but you must comply with *updated GMPs* and *personnel requirements* and all *existing local/state food safety laws*.
- You must also submit two certified statements ("attestations") to the FDA:  
(1) that you qualify for the exemption (i.e. based on human food sales) and (2) you either are complying with the HARCP provisions OR are complying with all applicable state/local food safety laws.
- Also, if you choose to comply with option (2), comply with applicable state/local food safety laws rather than the HARCP provisions, you have to provide your *name & full address* on every label or point of sale.

You have a **Partial Exemption**:

- You must *register* with the FDA.
- You must *keep sales records* to support your exemption.
- You don't have to comply with the HARPC provisions, but you must comply with *updated GMPs* and *personnel training requirements* as well as *all existing applicable state and federal laws*.

**Partial Exemption  
Compliance Dates:**

- Records-The FDA expects you to keep sales records as of Jan of 2016.
- All else-You must comply by the general compliance dates for Very Small Businesses (see far right).

**Qualified Exemption  
Compliance Dates:**

- Records-The FDA expects you to keep sales records as of Jan of 2016.
- Attestations-Must first be submitted by Dec 17, 2018-then every 2 years.
- Name & Address: Jan 1, 2020.
- All else-You must comply by the general compliance dates for Very Small Businesses (see far right).

**General Compliance Dates:**

- Very Small Businesses-If you gross less than \$1M/ year in all human food sales (avg 3 yrs), you must comply by Sep 17, 2018.
- Small Businesses-If you have less than 500 full-time employees, you must comply by Sep 18, 2017.
- Everyone else-You must comply by Sep 19, 2016.

Still have questions? Proceed to the next page.

## Still have questions?

You're not alone!! These are complex rules, and it's going to take some time to figure it all out. The following provides some guidance to get you started.

### I'm still confused on whether I must comply with either or both rules

#### **How do I know whether the produce I grow is covered by the Produce Rule (generally consumed raw)?**

The rule provides a definition of produce. The definition specifies that grains and oilseeds are not covered by the rule, but things like mushrooms and sprouts are. The rule includes a non-exhaustive list of produce that's generally consumed raw to offer examples of what's covered by the rule. The rule also provides an exhaustive list of produce that's not generally consumed raw (i.e. not covered). Take a look at these lists, as it's not intuitive. When in doubt, unless you're ONLY growing produce on the exhaustive list, assume that the produce you grow is generally consumed raw! The definition and lists are included in the appendix (p. 6).

**I'm confused about the FDA's definition of a "farm"— how do I know whether my farm operation or co-farming arrangement falls within the definition?** The FDA's definition of a farm is not easy to decipher. The definition evolved over time to address the sustainable farming community's concerns about aggregator and co-managed farming arrangements such as CSAs and food hubs. But it is not clear how the FDA will interpret the rule in certain scenarios as ambiguities remain. The FDA will be coming out with a guidance document on the "farm" definition, which may be helpful. Also, the FDA has encouraged folks to ask questions through their online Technical Assistance Network or "TAN." The FDA will send these questions to their lawyers and will respond. Be sure you are as specific as possible so you can get a specific answer. The FDA has begun posting frequently asked questions and answers on their website to provide guidance to the community. So you can look there as well for more guidance!!

**How do I know which limited activites my so called "primary production farm" or "secondary activities farm" can engage in without being subject to the Preventive Controls Rule?** These activities are limited to: (1) packaging and labeling raw agricultural commodities (RACs), (2) drying/dehydrating RACs (but no slicing or dicing) and packaging and labeling dried/dehydrated RACs, and (3) treating RACs to manipulate ripening. You can also do activities that fall within the definitions of "harvesting," "packing," or "holding"—which includes things like coating for storage/transporation. These definitions are included in the appendix (p. 7).

**How do I know which low-risk activities my so called "farm-mixed type facility" can engage in when making value added products and still qualify for the partial exemption of the Preventive Controls Rule?** The full list of such low-risk activities provided in the rule is included in the appendix (p. 8).

#### **I still have more questions about whether I need to comply with either or both of the rules!**

Don't panic, resources are out there and are forthcoming to help you.

- The National Sustainable Agricultural Coalition (NSAC) has done an amazing job at pulling together this information. Check out their materials at: [www.sustainableagriculture.net/fsma/](http://www.sustainableagriculture.net/fsma/)
- You can ask the FDA specific questions: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>
- We at Farm Commons are committed helping you navigate these rules, so look out for more materials soon!

### I know that I must comply; how can I learn more about what's required?

The good news is you have time! Here are a few steps you can take to stay on top of it all:

- The FDA will be issuing specific guidance documents on things like water quality requirements, updated GAP standards, requirements for sprouts for the Produce Rule; updated GMP standards for the Preventive Controls Rule; as well as a Small Business Compliance Guide for both rules. You can also ask the FDA specific questions through their Technical Assistance Network (TAN) (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>) and review the FAQs (<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>).
- Check out NSAC's website for latest updates and resources: [sustainableagriculture.net/fsma/](http://www.sustainableagriculture.net/fsma/)
- Watch for workshops and classes offered by extensions, support groups, and GAP and GMP training providers.
- Look out for more materials soon from Farm Commons!

### Use the “produce” definition and lists to determine whether the produce you grow is “generally consumed raw” and subject to the Produce Rule

The following is the definition of “Produce” and lists included in the Produce Rule to help farmers determine whether the produce they grow, harvest, pack, and hold is subject to or “covered” by the Produce Rule.

**Definition of “Produce”:** Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

#### Non-exhaustive list of produce that is “generally consumed raw” (i.e. covered produce):

Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unifruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and Mixes of intact fruits and vegetables (such as fruit baskets).

#### Exhaustive list of produce that is NOT generally consumed raw (i.e. not covered produce):

Asparagus, beans (black, great Northern, kidney, lima, navy, pinto), beets (garden (roots and tops) and sugar beets), cashews, sour cherries, chickpeas, cocoa beans, coffee beans, collards, sweet corn, cranberries, dates, dill (seeds and weed), eggplants, figs, ginger, hazelnuts, horseradish, lentils, okra, peanuts, pecans, peppermint, potatoes, pumpkins, winter squash, sweet potatoes, and water chestnuts.

### Types of limited activities farms can engage in while still being fully exempt from the Preventive Controls Rule rule

**"Primary production farms" and "secondary activities farms" as defined can engage in the following limited activities while still being exempt from the Preventive Controls Rule:**

- Pack or hold raw agricultural commodities;
- Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management; and
- Manufacture/process food, provided that:
  - » All food used in such activities is consumed on that farm or another farm under the same management; or
  - » Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
    - (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
    - (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
    - (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation).

**In addition, farms can engage in "harvesting," "packing," and "holding" activities as defined below without being subject to the Preventive Controls Rule:**

**Definition of "Harvesting":** Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

**Definition of "Packing":** Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing), but does not include activities that transform a raw agricultural commodity into a processed food. *Note: Packaging means placing food into a container that directly contacts the food and that the consumer receives. Packaging activities will subject the farm to the Preventative Controls Rule.*

**Definition of "Holding":** Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

***Note: While farms may be exempt from the Preventive Controls Rule, the Produce Rule may still apply.***

### List of processing/manufacuring activities a farm mixed-type facility may do and still qualify for a partial exemption under the Preventive Controls Rule

- Boiling gums, latexes, and resins;
- Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/ dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/ latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);
- Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens));
- Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea);
- Extracting (including by pressing, by distilling, and by solvent extraction) from dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh min chopped dried mint);
- Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables);
- Grinding/cracking/crushing/ milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);
- Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/jellies/ preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products, (provided that they are single ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

### List of processing/manufacuring activities a mixed-farm facility may do and still qualify for a partial exemption under the Preventive Controls Rule (cont'd)

- Making baked goods from milled grain products (e.g., breads and cookies);
- Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);
- Making cocoa products from roasted cocoa beans;
- Making dried pasta from grains;
- Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
- Making molasses and treacle from sugar beets and sugarcane;
- Making oat flakes from grains;
- Making popcorn from grains;
- Making snack chips from fruits and vegetables (e.g., making plantain and potato chips);
- Making soft drinks and carbonated water from sugar, syrups, and water;
- Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
- Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;
- Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);
- Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/ latexes/resins that are processed foods, honey (pasteurized), jams/ jellies/ preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
- Pasteurizing honey;
- Roasting and toasting baked goods (e.g., toasting bread for croutons);
- Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and
- Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).

### List of packing/holding activities a mixed-farm facility may engage in and still qualify for a partial exemption under the Preventive Controls Rule

- Baked goods (e.g., bread and cookies);
- Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);
- Cocoa beans (roasted);
- Cocoa products;
- Coffee beans (roasted);
- Game meat jerky;
- Gums, latexes, and resins that are processed foods;
- Honey (pasteurized);
- Jams, jellies, and preserves;
- Milled grain products (e.g., flour, bran, and corn meal);
- Molasses and treacle;
- Oils (e.g., olive oil and sunflower seed oil);
- Other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
- Other grain products (e.g., dried pasta, oat flakes, and popcorn);
- Other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);
- Peanut and tree nut products (e.g., roasted peanuts and tree nut flours);
- Processed seeds for direct consumption (e.g., roasted pumpkin seeds);
- Soft drinks and carbonated water;
- Sugar;
- Syrups (e.g., maple syrup and agave syrup);
- Trail mix and granola;
- Vinegar; and
- Any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).